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Contents

Federal Register

Vol. 68, No. 50

Friday, March 14, 2003

Agricultural Marketing Service
PROPOSED RULES
Cotton research and promotion order:
Cotton Board rules and regulations; amendments, 03–06164

Agriculture Department
See Agricultural Marketing Service
See Animal and Plant Health Inspection Service
See Farm Service Agency
See Food Safety and Inspection Service
See Forest Service

Animal and Plant Health Inspection Service
RULES
Animal welfare:
Dogs intended for hunting, breeding, or security purposes; dealer licensing and inspection requirements, 03–06161

Blind or Severely Disabled, Committee for Purchase From People Who Are
See Committee for Purchase From People Who Are Blind or Severely Disabled

Centers for Medicare & Medicaid Services
See Inspector General Office, Health and Human Services Department
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06139, 03–06140

Children and Families Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06149, 03–06150, 03–06151, 03–06152, 03–06153

Civil Rights Commission
NOTICES
Meetings; Sunshine Act, 03–06290

Coast Guard
RULES
Ports and waterways safety:
Long Island Sound and Captain of the Port Zone, NY; safety and security zones, 03–06327

Commerce Department
See International Trade Administration
See National Oceanic and Atmospheric Administration

Committee for Purchase From People Who Are Blind or Severely Disabled
NOTICES
Procurement list; additions and deletions, 03–06168, 03–06169

Commodity Futures Trading Commission
PROPOSED RULES
Commodity Exchange Act:
Eligible bunched customer orders; account identification, 03–06177

Community Development Financial Institutions Fund
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06147
Grants and cooperative agreements; availability, etc.:
Bank Enterprise Award Program; correction, 03–06148

Education Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Elementary and secondary education—
Public Charter Schools Program, 03–06160

Employment Standards Administration
NOTICES
Minimum wages for Federal and federally-assisted construction; general wage determination decisions, 03–05905

Energy Department
See Energy Efficiency and Renewable Energy Office
See National Nuclear Security Administration
NOTICES
Grants and cooperative agreements; availability, etc.:
Renewable energy development on Tribal lands, 03–06167

Energy Efficiency and Renewable Energy Office
NOTICES
Meetings:
State Energy Advisory Board, 03–06328

Environmental Protection Agency
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06193
Environmental statements; availability, etc.:
Agency statements—
Comment availability, 03–06196
Weekly receipts, 03–06195
Meetings:
State and tribal toxics action forum, 03–06300
Reports and guidance documents; availability, etc.:
Clinch and Powell Valley Watershed Ecological Risk Assessment, 03–06194

Executive Office of the President
See Management and Budget Office
See Presidential Documents

Farm Service Agency
PROPOSED RULES
Special programs:
Indian Tribal Land Acquisition Program; revision, 03–06162

Federal Aviation Administration
RULES
Aircraft:
Repair stations, 03–06181
Airworthiness directives:
Dornier, 03–05860

PROPOSED RULES
Airworthiness directives:
Eurocopter France, 03–06137

Federal Communications Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06143, 03–06144, 03–06145

Federal Deposit Insurance Corporation
NOTICES
Meetings; Sunshine Act, 03–06277

Federal Election Commission
NOTICES
Meetings; Sunshine Act, 03–06348

Federal Emergency Management Agency
RULES
Emergency Preparedness and Response Directorate:
Firefighters Assistance Grant Program, 03–06171
NOTICES
Grants and cooperative agreements; availability, etc.:
Firefighters Assistance Program, 03–06172

Federal Reserve System
PROPOSED RULES
Bank holding companies and change in bank control (Regulation Y):
Commodities underlying derivative contracts; title delivery, 03–06155
NOTICES
Banks and bank holding companies:
Formations, acquisitions, and mergers, 03–06156

Financial Management Service
See Fiscal Service

Fiscal Service
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06115

Fish and Wildlife Service
PROPOSED RULES
Endangered and threatened species:
Critical habitat designations—
Desert yellowhead, 03–06131
Vernal pool crustaceans and plants in California and Oregon, 03–06370
NOTICES
Meetings:
Hanford Reach National Monument Federal Advisory Committee, 03–06135

Food and Drug Administration
PROPOSED RULES
Human drugs and biological products:
Bar code label requirements, 03–05205
Pre- and postmarketing safety reporting requirements, 03–05204

Food Safety and Inspection Service
NOTICES
Meetings:
Codex Alimentarius Commission—
Food Labeling Committee, 03–06122

Forest Service
NOTICES
Environmental statements; notice of intent:
Helena National Forest, MT, 03–06042

General Services Administration
NOTICES
Acquisition regulations:
Request for Authorization of Additional Classification and Rate (SF 1444); form revision, 03–06125

Health and Human Services Department
See Centers for Medicare & Medicaid Services
See Children and Families Administration
See Food and Drug Administration
See Inspector General Office, Health and Human Services Department
RULES
Grants:
Sterilization of persons in federally assisted family planning projects, 03–05630

Homeland Security Department
See Coast Guard
See Federal Emergency Management Agency

Housing and Urban Development Department
NOTICES
Grants and cooperative agreements; availability, etc.:
Facilities to assist homeless—
Excess and surplus Federal property, 03–05786

Inspector General Office, Health and Human Services Department
NOTICES
Program exclusions; list, 03–06173

Interior Department
See Fish and Wildlife Service
See Land Management Bureau
See National Park Service
See Surface Mining Reclamation and Enforcement Office

Internal Revenue Service
RULES
Income taxes:
Stock dispositions; suspension of losses, 03–06119
PROPOSED RULES
Income taxes:
Stock dispositions; suspension of losses, 03–06118

International Trade Administration
NOTICES
Overseas trade missions:
2003 trade missions—
Asian Infrastructure Trade Mission, Istanbul, Turkey, et al., 03–06134
Applications, hearings, determinations, etc.:
University of—
Chicago, 03–06182
Missouri-Kansas City, 03–06183

International Trade Commission
NOTICES
Import investigations:
Generalized System of Preferences; possible modifications; 2002 review; correction, 03–06124
Steel; monitoring developments in domestic industry, 03–06123

Labor Department
See Employment Standards Administration
See Occupational Safety and Health Administration
See Veterans Employment and Training Service

Land Management Bureau
NOTICES
Meetings:
California Desert District Advisory Council, 03–06138
Resource management plans, etc.:
Gunnison Gorge National Conservation Area, CO, 03–05889

Management and Budget Office
NOTICES
Commercial activities performance (Circular A-76):
Federal pay raise assumptions and inflation factors (Transmittal Memorandum No. 25), 03–06127

Maritime Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06170

National Labor Relations Board
NOTICES
Senior Executive Service:
Performance Review Boards; membership, 03–06116

National Nuclear Security Administration
NOTICES
Grants and cooperative agreements; availability, etc.:
Renewable energy efficiency and emissions performance; reduction in parasitic energy losses in Class 3-8 trucks, 03–06166

National Oceanic and Atmospheric Administration
NOTICES
Endangered and threatened species:
Anadromous fish take—
Pacific salmon and steelhead, 03–06199
Fishery conservation and management:
Caribbean, Gulf, and South Atlantic fisheries—
Gulf of Mexico reef fish; greater amberjack rebuilding plan, 03–06197

National Park Service
NOTICES
Environmental statements; availability, etc.:
Canyon De Chelly National Monument, AZ, 03–06207
Glacier Bay National Park and Preserve, AK, 03–06206
Petrified Forest National Park, AZ, 03–06208
Rock Creek Park, Washington, DC, 03–06200
Tonto National Monument, AZ, 03–06204
Meetings:
Cape Cod National Seashore Advisory Commission, 03–06205
Chalmette Battlefield Task Force Committee, 03–06203
Gates of Arctic National Park Subsistence Resource Commission, 03–06209
National Register of Historic Places:
Pending nominations, 03–06201, 03–06202
Native American human remains and associated funerary objects:
Denver Art Museum, CO—
Medicine cord, etc., 03–06215
Justice Department, Federal Bureau of Investigation, Rapid City, SD—
Inventory from Crystal Cave Park, SD, 03–06216
Justice Department, Marshals Service, Oklahoma City, OK—
Inventory from Greer County, OK, 03–06214
Nevada State Museum, Reno, NV—
Inventory from Winnemucca Lake, Washoe County, NV, 03–06212
Oregon State Museum of Anthropology, Eugene, OR—
Inventory from Wasco County, OR, 03–06213
Peabody Museum of Archaeology and Ethnology, Harvard University, MA—
Inventory from varioius locations in Broome County, NY; correction, 03–06211
Inventory from various sites in New York; correction, 03–06210
Springfield Science Museum, MA—
Shell beads from Shield's Mound Complex, FL, 03–06218
UCLA Fowler Museum of Cultural History, Los Angeles, CA—
Inventory from Patterson, CA, 03–06217

Nuclear Regulatory Commission
NOTICES
Environmental statements; notice of intent:
Exelon Generation Co., LLC, 03–06157, 03–06158
Applications, hearings, determinations, etc.:
Tennessee Valley Authority, 03–06159

Occupational Safety and Health Administration
RULES
Safety and health standards:
Grain handling facilities, 03–06117

Office of Management and Budget
See Management and Budget Office

Pension Benefit Guaranty Corporation
RULES
Single-employer plans:
Allocation of assets—
Interest assumptions for valuing and paying benefits, 03–06142
NOTICES
Multiemployer plans:
Interest rates and assumptions, 03–06141
Privacy Act:
Systems of records, 03–06271

Presidential Documents
EXECUTIVE ORDERS
Global War on Terrorism Medals; establishment, 03–6445
ADMINISTRATIVE ORDERS
Iran; continuation of national emergency (Notice of March 12, 2003), 03–6421

Public Debt Bureau
See Fiscal Service

Securities and Exchange Commission
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06190, 03–06191
Meetings; Sunshine Act, 03–06326
Self-regulatory organizations; proposed rule changes:
American Stock Exchange LLC, 03–06129
Chicago Stock Exchange, Inc., 03–06130
National Association of Securities Dealers, Inc., 03–06128

Small Business Administration
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06120
Disaster loan areas:
Tennessee, 03–06121

Surface Mining Reclamation and Enforcement Office
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06189

Surface Transportation Board
NOTICES
Railroad operation, acquisition, construction, etc.:
Tongue River Railroad Co., 03–06176

Transportation Department
See Federal Aviation Administration
See Maritime Administration
See Surface Transportation Board
See Transportation Statistics Bureau
NOTICES
Aviation proceedings:
Agreements filed; weekly receipts, 03–06184

Transportation Statistics Bureau
NOTICES
Agency information collection activities; proposals, submissions, and approvals, 03–06185

Treasury Department
See Community Development Financial Institutions Fund
See Fiscal Service
See Internal Revenue Service

Veterans Employment and Training Service
NOTICES
Meetings:
Veterans Employment and Training Advisory Committee, 03–06146

Separate Parts In This Issue

Part II
Health and Human Services Department, Food and Drug Administration, 03–05204

Part III
Health and Human Services Department, Food and Drug Administration, 03–05205

Part IV
Education Department, 03–06160

Part V
Transportation Department, Federal Aviation Administration, 03–06181

Part VI
Homeland Security Department, Federal Emergency Management Agency, 03–06171, 03–06172

Part VII
Executive Office of the President, Presidential Documents, 03–6421

Part VIII
Executive Office of the President, Presidential Documents, 03–6445

Reader Aids

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

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CFR PARTS AFFECTED IN THIS ISSUE

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

3 CFR

Executive Orders:

10977 12567
12957 12563
12959 12563
12985 12567
13059 12563
13289 12567

Administrative Orders:

Notices:
Notice of March 12, 2003 12563

7 CFR

Proposed Rules:

770 12309
1205 12310

9 CFR

1 12283

12 CFR

Proposed Rules:

225 12316

14 CFR

39 12285
91 12542
121 12542
135 12542
145 12542

Proposed Rules:

39 12318

17 CFR

Proposed Rules:

1 12319

21 CFR

Proposed Rules:

201 12500
310 12406
312 12406
314 12406
320 12406
600 12406
601 12406
606 (2 documents) 12406, 12500
610 12500

26 CFR

1 12287
602 12287

Proposed Rules:

1 12324

29 CFR

1910 12301
4022 12303
4044 12303

33 CFR

165 12304

42 CFR

50 12306

44 CFR

152 12544

50 CFR

Proposed Rules:

17 (2 documents) 12326, 12336

Rules and Regulations

Federal Register
Vol. 68, No. 50
Friday, March 14, 2003

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

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DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

9 CFR Part 1

[Docket No. 99–087–3]

Licensing and Inspection Requirements for Dealers of Dogs Intended for Hunting, Breeding, or Security Purposes

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Final rule.

SUMMARY: We are amending the animal welfare regulations to reflect our policy of regulating only wholesale dealers, and not retail dealers, of dogs intended for hunting, breeding, or security purposes. We currently regulate these wholesale dealers under the same regulations in place for wholesale dealers of other dogs. This action makes the regulations consistent with our policy and, therefore, clarifies licensing and inspection requirements for affected dealers of dogs intended for hunting, breeding, or security purposes.

EFFECTIVE DATE: April 14, 2003.

FOR FURTHER INFORMATION CONTACT: Dr. Jerry DePoyster, Senior Staff Veterinarian, Animal Care, APHIS, 4700 River Road Unit 84, Riverdale, MD 20737–1234; (301) 734–7586.

SUPPLEMENTARY INFORMATION:

Background

The Animal Welfare Act (AWA) (7 U.S.C. 2131 *et seq.*) authorizes the Secretary of Agriculture to promulgate standards and other requirements governing the humane handling, housing, care, treatment, and transportation of certain animals by dealers, research facilities, exhibitors, carriers, and intermediate handlers. The Secretary of Agriculture has delegated the responsibility of enforcing the AWA to the Administrator of the Animal and Plant Health Inspection Service (APHIS). The regulations established under the AWA are contained in title 9 of the Code of Federal Regulations (9 CFR), chapter I, subchapter A, parts 1, 2, and 3. Part 1 defines various terms used in parts 2 and 3. Part 2 contains general requirements for regulated parties, and part 3 contains specific requirements for the care and handling of certain animals. Subpart A of part 3 contains the requirements applicable to cats and dogs.

Under section 4 of the AWA (7 U.S.C. 2134), a dealer may not sell an animal as a pet or for exhibition unless he or she first obtains a license from the Secretary. Section 4 also requires a dealer to have a license to buy from or sell to another dealer (*i.e.*, at the wholesale level). Because dogs sold for hunting, breeding, or security purposes are not sold to research facilities, or for use as pets or for exhibition, dealers in these dogs do not need a license to buy or sell them unless they do so at the wholesale level.

Section 13 of the AWA (7 U.S.C. 2143) directs the Secretary to promulgate standards of care with which regulated dealers must comply. Because section 4 of the AWA requires the regulation only of wholesale dealers of hunting, breeding, and security dogs, retail dealers of such dogs are not subject to the standards promulgated under section 13 of the AWA.

In accordance with the AWA, on July 19, 1999, we published in the **Federal Register** (64 FR 38546–38548, Docket No. 97–018–4) a decision and a policy statement that notified the public that, among other things, we had established a policy to license and inspect wholesale dealers of dogs intended primarily for hunting, breeding, or security purposes. This means that we currently regulate these dealers under the same regulations in place for wholesale dealers of other dogs. We instituted this policy to help ensure the humane handling, care, and treatment of hunting, breeding, and security dogs.

Because the regulations at § 2.1 require that all dealers of dogs must be licensed and inspected, we published in the **Federal Register** on December 4, 2000 (65 FR 75635–75637, Docket No. 99–087–1), a proposal to amend the regulations to reflect the intent of the AWA and our policy of regulating only wholesale dealers of dogs intended for hunting, breeding, or security purposes. Specifically, we proposed to amend the definition of *dealer* in § 1.1 to make it clear that, with respect to dealers of hunting, breeding, and security dogs, the term applies only to wholesale dealers of these dogs.

We solicited comments concerning our proposal for 60 days ending February 2, 2001. We extended the deadline for comments until April 3, 2001, in a document published in the **Federal Register** on January 22, 2001 (66 FR 6491–6492, Docket No. 99–087–2). We received 28,485 comments by April 3, 2001, the closing date of the extended comment period. The comments, which were primarily form letters or variations of form letters, were from dog breeders, animal welfare advocates (both individuals and organizations), dog owners and fanciers, representatives of State and local governments, and members and representatives of kennel clubs or specific dog breed associations. These comments are discussed below.

Several thousand commenters suggested that all breeders of dogs that can be considered hunting, breeding, or security dogs should be regulated at not only the wholesale level, but at the retail level as well. Many of these commenters also suggested that our policy and proposal were contrary to the intent of the AWA.

In response, it is important to note that we proposed this action in order to bring our regulations into accord with our policy of regulating only wholesale dealers of dogs intended for hunting, breeding, or security purposes. Our policy statement, discussed previously, clarified that we regulate only wholesale dealers of dogs intended for hunting, breeding, or security purposes. Again, this continuity-creating action helps ensure the humane handling, care, and treatment of hunting, breeding, and security dogs.

As described above, the regulations at § 2.1 require that all dealers of dogs must be licensed and inspected. Currently, then, because our definition of *dealer* in § 1.1 can be extended or interpreted to include both wholesale and retail dealers of hunting, breeding, and security dogs, our regulations have been inconsistent with our published policy. As stated previously and in the

proposed rule, the change will be reflected in the definition of *dealer* in § 1.1.

We do not believe that modifying the definition of *dealer* to reflect our policy is contrary to the intent of the AWA because the Act does not make retail dealers of dogs intended for hunting, breeding, or security purposes subject to Federal licensing and regulation. We believe it is important to modify the definition of *dealer* in order to make explicit the provisions of the Act. It is important to note that our change is consistent with congressional revisions of the AWA in which Congress did not alter our definition of *retail pet store.* Therefore, we are confident that the proposed rule and this final rule reflect Congress' original and continuing intent that, with respect to dealers of hunting, breeding, and security dogs, the definition of *dealer* focus solely on dealers who sell on the wholesale level.

We also believe that our implementation of the AWA has significantly improved the well-being of animals owned by the wholesale dealers we regulate, as well as that of animals owned by retail dealers. It is likely that many retail outlets have improved the living standards of their animals in order to meet the standards of their wholesale counterparts.

Further, we have determined that retail dealers, especially those who sell from their homes, are already subject to a degree of self-regulation and oversight by persons who purchase animals from the retailers' homes, as well as by breed and registry organizations, which require their registrants to meet certain guidelines related to the health and genetic makeup of animals bred and to the education of the registrants. Typically, wholesale dealers do not have the same amount of oversight from the public.

Other commenters suggested that unregulated retail dealers of purebred dogs have no regard for hereditary diseases they propagate. These commenters indicated that unsuspecting customers who purchase diseased animals have no means for Federal recourse. Many of these same commenters noted that retail dealers who are humane would welcome licensing and inspection requirements.

In response, retail dealers of pets are not unregulated. Many State and local laws and ordinances are in place to monitor and respond to allegations of inhumane treatment and inadequate housing for animals owned by private retail dealers.

Another large group of commenters supported most of the proposal, but requested that we further modify the definition of ''dealer'' in § 1.1 to include establishments referred to as ''puppy mills.'' These commenters indicated that retail dealers should remain excluded from the definition of ''dealer,'' but suggested that we need to regulate high-volume dealers.

Although there is no standard, fully encompassing definition for the term ''puppy mill,'' most people use it to refer to high-volume breeding establishments that sell dogs at the wholesale level and sell few, if any, dogs directly to the public. Therefore, as wholesale dealers, the sellers in question are subject to licensing and inspection requirements.

We are not making any changes to the rule as a result of these comments because we have determined that this rule will make our regulations more consistent with our policy to regulate only wholesale dealers of dogs intended for hunting, breeding, or security purposes, and will, therefore, clarify licensing and inspection requirements for affected dealers of these dogs.

We received a total of 1,238 comments expressing support for our proposal. The vast majority of these comments came from self-identified hobby breeders who indicated they were registered with kennel clubs or other breed registry organizations.

Many of these commenters indicated that their breeding dog was a family pet and their hobby breeding establishment was a home-based business. Most commenters shared the concern that additional regulation of retail dealers would require them to become registered dealers and to adhere to licensing and inspection requirements. Those who expressed this concern were adamantly opposed to paying licensing fees for their hobby breeding establishments and having their private homes inspected. Many suggested that such requirements would be cumbersome, if not impossible, to enforce.

In response, we are charged with enforcing the provisions of the AWA which require the regulation only of wholesale dealers of hunting, breeding, or security dogs.

Therefore, for the reasons given in the proposed rule and in this document, we are adopting the proposed rule as a final rule, without change.

Executive Order 12866 and Regulatory Flexibility Act

This rule has been reviewed under Executive Order 12866. The rule has been determined to be not significant for the purposes of Executive Order 12866 and, therefore, has not been reviewed by the Office of Management and Budget.

In accordance with 5 U.S.C. 604, we have performed a final regulatory flexibility analysis, which is set out below, regarding the economic effects of this rule on small entities.

This final rule amends the regulations to reflect our policy of regulating only wholesale dealers of dogs intended for hunting, breeding, or security purposes. As such, this action does not result in any change to our operations. We currently help ensure the humane handling, care, and treatment of hunting, breeding, and security dogs through the licensing and inspection of wholesale dealers of these dogs; we regulate these dealers under the same regulations in place for wholesale dealers of other types of dogs.

We have used all available data to estimate the potential economic effects of changing the definition of *dealer* in § 1.1 to reflect our policy of regulating wholesale dealers of hunting, breeding, or security dogs. However, specific data concerning the number of small entities that will be affected by this rule is not available. In our proposed rule, we invited comments. However, none of the comments we received specifically addressed potential economic effects.

To comply with our current policy and the regulations, wholesale dealers of dogs intended for hunting, breeding, or security purposes incur costs for licensing, as well as other expenses. The costs of licensing for affected dealers include an annual application fee of $10 and an annual class ''A'' license fee based on 50 percent of total gross sales or compensation from leased animals. License fee amounts are determined according to ranges shown in Table 1 of 9 CFR part 2, § 2.6.

Among other costs incurred by wholesale dealers of hunting, breeding, and security dogs are expenses related to veterinary care, tagging or tattoo marking for animal identification, recordkeeping, health certification of dogs commercially transported, and maintenance of appropriate facilities and operating standards (*see* 9 CFR part 3, subpart A). It is reasonable to assume, however, that these responsibilities are met by affected dealers simply as a matter of good business practice. When dealers satisfy the facilities and operating standards of the regulations by, for example, providing a safe and healthy environment (including appropriate heating, cooling and ventilation of the dogs' housing to adequate feeding and exercising programs), those dealers are contributing to their dogs' eventual sale value. As another example, records of transactions can only further a wholesale dealer's business success.

Therefore, it is in a dealer's financial interest to promote the health and well-being of his or her dogs in accordance with the regulations. However, if any wholesale dealers of hunting, breeding, or security dogs were not in compliance with the regulations in 9 CFR parts 2 and 3 prior to our policy announcement on July 19, 1999, they will likely have incurred expenses related to meeting these requirements. We do not have information on the number of such dealers or what their expenses might be.

The purpose of this rule is actually to remove requirements covering dealers who sell hunting, breeding, or security dogs at the retail level. Those dealers will experience no economic effects from this action since we have never enforced those provisions.

The Regulatory Flexibility Act requires that agencies consider the economic effects of rules on small entities. The Small Business Administration determines the criteria by which entities are classified as ''small,'' using the North American Industry Classification System (NAICS) categories. Wholesale dealers of hunting, breeding, or security dogs are included within NAICS category 112990, ''All Other Animal Production.'' Small entities in this category are ones with annual receipts of $750,000 or less. Although data is not available on the number of wholesale dealers of hunting, breeding, or security dogs, or their incomes, we presume the majority are small entities.

While a substantial number of affected dealers may be small entities, we expect the effect of this rule on these dealers will be insignificant because licensing and inspection fees will remain the same. This action simply makes our regulations consistent with our policy and, therefore, clarifies licensing and inspection requirements for affected dealers of dogs intended for hunting, breeding, and security purposes.

This rule contains various recordkeeping requirements, which were described in our proposed rule, and which have been approved by the Office of Management and Budget (See ''Paperwork Reduction Act'' below).

Executive Order 12372

This program/activity is listed in the Catalog of Federal Domestic Assistance under

No. 10.025 and is subject to Executive Order 12372, which requires intergovernmental consultation with State and local officials. (*See* 7 CFR part 3015, subpart V.)

Executive Order 12988

This final rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This rule will not preempt any State or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule. The Animal Welfare Act does not provide administrative procedures which must be exhausted prior to a judicial challenge to the provisions of this rule.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*), the information collection or recordkeeping requirements included in this rule have been approved by the Office of Management and Budget (OMB) under OMB control number 0579–0169.

Government Paperwork Elimination Act Compliance

The Animal and Plant Health Inspection Service is committed to compliance with the Government Paperwork Elimination Act (GPEA), which requires Government agencies in general to provide the public the option of submitting information or transacting business electronically to the maximum extent possible. For information pertinent to GPEA compliance related to this rule, please contact Mrs. Celeste Sickles, APHIS' Information Collection Coordinator, at (301) 734–7477.

List of Subjects in 9 CFR Part 1

Animal welfare, Pets, Reporting and recordkeeping requirements, Research.

Accordingly, we are amending 9 CFR Part 1 as follows:

PART 1—DEFINITION OF TERMS

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

Authority: 7 U.S.C. 2131–2159; 7 CFR 2.22, 2.80, and 371.7.

2. In § 1.1 the definition for *dealer* is revised to read as follows:

§ 1.1 Definitions.

* * * * *

Dealer means any person who, in commerce, for compensation or profit, delivers for transportation, or transports, except as a carrier, buys, or sells, or negotiates the purchase or sale of: Any dog or other animal whether alive or dead (including unborn animals, organs, limbs, blood, serum, or other parts) for research, teaching, testing, experimentation, exhibition, or for use as a pet; or any dog at the wholesale level for hunting, security, or breeding purposes. This term does not include: A retail pet store, as defined in this section, unless such store sells any animal to a research facility, an exhibitor, or a dealer (wholesale); any retail outlet where dogs are sold for hunting, breeding, or security purposes; or any person who does not sell or negotiate the purchase or sale of any wild or exotic animal, dog, or cat and who derives no more than $500 gross income from the sale of animals other than wild or exotic animals, dogs, or cats during any calendar year.

* * * * *

Done in Washington, DC, this 10th day of March, 2003.

Peter Fernandez,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 03–6161 Filed 3–13–03; 8:45 am]

BILLING CODE 3410–34–P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–NM–218–AD; Amendment 39–13084; AD 2003–05–08]

RIN 2120–AA64

Airworthiness Directives; Dornier Model 328–100 and –300 Series Airplanes

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new airworthiness directive (AD), applicable to certain Dornier Model 328–100 and –300 series airplanes, that requires replacement of certain flight data recorder (FDR) and cockpit voice recorder (CVR) impact switches with certain new impact switches. This action is necessary to prevent the loss of data recorded on the FDR and CVR, which, in the event of an accident, could result in the inability to retrieve data from the FDR and CVR during the accident investigation. This loss of data could hinder the identification of the unsafe condition which caused the accident, and prevent the FAA from developing and mandating actions to prevent additional accidents caused by that same unsafe condition.

DATES: Effective April 18, 2003.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of April 18, 2003.

ADDRESSES: The service information referenced in this AD may be obtained from Fairchild Dornier, Dornier Luftfahrt GmbH, P.O. Box 1103, D–82230 Wessling, Germany. This information may be examined at the Federal Aviation Administration (FAA), Transport Airplane Directorate, Rules Docket, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Dan Rodina, Aerospace Engineer, International Branch, ANM–116, FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington 98055–4056; telephone (425) 227–2125; fax (425) 227–1149.

SUPPLEMENTARY INFORMATION: A proposal to amend part 39 of the Federal Aviation Regulations (14 CFR part 39) to include an airworthiness directive (AD) that is applicable to certain Dornier Model 328–100 and –300 series airplanes was published in the **Federal Register** on December 10, 2002 (67 FR 75822). That action proposed to require replacement of certain flight data recorder (FDR) and cockpit voice recorder (CVR) impact switches with certain new impact switches.

Comments

Interested persons have been afforded an opportunity to participate in the making of this amendment. No comments were submitted in response to the proposal or the FAA's determination of the cost to the public.

Conclusion

The FAA has determined that air safety and the public interest require the adoption of the rule as proposed.

Cost Impact

The FAA estimates that 53 Model 328–100 series airplanes and 48 Model 328–300 series airplanes of U.S. registry would be affected by this AD, that it will take approximately 1 work hour per airplane to accomplish the required replacement, and that the average labor rate is $60 per work hour. Required parts will cost approximately $1,346 per airplane. Based on these figures, the cost impact of the AD on U.S. operators is estimated to be $142,006, or $1,406 per airplane.

The cost impact figure discussed above is based on assumptions that no operator has yet accomplished any of the requirements of this AD action, and that no operator would accomplish those actions in the future if this AD were not adopted. The cost impact figures discussed in AD rulemaking actions represent only the time necessary to perform the specific actions actually required by the AD. These figures typically do not include incidental costs, such as the time required to gain access and close up, planning time, or time necessitated by other administrative actions.

Regulatory Impact

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 the following new airworthiness directive:

2003–05–08 Dornier Luftfahrt GMBH: Amendment 39–13084. Docket 2002-NM–218–AD.

Applicability: Airplanes listed in the following table of this AD, certificated in any category:

TABLE.—APPLICABILITY

Model	Serial Nos.
328–100 series airplanes.	3005 through 3119 inclusive.
328–300 series airplanes.	3105 through 3223 inclusive.

Note 1: This AD applies to each airplane 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 airplanes 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 (c) 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, unless accomplished previously.

To prevent the loss of data recorded on the flight data recorder (FDR) and cockpit voice recorder (CVR), which, in the event of accident, could result in the inability to retrieve data from the FDR and CVR during the accident investigation, and hinder the identification of the unsafe condition which caused the accident, accomplish the following:

Switch Replacement

(a) For Model 328–100 series airplanes: Within 12 months after the effective date of this AD, replace the FDR and CVR 3g-impact switches, with new, 6g-impact switches, per the Accomplishment Instructions of Dornier Service Bulletin SB–328–31–390, dated September 6, 2001.

(b) For Model 328–300 series airplanes: Within 12 months after the effective date of this AD, replace the FDR and CVR 3g-impact switches, with new, 6g-impact switches, per the Accomplishment Instructions of Dornier Service Bulletin SB–328J–31–118, dated September 6, 2001.

Alternative Methods of Compliance

(c) 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, International Branch, ANM–116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Operations Inspector, who may add comments and then send it to the Manager, International Branch, ANM–116.

Note 2: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM–116.

Special Flight Permits

(d) Special flight permits may be issued in accordance with sections 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 accomplished.

Incorporation by Reference

(e) The actions shall be done in accordance with Dornier Service Bulletin SB–328–31–390, dated September 6, 2001; and Dornier Service Bulletin SB–328J–31–118, dated September 6, 2001; as applicable. 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 Fairchild Dornier, Dornier Luftfahrt GmbH, P.O. Box 1103, D–82230 Wessling, Germany. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 3: The subject of this AD is addressed in German airworthiness directives 2002–238 and 2002–239, both dated August 22, 2002.

Effective Date

(f) This amendment becomes effective on April 18, 2003.

Issued in Renton, Washington, on March 5, 2003.

Ali Bahrami,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 03–5860 Filed 3–13–03; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9048]

RIN 1545–BB95

Guidance Under Section 1502; Suspension of Losses on Certain Stock Dispositions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final and temporary regulations.

SUMMARY: This document contains final and temporary regulations under section 1502 that redetermine the basis of stock of a subsidiary member of a consolidated group immediately prior to certain transfers of such stock and certain deconsolidations of a subsidiary member. In addition, this document contains temporary regulations that suspend certain losses recognized on the disposition of stock of a subsidiary member. The regulations apply to corporations filing consolidated returns. The text of the temporary regulations serves as the text of the proposed regulations set forth in the Proposed Rules section of this issue of the **Federal Register**.

DATES: *Effective date:* These regulations are effective March 14, 2003.

Applicability Date: For dates of applicability, *see* §§ 1.1502–21T(h)(7), 1.1502–32T(h)(6), and 1.1502–35T(j).

FOR FURTHER INFORMATION CONTACT: Aimee K. Meacham, (202) 622–7530 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

These regulations are being issued without prior notice and public procedure pursuant to the Administrative Procedure Act (5 U.S.C. 553). For this reason, the collection of information contained in these temporary regulations has been reviewed and, pending receipt and evaluation of public comments, approved by the Office of Management and Budget (OMB) under 44 U.S.C. 3507 and assigned control number 1545–1828. Responses to this collection of information are voluntary.

An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless the collection of information displays a valid OMB control number.

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

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

Background and Explanation of Provisions

On October 18, 2002, the IRS and Treasury Department issued a notice of proposed rulemaking (REG–131478–02, 2002–47 I.R.B. 892 [67 FR 65060]) that included proposed regulations reflecting the principle set forth in Notice 2002–18 (2002–12 I.R.B. 644) that a consolidated group should not be able to obtain more than one tax benefit from a single economic loss. The rules in the proposed regulations were intended to address at least two situations in which a group may obtain more than one tax benefit from a single economic loss. In one situation, a group first recognizes and absorbs a subsidiary member's inside loss (*e.g.*, a loss carryforward, a deferred deduction, or a loss inherent in an asset) and a member of the group later recognizes a loss on the subsidiary member's stock that is duplicative of the previously recognized and absorbed inside loss. In the second situation, a member of the group recognizes a loss on a non-deconsolidating disposition of the subsidiary member's stock, the stock loss duplicates an unrecognized or unabsorbed loss of the subsidiary member, and the group later recognizes and absorbs the subsidiary's inside loss.

The proposed regulations consist primarily of two rules: a basis redetermination rule and a loss suspension rule. The proposed regulations also include a basis reduction rule that addresses certain cases of loss duplication that are not within the scope of the loss suspension rule, such as losses arising from the worthlessness of subsidiary member stock.

No public hearing regarding the proposed regulations was requested or held. Comments, however, were submitted.

The IRS and Treasury Department have studied, and are continuing to study, the comments received. The IRS and Treasury Department believe that the comments received, as well as the issues more generally raised by Notice 2002–18 and the proposed regulations, require significant further consideration. Accordingly, the IRS and Treasury Department will continue to study these issues and, as more fully set forth below, request comments on, and suggestions for possible alternative approaches to, the issues addressed in the regulations. Nonetheless, the IRS and Treasury Department believe that immediately effective rules are necessary to address the duplication of loss within a consolidated group so as to clearly reflect the income tax liability of the group. Accordingly, the IRS and Treasury Department are promulgating the proposed regulations as temporary regulations in this Treasury decision. The temporary regulations are substantially similar to the proposed regulations, but reflect certain revisions that were made based on comments received. The following sections describe these revisions.

A. Application of Basis Redetermination Rule Upon Deconsolidation of a Subsidiary Member

The proposed regulations require the reallocation of the basis of subsidiary member stock held by members of the

group upon certain dispositions and deconsolidations of subsidiary member stock. The rule applies differently when the subsidiary remains a member of the group from when the subsidiary does not remain a member of the group. The IRS and Treasury Department received several technical comments regarding the basis redetermination rule applicable when a subsidiary member leaves the group. The temporary regulations revise that rule in a manner that addresses these comments and clarifies its application.

In particular, under the temporary regulations, subject to certain exceptions, the rule applies upon a deconsolidation of a subsidiary member when any stock of the subsidiary member owned by a member of the group has a basis in excess of value. The revised rule generally applies regardless of whether the subsidiary member is deconsolidated as a result of a transfer of a gain share, a transfer of a loss share, or a stock issuance because, in each case, the effect is the same, *i.e.*, each share of subsidiary member stock owned by group members is deconsolidated. Further, in computing the basis that is reallocated, the revised rule takes into account all loss on members' shares of the subsidiary's stock and all prior negative basis adjustments to members' shares of the subsidiary stock that are not loss shares. The revised rule reflects that, unless all deconsolidations and all deconsolidated shares are treated similarly, opportunities to duplicate losses will continue to exist.

B. Application of Loss Suspension Rule

Under the loss suspension rule, if, after application of the basis redetermination rule, a member of a consolidated group recognizes a loss on the disposition of stock of a subsidiary member of the same group, and the subsidiary member is a member of the same group immediately after the disposition, then the selling member's stock loss is suspended to the extent of the duplicated loss with respect to such stock. Because a suspended stock loss reflects the subsidiary member's unrecognized or unabsorbed deductions and losses, under the proposed regulations, the suspended loss is reduced, with the result that it will not later be allowed, as the subsidiary member's deductions and losses are taken into account (*i.e.*, absorbed) in determining the group's consolidated taxable income (or loss). One comment received regarding the proposed regulations was that, in certain cases, the loss suspension rule could disallow a tax loss for an economic loss. This result was not intended. Accordingly, these temporary regulations include two changes from the proposed regulations that are intended to prevent this result.

First, the temporary regulations provide that the amount by which a suspended stock loss is reduced cannot exceed the excess of the amount of the subsidiary member's items of loss and deduction over the amount of such items that are taken into account in determining the basis adjustments made to stock of the subsidiary member (or any successor) owned by members of the group under the investment adjustment rules.

Second, they also include a provision stating that the loss suspension rule is not to be applied in a manner that permanently disallows an otherwise allowable deduction for an economic loss. Whether the loss suspension rule has resulted in such a disallowance is determined on the earlier of the date of the deconsolidation of the subsidiary (or any successor) the stock of which gave rise to the suspended stock loss and the date on which the stock of such subsidiary is determined to be worthless. When it is determined that the application of the loss suspension rule has permanently disallowed a deduction for an economic loss, the taxpayer will be permitted to treat the suspended stock loss as restored to the extent of such disallowance. The restoration of the suspended loss is deemed to occur immediately prior to the deconsolidation of the subsidiary or the determination of worthlessness.

C. Basis Reduction Rule for Worthless Stock and Stock of a Subsidiary With No Separate Return Year

The proposed regulations include a basis reduction rule intended to prevent the duplication of unabsorbed losses generated by a subsidiary member and loss with respect to the stock of that member if either (i) the stock of the subsidiary member becomes worthless or (ii) the stock of the subsidiary is disposed of and, immediately after the disposition, the subsidiary is no longer a member of the group and does not have a separate return year. Under this rule, immediately before a determination of worthlessness, or immediately before a disposition of a subsidiary that is not followed by a separate return year, the basis of the subsidiary's stock is reduced by the amount of any loss carryforwards that would be treated as attributable to the subsidiary under the principles of § 1.1502–21. This provision was included because neither situation was subject to the loss suspension rule and, without such a rule, taxpayers might take the position that a group is entitled to a subsidiary member's loss carryforwards even after the group has enjoyed full basis recovery through a worthless stock or other deduction. Such a result, however, would be in contravention of the principles of Notice 2002–18.

The proposed provision raised questions about the operation of the existing rules governing this situation. Commentators contended that the basis reduction rule could deny the group a single tax loss for its economic loss. As stated above, the proposed regulations, including the basis reduction rule, were not intended to disallow a tax loss for an economic loss, but rather were intended only to ensure that a group obtains no more than a single tax loss for an economic loss.

The temporary regulations address this situation by providing that the unabsorbed losses generated by the subsidiary do not remain available to the group. Specifically, the temporary regulations provide that, if stock of a subsidiary member is treated as worthless under section 165 (taking into account the provisions of § 1.1502–80(c)), or if a member of a group disposes of subsidiary member stock and on the following day the subsidiary is not a member of the group and does not have a separate return year, then all losses treated as attributable to the subsidiary member under the principles of § 1.1502–21, after computing the taxable income of the group, the subsidiary member, or a group of which the subsidiary member was previously a member for the taxable year that includes the determination of worthlessness or the disposition and any prior taxable year, shall be treated as expired, but not as absorbed by the group, as of the beginning of the group's taxable year that follows the taxable year that includes the determination of worthlessness or the disposition. Under this rule, the stock loss (or reduced stock gain), unreduced by any loss carryforwards attributable to the subsidiary member, is allowed. Moreover, because the losses are treated as expired, there is no possibility of a later, duplicative use of the loss carryforwards. This approach is consistent with the nature of a loss realized upon such a determination or disposition, *i.e.*, a loss on an investment in the subsidiary member.

Because the provisions of the proposed regulations raised questions about the operation of the existing rules, the temporary regulations include a special election for determinations of worthlessness and dispositions that occurred on or after March 7, 2002, and

before March 14, 2003. In such cases, as an alternative to the treatment described above, the common parent of the group may make an irrevocable election to reattribute to itself all or a portion of the losses attributable to the subsidiary member under the principles of § 1.1502–21. For purposes of applying the investment adjustment rules to stock of the subsidiary member owned by the group, the reattributed losses are treated as absorbed by the group immediately prior to the allowance of any loss or inclusion of any income or gain with respect to the determination of worthlessness or the disposition. The common parent, however, is treated as succeeding to the subsidiary's losses in a transaction described in section 381.

The IRS and Treasury Department request comments regarding whether a subsidiary member the stock of which is determined to be worthless (under the standards of § 1.1502–80(c)) should be treated as a new corporation for purposes of the Internal Revenue Code as of the date of the determination of worthlessness. In addition, the IRS and Treasury Department request comments regarding the desirability of further clarification or changes regarding the standards that govern determinations of worthlessness and the deductibility of losses (or the inclusion of excess loss accounts) when stock of a subsidiary member is determined to be worthless.

D. Deferral and Elimination of Gain

One comment noted that the basis redetermination rule of the proposed regulations could be used to shift the location of gain and loss within a consolidated group and even to eliminate gain in a manner that is unintended and contrary to the purposes underlying section 337(d). The following example illustrates this concern.

P, the common parent of a consolidated group, owns all of the stock of S1 and S2. The S2 stock has a basis of $400 and a value of $500. S1 owns 50% of the stock of the S3 common stock with a basis of $150 and value equal to such amount. S2 owns the remaining 50% of the S3 common stock with a basis of $100 and a value of $200 and one share of S3 preferred stock with a basis of $10 and a value of $9. P intends to sell all of its S2 stock to an unrelated buyer that does not want to acquire S3. P, therefore, engages in the following steps to dispose of S2 without recognizing a substantial portion of the built-in gain in S2. First, P causes a recapitalization of S3 in which S2's S3 common stock is exchanged for new S3 preferred shares. P then sells all of its S2 stock. Although the sale does not deconsolidate S3 (because all the S3 common stock is still held by S1), it does deconsolidate the S3 preferred shares held by S2, including the one share with a built-in loss. Accordingly, under the proposed regulations, the bases of all shares of S3 stock must be redetermined immediately before P's sale of S2. Under the basis redetermination rule, the total basis of S3 stock held by members of the P group is allocated first to the S3 preferred shares, up to their value of $209, and then to the remaining shares of S3 common held by S1. S2's aggregate basis in the S3 preferred stock is increased from $110 to $209. This increase tiers up and increases P's basis in the S2 stock from $400 to $499. Accordingly, P will recognize only $1 of gain on the sale of its S2 stock. Afterwards, P can cause S3 to redeem its preferred stock for $209. S2 will recognize no gain or loss from the redemption. Although the unrecognized gain is preserved in P's basis in S1, and S1's basis in S3, the group can defer or avoid recognizing that gain.

In this case, there is no significant duplication of loss. Moreover, the steps were structured with a view to avoiding the recognition of gain on a disposition of stock. The IRS and Treasury Department do not intend that the basis redetermination rule be applied to defer or eliminate gain in such cases. The IRS and Treasury Department considered adopting a mechanical test to prevent the application of the basis redetermination rule in such cases. They concluded that such a rule would not provide the flexibility necessary to obtain an appropriate balancing of the concerns underlying this regulation and those underlying section 337(d). Therefore, these temporary regulations include an anti-abuse rule that provides that, if a transaction is structured with a view to, and has the effect of, deferring or avoiding the recognition of gain on a disposition of stock by invoking application of the basis redetermination rule, and the stock loss attributable to the transferred shares or the duplicated loss of the subsidiary member that is reflected in subsidiary member stock owned by members of the group is not significant, the basis redetermination and loss suspension rules will not apply.

E. Request for Comments

As described above, the IRS and Treasury Department are continuing to study the comments received regarding the proposed regulations. In addition, the IRS and Treasury Department are considering alternative regimes that would prevent the duplication of loss within the group.

In particular, the IRS and Treasury Department are studying a comment that suggested applying the principles of section 704(c) to allocate negative investment adjustments arising from loss items at the subsidiary member level where there have been transfers of loss property to the subsidiary member. The comment asserts that this approach would address the case where the recognition and absorption of the inside loss precedes the recognition of the stock loss. The IRS and Treasury Department are concerned that this alternative approach addresses only duplicative losses that arise as a result of contributions of loss property, not duplicative losses that arise as a result of a loss incurred by a subsidiary member. In addition, the IRS and Treasury Department are concerned that the application of the principles of section 704(c) may be complex, especially in cases where there have been issuances of subsidiary member stock at different times. The IRS and Treasury Department request comments regarding how the principles of section 704(c) should be applied in the consolidated return context to prevent the duplication of loss.

The IRS and Treasury Department are also studying a suggestion that the type of transaction in which the stock loss is recognized prior to the absorption of the inside loss be addressed by a rule that allows the stock loss but limits the use of the subsidiary member's items of loss and deduction if there have been contributions of loss property with respect to the subsidiary member and there is any loss duplication at the subsidiary member level at the time the stock loss is recognized. That rule would not permit the use of the subsidiary's items of loss and deduction that are duplicative of the stock loss to offset income of another member of the group, but would permit such items to offset income of the subsidiary.

This rule effectively would permit the acceleration of stock loss. The IRS and Treasury Department request comments regarding whether permitting such acceleration would clearly reflect the income of the group.

In addition, because this rule would permit the subsidiary's losses to offset its items of income and gain, it would not prevent the duplication of losses within the group to that extent. The IRS and Treasury Department request comments regarding whether this duplication is appropriate given that the benefits associated with the subsidiary and its shareholder being members of the group (*e.g.*, positive basis

adjustments to the shareholder member's stock of the subsidiary member that reflect income of the subsidiary member and the group's ability to use the loss recognized by another member to offset income of the subsidiary member of the group) have been enjoyed by the group.

Finally, this rule would address only cases of duplication where there have been contributions of loss property. As described above, the IRS and Treasury Department are concerned that contributions of loss property are not the only types of transactions in which a group can obtain more than one tax benefit from a single economic loss.

The IRS and Treasury Department are considering a variation of this suggested rule to address the situation where the stock loss is recognized prior to the absorption of the inside loss. This variation would allow the stock loss when recognized, but would disallow the inside losses of the subsidiary to the extent that such losses reflect losses that were duplicate losses at the time of the recognition of the stock loss. Such losses may be attributable to contributed property or losses that arose in the subsidiary member. The IRS and Treasury Department request comments regarding this variation.

Finally, the IRS and Treasury Department continue to request comments regarding any other approaches that could be implemented to address the duplication of loss within a consolidated group.

Special Analyses

In *Rite Aid Corp.* v. *United States,* 255 F.3d 1357 (Fed. Cir. 2001), the United States Court of Appeals for the Federal Circuit held that the duplicated loss component of § 1.1502–20 was an invalid exercise of regulatory authority. In response to the *Rite Aid* decision, the IRS and Treasury Department issued Notice 2002–11 (2002–7 I.R.B. 526), stating that the interests of sound tax administration would not be served by the continued litigation of the validity of the duplicated loss component of § 1.1502–20. Notice 2002–11 also announced that because of the interrelationship in the operation of all of the loss disallowance factors, new rules governing loss disallowance on sales of subsidiary stock by members of consolidated groups should be implemented.

In Notice 2002–18 (2002–12 I.R.B. 644), the IRS and Treasury Department stated that regulations would be promulgated that would defer or otherwise limit the utilization of a loss on stock (or another asset that reflects the basis of stock) in transactions that facilitate the group's utilization of a single economic loss more than once. Notice 2002–18 further stated that such regulations would apply to dispositions occurring on or after March 7, 2002. These temporary regulations implement Notice 2002–18 and are necessary to provide taxpayers with immediate guidance regarding stock basis and allowable loss in connection with transfers of subsidiary member stock. Accordingly, good cause is found for dispensing with a delayed effective date pursuant to 5 U.S.C. 553(d)(3).

It has been determined that this Treasury decision is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations do not have a significant impact on a substantial number of small entities. This certification is based on the fact that these regulations will primarily affect affiliated groups of corporations, which tend to be larger businesses. Moreover, the number of taxpayers affected and the average burden are minimal. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

Drafting Information

The principle author of these regulations is Aimee K. Meacham of the Office of Chief Counsel (Corporate). However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects

26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

26 CFR Part 602

Reporting and recordkeeping requirements.

Amendments to the Regulations

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

PART 1—INCOME TAXES

Paragraph 1. The authority citation for part 1 is amended by adding entries in numerical order to read in part as follows:

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

Section 1.1502–21T(b)(1) and (b)(3)(v) also issued under 26 U.S.C. 1502. * * *

Section 1.1502–32T(a)(2), (b)(3)(iii)(C), (b)(3)(iii)(D), and (b)(4)(vi) also issued under 26 U.S.C. 1502. * * *

Section 1.1502–35T also issued under 26 U.S.C. 1502. * * *

Par. 2. In the list below, for each section indicated in the left column, remove the wording indicated in the middle column, and add the wording indicated in the right column.

Affected section	Remove	Add
§ 1.267(f)–1(k)	§§ 1.337(d)–1, §§ 1.337(d)–2, 1.1502–13(f)(6), and 1.1502–20.	§§ 1.337(d)–2T, 1.1502–13(f)(6), and 1.1502–35T.
§ 1.597–3(e)	*Loss disallowance.* For purposes of § 1.1502–20, FFA and the amount described in § 1.597–4(g)(3) are treated as an extraordinary gain disposition within the meaning of § 1.1502–20(c)(2)(i) and a Taxable Transfer is treated as an applicable asset acquisition under section 1060(c) within the meaning of § 1.1502–20(c)(2)(i)(A)(*4*).	[Reserved].
§ 1.597–4(g)(2)(v), second sentence.	(*See* §§ 1.337(d)–1 and 1.1502–20 for potential limitations on the group's worthless stock deduction).	(*See* §§ 1.337(d)–2T and 1.1502–35T(f) for rules applicable when a member of a consolidated group is entitled to a worthless stock deduction with respect to stock of another member of the group.)
§ 1.1502–11(b)(3)(ii) Example (c), third sentence.	*See also* § 1.1502–20 for rules applicable to losses from the sale of stock of subsidiaries.	*See also* §§ 1.337(d)–2T and 1.1502–35T for rules relating to basis adjustments and allowance of stock loss on dispositions of stock of a subsidiary member.

Affected section	Remove	Add
§ 1.1502–12(r)	For rulings relating to loss disallowance or basis reduction on the disposition or deconsolidation of stock of a subsidiary, see §§ 1.337(d)–1, 1.337(d)–2 and 1.1502–20.	*See* §§ 1.337(d)–2T and 1.1502–35T(f) for rules relating to basis adjustments and allowance of stock loss on dispositions of stock of a subsidiary member.
§ 1.1502–13(f)(7), Example 1(e), sixth sentence.	*See also* § 1.1502–20(b) (additional stock basis reductions applicable to certain deconsolidations).	
§ 1.1502–15(b)(2)(iii), first sentence.	(*e.g.*, under § 1.1502–20 or section 267)	(*e.g.*, under §§ 1.337(d)–2T, 1.1502–35T, or section 267)
§ 1.1502–21(b)(2)(i), third sentence.	For rules permitting the reattribution of losses of a subsidiary to the common parent when loss is disallowed on the disposition of subsidiary stock, see § 1.1502–20(g).	
§ 1.1502–32(b)(3)(iii)(B), third sentence.	§ 1.1502–20(b), or § 1.1502–20(g)	§ 1.1502–35T(b) or (f)(2)
§ 1.1502–32(b)(5)(ii), Example 2(b), last sentence.	*See also* § 1.1502–20(b) (possible stock basis reduction on the deconsolidation of S).	
§ 1.1502–32(e)(2), Example 4(a), fourth sentence.	(Section § 1.1502–20(b) does not reduce P's basis in the S stock as a result of S's deconsolidation).	
§ 1.1502–80(c), last sentence.	*See* § 1.1502–11(c) and 1.1502–20 for additional rules relating to stock loss.	*See* § 1.1502–11(c) and 1.1502–35T for additional rules relating to stock loss.
§ 1.1502–91(h)(2), first sentence.	(unless disallowed under § 1.1502–20 or otherwise)	(unless disallowed under § 1.337(d)–2T, 1.1502–35T, or otherwise)

Par. 3. Section 1.1502–21 is amended by:

1. Revising paragraph (b)(1).
2. Adding paragraphs (b)(3)(v) and (h)(7).

The revisions and addition read as follows:

§ 1.1502–21 Net operating losses.

* * * * *

(b) * * *

(1) [Reserved]. For further guidance, see § 1.1502–21T(b)(1).

* * * * *

(3) * * *

(v) [Reserved]. For further guidance, see § 1.1502–21T(b)(3)(v).

* * * * *

(h) * * *

(7) [Reserved]. For further guidance, see § 1.1502–21T(h)(7).

Par. 4. Section 1.1502–21T is revised to read as follows:

§ 1.1502–21T Net operating losses (temporary).

(a) [Reserved]. For further guidance, see § 1.1502–21(a).

(b) [Reserved]. For further guidance, see § 1.1502–21(b).

(1) *Carryovers and carrybacks generally.* The net operating loss carryovers and carrybacks to a taxable year are determined under the principles of section 172 and this section. Thus, losses permitted to be absorbed in a consolidated return year generally are absorbed in the order of the taxable years in which they arose, and losses carried from taxable years ending on the same date, and which are available to offset consolidated taxable income for the year, generally are absorbed on a pro rata basis. Additional rules under the Internal Revenue Code or regulations also apply. See, *e.g.*, section 382(l)(2)(B) (if losses are carried from the same taxable year, losses subject to limitation under section 382 are absorbed before losses that are not subject to limitation under section 382). See *Example 2* of paragraph (c)(1)(iii) of this section for an illustration of pro rata absorption of losses subject to a SRLY limitation. See paragraph (b)(3)(v) of this section regarding the treatment of any loss that is treated as expired under § 1.1502–35T(f)(1).

(b)(2) through (b)(3)(iv) [Reserved]. For further guidance, see § 1.1502–21(b)(2) through (b)(3)(iv).

(b)(3)(v) *Losses treated as expired under § 1.1502–35T(f)(1).* No loss treated as expired by § 1.1502–35T(f)(1) may be carried over to any consolidated return year of the group.

(c) through (h)(6) [Reserved]. For further guidance, see § 1.1502–21(c) through (h)(6).

(h)(7) *Losses treated as expired under § 1.1502–35T(f)(1).* Paragraph (b)(3)(v) of this section is effective for losses treated as expired under § 1.1502–35T(f)(1) on and after March 7, 2002, and no later than March 11. 2006.

Par. 5. Section 1.1502–32 is amended by:

1. Revising paragraph (a)(2).
2. Adding paragraphs (b)(3)(iii)(C), (b)(3)(iii)(D), (b)(4)(vi), and (h)(6).

The revision and additions read as follows:

§ 1.1502–32 Investment adjustments.

* * * * *

(a)(2) [Reserved]. For further guidance, see § 1.1502–32T(a)(2).

(b)(3)(iii)(C) and (D) [Reserved]. For further guidance, see § 1.1502–32T(b)(3)(iii)(C) and (D).

* * * * *

(b)(4)(vi) [Reserved]. For further guidance, see § 1.1502–32T(b)(4)(vi).

* * * * *

(h)(6) [Reserved]. For further guidance, see § 1.1502–32T(h)(6).

Par. 6. Section 1.1502–32T is revised to read as follows:

§ 1.1502–32T Investment adjustments (temporary).

(a) and (a)(1) [Reserved]. For further guidance, see § 1.1502–32(a) and (a)(1).

(a)(2) *Application of other rules of law.* The rules of this section are in addition to other rules of law. See, *e.g.*, section 358 (basis determinations for distributees), section 1016 (adjustments to basis), § 1.1502–11(b) (limitations on the use of losses), § 1.1502–19 (treatment of excess loss accounts), § 1.1502–31 (basis after a group structure change), and § 1.1502–35T (additional rules relating to stock loss, including losses attributable to worthlessness and certain dispositions not followed by a separate return year). P's basis in S's stock must not be adjusted under this section and other rules of law in a manner that has the effect of duplicating an adjustment. For example, if pursuant to § 1.1502–35T(c)(3) and paragraph (b)(3)(iii)(C) of this section the basis in stock is reduced to take into account a loss suspended under § 1.1502–35T(c)(1), such basis shall not be further reduced to take into account such loss, or a portion of such loss, if any, that is later allowed pursuant to § 1.1502–35T(c)(5). See also paragraph (h)(5) of this section for basis

reductions applicable to certain former subsidiaries.

(b) through (b)(3)(iii)(B) [Reserved]. For further guidance, see § 1.1502–32(b) through (b)(3)(iii)(B).

(b)(3)(iii)(C) *Loss suspended under § 1.1502–35T(c).* Any loss suspended pursuant to § 1.1502–35T(c) is treated as a noncapital, nondeductible expense incurred during the taxable year that includes the date of the disposition to which such section applies. See § 1.1502–35T(c)(3). Consequently, the basis of a higher-tier member's stock of P is reduced by the suspended loss in the year it is suspended.

(D) *Loss disallowed under § 1.1502–35T(g)(3)(iii).* Any loss or deduction the use of which is disallowed pursuant to § 1.1502–35T(g)(3)(iii) (other than a loss or deduction described in § 1.1502–35T(g)(3)(i)(B)(*11*)), and with respect to which no waiver described in paragraph (b)(4) of this section is filed, is treated as a noncapital, nondeductible expense incurred during the taxable year that such loss would otherwise be absorbed. See § 1.1502–35T(g)(3)(iv).

(b)(4) through (b)(4)(v) [Reserved]. For further guidance, see § 1.1502–32(b)(4) through (b)(4)(v).

(b)(4)(vi) *Special rules in the case of certain transactions subject to § 1.1502–35T.* If a member of a consolidated group transfers stock of a subsidiary member and such stock has a basis that exceeds its value immediately before such transfer or a subsidiary member is deconsolidated and any stock of such subsidiary member owned by members of the group immediately before such deconsolidation has a basis that exceeds its value, all members of the group are subject to the provisions of § 1.1502–35T(b), which generally require a redetermination of members' basis in all shares of subsidiary stock. In addition, if stock of a subsidiary member is treated as worthless under section 165 (taking into account the provisions of § 1.1502–80(c)), or if a member of a group disposes of subsidiary member stock and on the following day the subsidiary is not a member of the group and does not have a separate return year, and the common parent makes an election under § 1.1502–35T(f)(2) to reattribute to itself the losses treated as attributable to such subsidiary member, § 1.1502–35T(f)(2) requires a reduction of members' basis in shares of subsidiary stock.

(c) through (h)(5)(ii) [Reserved]. For further guidance, see § 1.1502–32(c) through (h)(5)(ii).

(h)(6) *Loss suspended under § 1.1502–35T(c) or disallowed under § 1.1502–35T(g)(3)(iii).* Paragraphs (a)(2), (b)(3)(iii)(C), (b)(3)(iii)(D) and (b)(4)(vi) of this section are effective on and after March 7, 2002, and expire on March 11, 2006.

Par. 7. Section 1.1502–35T is added to read as follows:

§ 1.1502–35T Transfers of subsidiary member stock and deconsolidations of subsidiary members (temporary).

(a) *Purpose.* The purpose of this section is to prevent a group from obtaining more than one tax benefit from a single economic loss. The provisions of this section shall be construed in a manner consistent with that purpose and in a manner that reasonably carries out that purpose.

(b) *Redetermination of basis on certain nondeconsolidating transfers of subsidiary member stock and on certain deconsolidations of subsidiary members*—(1) *Redetermination of basis on certain nondeconsolidating transfers of subsidiary member stock.* Except as provided in paragraph (b)(3)(i) of this section, if, immediately after a transfer of stock of a subsidiary member that has a basis that exceeds its value, the subsidiary member remains a member of the group, then the basis in each share of subsidiary member stock owned by each member of the group shall be redetermined in accordance with the provisions of this paragraph (b)(1) immediately before such transfer. All of the members' bases in the shares of subsidiary member stock immediately before such transfer shall be aggregated. Such aggregated basis shall be allocated first to the shares of the subsidiary member's preferred stock that are owned by the members of the group immediately before such transfer, in proportion to, but not in excess of, the value of those shares at such time. After allocation of the aggregated basis to all shares of the preferred stock of the subsidiary member pursuant to the preceding sentence, any remaining basis shall be allocated among all common shares of subsidiary member stock held by members of the group immediately before the transfer, in proportion to the value of such shares at such time.

(2) *Redetermination of basis on certain deconsolidations of subsidiary members.*—(i) *Allocation of reallocable basis amount.* Except as provided in paragraph (b)(3)(ii) of this section, if, immediately before a deconsolidation of a subsidiary member, any share of stock of such subsidiary owned by a member of the group has a basis that exceeds its value, then the basis in each share of the subsidiary member's stock owned by each member of the group shall be redetermined in accordance with the provisions of this paragraph (b)(2) immediately before such deconsolidation. The basis in each share of the subsidiary member's stock held by members of the group immediately before the deconsolidation that has a basis in excess of value at such time shall be reduced, but not below such share's value, in a manner that, to the greatest extent possible, causes the ratio of the basis to the value of each such share to be the same; provided, however, that the aggregate amount of such reduction shall not exceed the reallocable basis amount (as computed pursuant to paragraph (b)(2)(ii) of this section). Then, to the extent of the reallocable basis amount, the basis of each share of the preferred stock of the subsidiary member that are held by members of the group immediately before the deconsolidation shall be increased, but not above such share's value, in a manner that, to the greatest extent possible, causes the ratio of the basis to the value of each such share to be the same. Then, to the extent that the reallocable basis amount does not increase the basis of shares of preferred stock of the subsidiary member pursuant to the third sentence of this paragraph (b)(2)(i), such amount shall increase the basis of all common shares of the subsidiary member's stock held by members of the group immediately before the deconsolidation in a manner that, to the greatest extent possible, causes the ratio of the basis to the value of each such share to be the same.

(ii) *Calculation of reallocable basis amount.* The reallocable basis amount shall equal the lesser of—

(A) The aggregate of all amounts by which, immediately before the deconsolidation, the basis exceeds the value of a share of subsidiary member stock owned by any member of the group at such time; and

(B) The total of the subsidiary member's (and any predecessor's) items of deduction and loss, and the subsidiary member's (and any predecessor's) allocable share of items of deduction and loss of all lower-tier subsidiary members, that were taken into account in computing the adjustment under § 1.1502–32 to the bases of shares of stock of the subsidiary member (and any predecessor) held by members of the group immediately before the deconsolidation, other than shares that have bases in excess of value immediately before the deconsolidation.

(3) *Exceptions to application of redetermination rules.* (i) Paragraph (b)(1) of this section shall not apply to a transfer of subsidiary member stock if—

(A) During the taxable year of such transfer, in one or more fully taxable transactions, the members of the group

dispose of all of the shares of the subsidiary member stock that they own immediately before the transfer, other than the shares the transfer of which would otherwise trigger the application of paragraph (b)(1) of this section, to a person or persons that are not members of the group;

(B) During the taxable year of such transfer, the members of the group are allowed a worthless stock loss under section 165(g) (taking into account the provisions of § 1.1502–80(c)) with respect to all of the shares of subsidiary member stock that they own immediately before the transfer, other than the shares the transfer of which would otherwise trigger the application of paragraph (b)(1) of this section; or

(C) Such transfer is to a member of the group and section 332 (provided the stock is transferred to an 80-percent distributee), section 351, or section 361 applies to such transfer.

(ii) Paragraph (b)(2) of this section shall not apply to a deconsolidation of a subsidiary member if—

(A) During the taxable year of such deconsolidation, in one or more fully taxable transactions, the members of the group dispose of all of the shares of the subsidiary member stock that they own immediately before the deconsolidation to a person or persons that are not members of the group;

(B) Such deconsolidation results from a fully taxable disposition, to a person or persons that are not members of the group, of some of the shares of the subsidiary member, and, during the taxable year of such deconsolidation, the members of the group are allowed a worthless stock loss under section 165(g) with respect to all of the shares of subsidiary member stock that they own immediately after the deconsolidation; or

(C) The deconsolidation of the subsidiary member results from the deconsolidation of a higher-tier subsidiary member and, immediately after the deconsolidation of the subsidiary member, none of the stock of the subsidiary member is owned by a group member.

(4) *Special rule for lower-tier subsidiaries.* If, immediately after a transfer of subsidiary member stock or a deconsolidation of a subsidiary member, a lower-tier subsidiary member some of the stock of which is owned by the subsidiary member is a member of the group, then, for purposes of applying paragraph (b) of this section, the subsidiary member shall be treated as having transferred its stock of the lower-tier subsidiary member. This principle shall apply to stock of subsidiary members that are owned by such lower-tier subsidiary member.

(5) *Stock basis adjustments for higher-tier stock.* The basis adjustments required under this paragraph (b) result in basis adjustments to higher-tier member stock. The adjustments are applied in the order of the tiers, from the lowest to highest. For example, if a common parent owns stock of a subsidiary member that owns stock of a lower-tier subsidiary member and the subsidiary member recognizes a loss on the disposition of a portion of its shares of the lower-tier subsidiary member stock, the common parent must adjust its basis in its subsidiary member stock under the principles of § 1.1502–32 to reflect the adjustments that the subsidiary member must make to its basis in its stock of the lower-tier subsidiary member.

(6) *Ordering rules.* (i) The rules of this paragraph (b) apply after the rules of § 1.1502–32 are applied.

(ii) The rules of this paragraph (b) apply before the rules of § 1.337(d)–2T and paragraph (c) of this section are applied.

(iii) Paragraph (b) of this section (and any resulting basis adjustments to higher-tier member stock made pursuant to paragraph (b)(5) of this section) applies to redetermine the basis of stock of a lower-tier subsidiary member before paragraph (b) of this section applies to a higher-tier member of such lower-tier subsidiary member.

(c) *Loss suspension*—(1) *General rule.* Any loss recognized by a member of a consolidated group with respect to the disposition of a share of subsidiary member stock shall be suspended to the extent of the duplicated loss with respect to such share of stock if, immediately after the disposition, the subsidiary is a member of the consolidated group of which it was a member immediately prior to the disposition (or any successor group).

(2) *Special rule for lower-tier subsidiaries.* This paragraph (c)(2) applies if neither paragraph (c)(1) nor (f) of this section applies to a member's disposition of a share of stock of a subsidiary member (the departing member), a loss is recognized on the disposition of such share, and the departing member owns stock of one or more other subsidiary members (a remaining member) that is a member of such group immediately after the disposition. In that case, such loss shall be suspended to the extent the duplicated loss with respect to the departing member stock disposed of is attributable to the remaining member or members.

(3) *Treatment of suspended loss.* For purposes of the rules of § 1.1502–32, any loss suspended pursuant to paragraph (c)(1) or (c)(2) of this section is treated as a noncapital, nondeductible expense of the member that disposes of subsidiary member stock, incurred during the taxable year that includes the date of the disposition of stock to which paragraph (c)(1) or (c)(2) of this section applies. See § 1.1502–32T(b)(3)(iii)(C). Consequently, the basis of a higher-tier member's stock of the member that disposes of subsidiary member stock is reduced by the suspended loss in the year it is suspended.

(4) *Reduction of suspended loss*—(i) *General rule.* The amount of any loss suspended pursuant to paragraphs (c)(1) and (c)(2) of this section shall be reduced, but not below zero, by the subsidiary member's (and any successor's) items of deduction and loss, and the subsidiary member's (and any successor's) allocable share of items of deduction and loss of all lower-tier subsidiary members, that are allocable to the period beginning on the date of the disposition that gave rise to the suspended loss and ending on the day before the first date on which the subsidiary member (or any successor) is not a member of the group of which it was a member immediately prior to the disposition (or any successor group), and that are taken into account in determining consolidated taxable income (or loss) of such group for any taxable year that includes any date on or after the date of the disposition and before the first date on which the subsidiary member (or any successor) is not a member of such group; provided, however, that such reduction shall not exceed the excess of the amount of such items over the amount of such items that are taken into account in determining the basis adjustments made under § 1.1502–32 to stock of the subsidiary member (or any successor) owned by members of the group. The preceding sentence shall not apply to items of deduction and loss to the extent that the group can establish that all or a portion of such items was not reflected in the computation of the duplicated loss with respect to the subsidiary member on the date of the disposition of stock that gave rise to the suspended loss.

(ii) *Operating rules*—(A) *Year in which deduction or loss is taken into account.* For purposes of paragraph (c)(4)(i) of this section, a subsidiary member's (or any successor's) deductions and losses are treated as taken into account when and to the extent they are absorbed by the subsidiary member (or any successor) or

any other member. To the extent that the subsidiary member's (or any successor's) deduction or loss is absorbed in the year it arises or is carried forward and absorbed in a subsequent year (*e.g.*, under section 172, 465, or 1212), the deduction is treated as taken into account in the year in which it is absorbed. To the extent that a subsidiary member's (or any successor's) deduction or loss is carried back and absorbed in a prior year (whether consolidated or separate), the deduction or loss is treated as taken into account in the year in which it arises and not in the year in which it is absorbed.

(B) *Determination of items that are allocable to the post-disposition, pre-deconsolidation period.* For purposes of paragraph (c)(4)(i) of this section, the determination of whether a subsidiary member's (or any successor's) items of deduction and loss and allocable share of items of deduction and loss of all lower-tier subsidiary members are allocable to the period beginning on the date of the disposition of subsidiary stock that gave rise to the suspended loss and ending on the day before the first date on which the subsidiary member (or any successor) is not a member of the consolidated group of which it was a member immediately prior to the disposition (or any successor group) is determined pursuant to the rules of § 1.1502–76(b)(2), without regard to § 1.1502–76(b)(2)(ii)(D), as if the subsidiary member ceased to be a member of the group at the end of the day before the disposition and filed separate returns for the period beginning on the date of the disposition and ending on the day before the first date on which it is not a member of such group.

(5) *Allowable loss*—(i) *General rule.* To the extent not reduced under paragraph (c)(4) of this section, any loss suspended pursuant to paragraph (c)(1) or (c)(2) of this section shall be allowed, to the extent otherwise allowable under applicable provisions of the Internal Revenue Code and regulations thereunder, on a return filed by the group of which the subsidiary was a member on the date of the disposition of subsidiary stock that gave rise to the suspended loss (or any successor group) for the taxable year that includes the day before the first date on which the subsidiary (or any successor) is not a member of such group or the date the group is allowed a worthless stock loss under section 165(g) (taking into account the provisions of § 1.1502–80(c)) with respect to all of the subsidiary member stock owned by members.

(ii) *No tiering up of certain adjustments.* No adjustments shall be made to a member's basis of stock of a subsidiary member (or any successor) for a suspended loss that is taken into account under paragraph (c)(5)(i) of this section. See § 1.1502–32T(a)(2).

(iii) *Statement of allowed loss.* Paragraph (c)(5)(i) of this section applies only if the separate statement required under this paragraph (c)(5)(iii) is filed with, or as part of, the taxpayer's return for the year in which the loss is allowable. The statement must be entitled ''ALLOWED LOSS UNDER § 1.1502–35T(c)(5)'' and must contain the name and employer identification number of the subsidiary the stock of which gave rise to the loss.

(6) *Special rule for dispositions of certain carryover basis assets.* If—

(i) A member of a group recognizes a loss on the disposition of an asset other than stock of a subsidiary member;

(ii) Such member's basis in the asset disposed of was determined, directly or indirectly, in whole or in part, by reference to the basis of stock of a subsidiary member and, at the time of the determination of the member's basis in the asset disposed of, there was a duplicated loss with respect to such stock of the subsidiary member; and

(iii) Immediately after the disposition, the subsidiary member is a member of such group, then such loss shall be suspended pursuant to the principles of paragraphs (c)(1) and (c)(2) of this section to the extent of the duplicated loss with respect to such stock at the time of the determination of basis of the asset disposed of. Principles similar to those set forth in paragraphs (c)(3), (c)(4), and (c)(5) of this section shall apply to a loss suspended pursuant to this paragraph (c)(6).

(7) *Coordination with loss deferral, loss disallowance, and other rules*—(i) *In general.* Loss recognized on the disposition of subsidiary member stock or another asset is subject to redetermination, deferral, or disallowance under other applicable provisions of the Internal Revenue Code and regulations thereunder, including sections 267(f) and 482. Paragraphs (c)(1), (c)(2), and (c)(6) of this section do not apply to a loss that is disallowed under any other provision. If loss is deferred under any other provision, paragraphs (c)(1), (c)(2), and (c)(6) of this section apply when the loss would otherwise be taken into account under such other provision. However, if an overriding event described in paragraph (c)(7)(ii) of this section occurs before the deferred loss is taken into account, paragraphs (c)(1), (c)(2), and (c)(6) of this section apply to the loss immediately before the event occurs, even though the loss may not be taken into account until a later time.

(ii) *Overriding events.* For purposes of paragraph (c)(7)(i) of this section, the following are overriding events—

(A) The stock ceases to be owned by a member of the consolidated group;

(B) The stock is canceled or redeemed (regardless of whether it is retired or held as treasury stock); or

(C) The stock is treated as disposed of under § 1.1502–19(c)(1)(ii)(B) or (c)(1)(iii).

(8) *Application.* This paragraph (c) shall not be applied in a manner that permanently disallows a deduction for an economic loss, provided that such deduction is otherwise allowable. If the application of any provision of this paragraph (c) results in such a disallowance, proper adjustment may be made to prevent such a disallowance. Whether a provision of this paragraph (c) has resulted in such a disallowance is determined on the date on which the subsidiary (or any successor) the disposition of the stock of which gave rise to a suspended stock loss is not a member of the group or the date the group is allowed a worthless stock loss under section 165(g) (taking into account the provisions of § 1.1502–80(c)) with respect to all of such subsidiary member stock owned by members. Proper adjustment in such cases shall be made by restoring the suspended stock loss immediately before the subsidiary ceases to be a member of the group or the group is allowed a worthless stock loss under section 165(g) (taking into account the provisions of § 1.1502–80(c)) with respect to all of such subsidiary member stock owned by members, to the extent that its reduction pursuant to paragraph (c)(4) of this section had the result of permanently disallowing a deduction for an economic loss.

(9) *Ordering rule.* The rules of this paragraph (c) apply after the rules of paragraph (b) of this section and § 1.337(d)–2T are applied.

(d) *Definitions*—(1) *Disposition. Disposition* means any event in which gain or loss is recognized, in whole or in part.

(2) *Deconsolidation. Deconsolidation* means any event that causes a subsidiary member to no longer be a member of the consolidated group.

(3) *Value. Value* means fair market value.

(4) *Duplicated loss*—(i) *In general.* Duplicated loss is determined immediately after a disposition and equals the excess, if any, of—

(A) The sum of—

(*1*) The aggregate adjusted basis of the subsidiary member's assets other than any stock that subsidiary member owns in another subsidiary member; and

(*2*) Any losses attributable to the subsidiary member and carried to the subsidiary member's first taxable year following the disposition; and

(3) Any deductions of the subsidiary member that have been recognized but are deferred under a provision of the Internal Revenue Code (such as deductions deferred under section 469); over

(B) The sum of—

(*1*) The value of the subsidiary member's stock; and

(*2*) Any liabilities of the subsidiary member that have been taken account for tax purposes.

(ii) *Special rules.* (A) The amounts determined under paragraph (d)(4)(i) (other than amounts described in paragraph (d)(4)(i)(B)(*1*)) of this section with respect to a subsidiary member include its allocable share of corresponding amounts with respect to all lower-tier subsidiary members. If 80 percent or more in value of the stock of a subsidiary member is acquired by purchase in a single transaction (or in a series of related transactions during any 12-month period), the value of the subsidiary member's stock may not exceed the purchase price of the stock divided by the percentage of the stock (by value) so purchased. For this purpose, stock is acquired by purchase if the transferee is not related to the transferor within the meaning of sections 267(b) and 707(b)(1), using the language "'10 percent'" instead of "'50 percent'" each place that it appears, and the transferee's basis in the stock is determined wholly by reference to the consideration paid for such stock.

(B) The amounts determined under paragraph (d)(4)(i) of this section are not applied more than once to suspend a loss under this section.

(5) *Predecessor and Successor.* A predecessor is a transferor of assets to a transferee (the successor) in a transaction—

(i) To which section 381(a) applies;

(ii) In which substantially all of the assets of the transferor are transferred to members in a complete liquidation;

(iii) In which the successor's basis in assets is determined (directly or indirectly, in whole or in part) by reference to the transferor's basis in such assets, but the transferee is a successor only with respect to the assets the basis of which is so determined; or

(iv) Which is an intercompany transaction, but only with respect to assets that are being accounted for by the transferor in a prior intercompany transaction.

(6) *Successor group.* A surviving group is treated as a successor group of a consolidated group (the terminating group) that ceases to exist as a result of—

(i) The acquisition by a member of another consolidated group of either the assets of the common parent of the terminating group in a reorganization described in section 381(a)(2), or the stock of the common parent of the terminating group; or

(ii) The application of the principles of § 1.1502–75(d)(2) or (3).

(7) *Preferred stock, common stock.* Preferred stock and common stock shall have the meanings set forth in § 1.1502–32(d)(2) and (3), respectively.

(8) *Higher-tier.* A subsidiary member is *higher-tier* with respect to a member if or to the extent investment basis adjustments under § 1.1502–32 with respect to the stock of the latter member would affect investment basis adjustments with respect to the stock of the former member.

(9) *Lower-tier.* A subsidiary member is *lower-tier* with respect to a member if or to the extent investment basis adjustments under § 1.1502–32 with respect to the stock of the former member would affect investment basis adjustments with respect to the stock of the latter member.

(e) *Examples.* For purposes of the examples in this section, all groups file consolidated returns on a calendar-year basis, the facts set forth the only corporate activity, all transactions are between unrelated persons unless otherwise specified, and tax liabilities are disregarded. The principles of paragraphs (a) through (d) of this section are illustrated by the following examples:

Example 1. Nondeconsolidating sale of preferred stock of lower-tier subsidiary member. (i) *Facts.* P owns 100 percent of the common stock of each of S1 and S2. S1 and S2 each have only one class of stock outstanding. P's basis in the stock of S1 is $100 and the value of such stock is $130. P's basis in the stock of S2 is $120 and the value of such stock is $90. P, S1, and S2 are all members of the P group. S1 and S2 form S3. In Year 1, in transfers to which section 351 applies, S1 contributes $100 to S3 in exchange for all of the common stock of S3 and S2 contributes an asset with a basis of $50 and a value of $20 to S3 in exchange for all of the preferred stock of S3. S3 becomes a member of the P group. In Year 3, in a transaction that is not part of the plan that includes the contributions to S3, S2 sells the preferred stock of S3 for $20. Immediately after the sale, S3 is a member of the P group.

(ii) *Application of basis redetermination rule.* Because S2's basis in the preferred stock of S3 exceeds its value immediately prior to the sale and S3 is a member of the P group immediately after the sale, all of the P group members' bases in the stock of S3 is redetermined pursuant to paragraph (b)(1) of this section. Of the group members' total basis of $150 in the S3 stock, $20 is allocated to the preferred stock, the fair market value of the preferred stock on the date of the sale, and $130 is allocated to the common stock. S2's sale of the preferred stock results in the recognition of $0 of gain/loss. Pursuant to paragraph (b)(5) of this section, the redetermination of S1's and S2's bases in the stock of S3 results in adjustments to P's basis in the stock of S1 and S2. In particular, P's basis in the stock of S1 is increased by $30 to $130 and its basis in the stock of S2 is decreased by $30 to $90.

Example 2. Deconsolidating sale of common stock. (i) *Facts.* In Year 1, in a transfer to which section 351 applies, P contributes Asset A with a basis of $900 and a value of $200 to S in exchange for one share of S common stock (CS1). In Years 2 and 3, in successive but unrelated transfers to which section 351 applies, P transfers $200 to S in exchange for one share of S common stock (CS2), Asset B with a basis of $300 and a value of $200 in exchange for one share of S common stock (CS3), and Asset C with a basis of $1000 and a value of $200 in exchange for one share of S common stock (CS4). In Year 4, S sells Asset A for $200, recognizing $700 of loss that is used to offset income of P recognized during Year 4. As a result of the sale of Asset A, the basis of each of P's four shares of S common stock is reduced by $175. Therefore, the basis of CS1 is $725. The basis of CS2 is $25. The basis of CS3 is $125, and the basis of CS4 is $825. In Year 5 in a transaction that is not part of a plan that includes the Year 1 contribution, P sells CS4 for $200. Immediately after the sale of CS4, S is not a member of the P group.

(ii) *Application of basis redetermination rule.* Because P's basis in each of CS1 and CS4 exceeds its value immediately prior to the deconsolidation of S, P's basis in its shares of S common stock is redetermined pursuant to paragraph (b)(2) of this section. Pursuant to paragraph (b)(2)(ii) of this section, the reallocable basis amount is $350 (the lesser of $1150, the gross loss inherent in the stock of S owned by P immediately before the sale, and $350, the aggregate amount of S's items of deduction and loss that were previously taken into account in the computation of the adjustment to the basis of the stock of S that P did not hold at a loss immediately before the deconsolidation). Pursuant to paragraph (b)(2)(i) of this section, first, P's basis in CS1 is reduced from $725 to $600 and P's basis in CS4 is reduced from $825 to $600. Then, the reallocable basis amount increases P's basis in CS2 from $25 to $250 and P's basis in CS3 from $125 to $250. P recognizes $400 of loss on the sale of CS4. The loss suspension rule does not apply because S is no longer a member of the P group. Thus, the loss is allowable at that time.

Example 3. Nondeconsolidating sale of common stock. (i) *Facts.* In Year 1, P forms S with a contribution of $80 in exchange for 80 shares of the common stock of S, which at that time represents all of the outstanding

stock of S. S becomes a member of the P group. In Year 2, P contributes Asset A with a basis of $50 and a value of $20 in exchange for 20 shares of the common stock of S in a transfer to which section 351 applies. In Year 3, in a transaction that is not part of the plan that includes the Year 2 contribution, P sells the 20 shares of the common stock of S that it acquired in Year 2 for $20. Immediately after the Year 3 stock sale, S is a member of the P group. At the time of the Year 3 stock sale, S has $80 and Asset A. In Year 4, S sells Asset A , the basis and value of which have not changed since its contribution to S. On the sale of Asset A for $20, S recognizes a $30 loss. The P group cannot establish that all or a portion of the $30 loss was not reflected in the calculation of the duplicated loss of S on the date of the Year 3 stock sale. The $30 loss is used on the P group return to offset income of P. In Year 5, P sells its remaining S common stock for $80.

(ii) *Application of basis redetermination and loss suspension rules.* Because P's basis in the common stock sold exceeds its value immediately prior to the sale and S is a member of the P group immediately after the sale, P's basis in all of the stock of S is redetermined pursuant to paragraph (b)(1) of this section. Of P's total basis of $130 in the S common stock, a proportionate amount is allocated to each of the 100 shares of S common stock. Accordingly, $26 is allocated to the common stock of S that is sold and $104 is allocated to the common stock of S that is retained. On P's sale of the 20 shares of the common stock of S for $20, P recognizes a loss of $6. Because the sale of the 20 shares of common stock of S does not result in the deconsolidation of S, under paragraph (c)(1) of this section, that loss is suspended to the extent of the duplicated loss with respect to the shares sold. The duplicated loss with respect to the shares sold is $6. Therefore, the entire $6 loss is suspended.

(iii) *Effect of subsequent asset sale on stock basis.* Of the $30 loss recognized on the sale of Asset A, $24 is taken into account in determining the basis adjustments made under § 1.1502–32 to the stock of S owned by P. Accordingly, P's basis in its S stock is reduced by $24 from $104 to $80.

(iv) *Effect of subsequent asset sale on suspended loss.* Because P cannot establish that all or a portion of the loss recognized on the sale of Asset A was not reflected in the calculation of the duplicated loss of S on the date of the Year 3 stock sale and such loss is allocable to the period beginning on the date of the Year 3 disposition of the S stock and ending on the day before the first date on which S is not a member of the P group and is taken into account in determining consolidated taxable income (or loss) of the P group for a taxable year that includes a date on or after the date of the Year 3 disposition and before the first date on which S is not a member of the P group, such asset loss reduces the suspended loss pursuant to paragraph (c)(4) of this section. The amount of such reduction, however, cannot exceed $6, the excess of the amount of such loss, $30, over the amount of such loss that is taken into account in determining the basis adjustment made to the stock of S owned by P, $24. Therefore, the suspended loss is reduced to zero.

(v) *Effect of subsequent stock sale.* P recognizes $0 gain/loss on the Year 5 sale of its remaining S common stock. No amount of suspended loss remains to be allowed under paragraph (c)(5) of this section.

Example 4. Nondeconsolidating sale of common stock of lower-tier subsidiary. (i) Facts. In Year 1, P forms S1 with a contribution of $200 in exchange for all of the common stock of S1, which represents all of the outstanding stock of S1. In the same year, S1 forms S2 with a contribution of $80 in exchange for 80 shares of the common stock of S2, which at that time represents all of the outstanding stock of S2. S1 and S2 become members of the P group. In the same year, S2 purchases Asset A for $80. In Year 2, S1 contributes Asset B with a basis of $50 and a value of $20 in exchange for 20 shares of the common stock of S2 in a transfer to which section 351 applies. In Year 3, S1 sells the 20 shares of the common stock of S2 that it acquired in Year 2 for $20. Immediately after the Year 3 stock sale, S2 is a member of the P group. At the time of the Year 3 stock sale, the bases and values of Asset A and Asset B are unchanged. In Year 4, S2 sells Asset B for $45, recognizing a $5 loss. The P group cannot establish that all or a portion of the $5 loss was not reflected in the calculation of the duplicated loss of S2 on the date of the Year 3 stock sale. The $5 loss is used on the P group return to offset income of P. In Year 5, S1 sells its remaining S2 common stock for $100.

(ii) *Application of basis redetermination and loss suspension rules.* Because S1's basis in the S2 common stock sold exceeds its value immediately prior to the sale and S2 is a member of the P group immediately after the sale, S1's basis in all of the stock of S2 is redetermined pursuant to paragraph (b)(1) of this section. Of S1's total basis of $130 in the S2 common stock, a proportionate amount is allocated to each of the 100 shares of S2 common stock. Accordingly, a total of $26 is allocated to the common stock of S2 that is sold and $104 is allocated to the common stock of S2 that is retained. On S1's sale of the 20 shares of the common stock of S2 for $20, S1 recognizes a loss of $6. Because the sale of the 20 shares of common stock of S2 does not result in the deconsolidation of S2, under paragraph (c)(1) of this section, that loss is suspended to the extent of the duplicated loss with respect to the shares sold. The duplicated loss with respect to the shares sold is $6. Therefore, the entire $6 loss is suspended. Pursuant to paragraph (c)(3) of this section and § 1.1502–32T(b)(3)(iii)(C), the suspended loss is treated as a noncapital, nondeductible expense incurred by S1 during the tax year that includes the date of the disposition of stock to which paragraph (c)(1) of this section applies. Accordingly, P's basis in its S1 stock is reduced from $200 to $194.

(iii) *Effect of subsequent asset sale on stock basis.* Of the $5 loss recognized on the sale of Asset B, $4 is taken into account in determining the basis adjustments made under § 1.1502–32 to the stock of S2 owned by S1. Accordingly, S1's basis in its S2 stock is reduced by $4 from $104 to $100 and P's basis in its S1 stock is reduced by $4 from $194 to $190.

(iv) *Effect of subsequent asset sale on suspended loss.* Because P cannot establish that all or a portion of the loss recognized on the sale of Asset B was not reflected in the calculation of the duplicated loss of S2 on the date of the Year 3 stock sale and such loss is allocable to the period beginning on the date of the Year 3 disposition of the S2 stock and ending on the day before the first date on which S2 is not a member of the P group and is taken into account in determining consolidated taxable income (or loss) of the P group for a taxable year that includes a date on or after the date of the Year 3 disposition and before the first date on which S2 is not a member of the P group, such asset loss reduces the suspended loss pursuant to paragraph (c)(4) of this section. The amount of such reduction, however, cannot exceed $1, the excess of the amount of such loss, $5, over the amount of such loss that is taken into account in determining the basis adjustment made to the stock of S2 owned by members of the P group, $4. Therefore, the suspended loss is reduced to $5.

(v) *Effect of subsequent stock sale.* In Year 5, when S1 sells its remaining S2 stock for $100, it recognizes $0 gain/loss. Pursuant to paragraph (c)(5) of this section, the remaining $5 of the suspended loss is allowed on the P group's return for Year 5 when S1 sells its remaining S2 stock.

Example 5. Deconsolidating sale of subsidiary member owning stock of another subsidiary member that remains in group. (i) *Facts.* In Year 1, P forms S1 with a contribution of Asset A with a basis of $50 and a value of $20 in exchange for 100 shares of common stock of S1 in a transfer to which section 351 applies. Also in Year 1, P and S1 form S2. P contributes $80 to S2 in exchange for 80 shares of common stock of S2. S1 contributes Asset A to S2 in exchange for 20 shares of common stock of S2 in a transfer to which section 351 applies. In Year 3, in a transaction that is not part of a plan that includes the Year 1 contributions, P sells its 100 shares of S1 common stock for $20. Immediately after the Year 3 stock sale, S2 is a member of the P group. At the time of the Year 3 stock sale, S1 owns 20 shares of common stock of S2, and S2 has $80 and Asset A. In Year 4, S2 sells Asset A, the basis and value of which have not changed since its contribution to S2. On the sale of Asset A for $20, S2 recognizes a $30 loss. That $30 loss is used on the P group return to offset income of P. In Year 5, P sells its S2 common stock for $80.

(ii) *Application of basis redetermination and loss suspension rules.* Pursuant to paragraph (b)(4) of this section, because immediately before P's transfer of S1 stock S1 owns stock of S2 (another subsidiary member of the same group) that has a basis that exceeds its value, paragraph (b) of this section applies as if S1 had transferred its stock of S2. Because S2 is a member of the group immediately after the transfer of the S1 stock, the group member's basis in the S2 stock is redetermined pursuant to paragraph (b)(1) of this section immediately prior to the sale of the S1 stock. Of the group members' total basis of $130 in the S2 stock, $26 is

allocated to S1's 20 shares of S2 common stock and $104 is allocated to P's 80 shares of S2 common stock. Pursuant to paragraph (b)(5) of this section, the redetermination of S1's basis in the stock of S2 results in an adjustment to P's basis in the stock of S1. In particular, P's basis in the stock of S1 is decreased by $24 to $26. On P's sale of its 100 shares of S1 common stock for $20, P recognizes a loss of $6. Because S1 is not a member of the P group immediately after P's sale of the S1 stock, paragraph (c)(1) of this section does not apply to suspend such loss. However, because P recognizes a loss with respect to the disposition of the S1 stock and S1 owns stock of S2 (which is a member of the P group immediately after the disposition), paragraph (c)(2) of this section does apply to suspend up to $6 of that loss, an amount equal to the amount by which the duplicated loss with respect to the stock of S1 sold is attributable to S2's adjusted basis in its assets, loss carryforwards, and deferred deductions.

(iii) *Effect of subsequent asset sale on stock basis.* Of the $30 loss recognized on the sale of Asset A, $24 is taken into account in determining the basis adjustments made under § 1.1502–32 to the stock of S2 owned by P. Accordingly, P's basis in its S2 stock is reduced by $24 from $104 to $80.

(iv) *Effect of subsequent asset sale on suspended loss.* Because P cannot establish that all or a portion of the loss recognized on the sale of Asset A was not reflected in the calculation of the duplicated loss of S2 on the date of the Year 3 stock sale and such loss is allocable to the period beginning on the date of the Year 3 deemed disposition of the S2 stock and ending on the day before the first date on which S2 is not a member of the P group and is taken into account in determining consolidated taxable income (or loss) of the P group for a taxable year that includes a date on or after the date of the Year 3 deemed disposition and before the first date on which S2 is not a member of the P group, such asset loss reduces the suspended loss pursuant to paragraph (c)(4) of this section. The amount of such reduction, however, cannot exceed $6, the excess of the amount of such loss, $30, over the amount of such loss that is taken into account in determining the basis adjustment made to the stock of S2 owned by P, $24. Therefore, the suspended loss is reduced to zero.

(v) *Effect of subsequent stock sale.* P recognizes $0 gain/loss on the Year 5 sale of its remaining S2 common stock. No amount of suspended loss remains to be allowed under paragraph (c)(5) of this section.

Example 6. Loss recognized on asset with basis determined by reference to stock basis of subsidiary member. (i) *Facts.* In Year 1, P forms S with a contribution of $80 in exchange for 80 shares of common stock of S which at that time represents all of the outstanding stock of S. S becomes a member of the P group. In Year 2, P contributes Asset A with a basis of $50 and a value of $20 in exchange for 20 shares of common stock of S in a transfer to which section 351 applies. In Year 3, in a transaction that is not part of a plan that includes the Year 1 and Year 2 contributions, P contributes the 20 shares of S common stock it acquired in Year 2 to PS, a partnership, in exchange for a 20 percent capital and profits interest in a transaction described in section 721. Immediately after the contribution to PS, S is a member of the P group. In Year 4, P sells its interest in PS for $20, recognizing a $30 loss.

(ii) *Application of basis redetermination rule upon nonrecognition transfer.* Because P's basis in the S common stock contributed to PS exceeds its value immediately prior to the transfer and S is a member of the P group immediately after the transfer, P's basis in all of the S stock is redetermined pursuant to paragraph (b)(1) of this section. Of P's total basis of $130 in the common stock of S, a proportionate amount is allocated to each share of S common stock. Accordingly, $26 is allocated to the S common stock that is contributed to PS and, under section 722, P's basis in its interest in PS is $26.

(iii) *Application of loss suspension rule on disposition of asset with basis determined by reference to stock basis of subsidiary member.* P recognizes a $6 loss on its disposition of its interest in PS. Because P's basis in its interest in PS was determined by reference to the basis of S stock and at the time of the determination of P's basis in its interest in PS such S stock had a duplicated loss of $6, and, immediately after the disposition, S is a member of the P group, such loss is suspended to the extent of such duplicated loss. Principles similar to those of paragraphs (c)(3), (c)(4), and (c)(5) of this section shall apply to such suspended loss.

(f) *Worthlessness and certain dispositions not followed by separate return years*—(1) *General rule.* Notwithstanding any other provision in the regulations under section 1502, if stock of a subsidiary member is treated as worthless under section 165 (taking into account the provisions of § 1.1502–80(c)), or if a member of a group disposes of subsidiary member stock and on the following day the subsidiary is not a member of the group and does not have a separate return year, then all losses treated as attributable to the subsidiary member under the principles of § 1.1502–21(b)(2)(iv), after computing the taxable income of the group, the subsidiary member, or a group of which the subsidiary member was previously a member for the taxable year that includes the determination of worthlessness or the disposition and any prior taxable year, shall be treated as expired, but not as absorbed by the group, as of the beginning of the group's taxable year that follows the taxable year that includes the determination of worthlessness or the disposition.

(2) *Election in the case of determinations of worthlessness and dispositions not followed by a separate return that occurred prior to March 14, 2003.* If stock of a subsidiary member is treated as worthless under section 165 (taking into account the provisions of § 1.1502–80(c)) on or after March 7, 2002, and prior to March 14, 2003, or if a member of a group disposes of subsidiary member stock on or after March 7, 2002, and prior to March 14, 2003 and on the following day the subsidiary is not a member of the group and does not have a separate return year, then, notwithstanding paragraph (f)(1) of this section, the common parent may make an irrevocable election to reattribute to itself all or any portion of the losses treated as attributable to such subsidiary member under the principles of § 1.1502–21(b)(2)(iv). The election shall be in the form of a statement filed with or as part of the group's return for the taxable year in which the worthlessness is established or the disposition occurs. The statement shall be entitled ''Election under Section 1.1502–35T(f)(2)'' and must state that the common parent is making an irrevocable election under this paragraph (f)(2) to reattribute to itself the losses of the subsidiary member the stock of which is worthless or disposed of. In addition, it must identify the subsidiary to which the election relates and the portion of losses subject to the election. If the election provided in this paragraph is made, the common parent shall be treated as succeeding to the reattributed losses as if the losses were succeeded to in a transaction described in section 381(a). For purposes of applying the provisions of § 1.1502–32, the reattributed losses shall be treated as absorbed by the group immediately prior to the allowance of any loss or inclusion of any income or gain with respect to the determination of worthlessness or the disposition. In the case of an election to reattribute less than all of the losses otherwise treated as attributable to such subsidiary member under the principles of § 1.1502–21(b)(2)(iv), paragraph (f)(1) of this section shall apply to that portion of the losses for which an election under this paragraph (f)(2) is not made.

(g) *Anti-avoidance rules*—(1) *Transfer of share without a loss in avoidance.* If a share of subsidiary member stock has a basis that does not exceed its value and the share is transferred with a view to avoiding application of the rules of paragraph (b) of this section prior to the transfer of a share of subsidiary member stock that has a basis that does exceed its value or a deconsolidation of a subsidiary member, the rules of paragraph (b) of this section shall apply immediately prior to the transfer of stock that has a basis that does not exceed its value.

(2) *Transfers of loss property in avoidance.* If a member of a consolidated group contributes an asset with a basis that exceeds its value to a

partnership in a transaction described in section 721 or a corporation that is not a member of such group in a transfer described in section 351, such partnership or corporation contributes such asset to a subsidiary member in a transfer described in section 351, and such contributions are undertaken with a view to avoiding the rules of paragraph (b) or (c) of this section, adjustments must be made to carry out the purposes of this section.

(3) *Anti-loss reimportation*—(i) *Application.* This paragraph (g)(3) applies if—

(A) A member of a group recognizes and is allowed a loss on the disposition of a share of stock of a subsidiary member with respect to which there is a duplicated loss; and

(B) Within the 10-year period beginning on the date the subsidiary member (or any successor) ceases to be a member of such group—

(*1*) The subsidiary member (or any successor) again becomes a member of such group (or any successor group) when the subsidiary member (or any successor) owns any asset that has a basis in excess of value at such time and that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date;

(*2*) The subsidiary member (or any successor) again becomes a member of such group (or any successor group) when the subsidiary member (or any successor) owns any asset that has a basis in excess of value at such time and that has a basis that reflects, directly or indirectly, in whole or in part, the basis of any asset that was owned by the subsidiary member on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date;

(*3*) In a transaction described in section 381 or section 351, any member of such group (or any successor group) acquires any asset of the subsidiary member (or any successor) that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of its value on such date, or any asset that has a basis that reflects, directly or indirectly, in whole or in part, the basis of any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of its value on such date, and, immediately after the acquisition of such asset, such asset has a basis in excess of its value;

(*4*) The subsidiary member (or any successor) again becomes a member of such group (or any successor group) when the subsidiary member (or any successor) has a liability (within the meaning of section 358(h)(3)) that it had on the date of a disposition of stock of such subsidiary member (or any successor) and such liability will give rise to a deduction;

(*5*) In a transaction described in section 381 or section 351, any member of such group (or any successor group) assumes a liability (within the meaning of section 358(h)(3)) that was a liability of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor);

(*6*) The subsidiary member (or any successor) again becomes a member of such group (or any successor group) when the subsidiary member (or any successor) has any losses or deferred deductions that were losses or deferred deductions of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor);

(*7*) The subsidiary member (or any successor) again becomes a member of such group (or any successor group) when the subsidiary member (or any successor) has any losses or deferred deductions that are attributable to any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date;

(*8*) The subsidiary member (or any successor) again becomes a member of such group (or any successor group) when the subsidiary member (or any successor) has any losses or deferred deductions that are attributable to any asset that had a basis that reflected, directly or indirectly, in whole or in part, the basis of any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date;

(*9*) The subsidiary member (or any successor) again becomes a member of such group (or any successor group) when the subsidiary member (or any successor) has any losses or deferred deductions that are attributable to a liability (within the meaning of section 358(h)(3)) that it had on the date of a disposition of stock of such subsidiary member (or any successor);

(*10*) Any member of such group (or any successor group) succeeds to any losses or deferred deductions of the subsidiary member (or any successor) that were losses or deferred deductions of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor), that are attributable to any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date, that are attributable to any asset that had a basis that reflected, directly or indirectly, in whole or in part, the basis of any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date, or that are attributable to a liability (within the meaning of section 358(h)(3)) of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor); or

(*11*) Any losses or deferred deductions of the subsidiary member (or any successor) that were losses or deferred deductions of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor), that are attributable to any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date, that are attributable to any asset that had a basis that reflected, directly or indirectly, in whole or in part, the basis of any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date, or that are attributable to a liability (within the meaning of section 358(h)(3)) of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) are carried back to a pre-disposition taxable year of the subsidiary member.

(ii) *Operating rules.* (A) For purposes of paragraph (g)(3)(i)(B) of this section, assets shall include stock and securities and the subsidiary member (or any successor) shall be treated as having its allocable share of losses and deferred deductions of all lower-tier subsidiary members and as owning its allocable share of each asset of all lower-tier subsidiary members.

(B) For purposes of paragraphs (g)(3)(i)(B)(*6*), (*7*), (*8*), and (*9*) of this section, unless the group can establish otherwise, if the subsidiary member (or any successor) again becomes a member of such group (or any successor group) at a time when the subsidiary member (or any successor) has any losses or deferred deductions, such losses and deferred deductions shall be treated as losses or deferred deductions that were losses or deferred deductions of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor), losses or deferred deductions that are attributable to assets that were owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had bases in excess of value on such date, losses or deferred deductions that are attributable to assets that had bases that reflected, directly or indirectly, in whole or in part, the bases of assets that were owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had bases in excess of value on such date, or losses or deferred deductions attributable to a liability (within the meaning of section 358(h)(3)) of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor).

(C) For purposes of paragraph (g)(3)(i)(B)(*10*) of this section, unless the group can establish otherwise, if a member of such group (or any successor group) succeeds to any losses or deferred deductions of the subsidiary member (or any successor), such losses and deferred deductions shall be treated as losses or deferred deductions that were losses or deferred deductions of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor), losses or deferred deductions that are attributable to assets that were owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had bases in excess of value on such date, losses or deferred deductions that are attributable to assets that had bases that reflected, directly or indirectly, in whole or in part, the bases of assets that were owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had bases in excess of value on such date, or losses or deferred deductions attributable to a liability (within the meaning of section 358(h)(3)) of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor).

(D) For purposes of paragraph (g)(3)(i)(B)(*11*) of this section, unless the group can establish otherwise, if any losses or deferred deductions of the subsidiary member (or any successor) are carried back to a pre-disposition taxable year of the subsidiary member, such losses and deferred deductions shall be treated as losses or deferred deductions that were losses or deferred deductions of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor), losses or deferred deductions that are attributable to assets that were owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date, losses or deferred deductions that are attributable to assets that had bases that reflected, directly or indirectly, in whole or in part, the bases of assets that were owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date, or losses or deferred deductions that are attributable to a liability (within the meaning of section 358(h)(3)) of the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor).

(iii) *Loss disallowance.* If this paragraph (g)(3) applies, then, to the extent that the aggregate amount of loss recognized by members of the group (and any successor group) on dispositions of the subsidiary member stock was attributable to a duplicated loss of such subsidiary member that was allowed, such group (or any successor group) will be denied the use of—

(A) Any loss recognized that is attributable to, directly or indirectly, an asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of value on such date, to the extent of the lesser of the loss inherent in such asset on the date of a disposition of the stock of the subsidiary member (or any successor) and the loss inherent in such asset on the date of the event described in paragraph (g)(3)(i)(B) of this section that gives rise to the application of this paragraph (g)(3);

(B) Any loss recognized that is attributable to, directly or indirectly, an asset that has a basis that reflects, directly or indirectly, in whole or in part, the basis of any asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) and that had a basis in excess of its value on such date, to the extent of the lesser of the loss inherent in the asset that was owned by the subsidiary member (or any successor) on the date of a disposition of stock of such subsidiary member (or any successor) the basis of which is reflected, directly or indirectly, in whole or in part, in the basis of such asset on the date of the disposition and the loss inherent in such asset on the date of the event described in paragraph (g)(3)(i)(B) of this section that gives rise to the application of this paragraph (g)(3);

(C) Any loss or deduction that is attributable to a liability described in paragraph (g)(3)(i)(B)(*4*) or (*5*) of this section; and

(D) Any loss or deduction described in paragraph (g)(3)(i)(B)(*6*), (*7*), (*8*), (*9*), (*10*), or (*11*) of this section, provided that a loss or deferred deduction described in paragraph (g)(3)(i)(B)(*11*) of this section shall be allowed to be carried forward to a post-disposition taxable year of the subsidiary member.

(iv) *Treatment of disallowed loss.* For purposes of § 1.1502–32(b)(3)(iii), any loss or deduction the use of which is disallowed pursuant to paragraph (g)(3)(iii) of this section (other than a loss or deduction described in paragraph (g)(3)(i)(B)(*11*) of this section), and with respect to which no waiver described in § 1.1502–32(b)(4) is filed, is treated as a noncapital, nondeductible expense incurred during the taxable year that such loss would otherwise be absorbed.

(4) *Avoidance of recognition of gain.* (i) If a transaction is structured with a view to, and has the effect of, deferring or avoiding the recognition of gain on a disposition of stock by invoking the application of paragraph (b)(1) of this section to redetermine the basis of stock of a subsidiary member, and the stock loss that gives rise to the application of paragraph (b)(1) of this section is not significant, paragraphs (b) and (c) of this section shall not apply.

(ii) If a transaction is structured with a view to, and has the effect of, deferring or avoiding the recognition of gain on a disposition of stock by invoking the application of paragraph (b)(2) of this section to redetermine the basis of stock of a subsidiary member, and the duplicated loss of the subsidiary

member that is reflected in stock of the subsidiary member owned by members of the group immediately before the deconsolidation is not significant, paragraphs (b) and (c) of this section shall not apply.

(5) *Examples.* The principles of this paragraph (g) are illustrated by the following examples:

Example 1. Transfers of property in avoidance of basis redetermination rule. (i) *Facts.* In Year 1, P forms S with a contribution of $100 in exchange for 100 shares of common stock of S which at that time represents all of the outstanding stock of S. S becomes a member of the P group. In Year 2, P contributes 20 shares of common stock of S to PS, a partnership, in exchange for a 20 percent capital and profits interest in a transaction described in section 721. In Year 3, P contributes Asset A with a basis of $50 and a value of $20 to PS in exchange for an additional capital and profits interest in PS in a transaction described in section 721. Also in Year 3, PS contributes Asset A to S and P contributes an additional $80 to S in transfers to which section 351 applies. In Year 4, S sells Asset A for $20, recognizing a loss of $30. The P group uses that loss to offset income of P. Also in Year 4, P sells its entire interest in PS for $40, recognizing a loss of $30.

(ii) *Analysis.* Pursuant to paragraph (g)(2) of this section, if P's contributions of S stock and Asset A to PS were undertaken with a view to avoiding the application of the basis redetermination or the loss suspension rule, adjustments must be made such that the group does not obtain more than one tax benefit from the $30 loss inherent in Asset A.

Example 2. Transfers effecting a reimportation of loss. (i) *Facts.* In Year 1, P forms S with a contribution of Asset A with a value of $100 and a basis of $120, Asset B with a value of $50 and a basis of $70, Asset C with a value of $90 and a basis of $100 in exchange for all of the common stock of S and S becomes a member of the P group. In Year 2, in a transaction that is not part of a plan that includes the contribution, P sells the stock of S for $240, recognizing a loss of $50. At such time, the bases and values of Assets A, B, and C have not changed since their contribution to S. In Year 3, S sells Asset A, recognizing a $20 loss. In Year 3, S merges into M in a reorganization described in section 368(a)(1)(A). In Year 8, P purchases all of the stock of M for $300. At that time, M has a $10 net operating loss. In addition, M owns Asset D, which was acquired in an exchange described in section 1031 in connection with the surrender of Asset B. Asset C has a value of $80 and a basis of $100. Asset D has a value of $60 and a basis of $70. In Year 9, P has operating income of $100 and M recognizes $20 of loss on the sale of Asset C. In Year 10, P has operating income of $50 and M recognizes $50 of loss on the sale of Asset D.

(ii) *Analysis.* P's $50 loss on the sale of S stock is entirely attributable to duplicated loss. Therefore, pursuant to paragraph (g)(3) of this section, assuming the P group cannot establish otherwise, M's $10 net operating loss is treated as attributable to assets that were owned by S on the date of the disposition and that had bases in excess of value on such date. Without regard to any other limitations on the group's use of M's net operating loss, the P group cannot use M's $10 net operating loss pursuant to paragraph (g)(3)(iii)(D) of this section. Pursuant to paragraph (g)(3)(iv) of this section and § 1.1502–32T(b)(3)(iii)(D), such loss is treated as a noncapital, nondeductible expense of M incurred during the taxable year that includes the day after the reorganization. In addition, the P group is denied the use of $10 of the loss recognized on the sale of Asset C. Finally, the P group is denied the use of $10 of the loss recognized on the sale of Asset D. Pursuant to paragraph (g)(3)(iv) of this section and § 1.1502–32T(b)(3)(iii)(D), each such disallowed loss is treated as a noncapital, nondeductible expense of M incurred during the taxable year that includes the date of the disposition of the asset with respect to which such loss was recognized.

Example 3. Transfers to avoid recognition of gain. (i) *Facts.* P owns all of the stock of S1 and S2. The S2 stock has a basis of $400 and a value of $500. S1 owns 50% of the stock of the S3 common stock with a basis of $150. S2 owns the remaining 50% of the S3 common stock with a basis of $100 and a value of $200 and one share of S3 preferred stock with a basis of $10 and a value of $9. P intends to sell all of its S2 stock to an unrelated buyer. P, therefore, engages in the following steps to dispose of S2 without recognizing a substantial portion of the built-in gain in S2. First, P causes a recapitalization of S3 in which S2's S3 common stock is exchanged for new S3 preferred shares. P then sells all of its S2 stock. Immediately after the sale of the S2 stock, S3 is a member of the P group.

(ii) *Analysis.* Pursuant to paragraph (b)(4) of this section, because S2 owns stock of S3 (another subsidiary member of the same group) and, immediately after the sale of the S2 stock, S3 is a member of the group, then for purposes of applying paragraph (b) of this section, S2 is deemed to have transferred its S3 stock. Because S3 is a member of the group immediately after the transfer of the S2 stock and the S3 stock deemed transferred has a basis in excess of value, the group member's basis in the S3 stock is redetermined pursuant to paragraph (b)(1) of this section immediately prior to the sale of the S2 stock. Pursuant to paragraph (b)(1) of this section, the total basis of S3 stock held by members of the P group is allocated first to the S3 preferred shares, up to their value of $209, and then to the remaining shares of S3 common held by S1. S2's aggregate basis in the S3 preferred stock is increased from $110 to $209. This increase tiers up and increases P's basis in the S2 stock from $400 to $499. Accordingly, P will recognize only $1 of gain on the sale of its S2 stock. However, because the recapitalization of S3 was structured with a view to, and has the effect of, avoiding the recognition of gain on a disposition of stock by invoking the application of paragraph (b) of this section, paragraph (g)(4)(i) of this section applies. Accordingly, paragraph (b) of this section does not apply upon P's disposition of the S2 stock and P recognizes $100 of gain on the disposition of the S2 stock.

(h) *Application of other anti-abuse rules.* The rules of this section do not preclude the application of anti-abuse rules under other provisions of the Internal Revenue Code and regulations thereunder.

(i) [Reserved].

(j) *Effective date.* This section, except for paragraph (g)(3) of this section, applies with respect to stock transfers, deconsolidations of subsidiary members, determinations of worthlessness, and stock dispositions on or after March 7, 2002, and no later than March 11, 2006, but only if such events occur during a taxable year the original return for which is due (without regard to extensions) after March 14, 2003. Paragraph (g)(3) of this section applies to events described in paragraph (g)(3)(iii) of this section occurring on or after October 18, 2002, and no later than March 11, 2006, but only if such events occur during a taxable year the original return for which is due (without regard to extensions) after March 14, 2003.

PART 602—[AMENDED]

Par. 8. The authority citation for part 602 continues to read as follows:

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

Par. 9. In § 602.101, paragraph (b) is amended by adding an entry to the table in numerical order for to read as follows:

§ 602.101 OMB Control numbers.

* * * * *

(b) * * *

CFR part or section where identified and described	Current OMB control No.
* * * * *	
1.1502–35T	1545–1828
* * * * *	

David A. Mader,

Assistant Deputy Commissioner of Internal Revenue.

Approved: March 7, 2003.

Pamela F. Olson,

Assistant Secretary of the Treasury.

[FR Doc. 03–6119 Filed 3–11–03; 1:04 pm]

BILLING CODE 4830–01–P

DEPARTMENT OF LABOR

Occupational Safety and Health Administration

29 CFR Part 1910

[Docket No. H–117C]

RIN 1218–AB73

Grain Handling Facilities Standard

AGENCY: Occupational Safety and Health Administration (OSHA), Labor.

ACTION: Completion of regulatory review.

SUMMARY: The Occupational Safety and Health Administration (OSHA), has completed a section 610 (''lookback'') review of its Grain Handling Facilities Standard, 29 CFR 1910.272, pursuant to section 610 of the Regulatory Flexibility Act and section 5 of Executive Order 12866. That review, ''Regulatory Review of OSHA's Grain Handling Standard, February 2003,'' demonstrates that the Standard has reduced injuries 55% and deaths 70% from grain explosions and reduced deaths from grain suffocations by 44%. On average, the Standard has prevented 9.4 deaths per year. The review indicates that the standard does not impose a significant economic impact on small businesses and that public commenters agree that the standard should remain in effect. Based on comments, OSHA will issue several clarifications and will consider several possible improvements. Based on this review, OSHA concludes that the Grain Handling Facilities Standard should be continued without major change.

DATES: Effective March 14, 2003.

FOR FURTHER INFORMATION CONTACT: Joanna Dizikes Friedrich, Directorate of Policy Rm. N3641, OSHA, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone (202) 693–1939. Direct technical inquiries about the Grain Handling Standard to: Alcmene Haloftis, Directorate of Compliance, Rm. 3603, telephone (202) 693–1850, or visit the OSHA Homepage at *www.OSHA.dol.gov.* Direct press inquiries to Bonnie Friedman, Director of Information and Consumer Affairs, Rm. N–3647, telephone (202) 693–1999.

ADDRESSES: Copies of the entire report may be obtained from the OSHA Publication Office, Rm. N–3101, 200 Constitution Avenue, NW., Washington, DC 20210, tel., (202) 693–1888, Fax (202) 693–2498. The full report, comments, and referenced documents are available for review at the OSHA Docket Office, Docket No. H–117C Rm, 2625, 200 Constitution Avenue, NW., Washington, DC 20210, tel. (202) 693–2119.

SUPPLEMENTARY INFORMATION: The Occupational Safety and Health Administration (OSHA) issued its final Grain Handling Facilities Standard December 31, 1987, at 52 FR 49592. OSHA published supplemental statements of reasons on December 4, 1989, at 54 FR 49971 and on April 1, 1994, at 54 FR 15339. On March 8, 1996, OSHA amended the Standard to clarify requirements for entry into flat storage structures (61 FR 9577). The standard is codified at 29 CFR 1910.272.

The Grain Handling Facilities Standard contains requirements for the control of grain dust fires and explosions, and certain other safety hazards associated with grain handling facilities. It applies in addition to all other relevant provisions of part 1910 (or part 1917 at marine terminals).

The Grain Handling Facilities Standard applies to the following types of grain handling facilities: grain elevators, feed mills, flour mills, rice mills, dust pelletizing plants, dry corn mills, soybean flaking operations, and the dry grinding operations of soycake.

The Grain Handling Facilities Standard contains provisions that address several safety hazards. The hazards these provisions address include: Fires; explosions; toxic substance and oxygen deficiences from entry into bins, silos, or tanks; release of hazardous energy from equipment; and engulfment by grain in bins, silos, or tanks.

This section 610 review for the Grain Handling Facilities Standard focused on two endpoints for its risk reduction analyses: (1) Injuries and fatalities from grain dust explosions; and (2) suffocations which result when a worker is engulfed or crushed by grain. These endpoints were selected because accessible data existed for these endpoints. Furthermore, a reduction in fatalities from suffocations and reductions in both injuries and fatalities from explosions are primary and substantial benefits anticipated from the promulgation of the Standard.

In 1998, the Occupational Safety and Health Administration (OSHA) began a review of its Grain Handling Facility Standard, under section 610 of the Regulatory Flexibility Act (5 U.S.C. 601, 610) and section 5 of Executive Order (EO) 12866 on Regulatory Planning and Review. OSHA has completed this review of the Grain Handling Facilities Standard, and it is presented in the document titled ''Regulatory Review of OSHA's Grain Handling Facilities Standard, February 2003.'' This **Federal Register** document announces the availability of that review document and briefly summarizes it.

The purpose of a review under section 610 of the Regulatory Flexibility Act (RFA);

(S)hall be to determine whether such rule should be continued without change, or should be rescinded, or amended consistent with the stated objectives of applicable statutes to minimize any significant impact of the rules on a substantial number of small entities.

The Agency shall consider the following factors:

(1) The continued need for the rule;

(2) The nature of complaints or comments received concerning the rule from the public;

(3) The complexity of the rule;

(4) The extent to which the rule overlaps, duplicates or conflicts with other Federal rules, and to the extent feasible, with State and local governmental rules; and

(5) The length of time since the rule has been evaluated or the degree to which technology, economic conditions, or other factors have changed in the area affected by the rule.

The review requirements of section 5 of EO 12866 require agencies:

To reduce the regulatory burden on the American people, their families, their communities, their State, local, and tribal governments and their industries; to determine whether regulations promulgated by the [agency] have become unjustified or unnecessary as a result of changed circumstances; to confirm that regulations are both compatible with each other and not duplicative or inappropriately burdensome in the aggregate; to ensure that all regulations are consistent with the President's priorities and the principles set forth in this Executive Order, within applicable law; and to otherwise improve the effectiveness of existing regulations.

To carry out these reviews, on June 23, 1998, OSHA asked the public for comments on all issued raised by these provisions (63 FR 34139). Among other things, OSHA requested comments on: The benefits and utility of the rule in its current form; the continued need for the rule; the complexity of the rule; and whether, and to what extent, the rule overlaps, duplicates, or conflicts with other Federal, State, and local government rules. OSHA asked for comments on new developments in technology, economic conditions, or other factors affecting the ability of covered firms to comply with the Grain Handling Facilities Standard. OSHA also requested information on the

impacts of the Standard on small businesses and on alternatives to the rules that would minimize significant impacts on small businesses while achieving the objectives of the Occupational Safety and Health Act.

OSHA accepted written comments from June 23, 1998, through August 31, 1998. OSHA also conducted two public meetings, on July 28, 1998, in Chicago, Illinois and on July 31, 1998, in Washington, DC. Comments were received from employers, trade associations, unions, and grain workers. OSHA also considered studies and reports on relevant issues. All documents, studies, and comments received relevant to the review, transcripts of the oral hearings and documents discussed in this report are available at the OSHA Docket Office, Docket No. H–117C, Room N–3625, U.S. Department of Labor, 200 Constitution Avenue, NW., Washington, DC 20210, telephone: (202) 693–2350.

Conclusions: Based on the comments and testimony of participants in this lookback review process and the studies and other evidence submitted to the public docket, OSHA concludes, as discussed in depth in ''Regulatory Review of OSHA's Grain Handing Facilities Standard, February 2003'' that the Agency's Standard should be continued without major change. The evidence also demonstrates that the Standard does not need to be rescinded or substantially amended to minimize significant impacts on a substantial number of small entities.

OSHA also finds that the Grain Handling Facilities Standard is necessary to protect employee health, is compatible with other OSHA standards, is not duplicative or in conflict with other Federal, State, or local government rules, is not inappropriately burdensome, and is consistent with the President's priorities and the principles of EO 12866. Further, no changes have occurred in technological, economic, or other factors that would warrant revision of the Standard at this time. The major industry and union groups recommend that the Standard remain in effect.

The major sectors affected by the Grain Handling Facilities Standard are grain elevators and grain mills. The Department of Agriculture estimated that in 1999 there were approximately 10,000 off-farm grain elevators with a storage capacity of 8 billion bushels. The SBA provided Bureau of Census data which estimated that, in 1996, there were approximately 92,000 grain elevator and 68,000 grain mill employees in the sectors principally impacted by the Standard. They worked in approximately 5200 grain elevator firms and 1500 grain mill firms.

Prior to the issuance at the final Grain Handling Facilities Standard, from 1958 to 1987, there were an average of 7.3 deaths and 29.1 injuries per year related to grain explosions. After the Standard, from 1988–1998 there were an average of 2.3 deaths and 13.2 injuries per year. This is approximately a 70% reduction in deaths or, on average, 5 fatalities per year have been prevented, and there has been a 55% reduction in injuries. Deaths from grain explosions began to decrease in the five years prior to the issuance of the final Grain Handling Facilities Standard, as industry started instituting controls in response to the National Academy of Sciences (NAS) recommendations, the National Grain and Feed Association (NGFA) guidelines, various government recommendations, and the development of OSHA's proposed Grain Handling Facilities Standard.

Deaths from suffocations in grain also declined. In the 1977–1981 period analyzed for OSHA's Grain Handling Facilities Standard, suffocation deaths from grain averaged 10 per year. From 1988–1999 deaths from suffocation in grain averaged 5.6 per year. As in the case of deaths from explosions, the number of deaths from suffocations began decreasing in the early to mid-1980's, reflecting, in particular, the development of OSHA's proposed Grain Handling Facilities Standard. In the years since the promulgation of the Grain Handling Facilities Standard, the average number of annual grain suffocations has decreased by 44%; an average of 4.4 lives have been saved each year. Therefore, the Grain Handling Facilities Standard has substantially contributed to preventing an average of 9.4 fatalities per year from grain explosions and suffocations.

It is also clear that the Standard did not have any significant negative economic impact on a substantial number of small businesses. The large majority of firms effected are small businesses as defined by the Small Business Administration (SBA). Small businesses showed continued economic strength after OSHA issued the Grain Handling Facilities Standard at the end of 1987. Despite some consolidation in the industry, the percentage of businesses which are small by SBA definition has increased, in some cases substantially. From 1990 to 1996, the percentage of businesses which are small remained at 99% in SIC 5153 (Grain and Field Beans), increased from 91% to 92% in SIC 2041 (Flour Mill Products); from 81 to 88% in SIC 2044 (Rice milling), and there were similar increases in other SICs. This increase in the percentage of firms which are small businesses indicate that the smaller firms still successfully compete against the larger firms and remain economically viable after the issuance of the Grain Handling Facilities Standard.

The data on number of firms by employee size also demonstrates the continuous competitiveness of affected small businesses after OSHA issued the Grain Handling Facilities Standard. From 1990–1996, in the major grain elevator SICs (723, 4221, 5153), the number of firms in the 1–19 employee category decreased about 14%, remained almost the same in the 20–99 employee category, and increased about 12% in the 100–499 employee category. From 1990–1996, in the major grain mill SICs (2041, 2044, 2042, 2048, 2079), the number of firms with 1–19 employees increased slightly, the number of firms with 20–99 employees increased by 14%, and the number with 100–499 employees decreased 15%.

These data indicate that, broken down by size categories, there were small fluctuations, but overall, the number of smaller firms in the various employment categories increased as often as they decreased. This evidence suggests that smaller firms remained economically competitive and viable.

Further evidence that small businesses remained economically competitive after the Grain Handling Facilities Standard was issued is indicated by the employment data. Small businesses (1–499 employees) in the major grain handling SICs had no reduction in employment from 1990–1996, employment being approximately 73,000 in both years. In the major grain mill SICs, employment in small businesses declined slightly in that period from 29,000 to 28,000.

Thus, data available to OSHA indicate that the small businesses in the grain handling industries remained economically competitive after OSHA issued the Grain Handling Facilities Standard. The number of small business firms and employment in small business firms, generally, did not decline, and the percentage of firms that were small businesses increased.

Furthermore, OSHA asked the public for comments in the **Federal Register** document and at the public meetings on the impacts of the Standard on small businesses. OSHA received no complaints from small businesses on the overall impact of the Standard on small businesses.

There is a continued need for the Grain Handling Facilities Standard. Workers continue to be at risk of death and injury from grain explosions, fires,

engulfments and other hazards. A 1998 explosion which resulted in a number of deaths was contributed to by various violations of the Standard.

Many public commenters viewed the Grain Handling Facilities Standard as both needed and effective; no commenter indicated that the Standard should be rescinded. Both the National Grain and Feed Association (NGFA) representing grain elevator and mill owners, and the Food and Allied Services Trades Union (FAST), representing workers in those facilities, supported the retention of the Standard and cited the reduction of deaths and injuries as a reason for its retention.

There were a few comments recommending minor amendments to the Grain Handling Facilities Standard. OSHA responds to those comments in chapter V of the Regulatory Review document. In some cases, the comments reflect a misunderstanding which the Regulatory Review clarifies. In other cases, OSHA believes the existing provision is more protective based on the existing evidence. Several minor updates were suggested which OSHA believes may make the Standard clearer or simplify compliance. OSHA will add to the Standard a cross reference to the Marine Terminal Settlement and consider in the Standards Improvement Project III whether the Grain Handling Facilities Standard confined space provisions should replace generic confined space requirements that now apply in certain operations. As part of a project to update standards based on National Consensus Standards, OSHA will consider whether several fire protection provisions of the Grain Handling Facilities Standard need to be updated.

Signed in Washington, DC this 6th day of March, 2003.

John L. Henshaw,

Assistant Secretary of Labor.

[FR Doc. 03–6117 Filed 3–13–03; 8:45 am]

BILLING CODE 4510–26–P

PENSION BENEFIT GUARANTY CORPORATION

29 CFR Parts 4022 and 4044

Benefits Payable in Terminated Single-Employer Plans; Allocation of Assets in Single-Employer Plans; Interest Assumptions for Valuing and Paying Benefits

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Final rule.

SUMMARY: The Pension Benefit Guaranty Corporation's regulations on Benefits Payable in Terminated Single-Employer Plans and Allocation of Assets in Single-Employer Plans prescribe interest assumptions for valuing and paying benefits under terminating single-employer plans. This final rule amends the regulations to adopt interest assumptions for plans with valuation dates in April 2003. Interest assumptions are also published on the PBGC's Web site (*http://www.pbgc.gov*).

EFFECTIVE DATE: April 1, 2003.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The PBGC's regulations prescribe actuarial assumptions—including interest assumptions—for valuing and paying plan benefits of terminating single-employer plans covered by title IV of the Employee Retirement Income Security Act of 1974. The interest assumptions are intended to reflect current conditions in the financial and annuity markets.

Three sets of interest assumptions are prescribed: (1) a set for the valuation of benefits for allocation purposes under section 4044 (found in Appendix B to part 4044), (2) a set for the PBGC to use to determine whether a benefit is payable as a lump sum and to determine lump-sum amounts to be paid by the PBGC (found in Appendix B to part 4022), and (3) a set for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology (found in Appendix C to part 4022).

Accordingly, this amendment (1) adds to Appendix B to part 4044 the interest assumptions for valuing benefits for allocation purposes in plans with valuation dates during April 2003, (2) adds to Appendix B to part 4022 the interest assumptions for the PBGC to use for its own lump-sum payments in plans with valuation dates during April 2003, and (3) adds to Appendix C to part 4022 the interest assumptions for private-sector pension practitioners to refer to if they wish to use lump-sum interest rates determined using the PBGC's historical methodology for valuation dates during April 2003.

For valuation of benefits for allocation purposes, the interest assumptions that the PBGC will use (set forth in Appendix B to part 4044) will be 4.90 percent for the first 20 years following the valuation date and 5.25 percent thereafter. These interest assumptions represent a decrease of 0.20 percent (from those in effect for March 2003) for the first 20 years following the valuation date and are otherwise unchanged.

The interest assumptions that the PBGC will use for its own lump-sum payments (set forth in Appendix B to part 4022) will be 3.50 percent for the period during which a benefit is in pay status and 4.00 percent during any years preceding the benefit's placement in pay status. These interest assumptions represent a decrease (from those in effect for March 2003) of 0.25 percent for the period during which a benefit is in pay status and are otherwise unchanged.

For private-sector payments, the interest assumptions (set forth in Appendix C to part 4022) will be the same as those used by the PBGC for determining and paying lump sums (set forth in Appendix B to part 4022).

The PBGC has determined that notice and public comment on this amendment are impracticable and contrary to the public interest. This finding is based on the need to determine and issue new interest assumptions promptly so that the assumptions can reflect, as accurately as possible, current market conditions.

Because of the need to provide immediate guidance for the valuation and payment of benefits in plans with valuation dates during April 2003, the PBGC finds that good cause exists for making the assumptions set forth in this amendment effective less than 30 days after publication.

The PBGC has determined that this action is not a ''significant regulatory action'' under the criteria set forth in Executive Order 12866.

Because no general notice of proposed rulemaking is required for this amendment, the Regulatory Flexibility Act of 1980 does not apply. *See* 5 U.S.C. 601(2).

List of Subjects

29 CFR Part 4022

Employee benefit plans, Pension insurance, Pensions, Reporting and recordkeeping requirements.

29 CFR Part 4044

Employee benefit plans, Pension insurance, Pensions.

In consideration of the foregoing, 29 CFR parts 4022 and 4044 are amended as follows:

PART 4022—BENEFITS PAYABLE IN TERMINATED SINGLE-EMPLOYER PLANS

1. The authority citation for part 4022 continues to read as follows:

Authority: 29 U.S.C. 1302, 1322, 1322b, 1341(c)(3)(D), and 1344.

2. In appendix B to part 4022, Rate Set 114, as set forth below, is added to the table. (The introductory text of the table is omitted.)

Appendix B to Part 4022—Lump Sum Interest Rates For PBGC Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*	*	*	*		*		*
114	4–1–03	5–1–03	3.50	4.00	4.00	4.00	7	8

3. In appendix C to part 4022, Rate Set 114, as set forth below, is added to the table. (The introductory text of the table is omitted.)

Appendix C to Part 4022—Lump Sum Interest Rates For Private-Sector Payments

* * * * *

Rate set	For plans with a valuation date		Immediate annuity rate (percent)	Deferred annuities (percent)				
	On or after	Before		i_1	i_2	i_3	n_1	n_2
*	*	*	*	*		*		*
114	4–1–03	5–1–03	3.50	4.00	4.00	4.00	7	8

PART 4044—ALLOCATION OF ASSETS IN SINGLE-EMPLOYER PLANS

4. The authority citation for part 4044 continues to read as follows:

Authority: 29 U.S.C. 1301(a), 1302(b)(3), 1341, 1344, 1362.

5. In appendix B to part 4044, a new entry, as set forth below, is added to the table. (The introductory text of the table is omitted.)

Appendix B to Part 4044—Interest Rates Used to Value Benefits

* * * * *

For valuation dates occurring in the month—	The values of i_t are:					
	i_t	for t =	i_t	for t =	i_t	for t =
*	*	*	*		*		*
April 2003	.0490	1–20	.0525	>20	N/A	N/A

Issued in Washington, DC, on this 10th day of March, 2003.

Joseph H. Grant,

Deputy Executive Director and Chief Operating Officer, Pension Benefit Guaranty Corporation.

[FR Doc. 03–6142 Filed 3–13–03; 8:45 am]

BILLING CODE 7708–01–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[CGD01–01–187]

RIN 2115–AA00, AA11

Regulated Navigation Area, Safety and Security Zones; Long Island Sound Marine Inspection and Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule; change in effective period.

SUMMARY: The Coast Guard is extending the effective period of a regulated navigation area (RNA) and certain safety and security zones published January 4, 2002. This change will extend the effective period of the temporary final rule through August 15, 2003, allowing adequate time for informal rulemaking to develop a permanent rule. This rule will continue to regulate the conditions under which certain vessels may enter, transit or operate within the regulated navigation area and will exclude all vessels from operating within 700 yards of the Millstone Nuclear Power Plant or 100 yards of anchored Coast Guard vessels.

DATES: The amendments of §§ 165.T01–153 and 165.T01.154 in this rule are effective March 15, 2003. Sections 165.T01–153 and 165.T01–154, added at 67 FR 519 and 520, January 4, 2002, effective December 10, 2001, until June 15, 2002, extended at 67 FR 40861, June 14, 2002, through November 15, 2002, and extended at 67 FR 69132, November 15, 2002, through March 15, 2003, as amended in this rule, are extended in effect through August 15, 2003.

ADDRESSES: Documents indicated in this preamble are available for inspection and copying at Waterways Management, U.S. Coast Guard Group/Marine Safety Office (MSO) Long Island Sound, 120 Woodward Ave., New Haven, CT 06512, between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant A. Logman, Waterways Management, U.S. Coast Guard Group/MSO Long Island Sound at (203) 468–4429.

Regulatory Information

On January 4, 2002, we published a temporary final rule (TFR) entitled ''Regulated Navigation Areas, Safety And Security Zones: Long Island Sound Marine Inspection Zone and Captain of the Port Zone'' in the **Federal Register** (67 FR 517). The effective period for that rule was from December 10, 2001, until June 15, 2002. The effective period for that rule was extended through November 15, 2002 (67 FR 40861, June 14, 2002), and it was then extended through March 15, 2003 (67 FR 69132, November 15, 2002).

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing an NPRM. The original TFR was urgently required to prevent terrorist strikes within and adjacent to waters within the Long Island Sound Marine Inspection Zone and Captain of the Port Zone. It was anticipated that we would assess the security environment at the end of the effective period to determine whether continuing security precautions were required and, if so, propose regulations responsive to existing conditions. We have determined that the need for continued security regulations exists. The Coast Guard will utilize the extended effective period of this TFR to engage in notice and comment rulemaking to develop permanent regulations tailored to the present and foreseeable security environment within the ports of Long Island Sound.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. The measures contemplated by the rule were intended to prevent future terrorist attacks. The delay inherent in the NPRM process for developing a permanent rule is contrary to the public interest insofar as it may render individuals, vessels and facilities within and adjacent to the Long Island Sound Marine Inspection Zone and Captain of the Port Zone vulnerable to subversive activity, sabotage or terrorist attack. The Coast Guard will be publishing an NPRM to establish permanent safety and security zones that are temporarily effective under this rule. This revision preserves the *status quo* within the Port while permanent rules are developed. The present TFR has not been burdensome on the maritime public. The Coast Guard has not received written comments or suggestions to modify the scope of the existing TFR.

Background and Purpose

On September 11, 2001, two commercial aircraft were hijacked from Logan Airport in Boston, MA and flown into the World Trade Center in New York, NY inflicting catastrophic human casualties and property damage. A similar attack was conducted on the Pentagon with a plane launched from Newark, NJ on the same day. National security and intelligence officials warn that future terrorist attacks against civilian targets may be anticipated. The Coast Guard established RNAs and safety and security zones within defined areas of water as part of a comprehensive, port security regime designed to safeguard human life, vessels and waterfront facilities from sabotage or terrorist acts. As mentioned in the original TFR, these regulations were designed to provide the Captain of the Port of Long Island Sound with maximum flexibility to respond to emergent threats and dangerous conditions. When less stringent security measures are required, the Captain of the Port communicates relaxed enforcement policies to the public. As a result, the full scope of these regulations is rarely imposed. Nevertheless, the flexibility to utilize those measures permitted by the TFR and required by the circumstances is vital to ensure port security in the present environment.

A change in the effective period of this rule was published on June 14, 2002 (67 FR 40859), which extended the rule through November 15, 2002. A second change in effective period of this rule was published on November 15, 2002 (67 FR 69132), which extended the rule through March 15, 2003. This change was necessary in order to conduct rulemaking for the establishment of permanent safety and security zones and regulated navigation area. Additional time is necessary to ensure the public has sufficient time to participate in the rulemaking process. The Coast Guard is therefore extending the effective date of this rule until August 15, 2003, to allow the establishment of permanent safety and security zones and a regulated navigation area by notice and comment rulemaking.

Regulatory Evaluation

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

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation under the regulatory policies and procedures of DHS is unnecessary. This regulation may have some impact on the public, but these potential impacts will be minimized for the following reasons: the sizes of the zones are the minimum necessary to provide adequate protection for the public, vessels, and vessel crews. Any vessels seeking entry into or movement within the safety and security zones must request permission from the Captain of the Port, Long Island Sound or his authorized patrol representative. Any hardships experienced by persons or vessels are considered minimal compared to the national interest in protecting the public, vessels, and vessel crews from further devastating consequences of the aforementioned acts of terrorism, and from potential future sabotage or other subversive acts, accidents, or other causes of a similar nature.

The Coast Guard will be publishing an NPRM to establish permanent safety and security zones and the regulated navigation area that are temporarily effective under this rule.

Small Entities

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

dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

For the reasons addressed under the ''Regulatory Evaluation'' section above, the Coast Guard expects the impact of this regulation to be minimal and certifies under section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601–612) that this final rule will not have a significant economic impact on a substantial number of small entities. Maritime advisories will be initiated by normal methods and means and be widely available to users of the area.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact Lieutenant A. Logman, Waterways Management, Coast Guard Group/MSO Long Island Sound, (203) 468–4429.

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

Collection of Information

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

Federalism

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

Unfunded Mandates

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

Taking of Private Property

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

Civil Justice Reform

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

Protection of Children

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

Indian Tribal Governments

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

Environment

We have considered the environmental impact of this rule and concluded that under figure 2–1, paragraph 34(g), of Commandant Instruction M16475.1D, this rule is categorically excluded from further environmental documentation. A ''Categorical Exclusion Determination'' is available in the docket for inspection or copying where indicated under **ADDRESSES.**

Energy Effects

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

List of Subjects in 33 CFR Part 165

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

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

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

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

Authority: 33 U.S.C. 1231; 50 U.S.C. 191; 33 CFR 1.05–1(g), 6.04–1, 6.04–6, and 160.5; 49 CFR 1.46.

2. Revise temporary § 165.T01–153(c) to read as follows:

§ 165.T01–153 Regulated Navigation Area; Long Island Sound Marine Inspection Zone and Captain of the Port Zone.

* * * * *

(c) *Effective dates.* This section is effective from December 15, 2001, through August 15, 2003.

* * * * *

3. Revise temporary 165.T01–154(b) to read as follows:

§ 165.T01–154 Safety and Security Zones; Long Island Sound Marine Inspection Zone and Captain of the Port Zone.

* * * * *

(b) *Effective dates.* This section is effective from December 10, 2001, through August 15, 2003.

* * * * *

Dated: March 5, 2003.

Vivien S. Crea,

Rear Admiral, U.S. Coast Guard, Commander First Coast Guard District.

[FR Doc. 03–6327 Filed 3–12–03; 2:53 pm]

BILLING CODE 4910–15–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

42 CFR Part 50

Sterilization of Persons in Federally Assisted Family Planning Projects

AGENCY: Department of Health and Human Services, Office of the Secretary, Office of Public Health and Science, Office of Population Affairs.

ACTION: Final rule; technical amendment.

SUMMARY: This final rule amends Public Health Service (PHS) regulations, which govern the sterilization of persons in federally assisted family planning projects, by making technical revisions to the ''Required Consent Form''.

DATES: This rule is effective March 14, 2003.

FOR FURTHER INFORMATION CONTACT: Evelyn Kappeler, Office of Population Affairs, 4350 East West Highway, Suite 200, Bethesda, Maryland 20814; telephone number: (301) 594–7608; e-mail address: *EKappeler@osophs.dhhs.gov.*

SUPPLEMENTARY INFORMATION: On November 8, 1978, this Department published in the **Federal Register** (43 FR 52146), final rules prescribing the requirements for sterilizations funded under the various health programs administered by the Department. Included with the portion of the rules pertaining to those programs administered by the PHS, as part of the appendix to subpart B, is a copy of the required sterilization consent form. These rules, including the appendix, have been codified at 42 CFR part 50, subpart B.

This final rule amends 42 CFR part 50 by revising the sterilization consent form contained in the appendix to subpart B. These amendments will make the codified PHS regulations conform with (1) recent government-wide directives issued by the Office of Management and Budget (OMB) concerning standards for maintaining, collecting and presenting Federal data on race and ethnicity for all Federal reporting purposes, and (2) the requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*) regarding the respondent burden statement. In order to effect a change in the materials codified in the Code of Federal Regulations, however, the Department must issue these changes in the form of a final rule.

Race and Ethnicity Data

Although not required, respondents to the sterilization consent form are requested to supply information on their race and ethnicity. The sterilization consent form contains information collections subject to OMB approval under the Paperwork Reduction Act (PRA), and is being revised to reflect more recent guidance on the appropriate racial and ethnic information classifications.

After a comprehensive review process, including a notice and public comment period, OMB revised its standards for the classification of Federal Data on Race and Ethnicity (''Statistical Policy Directive No. 15, Race and Ethnic Standards for Federal Statistics and Administrative Reporting''). The revised classification provides minimum standards for maintaining, collecting and presenting data on race and ethnicity for all Federal reporting purposes. The standards were developed to provide a common language for uniformity and comparability in the collection and use of data on race and ethnicity by Federal agencies. The standards provide two formats that may be used for data on race and ethnicity. Self-reporting and self-identification using two separate questions is the OMB preferred method for collecting data on race and ethnicity. To provide flexibility and ensure data quality, the OMB directs that separate questions be used whenever feasible for reporting race and ethnicity. Additionally, when race and ethnicity are collected separately, ethnicity must be collected first. If race and ethnicity are collected separately, OMB's minimum designations are as follows: Ethnicity—Hispanic or Latino; Not Hispanic or Latino Race; Race—American Indian or Alaska Native; Asian; Black or African American; Native Hawaiian or Other Pacific Islander; White. Self-reporting or self-identification using two separate questions is the OMB preferred method for collecting data on race and ethnicity. The OMB standards also state that respondents shall be offered the option of selecting one or more racial designations. Consistent with these standards, this final rule adopts the two-question format with an instruction to ''mark one or more'' racial categories in the required sterilization consent form.

Respondent Burden Statement

The sterilization consent form is also being amended to incorporate the respondent burden statement, as required by the Paperwork Reduction Act. This will ensure that each respondent receives, directly, a copy of the required statement. Under the PRA, as well as the statute's implementing regulations (5 CFR part 1320), the term ''burden'' means the ''total time, effort, or financial resources'' the public expends to provide information to or for a Federal agency, including reviewing instructions; using technology to collect, process, and disclose information; adjusting existing practices to comply with requirements; searching data sources; completing and reviewing the collection of information; and transmitting or disclosing information. Under the Paperwork Reduction Act, agencies must take into account the burden that their information collections impose on the public. This burden is balanced with the ''practical utility'' of the information to be collected. 44 U.S.C. 3502(2); 5 CFR 1320.3(b).

Justification for Omitting Notice of Proposed Rulemaking

Section 553(b)(B) of the Administrative Procedure Act (5 U.S.C. 553) provides that, when an agency for good cause finds that notice and public procedures are impracticable, unnecessary or contrary to the public interest, the agency may issue a rule without providing notice and an opportunity for public comment. DHHS has determined that it is unnecessary and impractical to follow proposed rulemaking procedures or to delay the effective date of this regulation, since this amendment is purely technical in nature, and simply amends the sterilization consent form to conform with current OMB directives regarding the classification of race and ethnicity data, which went through a notice and comment period, as well as to reflect the statutory requirements of the PRA.

Regulatory Assessment Requirements

This final rule implements technical amendments which have no substantive impact on the underlying regulations, and it does not otherwise impose or amend any requirements. As such, it is not a ''significant regulatory action'' subject to review by OMB under Executive Order 12866, entitled Regulatory Planning and Review. This final rule contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act (44 U.S.C. 3501 *et seq.*). Furthermore, since the action does not require the issuance of a proposed rule, the requirements of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply. In addition, DHHS has determined that this final rule does not impose any enforceable duty or contain any unfunded mandate as described under Title II of the Unfunded Mandates Reform Act of 1995 (Pub. L. 104–4), and 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, as specified in Executive Order 13132, entitled *Federalism.* As there are no Federalism implications, a Federalism impact statement is not required.

List of Subjects in 42 CFR Part 50

Drugs, Family planning, Grant programs-health, Healthcare, Reporting and recordkeeping requirements, Sterilization.

Dated: January 30, 2003.

Alma L. Golden,

Deputy Assistant Secretary for Population Affairs.

Accordingly, in 42 CFR part 50, the appendix to subpart B, ''Required Consent Form,'' is amended as set forth below:

PART 50—POLICIES OF GENERAL APPLICABILITY

1. The authority citation for 42 CFR part 50 continues to read as follows:

Authority: Sec. 215, Public Health Service Act, 58 Stat. 690 (42 U.S.C. 216); Sec. 1006, Public Health Service Act, 84 Stat. 1507 (42 U.S.C. 300a–4), unless otherwise noted.

Subpart B—Sterilization of Persons in Federally Assisted Family Planning Projects

2. The appendix to subpart B is amended by:

(A) Under Consent to Sterilization, by removing the text regarding race and ethnicity designation, which begins after the statement, ''You are requested to supply the following information, but it is not required:'' and adding the following text regarding race and ethnicity designation in its place:

* * * * *

Ethnicity and Race Designation

Ethnicity:

☐ Hispanic or Latino
☐ Not Hispanic or Latino

Race (mark one or more):

☐ American Indian or Alaska Native
☐ Asian
☐ Black or African American
☐ Native Hawaiian or Other Pacific Islander
☐ White

* * * * *

(B) Adding the following statement to the end of the sterilization consent form:

* * * * *

Paperwork Reduction Act Statement

A Federal agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays the currently valid OMB control number. Public reporting burden for this collection of information will vary; however, we estimate an average of one hour per response, including for reviewing instructions, gathering and maintaining the necessary data, and disclosing the information. Send any comment regarding the burden estimate or any other aspect of this collection of information to the OS Reports Clearance Officer, ASBTF/Budget Room 503 HHH Building, 200 Independence Avenue, SW., Washington, DC 20201.

Respondents should be informed that the collection of information requested on this form is authorized by 42 CFR part 50, subpart B, relating to the sterilization of persons in federally assisted public health programs. The purpose of requesting this information is to ensure that individuals requesting sterilization receive information regarding the risks, benefits and consequences, and to assure the voluntary and informed consent of all persons undergoing sterilization procedures in federally assisted public health programs. Although not required, respondents are requested to supply information on their race and ethnicity. Failure to provide the other information requested on this consent form, and to sign this consent form, may result in an inability to receive sterilization procedures funded through federally assisted public health programs.

All information as to personal facts and circumstances obtained through this form will be held confidential, and not disclosed without the individual's consent, pursuant to any applicable confidentiality regulations.

[FR Doc. 03–5630 Filed 3–13–03; 8:45 am]

BILLING CODE 4150–34–P

Proposed Rules

Federal Register
Vol. 68, No. 50
Friday, March 14, 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

Farm Service Agency

7 CFR Part 770

RIN 0560–AG87

Revision of Indian Tribal Land Acquisition Program Loan Regulations

AGENCY: Farm Service Agency, USDA.

ACTION: Proposed rule.

SUMMARY: This rule proposes to clarify and revise the Indian Tribal Land Acquisition Program (ITLAP) regulations for borrowers who apply for a rental value write-down. The rule proposes to change the method for determining the rental value of security for purposes of a write-down, adds a definition of ''rental value,'' clarifies other write-down eligibility provisions, and limits new loan eligibility for borrowers who have received a write-down in the past. These changes are intended to reduce the borrower's costs of applying for a rental value write-down, and reduce the burden on Agency employees in processing requests.

DATES: Comments on the proposed rule must be received on or before May 13, 2003, to be assured of consideration.

ADDRESSES: Mail comments on the proposed rule to: Veldon Hall, Director, Farm Loan Programs, Loan Servicing and Property Management Division, Farm Service Agency, USDA, 1400 Independence Avenue, SW., Stop 0523, Washington, DC 20250–0523, or hand deliver to Suite 500, 1250 Maryland Avenue, SW., Washington, DC 20024 during normal business hours. All comments and supporting documents on this rule may be viewed by contacting the information contact listed below. All comments received, including names and addresses, will become a matter of public record.

FOR FURTHER INFORMATION CONTACT: Mel Thompson, Senior Loan Officer, Farm Service Agency; telephone: 202–720–7862; facsimile: 202–690–1196; e-mail: *mel_thompson@wdc.fsa.usda.gov*. Persons with disabilities who require alternative means for communication (Braille, large print, audio tape, etc.) should contact the USDA Target Center at (202) 720–2600 (voice and TDD).

SUPPLEMENTARY INFORMATION:

Executive Order 12866

This rule has been determined under Executive Order 12866 to be not significant and was not reviewed by the Office of Management and Budget.

Regulatory Flexibility Act

The Agency certifies that this rule will not have a significant economic effect on a substantial number of small entities, because it does not require additional actions by the borrower. The Agency, therefore, is not required to perform a Regulatory Flexibility Analysis as required by the Regulatory Flexibility Act, Pub. L. 96–534, as amended (5 U.S.C. 601). This rule does not impact small entities to a greater extent than large entities.

Environmental Evaluation

The environmental impacts of this proposed rule have been considered in accordance with the provisions of the National Environmental Policy Act of 1969 (NEPA), 42 U.S.C. 4321 *et seq.*, the regulations of the Council on Environmental Quality (40 CFR Parts 1500–1508), and the FSA regulations for compliance with NEPA, 7 CFR parts 799, and 1940, subpart G. FSA completed an environmental evaluation and concluded the rule requires no further environmental review. No extraordinary circumstances or other unforeseeable factors exist which would require preparation of an environmental assessment or environmental impact statement. A copy of the environmental evaluation is available for inspection and review upon request.

Executive Order 12988

This rule has been reviewed in accordance with E.O. 12988, Civil Justice Reform. In accordance with that Executive Order: (1) All State and local laws and regulations that are in conflict with this rule will be preempted; (2) no retroactive effect will be given to this rule; and (3) administrative proceedings in accordance with 7 CFR parts 11 and 780 must be exhausted before requesting judicial review.

Executive Order 12372

As stated in the Notice related to 7 CFR part 3015, subpart V (48 FR 29115, June 24, 1983) the programs and activities within this rule do not require consultation with state and local officials under the scope of Executive Order 12372.

Unfunded Mandates

Title II of the Unfunded Mandates Reform Act of 1995 (UMRA), Pub. L. 104–4, requires Federal agencies to assess the effects of their regulatory actions on state, local, and tribal governments or the private sector of expenditures of $100 million or more in any one year. This rule contains no Federal mandates, as defined by title II of the UMRA; therefore, this rule is not subject to sections 202 and 205 of the UMRA.

Executive Order 13132

The policies contained in this rule do not have any substantial direct effect on 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. Nor does this rule impose substantial direct compliance costs on state and local governments. Therefore, consultation with the states is not required.

Paperwork Reduction Act

The amendments to 7 CFR part 770 contained in this proposed rule require no revisions to the information collection requirements that were previously approved by OMB and assigned OMB control number 0560–0198 under the provisions of 44 U.S.C. chapter 35, nor do they significantly affect the aggregate information collection burden of the Agency. Removing the requirement for an appraisal and replacing it with a market value rent study report, which is much smaller in scope, reduces the amount of information provided by the appraiser at the expense of the borrower. The number of estimated annual respondents and the time burden to provide a copy of the report is the same.

Federal Assistance Program

The proposed changes affect the following program listed in the Catalog of Federal Domestic Assistance:

10.421—Indian Tribes and Tribal Corporation Loans.

Discussion of the Proposed Rule

This proposed rule revises and clarifies the write-down servicing policies of the Farm Service Agency's Indian Tribal Land Acquisition Loan Program. The first proposed change is to clarify ''rental value''. Applicants and borrowers have misunderstood this term. Therefore, a definition is added in the proposed rule at § 770.2(b). A second revision changes the current appraisal needed to apply for a rental value write-down. An appraisal provides a substantial amount of information at the borrower's expense that is not necessary for calculating rental value write-downs. The information FSA needs can be provided by a rental value market study report prepared by a certified general appraiser. This change will dramatically reduce the borrower's costs. Also, since it requires less work for the appraiser, it reduces the appraiser's delay in completing the report, thus reducing FSA's processing time.

A third change is proposed in the eligibility requirements for both ITLAP land value and rental value write-downs. The eligibility requirements currently in the reamortization paragraph at § 770.10(a)(1) are being proposed for the write-down sections as well in §§ 770.10(e)(3)(v) and (e)(4)(v). These standards would require borrowers to submit complete application forms and establish that the delinquency is beyond the borrowers' control which cannot be brought current within one year and borrowers cannot meet the annual loan payments. These eligibility requirements will help assure that write-downs will be provided only to those financially distressed borrowers who are faced with circumstances outside their control. Several FSA loan servicing programs contain similar eligibility requirements. *See* 7 CFR 1951.909(c).

For *rental value write-downs*, the current rule at § 770.10(e)(4)(iv) prevents additional write-downs only when the specific ITLAP loan has received a rental value write-down previously and the specific loan has received a land value write-down within the last 5 years. The proposed rule would modify this paragraph to preclude an additional rental value write-down when *any loan* has ever received a rental value write-down or any loan has received a land value write-down within the last 5 years. The proposed revisions will limit FSA's losses when it provides rental value write-downs.

Similarly, the proposed rule seeks to add an additional loan eligibility requirement to § 770.3. Since write-downs are the consequence of a borrower's seriously deteriorating financial condition, the proposed rule adds a requirement for additional ITLAP loan eligibility requiring that borrowers must not have received an ITLAP rental value or land value write-down within the last five years. The additional eligibility requirement will enable FSA to make more creditworthy loans and decrease the possibility of further Agency losses.

The proposed rule will result in better service and substantial monetary and time savings for borrowers who apply for a write-down based on rental value. In addition, it will increase the protection of the taxpayers from potential loss and reduce the agency official's burden in administering the servicing of the Indian Tribal Land Acquisition Program Loans.

List of Subjects in 7 CFR Part 770

Agriculture, Credit, Indians, Rural areas, Loan Programs.

Accordingly, for the reasons stated in the preamble, 7 CFR part 770 is proposed to be amended as follows:

PART 770—INDIAN TRIBAL LAND ACQUISITION LOANS

1. The authority citation for part 770 continues to read as follows:

Authority: 5 U.S.C. 301, 25 U.S.C. 490.

2. Amend § 770.2 by adding an abbreviation in paragraph (a) and a definition in paragraph (b) to read as follows:

§ 770.2 Abbreviations and definitions.

(a) *Abbreviations.*

* * * * *

USPAP: Uniform Standards of Professional Appraisal Practice.

(b) *Definitions.*

* * * * *

Rental Value is the potential annual rental income of a parcel of real estate as determined by a market analysis of annual rental incomes of like real estate in the subject property area.

* * * * *

3. Amend § 770.3 by adding paragraph (h) to read as follows:

§ 770.3 Eligibility requirements.

* * * * *

(h) Have not received a write-down as provided in § 770.10(e) within the preceding 5 years.

4. Amend § 770.10 by adding paragraph (e)(3)(v), revising paragraphs (e)(4)(iii) and (e)(4)(iv) and adding paragraph (e)(4)(v) to read as follows:

§ 770.10 Servicing.

* * * * *

(e) *Debt Write-down.*

* * * * *

(3) Land Value Write-down.

* * * * *

(v) The borrower must meet the eligibility requirements of paragraphs (a)(1)(ii), or (iii) of this section.

(4) Rental Value Write-down.

* * * * *

(iii) The borrower provides a current market value rent study report for the land for the preceding 5 years, which identifies the average rental value. The report must be prepared by a Certified General Appraiser and meet the requirements of USPAP.

(iv) The borrower has not previously received a write-down under this paragraph on any loan and has not had a loan written down within the last 5 years under paragraph (e)(3) of this section.

(v) The borrower must meet the eligibility requirements of paragraph (a)(1) (ii), or (iii) of this section.

Signed in Washington, DC, on February 26, 2003.

James R. Little,

Administrator, Farm Service Agency.

[FR Doc. 03–6162 Filed 3–13–03; 8:45 am]

BILLING CODE 3410–05–P

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 1205

[Doc. No. CN–03–002]

Cotton Board Rules and Regulations: Adjusting Supplemental Assessment on Imports, (2003 Amendments)

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Agricultural Marketing Service (AMS) is proposing to amend the Cotton Board Rules and Regulations by lowering the value assigned to imported cotton for the purpose of calculating supplemental assessments collected for use by the Cotton Research and Promotion Program. An adjustment is required on an annual basis to ensure that the assessments collected on imported cotton and the cotton content of imported products remain similar to those paid on domestically produced cotton.

DATES: Comments must be received on or before April 14, 2003.

ADDRESSES: Interested persons are invited to submit written comments

concerning this proposed rule to Whitney Rick, Chief, Research and Promotion Staff, Cotton Program, Agricultural Marketing Service, USDA, STOP 0224, Washington, DC 20250–0224. Comments should be submitted in triplicate. Comments may also be submitted electronically to: *cottoncomments@usda.gov*. All comments should reference the docket number and the date and page number of this issue of the **Federal Register**. All comments received will be made available for public inspection at Cotton Program, AMS, USDA, Room 2641–S, 1400 Independence Ave., SW., Washington, DC 20250 during regular business hours. A copy of this notice may be found at: *www.ams.usda.gov/cotton/rulemaking.htm*.

FOR FURTHER INFORMATION CONTACT: Whitney Rick, Chief, Research and Promotion Staff, Cotton Program, AMS, USDA, STOP 0224, 1400 Independence Ave., SW., Washington, DC 20250–0224, telephone (202) 720–2259, facsimile (202) 690–1718, or e-mail at *whitney.rick@usda.gov*.

SUPPLEMENTARY INFORMATION:

Executive Order 12866

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

Executive Order 12988

This proposed rule has been reviewed under Executive Order 12988, Civil Justice Reform. It is not intended to have retroactive effect. This proposed rule would not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Cotton Research and Promotion Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 12 of the Act, any person subject to an order may file with the Secretary a petition stating that the order, any provision of the plan, or any obligation imposed in connection with the order is not in accordance with law and requesting a modification of the order or to be exempted therefrom. Such person is afforded the opportunity for a hearing on the petition. After the hearing, the Secretary would rule on the petition. The Act provides that the District Court of the United States in any district in which the person is an inhabitant, or has his principal place of business, has jurisdiction to review the Secretary's ruling, provided a complaint is filed within 20 days from the date of the entry of ruling.

Regulatory Flexibility Act

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*) AMS has considered the economic impact of this action on small entities and has determined that its implementation will not have a significant economic impact on a substantial number of small businesses.

There are an estimated 10,000 importers who are presently subject to rules and regulations issued pursuant to the Cotton Research and Promotion Order. This proposed rule would affect importers of cotton and cotton-containing products. The majority of these importers are small businesses under the criteria established by the Small Business Administration. This proposed rule would lower the assessments paid by the importers under the Cotton Research and Promotion Order. Even though the assessment would be lowered, the decrease is small and will not significantly affect small businesses. The current assessment on imported cotton is $0.00862 per kilogram of imported cotton. The proposed assessment is $0.008267, a decrease of $0.000353 or a 4.1 percent decrease. From January through December 2002 approximately $24 million was collected. Should the volume of cotton products imported into the U.S. remain at the same level in 2003, one could expect the decreased assessment to generate approximately $23 million or a 4.1 percent decrease from 2002.

Paperwork Reduction

In compliance with Office of Management and Budget (OMB) regulations (5 CFR part 1320) which implement the Paperwork Reduction Act (PRA) (44 U.S.C. 3501 *et seq.*) the information collection requirements contained in the regulation to be amended have been previously approved by OMB and were assigned control number 0581–0093.

Background

The Cotton Research and Promotion Act Amendments of 1990 enacted by Congress under Subtitle G of Title XIX of the Food, Agriculture, Conservation and Trade Act of 1990 on November 28, 1990, contained two provisions that authorized changes in the funding procedures for the Cotton Research and Promotion Program.

These provisions are: (1) The assessment of imported cotton and cotton products; and (2) termination of the right of cotton producers to demand a refund of assessments.

An amended Cotton Research and Promotion Order was approved by producers and importers voting in a referendum held July 17–26, 1991, and the amended Order was published in the **Federal Register** on December 10, 1991, (56 FR 64470). A proposed rule implementing the amended Order was published in the **Federal Register** on December 17, 1991, (56 FR 65450). Implementing rules were published on July 1 and 2, 1992, (57 FR 29181) and (57 FR 29431), respectively.

This proposed rule would decrease the value assigned to imported cotton in the Cotton Board Rules and Regulations (7 CFR 1205.510(b)(2)). This value is used to calculate supplemental assessments on imported cotton and the cotton content of imported products. Supplemental assessments are the second part of a two-part assessment. The first part of the assessment is levied on the weight of cotton produced or imported at a rate of $1 per bale of cotton which is equivalent to 500 pounds or $1 per 226.8 kilograms of cotton.

Supplemental assessments are levied at a rate of five-tenths of one percent of the value of domestically produced cotton, imported cotton, and the cotton content of imported products. The agency has adopted the practice of assigning the calendar year weighted average price received by U.S. farmers for Upland cotton to represent the value of imported cotton. This is done so that the assessment on domestically produced cotton and the assessment on imported cotton and the cotton content of imported products remain similar. The source for the average price statistic is ''Agricultural Prices'', a publication of the National Agricultural Statistics Service (NASS) of the Department of Agriculture. Use of the weighted average price figure in the calculation of supplemental assessments on imported cotton and the cotton content of imported products yields an assessment that approximates assessments paid on domestically produced cotton in the prior calendar year.

The current value of imported cotton as published in the **Federal Register** (67 FR 36793) on May 28, 2002, for the purpose of calculating supplemental assessments on imported cotton is $.8422 per kilogram. This number was calculated using the annual weighted average price received by farmers for Upland cotton during the calendar year 2001 which was $0.382 per pound and multiplying by the conversion factor 2.2046. Using the Average Weighted Price received by U.S. farmers for Upland cotton for the calendar year 2002, which is $0.35 per pound, the new value of imported cotton is $0.7716 per kilogram. The proposed value is

$.0706 per kilogram less than the previous value.

An example of the complete assessment formula and how the various figures are obtained is as follows:

One bale is equal to 500 pounds.

One kilogram equals 2.2046 pounds.

One pound equals 0.453597 kilograms.

One Dollar Per Bale Assessment Converted to Kilograms

A 500 pound bale equals 226.8 kg. (500 x .453597).

$1 per bale assessment equals $0.002000 per pound (1/500) or $0.004409 per kg. (1/226.8).

Supplemental Assessment of 5/10 of One Percent of the Value of the Cotton Converted to Kilograms.

The 2002 calendar year weighted average price received by producers for Upland cotton is $0.35 per pound or $0.7716 per kg. (0.35 x 2.2046).

Five tenths of one percent of the average price in kg. equals $0.003858 per kg. (0.7716 x .005).

Total Assessment

The total assessment per kilogram of raw cotton is obtained by adding the $1 per bale equivalent assessment of $0.004409 per kg. and the supplemental assessment $0.003858 per kg. which equals $0.008267 per kg.

The current assessment on imported cotton is $0.008620 per kilogram of imported cotton. The proposed assessment is $0.008267, a decrease of $0.000353 per kilogram. This decrease reflects the decrease in the Average Weighted Price of Upland Cotton received by U.S. Farmers during the period January through December 2002.

Since the value of cotton is the basis of the supplemental assessment calculation and the figures shown in the right hand column of the Import Assessment Table 1205.510(b)(3) are a result of such a calculation, the figures in this table have been revised. These figures indicate the total assessment per kilogram due for each Harmonized Tariff Schedule (HTS) number subject to assessment.

A thirty day comment period is provided to comment on the changes to the Cotton Board Rules and Regulations proposed herein. This period is deemed appropriate because this proposal would lower the assessments paid by importers under the Cotton Research and Promotion Order. Accordingly, the change proposed in this rule, if adopted, should be implemented as soon as possible.

List of Subjects in 7 CFR Part 1205

Advertising, Agricultural research, Cotton, Marketing agreements, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble 7 CFR part 1205 is proposed to be amended as follows:

PART 1205—COTTON RESEARCH AND PROMOTION

1. The authority citation for part 1205 continues to read as follows:

Authority: 7 U.S.C. 2101–2118.

2. In § 1205.510, paragraph (b)(2) and the table in paragraph (b)(3)(ii) are revised to read as follows:

§ 1205.510 Levy of assessments.

* * * * *

(b) * * *

(2) The 12-month average of monthly weighted average prices received by U.S. farmers will be calculated annually. Such weighted average will be used as the value of imported cotton for the purpose of levying the supplemental assessment on imported cotton and will be expressed in kilograms. The value of imported cotton for the purpose of levying this supplemental assessment is $0.8267 per kilogram.

(3) * * *

(ii) * * *

IMPORT ASSESSMENT TABLE

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
5201000500 ..	0	0.8267
5201001200 ..	0	0.8267
5201001400 ..	0	0.8267
5201001800 ..	0	0.8267
5201002200 ..	0	0.8267
5201002400 ..	0	0.8267
5201002800 ..	0	0.8267
5201003400 ..	0	0.8267
5201003800 ..	0	0.8267
5204110000 ..	1.1111	0.9185
5204200000 ..	1.1111	0.9185
5205111000 ..	1.1111	0.9185
5205112000 ..	1.1111	0.9185
5205121000 ..	1.1111	0.9185
5205122000 ..	1.1111	0.9185
5205131000 ..	1.1111	0.9185
5205132000 ..	1.1111	0.9185
5205141000 ..	1.1111	0.9185
5205210020 ..	1.1111	0.9185
5205210090 ..	1.1111	0.9185
5205220020 ..	1.1111	0.9185
5205220090 ..	1.1111	0.9185
5205230020 ..	1.1111	0.9185
5205230090 ..	1.1111	0.9185
5205240020 ..	1.1111	0.9185
5205240090 ..	1.1111	0.9185
5205310000 ..	1.1111	0.9185
5205320000 ..	1.1111	0.9185
5205330000 ..	1.1111	0.9185
5205340000 ..	1.1111	0.9185

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
5205410020 ..	1.1111	0.9185
5205410090 ..	1.1111	0.9185
5205420020 ..	1.1111	0.9185
5205420090 ..	1.1111	0.9185
5205440020 ..	1.1111	0.9185
5205440090 ..	1.1111	0.9185
5206120000 ..	0.5556	0.4593
5206130000 ..	0.5556	0.4593
5206140000 ..	0.5556	0.4593
5206220000 ..	0.5556	0.4593
5206230000 ..	0.5556	0.4593
5206240000 ..	0.5556	0.4593
5206310000 ..	0.5556	0.4593
5207100000 ..	1.1111	0.9185
5207900000 ..	0.5556	0.4593
5208112020 ..	1.1455	0.9470
5208112040 ..	1.1455	0.9470
5208112090 ..	1.1455	0.9470
5208114020 ..	1.1455	0.9470
5208114060 ..	1.1455	0.9470
5208114090 ..	1.1455	0.9470
5208118090 ..	1.1455	0.9470
5208124020 ..	1.1455	0.9470
5208124040 ..	1.1455	0.9470
5208124090 ..	1.1455	0.9470
5208126020 ..	1.1455	0.9470
5208126040 ..	1.1455	0.9470
5208126060 ..	1.1455	0.9470
5208126090 ..	1.1455	0.9470
5208128020 ..	1.1455	0.9470
5208128090 ..	1.1455	0.9470
5208130000 ..	1.1455	0.9470
5208192020 ..	1.1455	0.9470
5208192090 ..	1.1455	0.9470
5208194020 ..	1.1455	0.9470
5208194090 ..	1.1455	0.9470
5208196020 ..	1.1455	0.9470
5208196090 ..	1.1455	0.9470
5208224040 ..	1.1455	0.9470
5208224090 ..	1.1455	0.9470
5208226020 ..	1.1455	0.9470
5208226060 ..	1.1455	0.9470
5208228020 ..	1.1455	0.9470
5208230000 ..	1.1455	0.9470
5208292020 ..	1.1455	0.9470
5208292090 ..	1.1455	0.9470
5208294090 ..	1.1455	0.9470
5208296090 ..	1.1455	0.9470
5208298020 ..	1.1455	0.9470
5208312000 ..	1.1455	0.9470
5208321000 ..	1.1455	0.9470
5208323020 ..	1.1455	0.9470
5208323040 ..	1.1455	0.9470
5208323090 ..	1.1455	0.9470
5208324020 ..	1.1455	0.9470
5208324040 ..	1.1455	0.9470
5208325020 ..	1.1455	0.9470
5208330000 ..	1.1455	0.9470
5208392020 ..	1.1455	0.9470
5208392090 ..	1.1455	0.9470
5208394090 ..	1.1455	0.9470
5208396090 ..	1.1455	0.9470
5208398020 ..	1.1455	0.9470
5208412000 ..	1.1455	0.9470
5208416000 ..	1.1455	0.9470
5208418000 ..	1.1455	0.9470
5208421000 ..	1.1455	0.9470
5208423000 ..	1.1455	0.9470
5208424000 ..	1.1455	0.9470

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
5208425000 ..	1.1455	0.9470
5208430000 ..	1.1455	0.9470
5208492000 ..	1.1455	0.9470
5208494020 ..	1.1455	0.9470
5208494090 ..	1.1455	0.9470
5208496010 ..	1.1455	0.9470
5208496090 ..	1.1455	0.9470
5208498090 ..	1.1455	0.9470
5208512000 ..	1.1455	0.9470
5208516060 ..	1.1455	0.9470
5208518090 ..	1.1455	0.9470
5208523020 ..	1.1455	0.9470
5208523045 ..	1.1455	0.9470
5208523090 ..	1.1455	0.9470
5208524020 ..	1.1455	0.9470
5208524045 ..	1.1455	0.9470
5208524065 ..	1.1455	0.9470
5208525020 ..	1.1455	0.9470
5208530000 ..	1.1455	0.9470
5208592025 ..	1.1455	0.9470
5208592095 ..	1.1455	0.9470
5208594090 ..	1.1455	0.9470
5208596090 ..	1.1455	0.9470
5209110020 ..	1.1455	0.9470
5209110035 ..	1.1455	0.9470
5209110090 ..	1.1455	0.9470
5209120020 ..	1.1455	0.9470
5209120040 ..	1.1455	0.9470
5209190020 ..	1.1455	0.9470
5209190040 ..	1.1455	0.9470
5209190060 ..	1.1455	0.9470
5209190090 ..	1.1455	0.9470
5209210090 ..	1.1455	0.9470
5209220020 ..	1.1455	0.9470
5209220040 ..	1.1455	0.9470
5209290040 ..	1.1455	0.9470
5209290090 ..	1.1455	0.9470
5209313000 ..	1.1455	0.9470
5209316020 ..	1.1455	0.9470
5209316035 ..	1.1455	0.9470
5209316050 ..	1.1455	0.9470
5209316090 ..	1.1455	0.9470
5209320020 ..	1.1455	0.9470
5209320040 ..	1.1455	0.9470
5209390020 ..	1.1455	0.9470
5209390040 ..	1.1455	0.9470
5209390060 ..	1.1455	0.9470
5209390080 ..	1.1455	0.9470
5209390090 ..	1.1455	0.9470
5209413000 ..	1.1455	0.9470
5209416020 ..	1.1455	0.9470
5209416040 ..	1.1455	0.9470
5209420020 ..	1.0309	0.8522
5209420040 ..	1.0309	0.8522
5209430030 ..	1.1455	0.9470
5209430050 ..	1.1455	0.9470
5209490020 ..	1.1455	0.9470
5209490090 ..	1.1455	0.9470
5209516035 ..	1.1455	0.9470
5209516050 ..	1.1455	0.9470
5209520020 ..	1.1455	0.9470
5209590025 ..	1.1455	0.9470
5209590040 ..	1.1455	0.9470
5209590090 ..	1.1455	0.9470
5210114020 ..	0.6873	0.5682
5210114040 ..	0.6873	0.5682
5210116020 ..	0.6873	0.5682
5210116040 ..	0.6873	0.5682
5210116060 ..	0.6873	0.5682

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
5210118020 ..	0.6873	0.5682
5210120000 ..	0.6873	0.5682
5210192090 ..	0.6873	0.5682
5210214040 ..	0.6873	0.5682
5210216020 ..	0.6873	0.5682
5210216060 ..	0.6873	0.5682
5210218020 ..	0.6873	0.5682
5210314020 ..	0.6873	0.5682
5210314040 ..	0.6873	0.5682
5210316020 ..	0.6873	0.5682
5210318020 ..	0.6873	0.5682
5210414000 ..	0.6873	0.5682
5210416000 ..	0.6873	0.5682
5210418000 ..	0.6873	0.5682
5210498090 ..	0.6873	0.5682
5210514040 ..	0.6873	0.5682
5210516020 ..	0.6873	0.5682
5210516040 ..	0.6873	0.5682
5210516060 ..	0.6873	0.5682
5211110090 ..	0.6873	0.5682
5211120020 ..	0.6873	0.5682
5211190020 ..	0.6873	0.5682
5211190060 ..	0.6873	0.5682
5211210025 ..	0.6873	0.5682
5211210035 ..	0.4165	0.3443
5211210050 ..	0.6873	0.5682
5211290090 ..	0.6873	0.5682
5211320020 ..	0.6873	0.5682
5211390040 ..	0.6873	0.5682
5211390060 ..	0.6873	0.5682
5211490020 ..	0.6873	0.5682
5211490090 ..	0.6873	0.5682
5211590025 ..	0.6873	0.5682
5212146090 ..	0.9164	0.7576
5212156020 ..	0.9164	0.7576
5212216090 ..	0.9164	0.7576
5509530030 ..	0.5556	0.4593
5509530060 ..	0.5556	0.4593
5513110020 ..	0.4009	0.3314
5513110040 ..	0.4009	0.3314
5513110060 ..	0.4009	0.3314
5513110090 ..	0.4009	0.3314
5513120000 ..	0.4009	0.3314
5513130020 ..	0.4009	0.3314
5513210020 ..	0.4009	0.3314
5513310000 ..	0.4009	0.3314
5514120020 ..	0.4009	0.3314
5516420060 ..	0.4009	0.3314
5516910060 ..	0.4009	0.3314
5516930090 ..	0.4009	0.3314
5601210010 ..	1.1455	0.9470
5601210090 ..	1.1455	0.9470
5601300000 ..	1.1455	0.9470
5602109090 ..	0.5727	0.4735
5602290000 ..	1.1455	0.9470
5602906000 ..	0.526	0.4348
5604900000 ..	0.5556	0.4593
5607909000 ..	0.8889	0.7349
5608901000 ..	1.1111	0.9185
5608902300 ..	1.1111	0.9185
5609001000 ..	1.1111	0.9185
5609004000 ..	0.5556	0.4593
5701104000 ..	0.0556	0.0460
5701109000 ..	0.1111	0.0918
5701901010 ..	1.0444	0.8634
5702109020 ..	1.1	0.9094
5702312000 ..	0.0778	0.0643
5702411000 ..	0.0722	0.0597
5702412000 ..	0.0778	0.0643

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
5702421000 ..	0.0778	0.0643
5702913000 ..	0.0889	0.0735
5702991010 ..	1.1111	0.9185
5702991090 ..	1.1111	0.9185
5703900000 ..	0.4489	0.3711
5801210000 ..	1.1455	0.9470
5801230000 ..	1.1455	0.9470
5801250010 ..	1.1455	0.9470
5801250020 ..	1.1455	0.9470
5801260020 ..	1.1455	0.9470
5802190000 ..	1.1455	0.9470
5802300030 ..	0.5727	0.4735
5804291000 ..	1.1455	0.9470
5806200010 ..	0.3534	0.2922
5806200090 ..	0.3534	0.2922
5806310000 ..	1.1455	0.9470
5806400000 ..	0.4296	0.3552
5808107000 ..	0.5727	0.4735
5808900010 ..	0.5727	0.4735
5811002000 ..	1.1455	0.9470
6001106000 ..	1.1455	0.9470
6001210000 ..	0.8591	0.7102
6001220000 ..	0.2864	0.2368
6001910010 ..	0.8591	0.7102
6001910020 ..	0.8591	0.7102
6001920020 ..	0.2864	0.2368
6001920030 ..	0.2864	0.2368
6001920040 ..	0.2864	0.2368
6003203000 ..	0.8681	0.7177
6003306000 ..	0.2894	0.2392
6003406000 ..	0.2894	0.2392
6005210000 ..	0.8681	0.7177
6005220000 ..	0.8681	0.7177
6005230000 ..	0.8681	0.7177
6005240000 ..	0.8681	0.7177
6005310010 ..	0.2894	0.2392
6005320010 ..	0.2894	0.2392
6005330010 ..	0.2894	0.2392
6005340010 ..	0.2894	0.2392
6005410010 ..	0.2894	0.2392
6005420010 ..	0.2894	0.2392
6005430010 ..	0.2894	0.2392
6005440010 ..	0.2894	0.2392
6005310080 ..	0.2894	0.2392
6005320080 ..	0.2894	0.2392
6005330080 ..	0.2894	0.2392
6005340080 ..	0.2894	0.2392
6005410080 ..	0.2894	0.2392
6005420080 ..	0.2894	0.2392
6005430080 ..	0.2894	0.2392
6005440080 ..	0.2894	0.2392
6006211000 ..	1.1574	0.9568
6006221000 ..	1.1574	0.9568
6006231000 ..	1.1574	0.9568
6006241000 ..	1.1574	0.9568
6006310040 ..	0.1157	0.0956
6006320040 ..	0.1157	0.0956
6006330040 ..	0.1157	0.0956
6006340040 ..	0.1157	0.0956
6006310080 ..	0.1157	0.0956
6006320080 ..	0.1157	0.0956
6006330080 ..	0.1157	0.0956
6006340080 ..	0.1157	0.0956
6006410085 ..	0.1157	0.0956
6006420085 ..	0.1157	0.0956
6006430085 ..	0.1157	0.0956
6006440085 ..	0.1157	0.0956
6101200010 ..	1.0094	0.8345
6101200020 ..	1.0094	0.8345

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
6102200010 ..	1.0094	0.8345
6102200020 ..	1.0094	0.8345
6103421020 ..	0.8806	0.7280
6103421040 ..	0.8806	0.7280
6103421050 ..	0.8806	0.7280
6103421070 ..	0.8806	0.7280
6103431520 ..	0.2516	0.2080
6103431540 ..	0.2516	0.2080
6103431550 ..	0.2516	0.2080
6103431570 ..	0.2516	0.2080
6104220040 ..	0.9002	0.7442
6104220060 ..	0.9002	0.7442
6104320000 ..	0.9207	0.7611
6104420010 ..	0.9002	0.7442
6104420020 ..	0.9002	0.7442
6104520010 ..	0.9312	0.7698
6104520020 ..	0.9312	0.7698
6104622006 ..	0.8806	0.7280
6104622011 ..	0.8806	0.7280
6104622016 ..	0.8806	0.7280
6104622021 ..	0.8806	0.7280
6104622026 ..	0.8806	0.7280
6104622028 ..	0.8806	0.7280
6104622030 ..	0.8806	0.7280
6104622060 ..	0.8806	0.7280
6104632006 ..	0.3774	0.3120
6104632011 ..	0.3774	0.3120
6104632026 ..	0.3774	0.3120
6104632028 ..	0.3774	0.3120
6104632030 ..	0.3774	0.3120
6104632060 ..	0.3774	0.3120
6104692030 ..	0.3858	0.3189
6105100010 ..	0.985	0.8143
6105100020 ..	0.985	0.8143
6105100030 ..	0.985	0.8143
6105202010 ..	0.3078	0.2545
6105202030 ..	0.3078	0.2545
6106100010 ..	0.985	0.8143
6106100020 ..	0.985	0.8143
6106100030 ..	0.985	0.8143
6106202010 ..	0.3078	0.2545
6106202030 ..	0.3078	0.2545
6107110010 ..	1.1322	0.9360
6107110020 ..	1.1322	0.9360
6107120010 ..	0.5032	0.4160
6107210010 ..	0.8806	0.7280
6107220015 ..	0.3774	0.3120
6107220025 ..	0.3774	0.3120
6107910040 ..	1.2581	1.0401
6108210010 ..	1.2445	1.0288
6108210020 ..	1.2445	1.0288
6108310010 ..	1.1201	0.9260
6108310020 ..	1.1201	0.9260
6108320010 ..	0.2489	0.2058
6108320015 ..	0.2489	0.2058
6108320025 ..	0.2489	0.2058
6108910005 ..	1.2445	1.0288
6108910015 ..	1.2445	1.0288
6108910025 ..	1.2445	1.0288
6108910030 ..	1.2445	1.0288
6108920030 ..	0.2489	0.2058
6109100005 ..	0.9956	0.8231
6109100007 ..	0.9956	0.8231
6109100009 ..	0.9956	0.8231
6109100012 ..	0.9956	0.8231
6109100014 ..	0.9956	0.8231
6109100018 ..	0.9956	0.8231
6109100023 ..	0.9956	0.8231
6109100027 ..	0.9956	0.8231

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
6109100037 ..	0.9956	0.8231
6109100040 ..	0.9956	0.8231
6109100045 ..	0.9956	0.8231
6109100060 ..	0.9956	0.8231
6109100065 ..	0.9956	0.8231
6109100070 ..	0.9956	0.8231
6109901007 ..	0.3111	0.2572
6109901009 ..	0.3111	0.2572
6109901049 ..	0.3111	0.2572
6109901050 ..	0.3111	0.2572
6109901060 ..	0.3111	0.2572
6109901065 ..	0.3111	0.2572
6109901090 ..	0.3111	0.2572
6110202005 ..	1.1837	0.9786
6110202010 ..	1.1837	0.9786
6110202015 ..	1.1837	0.9786
6110202020 ..	1.1837	0.9786
6110202025 ..	1.1837	0.9786
6110202030 ..	1.1837	0.9786
6110202035 ..	1.1837	0.9786
6110202040 ..	1.1574	0.9568
6110202045 ..	1.1574	0.9568
6110202065 ..	1.1574	0.9568
6110202075 ..	1.1574	0.9568
6110909022 ..	0.263	0.2174
6110909024 ..	0.263	0.2174
6110909030 ..	0.3946	0.3262
6110909040 ..	0.263	0.2174
6110909042 ..	0.263	0.2174
6111201000 ..	1.2581	1.0401
6111202000 ..	1.2581	1.0401
6111203000 ..	1.0064	0.8320
6111205000 ..	1.0064	0.8320
6111206010 ..	1.0064	0.8320
6111206020 ..	1.0064	0.8320
6111206030 ..	1.0064	0.8320
6111206040 ..	1.0064	0.8320
6111305020 ..	0.2516	0.2080
6111305040 ..	0.2516	0.2080
6112110050 ..	0.7548	0.6240
6112120010 ..	0.2516	0.2080
6112120030 ..	0.2516	0.2080
6112120040 ..	0.2516	0.2080
6112120050 ..	0.2516	0.2080
6112120060 ..	0.2516	0.2080
6112390010 ..	1.1322	0.9360
6112490010 ..	0.9435	0.7800
6114200005 ..	0.9002	0.7442
6114200010 ..	0.9002	0.7442
6114200015 ..	0.9002	0.7442
6114200020 ..	1.286	1.0631
6114200040 ..	0.9002	0.7442
6114200046 ..	0.9002	0.7442
6114200052 ..	0.9002	0.7442
6114200060 ..	0.9002	0.7442
6114301010 ..	0.2572	0.2126
6114301020 ..	0.2572	0.2126
6114303030 ..	0.2572	0.2126
6115198010 ..	1.0417	0.8612
6115929000 ..	1.0417	0.8612
6115936020 ..	0.2315	0.1914
6116101300 ..	0.3655	0.3022
6116101720 ..	0.8528	0.7050
6116926420 ..	1.0965	0.9065
6116926430 ..	1.2183	1.0072
6116926440 ..	1.0965	0.9065
6116928800 ..	1.0965	0.9065
6117809510 ..	0.9747	0.8058
6117809540 ..	0.3655	0.3022

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
6201121000 ..	0.948	0.7837
6201122010 ..	0.8953	0.7401
6201122050 ..	0.6847	0.5660
6201122060 ..	0.6847	0.5660
6201134030 ..	0.2633	0.2177
6201921000 ..	0.9267	0.7661
6201921500 ..	1.1583	0.9576
6201922010 ..	1.0296	0.8512
6201922021 ..	1.2871	1.0640
6201922031 ..	1.2871	1.0640
6201922041 ..	1.2871	1.0640
6201922051 ..	1.0296	0.8512
6201922061 ..	1.0296	0.8512
6201931000 ..	0.3089	0.2554
6201933511 ..	0.2574	0.2128
6201933521 ..	0.2574	0.2128
6201999060 ..	0.2574	0.2128
6202121000 ..	0.9372	0.7748
6202122010 ..	1.1064	0.9147
6202122025 ..	1.3017	1.0761
6202122050 ..	0.8461	0.6995
6202122060 ..	0.8461	0.6995
6202134005 ..	0.2664	0.2202
6202134020 ..	0.333	0.2753
6202921000 ..	1.0413	0.8608
6202921500 ..	1.0413	0.8608
6202922026 ..	1.3017	1.0761
6202922061 ..	1.0413	0.8608
6202922071 ..	1.0413	0.8608
6202931000 ..	0.3124	0.2583
6202935011 ..	0.2603	0.2152
6202935021 ..	0.2603	0.2152
6203122010 ..	0.1302	0.1076
6203221000 ..	1.3017	1.0761
6203322010 ..	1.2366	1.0223
6203322040 ..	1.2366	1.0223
6203332010 ..	0.1302	0.1076
6203392010 ..	1.1715	0.9685
6203399060 ..	0.2603	0.2152
6203422010 ..	0.9961	0.8235
6203422025 ..	0.9961	0.8235
6203422050 ..	0.9961	0.8235
6203422090 ..	0.9961	0.8235
6203424005 ..	1.2451	1.0293
6203424010 ..	1.2451	1.0293
6203424015 ..	0.9961	0.8235
6203424020 ..	1.2451	1.0293
6203424025 ..	1.2451	1.0293
6203424030 ..	1.2451	1.0293
6203424035 ..	1.2451	1.0293
6203424040 ..	0.9961	0.8235
6203424045 ..	0.9961	0.8235
6203424050 ..	0.9238	0.7637
6203424055 ..	0.9238	0.7637
6203424060 ..	0.9238	0.7637
6203431500 ..	0.1245	0.1029
6203434010 ..	0.1232	0.1018
6203434020 ..	0.1232	0.1018
6203434030 ..	0.1232	0.1018
6203434040 ..	0.1232	0.1018
6203498045 ..	0.249	0.2058
6204132010 ..	0.1302	0.1076
6204192000 ..	0.1302	0.1076
6204198090 ..	0.2603	0.2152
6204221000 ..	1.3017	1.0761
6204223030 ..	1.0413	0.8608
6204223040 ..	1.0413	0.8608
6204223050 ..	1.0413	0.8608
6204223060 ..	1.0413	0.8608

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
6204223065 ..	1.0413	0.8608
6204292040 ..	0.3254	0.2690
6204322010 ..	1.2366	1.0223
6204322030 ..	1.0413	0.8608
6204322040 ..	1.0413	0.8608
6204423010 ..	1.2728	1.0522
6204423030 ..	0.9546	0.7892
6204423040 ..	0.9546	0.7892
6204423050 ..	0.9546	0.7892
6204423060 ..	0.9546	0.7892
6204522010 ..	1.2654	1.0461
6204522030 ..	1.2654	1.0461
6204522040 ..	1.2654	1.0461
6204522070 ..	1.0656	0.8809
6204522080 ..	1.0656	0.8809
6204533010 ..	0.2664	0.2202
6204594060 ..	0.2664	0.2202
6204622010 ..	0.9961	0.8235
6204622025 ..	0.9961	0.8235
6204622050 ..	0.9961	0.8235
6204624005 ..	1.2451	1.0293
6204624010 ..	1.2451	1.0293
6204624020 ..	0.9961	0.8235
6204624025 ..	1.2451	1.0293
6204624030 ..	1.2451	1.0293
6204624035 ..	1.2451	1.0293
6204624040 ..	1.2451	1.0293
6204624045 ..	0.9961	0.8235
6204624050 ..	0.9961	0.8235
6204624055 ..	0.9854	0.8146
6204624060 ..	0.9854	0.8146
6204624065 ..	0.9854	0.8146
6204633510 ..	0.2546	0.2105
6204633530 ..	0.2546	0.2105
6204633532 ..	0.2437	0.2015
6204633540 ..	0.2437	0.2015
6204692510 ..	0.249	0.2058
6204692540 ..	0.2437	0.2015
6204699044 ..	0.249	0.2058
6204699046 ..	0.249	0.2058
6204699050 ..	0.249	0.2058
6205202015 ..	0.9961	0.8235
6205202020 ..	0.9961	0.8235
6205202025 ..	0.9961	0.8235
6205202030 ..	0.9961	0.8235
6205202035 ..	1.1206	0.9264
6205202046 ..	0.9961	0.8235
6205202050 ..	0.9961	0.8235
6205202060 ..	0.9961	0.8235
6205202065 ..	0.9961	0.8235
6205202070 ..	0.9961	0.8235
6205202075 ..	0.9961	0.8235
6205302010 ..	0.3113	0.2574
6205302030 ..	0.3113	0.2574
6205302040 ..	0.3113	0.2574
6205302050 ..	0.3113	0.2574
6505302070 ..	0.3113	0.2574
6205302080 ..	0.3113	0.2574
6206100040 ..	0.1245	0.1029
6206303010 ..	0.9961	0.8235
6206303020 ..	0.9961	0.8235
6206303030 ..	0.9961	0.8235
6206303040 ..	0.9961	0.8235
6206303050 ..	0.9961	0.8235
6206303060 ..	0.9961	0.8235
6206403010 ..	0.3113	0.2574
6206403030 ..	0.3113	0.2574
6206900040 ..	0.249	0.2058
6207110000 ..	1.0852	0.8971

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
6207199010 ..	0.3617	0.2990
6207210030 ..	1.1085	0.9164
6207220000 ..	0.3695	0.3055
6207911000 ..	1.1455	0.9470
6207913010 ..	1.1455	0.9470
6207913020 ..	1.1455	0.9470
6208210010 ..	1.0583	0.8749
6208210020 ..	1.0583	0.8749
6208220000 ..	0.1245	0.1029
6208911010 ..	1.1455	0.9470
6208911020 ..	1.1455	0.9470
6208913010 ..	1.1455	0.9470
6209201000 ..	1.1577	0.9571
6209203000 ..	0.9749	0.8059
6209205030 ..	0.9749	0.8059
6209205035 ..	0.9749	0.8059
6209205040 ..	1.2186	1.0074
6209205045 ..	0.9749	0.8059
6209205050 ..	0.9749	0.8059
6209303020 ..	0.2463	0.2036
6209303040 ..	0.2463	0.2036
6210109010 ..	0.2291	0.1894
6210403000 ..	0.0391	0.0323
6210405020 ..	0.4556	0.3766
6211111010 ..	0.1273	0.1052
6211111020 ..	0.1273	0.1052
6211118010 ..	1.1455	0.9470
6211118020 ..	1.1455	0.9470
6211320007 ..	0.8461	0.6995
6211320010 ..	1.0413	0.8608
6211320015 ..	1.0413	0.8608
6211320030 ..	0.9763	0.8071
6211320060 ..	0.9763	0.8071
6211320070 ..	0.9763	0.8071
6211330010 ..	0.3254	0.2690
6211330030 ..	0.3905	0.3228
6211330035 ..	0.3905	0.3228
6211330040 ..	0.3905	0.3228
6211420010 ..	1.0413	0.8608
6211420020 ..	1.0413	0.8608
6211420025 ..	1.1715	0.9685
6211420060 ..	1.0413	0.8608
6211420070 ..	1.1715	0.9685
6211430010 ..	0.2603	0.2152
6211430030 ..	0.2603	0.2152
6211430040 ..	0.2603	0.2152
6211430050 ..	0.2603	0.2152
6211430060 ..	0.2603	0.2152
6211430066 ..	0.2603	0.2152
6212105020 ..	0.2412	0.1994
6212109010 ..	0.9646	0.7974
6212109020 ..	0.2412	0.1994
6212200020 ..	0.3014	0.2492
6212900030 ..	0.1929	0.1595
6213201000 ..	1.1809	0.9763
6213202000 ..	1.0628	0.8786
6213901000 ..	0.4724	0.3905
6214900010 ..	0.9043	0.7476
6216000800 ..	0.2351	0.1944
6216001720 ..	0.6752	0.5582
6216003800 ..	1.2058	0.9968
6216004100 ..	1.2058	0.9968
6217109510 ..	1.0182	0.8417
6217109530 ..	0.2546	0.2105
6301300010 ..	0.8766	0.7247
6301300020 ..	0.8766	0.7247
6302100005 ..	1.1689	0.9663
6302100008 ..	1.1689	0.9663
6302100015 ..	1.1689	0.9663

IMPORT ASSESSMENT TABLE—Continued

[Raw Cotton Fiber]

HTS No.	Conv. fact.	Cents/kg.
6302215010 ..	0.8182	0.6764
6302215020 ..	0.8182	0.6764
6302217010 ..	1.1689	0.9663
6302217020 ..	1.1689	0.9663
6302217050 ..	1.1689	0.9663
6302219010 ..	0.8182	0.6764
6302219020 ..	0.8182	0.6764
6302219050 ..	0.8182	0.6764
6302222010 ..	0.4091	0.3382
6302222020 ..	0.4091	0.3382
6302313010 ..	0.8182	0.6764
6302313050 ..	1.1689	0.9663
6302315050 ..	0.8182	0.6764
6302317010 ..	1.1689	0.9663
6302317020 ..	1.1689	0.9663
6302317040 ..	1.1689	0.9663
6302317050 ..	1.1689	0.9663
6302319010 ..	0.8182	0.6764
6302319040 ..	0.8182	0.6764
6302319050 ..	0.8182	0.6764
6302322020 ..	0.4091	0.3382
6302322040 ..	0.4091	0.3382
6302402010 ..	0.9935	0.8213
6302511000 ..	0.5844	0.4831
6302512000 ..	0.8766	0.7247
6302513000 ..	0.5844	0.4831
6302514000 ..	0.8182	0.6764
6302600010 ..	1.1689	0.9663
6302600020 ..	1.052	0.8697
6302600030 ..	1.052	0.8697
6302910005 ..	1.052	0.8697
6302910015 ..	1.1689	0.9663
6302910025 ..	1.052	0.8697
6302910035 ..	1.052	0.8697
6302910045 ..	1.052	0.8697
6302910050 ..	1.052	0.8697
6302910060 ..	1.052	0.8697
6303110000 ..	0.9448	0.7811
6303910010 ..	0.6429	0.5315
6303910020 ..	0.6429	0.5315
6304111000 ..	1.0629	0.8787
6304190500 ..	1.052	0.8697
6304191000 ..	1.1689	0.9663
6304191500 ..	0.4091	0.3382
6304192000 ..	0.4091	0.3382
6304910020 ..	0.9351	0.7730
6304920000 ..	0.9351	0.7730
6505901540 ..	0.181	0.1496
6505902060 ..	0.9935	0.8213
6505902545 ..	0.5844	0.4831

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Dated: March 11, 2003.

Kenneth C. Clayton,

Acting Administrator, Agricultural Marketing Service.

[FR Doc. 03–6164 Filed 3–13–03; 8:45 am]

BILLING CODE 3410–02–P

FEDERAL RESERVE SYSTEM

12 CFR Part 225

[Regulation Y; Docket No. R–1146]

Bank Holding Companies and Change in Bank Control

AGENCY: Board of Governors of the Federal Reserve System.

ACTION: Proposed rule with request for public comments.

SUMMARY: The Board of Governors of the Federal Reserve System is proposing an amendment to Regulation Y that would permit bank holding companies to take and make delivery of title to commodities underlying derivative contracts on an instantaneous, pass-through basis.

DATES: Comments on the proposed rule must be received not later than April 14, 2003.

ADDRESSES: Comments should refer to Docket No. R–1146, and should be mailed to Ms. Jennifer J. Johnson, Secretary, Board of Governors of the Federal Reserve System, 20th Street and Constitution Avenue, NW., Washington, DC 20551, or mailed electronically to *regs.comments@federalreserve.gov*. Comments addressed to Ms. Johnson also may be delivered between 8:45 a.m. and 5:15 p.m. to the Board's mail facility in the West Courtyard of the Eccles Building, located on 21st Street between Constitution Avenue and C Street, NW. Members of the public may inspect comments in Room MP–500 of the Martin Building between 9 a.m. and 5 p.m. on weekdays pursuant to § 261.12, except as provided in § 261.14, of the Board's Rules Regarding Availability of Information, 12 CFR 261.12 and 261.14.

FOR FURTHER INFORMATION CONTACT: Scott G. Alvarez, Associate General Counsel (202/452–3583), Mark E. Van Der Weide, Counsel (202/452–2263), or Andrew S. Baer, Counsel (202/452–2246), Legal Division. For users of Telecommunications Device for the Deaf (TDD) only, contact 202/263–4869.

SUPPLEMENTARY INFORMATION:

Background

The Board's Regulation Y currently authorizes bank holding companies (''BHCs'') to engage as principal in forward contracts, options, futures, options on futures, swaps, and similar contracts, whether traded on exchanges or not, based on a rate, price, financial asset, nonfinancial asset, or group of assets (other than a bank-ineligible security) (''Commodity Contracts''). A BHC's authority to enter into Commodity Contracts is subject to certain restrictions that are designed to limit the BHC's activity to trading and investing in financial instruments rather than dealing directly in commodities. In particular, Regulation Y provides that a BHC may enter into a Commodity Contract only if (i) the commodity underlying the contract is eligible for investment by a state member bank; *or* (ii) the contract requires cash settlement; *or* (iii) the contract allows for assignment, termination, or offset prior to delivery or expiration (the ''Contractual Offset Requirement''), *and* the BHC makes every reasonable effort to avoid taking or making delivery of the underlying commodity (the ''Delivery Avoidance Requirement'').[1]

The effect of these restrictions is to allow a BHC to engage as principal in derivative contracts involving any type of commodity (other than bank-ineligible securities) but to limit the authority of a BHC to physically settle derivative contracts. Under these restrictions, a BHC may take or make delivery on derivative contracts based on commodities that a state member bank is permitted to own.[2] For all other types of physically settled commodity derivatives,[3] a BHC must make reasonable efforts to avoid delivery, and the contract must have assignment, termination, or offset provisions.

The Bank Holding Company Act (''BHC Act''), as amended by the Gramm-Leach-Bliley Act (Pub. L. No. 106–102, 113 Stat. 1338 (1999)) (''GLB Act''), permits a BHC to engage in activities that the Board had determined were closely related to banking, by regulation or order, prior to November 12, 1999. A BHC must conduct these activities in accordance with the terms and conditions contained in such regulations and orders, unless modified by the Board.

Citigroup Inc., New York, New York (''Citigroup''), and UBS AG, Zurich, Switzerland (''UBS''), have asked the Board to modify the restrictions in Regulation Y to allow BHCs to enter into derivative contracts that typically result in taking and making delivery of title to, but not physical possession of, commodities on an instantaneous, pass-through basis (regardless of whether the contracts contain specific assignment, termination, or offset provisions).[4]

In response to these requests, the Board has determined to seek public comment on the proposed rule described below.

Proposed Rule

As noted, Citigroup and UBS have urged the Board to permit BHCs to enter into Commodity Contracts that are settled by the BHC receiving and transferring title to the underlying commodity instantaneously, by operation of contract, and without taking physical possession of the commodity. Citigroup and UBS also have urged the Board to remove its regulatory requirement that BHCs only enter into Commodity Contracts that require cash settlement or specifically provide for assignment, termination, or offset prior to delivery.

These requests arise in large part because, in certain over-the-counter forward markets (U.S. energy markets, for example), the physically settled derivative contracts traded by market participants do not specifically provide for assignment, termination, or offset prior to delivery and, thus, do not conform to the Contractual Offset Requirement of Regulation Y. Moreover, participants in these markets generally settle the derivative contracts by temporarily taking and making delivery of title to the underlying commodities and, thus, do not comply with the Delivery Avoidance Requirement of Regulation Y.

Financial intermediary participants in these markets generally enter into back-to-back derivative contracts with third parties that effectively offset each other. That is, financial intermediaries in these markets that enter into a contract to buy, for example, a certain number of barrels of oil from a certain counterparty in a certain future month generally also will enter into another contract, prior to the expiration of the original contract, to sell the same number of barrels of oil to another counterparty in the same future month on substantially identical delivery terms. These market practices typically result in the creation of a chain of contractual relationships that begins with a commodity producer, passes through a number of intermediaries who have entered into matched contracts both to buy and sell the same commodity at the same future time, and

[1] 12 CFR 225.28(b)(8)(ii)(B).

[2] State member banks may own, for example, investment grade corporate debt securities, U.S. government and municipal securities, foreign exchange, and certain precious metals.

[3] These would include derivative contracts based on, for example, energy-related commodities and agricultural commodities.

[4] Citigroup and UBS also have asked the Board to allow financial holding companies to take and make physical delivery of a limited amount of commodities as an activity that is incidental or complementary to engaging as principal in BHC-permissible Commodity Contracts. The Board continues to review these broader requests.

ends with a purchaser that intends to take physical delivery of the commodity. On the maturity date of the derivative contracts, the producer will be responsible for making physical delivery and the ultimate buyer will be responsible for accepting physical delivery, while each intermediate participant in the chain will be deemed, by operation of contract, to have instantaneously received and transferred legal title to the commodity.

The Board adopted the restrictions in Regulation Y on the types of Commodity Contracts that a BHC may enter into as principal to reduce the potential that BHCs would become involved in and bear the risks of physical possession, transport, storage, delivery, and sale of bank-ineligible commodities. The restrictions ensure that the commodity derivatives business of a BHC is largely limited to acting as a financial intermediary that facilitates transactions for customers who use or produce commodities or are otherwise exposed to commodity price risk as part of their regular business.

Citigroup and UBS contend that a BHC that takes title to a commodity on an instantaneous, pass-through basis takes no risk that is greater than or different in kind from the risk that it has as a holder of a commodity derivative contract that meets the current requirements of Regulation Y. Instantaneous receipt and transfer of title to (but not physical possession of) commodities does not appear to involve the usual activities relating to, or risks attendant on, commodity ownership. Instead, such transactions involve the routine operations functions of passing notices, documents, and payments—functions that BHCs regularly perform in their role as financial intermediaries in other markets. Moreover, although BHCs that receive and transfer title to commodities on an instantaneous, pass-through basis face default risks, they are not significantly different than the default risks associated with cash-settled derivative contracts or derivative contracts that include the assignment, termination, or offset provisions required by Regulation Y.

In this light, the Board proposes to modify Regulation Y by changing the Delivery Avoidance Requirement to allow BHCs to take or make delivery of title to commodities underlying commodity derivative transactions on an instantaneous, pass-through basis.

In addition, the Board proposes to modify Regulation Y by changing the Contractual Offset Requirement to permit BHCs to participate in physically settled derivative markets where the standard industry documentation does not allow for assignment, termination, or offset. In particular, the proposal would allow BHCs to enter into Commodity Contracts that do not require cash settlement or specifically provide for assignment, termination, or offset prior to delivery so long as the contracts involve commodities for which futures contracts have been approved for trading on a U.S. futures exchange by the Commodity Futures Trading Commission (''CFTC'') (and the BHC complies with the revised Delivery Avoidance Requirement). Limiting this relief from the Contractual Offset Requirement to derivative contracts based on commodities approved for exchange trading (which are more likely to have reasonably liquid markets) is intended to provide some assurance that a BHC's reasonable efforts to avoid delivery would be successful. This requirement would, therefore, serve the same purpose as the current Contractual Offset Requirement, which facilitates the financial settlement of Commodity Contracts by requiring BHCs to have contractual rights to avoid taking or making delivery of the underlying commodities.

The proposed modifications of the derivatives provisions in Regulation Y would apply to all BHCs. Although the GLB Act prohibited the Board from adding to the list of activities permissible for all BHCs after November 11, 1999, the Act preserved the Board's authority to modify the terms and conditions that applied to such activities before that date.[5] The Board had authorized BHCs to engage as principal in commodity derivative transactions prior to November 11, 1999. The proposed rule would represent a relaxation of the current limitations that apply to a BHC's commodity derivative activities under Regulation Y and would not create a new permissible activity for BHCs.

The Board invites comment on all aspects of the proposed rule and particularly seeks comment on whether the proposed modifications to Regulation Y would expand the ability of BHCs to participate in commodity derivative markets without exposing them to significant additional risks.

Plain Language

Section 722 of the GLB Act requires the Board to use ''plain language'' in all proposed and final rules published after January 1, 2000. In light of this requirement, the Board has sought to present the proposed rule in a simple and straightforward manner. The Board invites comment on whether the Board could take additional steps to make the proposed rule easier to understand.

Regulatory Flexibility Act

In accordance with section 3(a) of the Regulatory Flexibility Act (5 U.S.C. 603(a)), the Board must publish an initial regulatory flexibility analysis with this proposed rule. The proposed rule, if adopted, would expand the scope of permissible commodity derivatives activities for a bank holding company. A description of the reasons for the Board's decision to issue the proposed rule and a statement of the objectives of, and legal basis for, the proposed rule are contained in the supplementary material provided above.

The proposed rule would apply to bank holding companies regardless of their size and should enhance the ability of all bank holding companies, including small ones, to compete with other providers of financial services in the United States and to respond to changes in the marketplace in which banking organizations compete. The Board specifically seeks comment on the likely burden the proposed rule would have on bank holding companies, especially small bank holding companies.

Paperwork Reduction Act

In accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3506; 5 CFR 1320 Appendix A.1), the Board has reviewed the proposed rule under authority delegated to the Board by the Office of Management and Budget. The proposed rule contains no collections of information pursuant to the Paperwork Reduction Act.

List of Subjects in 12 CFR Part 225

Administrative practice and procedures, Banks, Banking, Federal Reserve System, Holding companies, Reporting and recordkeeping requirements, Securities.

Authority and Issuance

For the reasons set forth in the preamble, the Board proposes to amend 12 CFR part 225 as follows:

PART 225—BANK HOLDING COMPANIES AND CHANGE IN BANK CONTROL (REGULATION Y)

1. The authority citation for part 225 continues to read as follows:

Authority: 12 U.S.C. 1817(j)(13), 1818, 1828(o), 1831i, 1831p–1, 1843(c)(8), 1843(k), 1844(b), 1972(1), 3106, 3108, 3310, 3331–3351, 3907, and 3909.

2. Section 225.28 would be amended by revising paragraph (b)(8)(ii)(B) to read as follows:

[5] *See* 12 U.S.C. 1843(c)(8).

§ 225.28 List of permissible nonbanking activities.

* * * * *

(b) * * *

(8) * * *

(ii) * * *

(B) Forward contracts, options, futures, options on futures, swaps, and similar contracts, whether traded on exchanges or not, based on any rate, price, financial asset (including gold, silver, platinum, palladium, copper, or any other metal approved by the Board), nonfinancial asset, or group of assets, other than a bank-ineligible security,[6] if:

(*1*) A state member bank is authorized to invest in the asset underlying the contract;

(*2*) The contract requires cash settlement;

(*3*) The contract allows for assignment, termination, or offset prior to delivery or expiration, and the company—

(*i*) makes every reasonable effort to avoid taking or making delivery of the asset underlying the contract; or

(*ii*) engages in the instantaneous receipt and transfer of title to the underlying asset, by operation of contract and without taking or making physical delivery of the underlying asset; or

(*4*) The contract is based on an asset for which futures contracts or options on futures contracts have been approved for trading on a U.S. contract market by the Commodity Futures Trading Commission, and the company—

(*i*) makes every reasonable effort to avoid taking or making delivery of the asset underlying the contract; or

(*ii*) engages in the instantaneous receipt and transfer of title to the underlying asset, by operation of contract and without taking or making physical delivery of the underlying asset.

* * * * *

By order of the Board of Governors of the Federal Reserve System, March 10, 2003.

Jennifer J. Johnson,

Secretary of the Board.

[FR Doc. 03–6155 Filed 3–13–03; 8:45 am]

BILLING CODE 6210–01–P

[6] A bank-ineligible security is any security that a state member bank is not permitted to underwrite or deal in under 12 U.S.C. 24 and 335.

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 2002–SW–56–AD]

RIN 2120–AA64

Airworthiness Directives; Eurocopter France Model SA330F, G, and J; AS332C, L, and L1; SA341G; SA342J; AS350B, BA, B1, B2, B3, and D; AS355E, F, F1, F2 and N; SA–365C, C1, and C2; SA–365N and N1; and AS–365N2 and N3 Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice of proposed rulemaking (NPRM).

SUMMARY: This document proposes adopting a new airworthiness directive (AD) for the specified Eurocopter France (ECF) model helicopters. This proposal would require determining whether specified main or tail rotor (rotor) parts are installed and, if so, updating and recording the correct hours time-in-service (TIS) or cycles of each part. If the hours TIS or cycles of any rotor part exceed its life limit, this AD would also require replacing that part with an airworthy part within 50 hours TIS. This proposal is prompted by the need to correct the Equipment Log Card (FME) to accurately reflect the total hours TIS and cycles of certain repaired or overhauled rotor parts. The actions specified by this proposed AD are intended to prevent failure of a life limited rotor part, loss of a rotor, and subsequent loss of control of the helicopter.

DATES: Comments must be received on or before May 13, 2003.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Regional Counsel, Southwest Region, Attention: Rules Docket No. 2002–SW–56–AD, 2601 Meacham Blvd., Room 663, Fort Worth, Texas 76137. You may also send comments electronically to the Rules Docket at the following address: *9-asw-adcomments@faa.gov.* Comments may be inspected at the Office of the Regional Counsel between 9 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Uday Garadi, Aviation Safety Engineer, FAA, Rotorcraft Directorate, Rotorcraft Standards Staff, Fort Worth, Texas 76193–0110, telephone (817) 222–5123, fax (817) 222–5961.

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 will be considered before taking action on the proposed rule. The proposals contained in this document 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 mailed comments submitted in response to this proposal must submit a self-addressed, stamped postcard on which the following statement is made: ''Comments to Docket No. 2002–SW–56–AD.'' The postcard will be date stamped and returned to the commenter.

Discussion

The Direction Generale De L'Aviation Civile (DGAC), the airworthiness authority for France, notified the FAA that an unsafe condition may exist on ECF Model SA330F, G, and J; AS332C, L, and L1; SA341G; SA342J; AS350B, BA, B1, B2, B3, and D; AS355E, F, F1, F2 and N; SA–365C, C1, and C2; SA–365N and N1; and AS–365 N2 and N3 helicopters. The DGAC advises of the discovery of a discrepancy in the computer program used to carry over the number of operating hours of parts following repair or overhaul, which is the cause of incorrect completion of FME's.

ECF has issued the following Alert Telexes for the helicopter model series specified: Nos. 65.110 for SA330, 62.00.58 for AS332, 65.60 for SA341 and SA342, 62.00.25 for AS350, 62.00.27 for AS355, 65.41 for SA–365C, and 62.00.19 for AS–365N, all dated August 13, 2002. These alert telexes specify correcting the FME to list the correct total number of operating hours and cycles for specified parts installed on dynamic components. After correcting the FME, if the parts have

exceeded their life limit, the alert telexes specify removing or monitoring the parts. The DGAC classified these alert telexes as mandatory and issued AD No. 2002–452(A), dated September 4, 2002, to ensure the continued airworthiness of these helicopters in France.

These helicopter models are manufactured in France and are type certificated for operation in the United States under the provisions of 14 CFR 21.29 and the applicable bilateral agreement. Pursuant to the applicable bilateral agreement, the DGAC has kept the FAA informed of the situation described above. The FAA has examined the findings of the DGAC, reviewed all available information, and determined that AD action is necessary for products of these type designs that are certificated for operation in the United States.

This unsafe condition is likely to exist or develop on other helicopters of the same type designs registered in the United States. Therefore, the proposed AD would require, within 10 hours TIS, determining whether the specified rotor part and serial numbers are installed by reference to the FME and, if installed, correcting the hours TIS and cycles. If a part exceeds its life limit, the AD would require replacing the part within 50 hours TIS. The actions would be required for the parts listed in the appendix of the alert telexes described previously.

The FAA estimates that this proposed AD would affect 760 helicopters of U.S. registry. The FAA also estimates that it would take approximately 1 work hour to determine the part and serial number and 8 hours to replace each affected part on 38 helicopters (5 percent of the total affected helicopters), and that the average labor rate is $60 per work hour. Required parts would cost approximately $64,560 depending on which part would be replaced. Based on these figures, the total cost impact of the proposed AD on U.S. operators is estimated to be $2,517,120.

The regulations proposed herein 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. Therefore, it is determined that this proposal would not have federalism implications under Executive Order 13132.

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 a new airworthiness directive to read as follows:

Eurocopter France: Docket No. 2002–SW–56–AD.

Applicability: Model SA330F, G, and J; AS332C, L, and L1; SA341G; SA342J; AS350B, BA, B1, B2, B3, and D; AS355E, F, F1, F2, and N; SA–365C, C1, and C2; SA–365N and N1; and AS–365 N2 and N3 helicopters, 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 (b) 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, unless accomplished previously.

To prevent failure of a main or tail rotor (rotor) part, loss of a rotor, and subsequent loss of control of the helicopter, accomplish the following:

(a) Within 10 hours time-in-service (TIS), determine by reference to the equipment log card (FME) whether any rotor part and serial number specified in Table 1, paragraph 3, of the Appendix of each of the following Eurocopter France (ECF) Alert Telexes for the specified helicopter model series is installed: Nos. 65.110 for SA330, 62.00.58 for AS332, 65.60 for SA341 and SA342, 62.00.25 for AS350, 62.00.27 for AS355, 65.41 for SA–365C, and 62.00.19 for SA365N and AS–365, all dated August 13, 2002.

(1) If none of the parts are installed, no further action is required.

(2) For each affected part listed in Table 1, paragraph 3, of the Appendix of each applicable ECF Alert Telex specified in paragraph (a) of this AD, add the hours TIS and cycles to the hours TIS and cycles recorded on the FME. If a part exceeds its life limit in TIS or cycles, replace the part with an airworthy part within 50 hours TIS.

(b) 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.

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

Note 3: The subject of this AD is addressed in Direction Generale De L'Aviation Civile (France) AD No. 2002–452(A), dated September 4, 2002.

Issued in Fort Worth, Texas, on March 6, 2003.

David A. Downey,

Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 03–6137 Filed 3–13–03; 8:45 am]

BILLING CODE 4910–13–P

COMMODITY FUTURES TRADING COMMISSION

17 CFR Part 1

RIN 3038–AB94

Account Identification for Eligible Bunched Orders

AGENCY: Commodity Futures Trading Commission.

ACTION: Proposed rule.

SUMMARY: The Commodity Futures Trading Commission (''Commission'' or ''CFTC'') is proposing to amend Commission Rule 1.35(a–1) (''Rule 1.35(a–1)''), which allows certain account managers to bunch customer orders for execution and to allocate them to individual accounts at the end of the trading session (hereinafter referred to as ''bunching''). The

proposed rule would expand the availability of bunching, simplify the process, and clarify the respective responsibilities of account managers and futures commission merchants (''FCMs'').

DATES: Comments must be received by April 28, 2003.

ADDRESSES: Interested persons should submit their views and comments to Jean A. Webb, Secretary, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. In addition, comments may be sent by facsimile transmission to facsimile number (202) 418–5521, or by electronic mail to *secretary@cftc.gov*. Reference should be made to ''Eligible orders.''

FOR FURTHER INFORMATION CONTACT: Christopher W. Cummings, Special Counsel, or R. Trabue Bland, Attorney-Advisor, Division of Clearing and Intermediary Oversight, Commodity Futures Trading Commission, Three Lafayette Centre, 1155 21st Street, NW., Washington, DC 20581. Telephone: (202) 418–5430. Email: *ccummings@cftc.gov or tbland@cftc.gov*.

SUPPLEMENTARY INFORMATION:

I. Background

A. Current Regulatory Requirements

Commission Rule 1.35(a–1), in effect since August 27, 1998, allows bunched orders for eligible customers to be placed on a contract market without specific customer account identification either at the time of order placement or at the time of report of execution. Rule 1.35(a–1) limits the types of customers whose orders may be bunched and requires eligible account managers [1] to make certain disclosures regarding the allocation methodology, the standard of fairness of allocations, composite or summary data of the trades, and whether the account manager has any interest in the bunched order.

Before placing an order eligible for post-execution allocation, the account manager must identify, to the FCM clearing the order, each eligible customer account to which fills will be allocated. Account managers must provide written certification that they have identified the eligible customer accounts to the FCM. Foreign account managers must provide written certification from foreign authorities that they are subject to regulation.

Currently, account managers must create and timestamp an order origination document, identify the order by group identifier on the office or floor order tickets, and identify the transaction on contract market trade registers. The current rule also requires contract markets to adopt audit procedures to determine compliance with Rule 1.35(a–1).

B. Developments Since Current Regulations Were Adopted

In December 2000, Congress passed the Commodity Futures Modernization Act (''CFMA''). One of the mandates of the CFMA was for the Commission to review its rules relating to intermediaries with an eye to identifying areas where greater flexibility might be warranted. Since the passage of the CFMA, numerous industry participants have stated to Commission staff that the regulations related to bunched orders needed to be revisited for a number of reasons.

For example, enhancements in technology have made it easier for account managers to enter orders directly, thereby making certain aspects of the current requirements less workable. Similarly, as markets become more global in scope, account managers, both domestic and foreign, have claimed that the current bunched order requirements serve as a disincentive to using U.S. futures markets.

On February 2, 2001, the National Futures Association and the Futures Industry Institute issued an industry-wide study of issues associated with order transmission and order entry process by commodity professionals (''Best Practices Study'').[2] The study found that although the current rule increased flexibility over previously applicable requirements, many commenters in the study felt that the current rule caused ''unnecessary processing delays without adding customer protections that otherwise could be realized through equally effective, less costly procedures.''[3] The rule the Commission is proposing today would adopt many of the approaches recommended in the Best Practices Study.

II. Proposed Changes to Rule 1.35(a–1)(5)

A. Eligible Customers

As noted, the current rule limits eligibility for bunching to certain types of sophisticated customers. The proposed rule would expand eligibility to all customers who provide written investment discretion to account managers.[4]

Bunched orders can provide advantages to account managers and their customers by facilitating the prompt execution of small orders. Customers can benefit when a bunched order is placed because a bunched order is more likely to be executed at a single price than would be the case for a series of separate orders. In fact, customers may be disadvantaged in the quality of the timing and execution of their order if their orders are not bunched. With proper protections in place under the proposed rule, customers should be assured that their trade allocations are fair and equitable. Thus, the Commission proposes to eliminate existing Rule 1.35(a–1)(5)(ii). Under the proposed rule, all customer orders would be eligible for inclusion in bunched orders and thus all customers that have granted written discretion to an eligible account manager would be able to benefit from the advantages of bunched orders.

The Commission invites comment on whether the proposed expansion of the class of eligible customers is appropriate and whether the rule contains proper protections.

On a related manner, in 1997, the Commission issued an interpretive notice currently found at Appendix C to part 1 which allows bunching under certain circumstances.[5] Specifically, the Commission allows CTAs to bunch orders if they prefile their allocation procedures with a clearing member, NFA, or an exchange. The Commission requests comments on whether this interpretive notice should be modified in any way given the proposed changes to Rule 1.35(a–1)(5).

B. Eligible Account Managers

The Commission also is proposing to expand the class of account managers permitted to bunch orders. The current rule applies to, among others, commodity trading advisors (''CTAs'') and investment advisers (''IAs'') who are registered with the Commission or the Securities Exchange Commission (''SEC''). The Commission is proposing to allow CTAs and IAs who are exempt from registration or are excluded from the definition of CTA or IA by operation of law or rule to be eligible account managers. Such entities are generally

[1] The term account manager as used herein includes commodity trading advisors, investment advisers and other persons identified in the proposed regulation, who would place orders and direct the allocation in accordance with the procedures set forth in the proposal.

[2] National Futures Association & Futures Industry Institute, Recommendations for Best Practices in Order Entry and Transmission of Exchange Traded Futures and Options Transactions (2001).

[3] *Id.* at 25.

[4] Rule 1.35(a–1)(5) and NFA Compliance Rule 2–8(a), require that grants of discretionary authority to account controllers be in writing.

[5] 17 CFR part 1, Appendix C (2002), 62 FR 25470 (May 8, 1997).

exempt from registration because their clients are sophisticated investors. Exempt account managers, however, remain subject to the antifraud provisions of the Commodity Exchange Act and the Commission's regulations. The proposed rule would not apply to associated persons or Introducing Brokers exempt from Commission registration as CTAs pursuant to Rule 4.14(a)(3) and (6).[6]

The current rule allows foreign advisors to be eligible account managers only if they are subject to regulation by a foreign regulator or self-regulatory organization that has been granted an exemption pursuant to Rule 30.10[7] or have entered into a Memorandum of Understanding or other arrangement with the Commission. As proposed, Rule 1.35(a–1)(5)(i)(D) would allow foreign advisors, who exercise discretionary trading authority over the accounts of non-United States persons, to be eligible account managers.[8]

The Commission, of course, would retain antifraud and antimanipulation authority. The Commission notes that foreign advisers under the proposed rule would be foreign brokers or foreign traders subject to Commission Rule 15.05, which makes the FCMs through which foreign advisers make or cause to be made trades the agents of the foreign advisers for purposes of communications from the Commission.[9]

As noted above, the proposal would expand the categories of entities permitted to bunch orders. The Commission requests comments on whether it is appropriate to permit these entities to be eligible account managers and whether the proposed protections are sufficient.

C. Disclosure

The Commission proposes to amend the disclosure requirement to be an information availability requirement based upon the fact that the Commission does not generally require registrants to affirmatively disclose the mechanics of the process of trading.[10]

Current Rule 1.35(a–1)(5)(iii) specifies certain disclosure requirements that account managers must provide to customers. The proposal would replace these requirements with more general requirements that eligible account managers make certain information available to customers upon request. Account managers would be required to make the following information available to customers: (1) The general nature of the allocation methodology the account manager uses; (2) summary or composite data sufficient for that customer to compare its results with those of other relevant customers and, if applicable, any account in which the account manager has an interest; and (3) whether accounts in which the account manager may have any interest may be included with customer accounts in bunched orders eligible for post-execution allocation. The Commission is proposing to delete the requirement that account managers set forth the standard by which they will judge the fairness of the post-execution allocations as this essential requirement is provided by the description of the nature of the methodology and monitoring the account manager's post execution allocations for bias over time. More importantly, the Commission is proposing to retain the requirement that summary or composite data, sufficient to compare results with the results of other comparable customers, be made available to customers. In addition, the Commission proposes to add a requirement that summary or composite data about accounts in which the account manager has an interest be made available to customers.

The Commission invites comment on whether the proposal to change the disclosure requirement into an information availability requirement is appropriate.

D. Account Certification

Current Rule 1.35(a–1)(5)(iv) requires that account managers make certain certifications to FCMs. Both account managers and FCMs have claimed that this requirement is burdensome, an impediment to the use of current procedures and that it contributes to uncertainty regarding the relative responsibility of FCMs and account managers. Accordingly, the Commission is proposing to delete this requirement.

E. Allocation

The proposed rule would retain the essential requirement contained in the existing rule that the allocation must be fair and equitable and that no account or group of accounts may receive consistently favorable or unfavorable treatment. The proposal, however, would make several changes to the provisions governing allocation.

First, as noted above, the Commission is proposing to expand eligibility to all customers who have provided written discretion to an eligible account manager. Thus, the proposal would eliminate existing Rule 1.35(a–1)(5)(v)(A) that requires that allocations only be made among eligible customers. Second, to minimize end-of-trading session congestion, the Commission proposes to amend existing Rule 1.35(a–1)(5)(v) by requiring account managers to provide allocation information to FCMs in a time sufficiently before the end of the trading session during which the order is executed to ensure that clearing records identify the ultimate customer for each trade. Third, the Commission proposes to modify the provision addressing independent review of allocations. The proposed rule would retain the requirement that allocation methodology must be sufficiently objective and specific to permit independent verification of the fairness of the allocation.[11] The Commission, however, is deleting the requirement that appropriate allocation of a given trade should be verifiable because that requirement, along with the accompanying recordkeeping requirement in Rule 1.35(a–1)(vi) required an assessment of ''appropriateness'' on an order-by-order basis. Industry representatives have stated that requiring an assessment of the fairness on an order-by-order basis may not result in the most efficient allocation of trades entered by an account manager.[12] Therefore, and consistent with the recommendation of the Best Practices Study, the proposed rule would require that verification of fairness be judged over time rather than on an order-by-order basis.[13]

The proposal also would clarify the respective responsibilities of account

[6] 17 CFR 4.14(a)(3) (2002), 17 CFR 4.14(a)(6) (2002).

[7] 17 CFR 30.10 (2002). Rule 30.10 permits any person to petition for an exemption from the Commission's Part 30 rules, which govern foreign futures and option trading by persons located in the United States. Commission orders issued pursuant to Rule 30.10 permit firms to solicit and accept orders for foreign futures and option contracts from United States customers without registering under the Commodity Exchange Act, based upon substituted compliance with the rules and regulations of the jurisdiction in which the firm is located.

[8] 48 FR 35248, 35261 (August 3, 1983); *see also,* CFTC Staff Letter No. 76–2 [1975–1977 Transfer Binder] Comm. Fut. L. Rep. (CCH) ¶ 20,222 (August 15, 1976)(Commission staff would not recommend enforcement action for failure to register as a CPO where such persons are located outside the U.S. and operating a pool that accepts no United States participants and no funds from United States sources).

[9] *See* 17 CFR 15.00(e) and 17 CFR 15.05 (2002).

[10] Registrants must provide such information if requested.

[11] Appendix C of part 1 contains examples of allocation methods. *See*, 17 CFR Part 1, Appendix C (2002), 62 FR 25470 (May 8, 1997). As noted in Appendix C, ''the appropriateness of any particular method for allocating split and partial fills depends on the CTA's overall trading approach. For example, a daily rotation of accounts may satisfy the general standards for CTAs who trade on a daily basis but inappropriate for CTAs who trade less frequently.''

[12] It is important to note that the standards for fair allocation of trades may shift over time.

[13] Best Practices Study at 26.

managers and FCMs. Proposed Rule 1.35(a–1)(5)(iii) would explicitly state that allocation of bunched orders must be made by account managers, not FCMs. Eliminating the certification requirements will reduce the administrative and recordkeeping burden on FCMs. Of course, FCMs will still have responsibility to monitor for unusual account activity. In an interpretive notice accompanying NFA Compliance Rule 2–10, NFA notes ''[t]he FCM has certain basic duties to its customers, including the duty to supervise its own activities in a way designed to ensure that it treats its customers fairly. Specifically, the FCM would violate this duty if it has actual or constructive notice that allocations for its customers may be fraudulent and fails to take appropriate action. The FCM with such notice must make a reasonable inquiry into the matter and, if appropriate, refer the matter to the proper regulatory authorities.''[14] Thus, FCMs will have an ongoing responsibility to monitor for unusual account activity.[15]

The Commission requests comment on whether the proposed changes strike the appropriate balance with regard to judging allocations and assigning responsibilities to account managers and FCMs.

F. Recordkeeping

Current Rule 1.35(a–1)(5)(vi) requires account managers and FCMs to keep specific information to identify customer orders and reconstruct trades. Pursuant to the proposed rule, the Commission is clarifying that the fairness of an allocation will not be assessed on an order-by-order basis but on an assessment over time. If divergent performance among client accounts occurs over time, the account manager must have records to demonstrate that the divergent performance is attributable to factors other than unfair trade allocation. Thus, the proposed rule will allow account managers and FCMs greater flexibility in recordkeeping, while retaining the ability of the Commission to determine unfair trade allocation.

Specifically, the Commission proposes to eliminate existing Rule 1.35(a–1)(5)(vi) and to replace the recordkeeping requirement with a requirement that account managers make certain information available to any representative of the Commission, the United States Department of Justice, or other appropriate regulatory agency. The information would include the information required to be made available to customers pursuant to proposed Rule 1.35(a–1)(5)(ii) and the allocation information created pursuant to proposed Rule 1.35(a–1)(5)(iii). Under proposed Rule 1.35(a–1)(5)(iv)(C), FCMs that execute trades for orders eligible for post-execution allocation, or that carry accounts to which contracts executed for such orders are allocated, must maintain records that identify each order subject to post-execution allocation and the accounts to which contracts executed for such order are allocated.[16]

For example, account managers employing post-execution allocation procedures generally would be expected to forward written allocation instructions to the clearing firm by facsimile or e-mail or other electronic means.[17] In those instances in which allocation instructions are furnished orally, the FCM must create a written record of the account manager's instructions. In each case, these records will be available to the Commission and other regulatory agencies or self-regulatory organizations. The Commission should be able to reconstruct trades from these records.

The proposal contains a provision to address cases in which account managers fail to provide the Commission with the information requested pursuant to proposed Rule 1.35(a–1)(5)(iv)(A) or proposed Rule 1.35(a–1)(5)(iv)(B). Specifically, the Commission may prohibit the account manager from submitting orders for execution on designated contract markets and prohibit FCMs from accepting orders from such account managers. Commission action under this provision would not require prior notice and hearing. The failure of an account manager to respond to a request for information under this rule would be sufficient. Any account manager that believes he or she is adversely affected by this process may use the procedures outlined in Rule 21.03(g).[18] Any prohibitions imposed pursuant to this Rule 1.35(a–1)(5)(iv)(D) would be without prejudice to other remedies the Commission or other regulatory body may have against the account manager in question for violation of the rule or any other legal requirements.[19]

G. Self-Regulatory Organization Rule Enforcement and Audit Procedures

Existing Rule 1.35(a–1)(5)(vii) requires contract markets to adopt audit procedures to determine compliance with the certification requirements of Rule 1.35(a–1)(5)(vi). As noted above, the Commission is proposing to eliminate the recordkeeping and certification requirement and, accordingly, to eliminate Rule 1.35(a–1)(5)(vii).

Although, the Commission proposes to eliminate Rule 1.35(a–1)(5)(vii), the Commission will work with NFA to evaluate NFA's audit and examination process to identify any supervisory enhancements that will be necessary to ensure that customers are adequately protected and treated fairly.

III. Requests For Comment

The Commission has identified throughout this release issues on which it requests comment. In addition to the specific issues raised above, the Commission welcomes comment on any aspect of the proposed rule.

IV. Other Matters

A. Regulatory Flexibility Act

The Regulatory Flexibility Act (''RFA''), 5 U.S.C. 601 *et. seq.,* requires that agencies, in proposing rules, consider the impact of those rules on small businesses. The Commission has previously determined that contract markets,[20] futures commission merchants,[21] registered commodity pool operators[22] and large traders[23] are not ''small entities'' for purposes of the Regulatory Flexibility Act. The Commission has previously determined to evaluate within the context of a particular rule proposal whether all or some commodity trading advisors should be considered ''small entities'' for purposes of the Regulatory Flexibility Act and, if so, to analyze the economic impact on commodity trading advisors of any such rule at that time.[24]

[14] Interpretive Notice, NFA Compliance Rule 2–10: The Allocation of Block Orders for Multiple Accounts (June 9, 1998).

[15] *Id; see also,* 17 CFR 166.3 (2002)(stating that Commission registrants have a duty to diligently supervise handling of all commodity interest accounts). FCMs also have a duty to monitor for money laundering and report such activities to the appropriate regulatory authority. Interpretive Notice, NFA Compliance Rule 2–9: FCM and IB Anti-Money Laundering Program. For example, if an adviser places bunched orders with an FCM and routinely instructs the FCM to allocate favorable trades or unfavorable trades in a bunched order to one customer account, then this could constitute unusual account activity that an FCM has a duty to investigate and if appropriate report to regulators.

[16] The recordkeeping provisions of Rule 1.31 would still apply. 17 CFR 1.31 (2002).

[17] It is important to note that unless the order is submitted consistent with the requirements of this proposed rule, the order must contain a customer identification number. *See,* 17 CFR 1.35(a–1) (2002).

[18] 17 CFR 21.03(g) (2002).

[19] *See,* 17 CFR 21.03(h) (2002).

[20] 47 FR 18618, 18619 (April 30, 1982).

[21] *Id.*

[22] *Id.* at 18620.

[23] *Id.*

[24] *Id.*

Commodity trading advisors who would place eligible orders pursuant to these procedures would likely do so for multiple clients and would likely be participating as investment managers in more than one financial market. Accordingly, the Commission does not believe that commodity trading advisors should be considered ''small entities'' for purposes of this rule.

Therefore, the Chairman, on behalf of the Commission, hereby certifies, pursuant to 5 U.S.C. 605(b), that the action proposed to be taken herein will not have a significant economic impact on a substantial number of small entities.

B. Paperwork Reduction Act of 1995

This proposed rulemaking affects information collection requirements. As required by the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), the Commission has submitted a copy of this section to the Office of Management and Budget for its review.

Collection of Information

Rules Pertaining to Contract Markets and Their Members, OMB Control Number 3038–0022.

The expected effect of the proposed amended rule will be to not change the burden previously approved by OMB for this collection because, although it will result in an increase in the number of filings by account managers, it will result in a decrease in filings by FCMs.

Specifically:

The burden associated with Commission Rule 1.35(a–1)(5) is expected to be unchanged:

Estimated number of respondents: 400.

Annual responses by each respondent: 1.

Estimated average hours per response: 13.

Annual reporting burden: 52 hours.

This annual reporting burden of 52 hours represents no change in the number of hours as a result of the proposed amendments to Rule 1.35(a–1).

Organizations and individuals desiring to submit comments on the information collection requirements should direct them to the Office of Information and Regulatory Affairs, OMB, Room 10235 New Executive Office Building, Washington, DC 20503; Attention: 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, usefulness, and clarity of the information to be collected; and
- Minimizing the burden of 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.

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 N.W., Washington, DC 20581, (202) 418–5160.

C. Cost-Benefit Analysis

Section 15(a) of the Act requires the Commission to consider the costs and benefits of its action before issuing a new regulation under the Act. By its terms, section 15(a) does not require the Commission to quantify the costs and benefits of a new regulation or to determine whether the benefits of the proposed regulation outweigh its costs. Rather, section 15(a) simply requires the Commission to ''consider the costs and benefits'' of its action.

Section 15(a) further specifies that costs and benefits shall be evaluated in light of five broad areas of market and public concern: Protection of market participants and the public; efficiency, competitiveness, and financial integrity of futures markets; price discovery; sound risk management practices; and other public interest considerations. Accordingly, the Commission could in its discretion give greater weight to any one of the five enumerated areas and could in its discretion determine that, notwithstanding its costs, a particular rule was necessary or appropriate to protect the public interest or to effectuate any of the provisions or to accomplish any of the purposes of the Act.

The proposed amendments are intended to facilitate increased flexibility and consistency, and to rationalize application of Commission regulations to entities subject to other regulatory frameworks. The Commission is considering the costs and benefits of these rules in light of the specific provisions of section 15(a) of the Act:

1. Protection of market participants and the public.

While certain of the proposed amendments are expected to lessen the burden imposed upon FCMs and account managers, market participants and the public will be protected by requirements in the allocation procedure. Accordingly, the proposed amendments should have no effect on the Commission's ability to protect market participants and the public.

2. Efficiency and competition.

The proposed amendments are expected to benefit efficiency in the commodity futures and options markets, resulting in greater liquidity and market efficiency.

3. Financial integrity of futures markets and price discovery.

The proposed amendments should have no effect, from the standpoint of imposing costs or creating benefits, on the financial integrity or price discovery function of the commodity futures and options markets.

4. Sound risk management practices.

The proposed amendments should have no effect on sound risk management practices.

5. Other public interest considerations.

The proposed amendments will also take into account certain effects of legislative changes and the passage of time.

After considering these factors, the Commission has determined to propose the amendments discussed above. The Commission invites public comment on its application of the cost-benefit provision. Commenters also are invited to submit any data that they may have quantifying the costs and benefits of the proposal with their comment letters.

List of Subjects in 17 CFR Part 1

Brokers, Commodity futures, Commodity options, Consumer protection, Contract markets, Customers, Members of contract markets, Noncompetitive trading, Reporting and recordkeeping requirements, Rule enforcement programs.

In consideration of the foregoing, and pursuant to the authority contained in the Commodity Exchange Act and, in

particular, sections 5, 5a, 5b, 6(a), 6b, 8a(7), and 8c, 7 U.S.C. 7, 7a, 7b, 8(a), 8b, 12a(7), 12a(9), and 12c, the Commission hereby proposes to amend Part 1 of Chapter I of Title 17 of the Code of Federal Regulations as follows:

PART 1—GENERAL REGULATIONS UNDER THE COMMODITY EXCHANGE ACT

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

Authority: 7 U.S.C. 1a, 2, 2a, 4, 4a, 6, 6a, 6b, 6c, 6d, 6e, 6f, 6g, 6h, 6i, 6j, 6k, 6l, 6m, 6n, 6o, 6p, 7, 7a, 7b, 8, 9, 12, 12a, 12c, 13a, 13a–1, 16, 16a, 19, 21, 23, 24.

2. Section 1.35 is proposed to be amended by revising paragraph (a–1)(5) to read as follows:

§ 1.35 Records of cash commodity, futures and option transactions.

* * * * *

(a–1) * * *

(5) *Post-execution allocation of bunched orders.* Specific customer account identifiers for accounts included in bunched orders need not be recorded at time of order placement or upon report of execution if the requirements of paragraphs (a–1)(5)(i)–(iv) are met.

(i) *Eligible account managers.* The person placing and directing the allocation of an order eligible for post-execution allocation must have been granted written investment discretion with regard to participating customer accounts. The following persons shall qualify as eligible account managers:

(A) A commodity trading advisor registered with the Commission pursuant to the Act or excluded or exempt from registration under the Act or the Commission's rules, except for entities exempt under § 4.14(a)(3) or § 4.14(a)(6) of this chapter;

(B) An investment adviser registered with the Securities and Exchange Commission pursuant to the Investment Advisers Act of 1940 or with a state pursuant to applicable state law or excluded or exempt from registration under such Act or applicable state law or rule;

(C) A bank, insurance company, trust company, or savings and loan association subject to federal or state regulation; or

(D) A foreign adviser that exercises discretionary trading authority solely over the accounts of non-U.S. persons, as defined in § 4.7(a)(1)(iv) of this chapter.

(ii) *Information.* Eligible account managers shall make the following information available to customers upon request:

(A) The general nature of the allocation methodology the account manager will use;

(B) Whether accounts in which the account manager may have any interest may be included with customer accounts in bunched orders eligible for post-execution allocation; and

(C) Summary or composite data sufficient for that customer to compare its results with those of other comparable customers and, if applicable, any account in which the account manager has an interest.

(iii) *Allocation.* Orders eligible for post-execution allocation must be allocated by an eligible account manager in accordance with the following:

(A) Allocations must be made as soon as practicable after the entire transaction is executed, but in any event account managers must provide allocation information to futures commission merchants no later than a time sufficiently before the end of the day the order is executed to ensure that clearing records identify the ultimate customer for each trade.

(B) Allocations must be fair and equitable. No account or group of accounts may receive consistently favorable or unfavorable treatment.

(C) The allocation methodology must be sufficiently objective and specific to permit independent verification of the fairness of the allocations using that methodology by appropriate regulatory and self-regulatory authorities and by outside auditors.

(iv) *Records.*

(A) Eligible account managers shall keep and must make available upon request of any representative of the Commission, the United States Department of Justice, or other appropriate regulatory agency, the information specified in paragraph (a–1)(5)(ii) of this section.

(B) Eligible account managers shall keep and must make available upon request of any representative of the Commission, the United States Department of Justice, or other appropriate regulatory agency, records sufficient to demonstrate that all allocations meet the standards of paragraph (a–1)(5)(iii) of this section and to permit the reconstruction of the handling of the order from the time of placement by the account manager to the allocation to individual accounts.

(C) Futures commission merchants that execute orders or that carry accounts eligible for post-execution allocation, and members of contract markets that execute such orders, must maintain records that, as applicable, identify each order subject to post-execution allocation and the accounts to which contracts executed for such order are allocated.

(D) In addition to any other remedies that may be available under the Act or otherwise, if the Commission has reason to believe that an account manager has failed to provide information requested pursuant to paragraph (a–1)(5)(iv)(A) or (a–1)(5)(iv)(B) of this section, the Commission may inform in writing any designated contract market or derivatives transaction execution facility and that designated contract market or derivatives transaction execution facility shall prohibit the account manager from submitting orders for execution except for liquidation of open positions and no futures commission merchants shall accept orders for execution on any designated contract market or derivatives transaction execution facility from the account manager except for liquidation of open positions.

(E) Any account manager that believes he or she is or may be adversely affected or aggrieved by action taken by the Commission under paragraph (D) of this section shall have the opportunity for a prompt hearing in accordance with the provisions of § 21.03(g) of this chapter.

* * * * *

Issued in Washington, DC on March 10, 2003 by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 03–6177 Filed 3–13–03; 8:45 am]

BILLING CODE 6351–01–P

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[REG–131478–02]

RIN 1545–BB25

Guidance Under Section 1502; Suspension of Losses on Certain Stock Dispositions

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Notice of proposed rulemaking by cross-reference to temporary regulations; withdrawal of notice of proposed rulemaking; and notice of public hearing.

SUMMARY: In the rules and regulations section of this issue of the **Federal Register**, the IRS is issuing temporary regulations under section 1502 that redetermine the basis of stock of a subsidiary member of a consolidated group immediately prior to certain

transfers of such stock. In addition, temporary regulations suspend certain losses recognized on the disposition of such stock. The regulations apply to corporations filing consolidated returns. The text of the temporary regulations serves as the text of these proposed regulations. This document also provides notice of a public hearing on these proposed regulations.

DATES: Written or electronic comments must be received by June 12, 2003. Outlines of topics to be discussed at the public hearing scheduled for June 20, 2003, at 10 a.m., must be received by May 30, 2003.

ADDRESSES: Send submissions to: CC:PA:RU (REG–131478–02), room 5226, Internal Revenue Service, POB 7604, Ben Franklin Station, Washington, DC 20044. Submissions may be hand delivered Monday through Friday between the hours of 8 a.m. and 4 p.m. to CC:PA:RU (REG–131478–02), Courier's Desk, Internal Revenue Service, 1111 Constitution Avenue, NW., Washington, DC 20044. Alternatively, taxpayers may submit electronic comments directly to the IRS Internet site at *www.irs.gov/regs.* The public hearing will be held in the IRS Auditorium, Internal Revenue Service Building, 1111 Constitution Avenue, NW., Washington, DC.

FOR FURTHER INFORMATION CONTACT: Concerning the proposed regulations, Aimee K. Meacham, (202) 622–7530; concerning submissions of comments, the hearing, and/or to be placed on the building access list to attend the hearing, Sonya M. Cruse, (202) 622–7180 (not toll-free numbers).

SUPPLEMENTARY INFORMATION:

Paperwork Reduction Act

The collection of information contained in this notice of proposed rulemaking has been submitted to the Office of Management and Budget for review in accordance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)). Comments on the collection of information should be sent to the Office of Management and Budget, Attn: Desk Officer for the Department of the Treasury, Office of Information and Regulatory Affairs, Washington, DC 20503, with copies to the Internal Revenue Service, Attn: IRS Reports Clearance Officer, W:CAR:MP:T:T:SP, Washington, DC 20224. Comments on the collection of information should be received by May 13, 2003.

Comments are specifically requested concerning:

Whether the proposed collection of information is necessary for the proper performance of the functions of the IRS, including whether the information will have practical utility;

The accuracy of the estimated burden associated with the proposed collection of information (see below);

How the quality, utility, and clarity of the information to be collected may be enhanced;

How the burden of complying with the proposed collection of information may be minimized, including through the application of automated collection techniques or other forms of information technology; and

Estimates of capital or start-up costs and costs of operation, maintenance, and purchase of services to provide information.

The collection of information in these proposed regulations is in §§ 1.1502–35T(c), 1.1502–35T(c)(5)(iii), 1.1502–35T(f)(2) and 1.1502–35T(g)(3). This information is required by the IRS to verify compliance with section 1502. This information will be used to determine whether the amount of tax has been calculated correctly. The collection of information is required to properly determine the amount permitted to be taken into account as a loss. The respondents are corporations filing consolidated returns. The collection of information is required to obtain a benefit.

Estimated total annual reporting and/or recordkeeping burden: 15,000 hours.

Estimated average annual burden per respondent and/or recordkeeper: 2 hours.

Estimated number of respondents and/or recordkeepers: 7,475.

Estimated annual frequency of responses: On occasion.

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

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

Background

Temporary regulations in the rules and regulations section of this issue of the **Federal Register** amend the Income Tax Regulations (26 CFR part 1) relating to section 1502. The text of those regulations also serves as the text of these proposed regulations. The preamble to the temporary regulations contains a full explanation of the reasons underlying the issuance of the proposed regulations.

Special Analyses

It has been determined that this notice of proposed rulemaking is not a significant regulatory action as defined in Executive Order 12866. Therefore, a regulatory assessment is not required. It is hereby certified that these regulations do not have a significant impact on a substantial number of small entities. This certification is based on the fact that these regulations will primarily affect affiliated groups of corporations, which tend to be larger businesses. Moreover, the number of taxpayers affected and the average burden are minimal. Therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, these regulations will be submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on their impact on small businesses.

Comments and Public Hearing

Before these proposed regulations are adopted as final regulations, consideration will be given to any written (a signed original and eight copies) or electronic comments that are submitted timely to the IRS. The IRS and Treasury Department request comments on the clarity of the proposed regulations and how they may be made easier to understand. All comments will be available for public inspection and copying.

A public hearing has been scheduled for June 20, 2003, beginning at 10 a.m. in the IRS Auditorium, Internal Revenue Building, 1111 Constitution Avenue, NW., Washington, DC. Due to building security procedures, visitors must enter at the Constitution Avenue entrance. In addition, all visitors must present photo identification to enter the building. Because of access restrictions, visitors will not be admitted beyond the immediate entrance area more than 30 minutes before the hearing starts. For information about having your name placed on the building access list to attend the hearing, see the **FOR FURTHER INFORMATION CONTACT** portion of this preamble.

The rules of 26 CFR 601.601(a)(3) apply to the hearing. Persons who wish to present oral comments must submit written or electronic comments and an outline of the topics to be discussed and the time to be devoted to each topic (a signed original and eight copies) by May 30, 2003. A period of 10 minutes will be allotted to each person for making comments. An agenda showing the scheduling of the speakers will be

prepared after the deadline for receiving outlines has passed. Copies of the agenda will be available free of charge at the hearing.

Drafting Information

The principal author of these regulations is Aimee K. Meacham of the Office of Associate Chief Counsel (Corporate), IRS. However, other personnel from the IRS and Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Proposed Amendments to the Regulations

Accordingly, proposed regulations published on October 23, 2002 (67 FR 65066), are withdrawn, and 26 CFR part 1 is proposed to be amended as follows:

PART 1—INCOME TAXES

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

Authority: 26 U.S.C. 7805 * * *; 26 U.S.C. 1502 * * *

Par. 2. Section 1.1502–21 is amended by:

1. Revising paragraph (b)(1).
2. Adding paragraph (b)(3)(v) and (h)(7).

The revision and addition read as follows:

§ 1.1502–21 Net operating losses.

* * * * *

(b) * * *

(1) [The text of the proposed amendment to § 1.1502–21(b)(1) is the same as the text of § 1.1502–21T(b)(1) published elsewhere in this issue of the **Federal Register**].

* * * * *

(3) * * *

(v) [The text of the proposed amendment to § 1.1502–21(b)(3)(v) is the same as the text of § 1.1502–21T(b)(3)(v) published elsewhere in this issue of the **Federal Register**].

* * * * *

(h) * * *

(7) [The text of the proposed amendment to § 1.1502–21(h)(7) is the same as the text of § 1.1502–21T(h)(7) published elsewhere in this issue of the **Federal Register**].

Par. 3. Section 1.1502–32 is amended by:

1. Revising paragraphs (a)(2) and (h).
2. Adding paragraphs (b)(3)(iii)(C), (b)(3)(iii)(D), (b)(3)(vi) and (h)(6).

The revision and additions read as follows:

§ 1.1502–32 Investment adjustments.

* * * * *

(a)(2) [The proposed amendment to § 1.1502–32(a)(2) is the same as § 1.1502–32T(a)(2) published elsewhere in this issue of the **Federal Register**].

* * * * *

(b) * * * (1) * * *

(3) * * *

(iii) * * *

(C) and (D) [The proposed amendment to § 1.1502–32(b)(3)(iii)(C) and (b)(3)(iii)(D) are the same as § 1.1502–32T(b)(3)(iii)(C) and (b)(3)(iii)(D) published elsewhere in this issue of the **Federal Register**].

* * * * *

(4)(i) * * *

(vi) [The proposed amendment to § 1.1502–32(b)(4)(vi) is the same as § 1.1502–32T(b)(4)(vi) published elsewhere in this issue of the **Federal Register**].

* * * * *

(h)(6) [The proposed amendment to § 1.1502–32(h)(6) is the same as § 1.1502–32T(h)(6) published elsewhere in this issue of the **Federal Register**].

Par. 4. Section 1.1502–35 is added to read as follows:

§ 1.1502–35 Transfers and issuances of subsidiary member stock.

[The text of proposed § 1.1502–35 is the same as the text of § 1.1502–35T published elsewhere in this issue of the **Federal Register**].

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David A. Mader,

Assistant Deputy Commissioner of Internal Revenue.

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AI69

Endangered and Threatened Wildlife and Plants; Proposed Designation of Critical Habitat for *Yermo xanthocephalus* (Desert Yellowhead)

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule.

SUMMARY: We, the Fish and Wildlife Service (Service), propose to designate critical habitat for *Yermo xanthocephalus* (desert yellowhead) pursuant to the Endangered Species Act (Act) of 1973. *Y. xanthocephalus* was federally listed as threatened throughout its range in central Wyoming in 2002. Approximately 146 hectares (ha) (360 acres (ac)) in Fremont County, Wyoming, are proposed for designation as critical habitat for *Y. xanthocephalus.* The proposed critical habitat occurs entirely on land managed by the Bureau of Land Management (BLM).

If this proposal is made final, section 7 of the Act requires Federal agencies to ensure that actions they fund, authorize, or carry out do not destroy or adversely modify critical habitat to the extent that the action appreciably diminishes the value of the critical habitat for the survival and recovery of the species. Section 4 of the Act requires us to consider economic and other impacts of specifying any particular area as critical habitat.

DATES: We will accept comments until the close of business on May 13, 2003. Public hearing requests must be received by April 28, 2003.

ADDRESSES: If you wish to comment, you may submit your comments and materials concerning this proposal by any one of several methods:

(1) You may submit written comments and information to the Field Supervisor, Wyoming Field Office, U.S. Fish and Wildlife Service, 4000 Airport Parkway, Cheyenne, Wyoming 82001.

(2) You may hand-deliver written comments to our Wyoming Field Office at the address given above.

(3) You may send comments by electronic mail (e-mail) to *fw6_desertyellowhead@fws.gov. See* the Public Comments Solicited section below for file format and other information about electronic filing.

Comments and materials received, as well as supporting documentation used in the preparation of this proposed rule, will be available for public inspection, by appointment, during normal business hours at the above address.

FOR FURTHER INFORMATION CONTACT: Jodi Bush, Assistant Field Supervisor, Wyoming Field Office, U.S. Fish and Wildlife Service, at the above address (telephone: 307–772–2374; facsimile: 307–772–2358; e-mail: *Jodi_Bush@fws.gov*).

SUPPLEMENTARY INFORMATION:

Background

Wyoming botanist Robert Dorn discovered *Yermo xanthocephalus* (desert yellowhead) while conducting field work in the Beaver Rim area of central Wyoming in 1990. Dorn discovered a small population of an unusual species of Composite (Asteraceae). Dorn's closer examination revealed that the species was unknown

to science and represented a new genus. Dorn (1991) named his discovery *Y. xanthocephalus,* or literally ''desert yellowhead.''

Yermo xanthocephalus is a tap-rooted, glabrous (hairless) perennial herb with leafy stems to 30 centimeters (cm) (12 inches (in)) high. The leathery leaves are alternate, lance-shaped to oval, 4 to 25 cm (1.5 to 10 in) long and often folded along the midvein. Leaf edges are smooth or toothed. Flower heads are many (25 to 180) and crowded at the top of the stem. Each head contains four to six yellow disk flowers (ray flowers are absent) surrounded by five yellow, keeled involucre (whorled) bracts (small leaves beneath the flower). The pappus (the outer whorl of flowering parts) consists of many white bristles.

Yermo xanthocephalus flowers from mid-June to August and may flower a second time in September. The start and end of flowering, as well as the duration of flowering, vary between years and seem dependent upon temperature and other climatic variables. Fruits have been observed from mid-July to early September, but do not persist after the flower has dried and bracts ruptured (Heidel 2002).

Yermo xanthocephalus appears to be an obligate outcrosser (cannot self-pollinate) (Heidel 2002) and is likely pollinated by visually-oriented insects attracted to the yellow flowers (Dorn 1991). Several Hymenopterans (order including sawflies, ants, bees, and wasps) have been collected from *Y. xanthocephalus* heads, and small skipper butterflies noted on them, although the identity of these potential pollinators is not currently known (Heidel 2002). No work has been done to document the status of these potential pollinators in this vicinity. However, of the skippers known from Fremont County that most likely use *Y. xanthocephalus* habitat, all have Nature Conservancy Global Ranks of G–4 (apparently secure globally) and G–5 (demonstrably secure globally) with no special conservation or management needs identified by Opler *et al.* (1995).

The fruits of *Yermo xanthocephalus* are single-seeded achenes (dry fruit) with a parachute-like pappus of slender bristles. At maturity, the fruits are exposed to the wind, which may disperse the seed over long distances. However, the clustered distribution pattern of *Y. xanthocephalus,* often along colluvial (rock debris) washes, suggests that dispersal distances are short and perhaps fostered by water erosion (Heidel 2002).

The species is restricted to shallow deflation hollows in outcrops of Miocene sandstones of the Split Rock Formation (Love 1961, Van Houten 1964). These hollows have been shaped by the microscale dynamics of local winds, as well as erosional processes, in an unstable portion of the landscape on sites lacking desert pavement and with low vegetation exposed to strong-wind (Bynum 1993). Within the hollows, *Yermo xanthocephalus* occurs on low slopes, rim margins, colluvial fans, and bottoms at elevations generally ranging from 2,050 to 2,060 meters (m) (6,720 to 6,760 feet (ft)) (Heidel 2002).

Yermo xanthocephalus grows in recent soils derived from sandstones and limestones of the Split Rock Formation at its junction with the White River Formation (Heidel 2002). Bynum (1993) found these are shallow, loamy soils of the Entisol order that can be classified as a coarse-loamy over sandy-skeletal mixed Lithic Torriorthent. In contrast, the surrounding sagebrush community occupies deep sandy loam of the Aridisol order. The surface stratum is mildly alkaline with little organic matter, while subsurface layers have no accumulation of humus, clay, gypsum, salts, or carbonates (Bynum 1993).

The shape and orientation of the wind-excavated hollows may allow for accumulation of moisture from sheet wash coming off adjacent areas, so the hollows may be more mesic (moist) than surrounding areas (R. Scott, Central Wyoming College, pers. comm. 2002). The vegetation of these sites is typically sparse, with vegetative cover often as low as 10 percent, and consists primarily of low-cushion plants and scattered clumps of Indian ricegrass (*Stipa hymenoides*). Species common to these communities include *Arenaria hookeri* (Hooker's sandwort), *Astragalus kentrophyta* (thistle milkvetch), *Hymenoxys acaulis* (stemless hymenoxy), and *Phlox muscoides* (squarestem phlox) (Fertig 1995). A more complete list of frequently associated species can be found in Heidel (2002).

Yermo xanthocephalus is currently known from a single population with plants widely scattered over an area of 20 ha (50 ac). This population consists of one large subpopulation at the base of Cedar Rim and two smaller subpopulations within 0.4 kilometer (km) (0.25 mile (mi)). Originally, Dorn observed approximately 500 plants within 1 ha (2.5 ac) in 1990 on Federal land managed by the BLM (Dorn 1991). The estimate of the plant population's size has increased from 500 in 1990 to 11,967 plants in 2001 (R. Scott, Central Wyoming College, pers. comm., 2001). However, Dorn's original estimate of 500 plants was an ocular estimate and did not include two nearby subpopulations, while Scott has been conducting extensive population censuses in all three subpopulations using a monitoring grid (Heidel 2002). Therefore, the difference in estimates may be largely the result of different techniques used over differing acreages and cannot be assumed to show a significantly increasing trend in population size between 1990 and 2001. Based upon Scott's data collected from 1995 through 2001, the actual population count has increased from 9,293 in 1995 to 11,967 in 2001, possibly in response to higher than normal precipitation over the study period (R. Scott, Central Wyoming College, pers. comm., 2001).

Surveys conducted between 1990 and 1994 failed to locate additional populations of *Yermo xanthocephalus* on outcrops of the Split Rock, White River, Wagon Bed, and Wind River formations in the Cedar Rim and Beaver Rim areas of southern Fremont County (Fertig 1995). No additional populations were located during follow-up surveys conducted during 1997 along Beaver Rim in Fremont and Natrona counties, as well as in the Shirley Basin in Carbon County (Heidel 2002). Additional surveys were conducted during 2001 in segments of Cedar Rim and Beaver Rim and surrounding areas not previously surveyed; however, no new populations were located (Heidel 2002).

Yermo xanthocephalus is vulnerable to extinction from randomly occurring, catastrophic events, as well as even small-scale habitat degradation, due to its small population size and limited geographic range. As described by Fertig (1995), the species is characterized by a long-lived perennial growth form, adaptation to severe habitats, and low annual reproductive output. This low reproductive output would make the species increasingly vulnerable to extinction due to chance events if the population size declined, because it is unlikely that the species would exhibit a high rate of population growth, even if environmental conditions improved after such an event.

While not known to have impacted *Yermo xanthocephalus* to date, oil and gas development could impact the population of *Y. xanthocephalus.* The known population is encompassed by, and adjacent to, oil and gas leases with no specific lease stipulations included to protect the plant. Construction of well pads, access roads, and pipelines through occupied habitat, as well as seismic exploration of oil and gas producing formations, could result in direct destruction or crushing of plants

and soil compaction and erosion. Additionally, a network of roads and well pads in the area would result in more human intrusion into what is now a relatively remote area.

The presence of locatable minerals in the area and their potential extraction could also impact the known *Yermo xanthocephalus* population. Uranium and zeolites, a locatable mineral with properties useful in water softening, manufacturing of catalysts, pollution control, and removal of radioactive products from radioactive waste, are found in the Beaver Rim area (BLM 1986). Private parties can stake a mining claim, explore for, and extract locatable minerals in accordance with the 1872 General Mining Law. Such activity should it occur in the vicinity of the known population could result in direct destruction of individual plants and habitat.

Recreational off-road vehicle use threatens to crush *Yermo xanthocephalus* plants and compact or erode soil. A two-track, four-wheel-drive vehicle trail leading to an abandoned oil well bisects the population and is open to recreationists driving four-wheel-drive trucks and other smaller all-terrain vehicles.

The *Yermo xanthocephalus* population is in a grazing allotment pasture where trampling may occur as cattle casually move along ''cow trails'' or other tracks while grazing or moving to water. Focused or prolonged use of the area by cattle could result in damage to the habitat and individual plants. Scott (2000) noted signs of moderate wild horse traffic adjacent to the habitat. However, at this time, grazing has not been documented as impacting the *Y. xanthocephalus* population.

Additionally, the invasion of non-native species, particularly noxious weeds, could accompany many of the activities discussed above. The resulting changes to the vegetative community could have significant adverse impacts on the population of *Yermo xanthocephalus.*

The current BLM Lander Resource Management Plan, which covers the area proposed for designation as critical habitat for *Yermo xanthocephalus,* was approved in 1987, 3 years prior to the species' discovery. Therefore, the Resource Management Plan does not specifically mention the plant. In response to the proposed listing of *Y. xanthocephalus,* the BLM developed a draft conservation agreement, assessment, and strategy for the plant (BLM 1998) in order to promote its conservation and recovery on BLM lands. However, the document was never finalized or signed.

In the 6 years that complete population counts have been done, the *Yermo xanthocephalus* population has appeared stable (Heidel 2002). Current conditions appear favorable to the species and its habitat. Even small changes to the habitat, such as protective fencing around the plant's location, or changes in livestock and wildlife use or numbers, may have negative impacts by altering water flow patterns and trails that currently carry water and soil flows. These kinds of changes also may allow native and non-native plant species to out-compete *Y. xanthocephalus* for water and habitat.

Previous Federal Action

In the plant Notice of Review published on September 30, 1993 (58 FR 51144), we designated *Yermo xanthocephalus* a Category 2 species for potential listing under the Endangered Species Act (Act) of 1973, as amended (16 U.S.C. 1531 *et seq.*). At that time, Category 2 species were those for which data in our possession indicated listing was possibly appropriate, but for which substantial data on biological vulnerability and threats were not currently known or on file to support a proposed rule. On February 28, 1996, we published a Notice of Review in the **Federal Register** (61 FR 7596) that discontinued the designation of Category 2 species as candidates. At that time, this species was upgraded to candidate status based upon its small population size, the failure to locate additional populations in similar habitats during additional surveys during 1994, and further analysis of threats. A candidate is a species for which we possess substantial information on biological vulnerability and threats to support preparation of a listing proposal.

On November 24, 1997, we received a petition from the Biodiversity Legal Foundation and Biodiversity Associates alleging that *Yermo xanthocephalus* warranted emergency listing. On December 22, 1997, we notified the petitioners that emergency listing was not appropriate because BLM regulations provided some conservation measures for the species, and current exploratory oil and gas activities near the known occupied habitat of *Y. xanthocephalus* were being coordinated with our staff in the Wyoming Field Office. In addition, we notified the petitioners that petitions for candidate species are considered second petitions, because candidate species are species for which we have already decided that listing is warranted. Therefore, no 90-day finding was required for Biodiversity Legal Foundation's petition.

We published the proposed rule to list *Yermo xanthocephalus* as threatened in the **Federal Register** on December 22, 1998 (63 FR 70745). In the proposed rule, we found that the designation of critical habitat was not prudent because the minimal benefits of such designation would be far outweighed by the increase of threats from over collection or other human activities. We believed critical habitat designation would provide no additional benefit to the species beyond that conferred under sections 7 and 9 of the Act by listing.

In a proposed rule published in the **Federal Register** on September 5, 2000 (65 FR 53691), we reopened the comment period. In the same proposed rule, we sought comments regarding a draft conservation agreement, assessment, and strategy submitted by BLM (BLM 1998) for our consideration when making the listing decision. The conservation agreement, assessment, and strategy was never finalized or signed and was not considered as a firm commitment to perform the actions when assessing conservation commitments in making the listing decision.

On August 9, 1999, BLM segregated (proposed withdrawal of) 1,521.26 ha (3,759.12 ac) surrounding the population of *Yermo xanthocephalus* for 2 years from location and entry under the general Mining Act of 1872, and from settlement, sale, location, and entry under the general land laws (64 FR 43209). However, this segregation expired on August 9, 2001, with no finalized withdrawal in place.

On November, 12, 2001, Biodiversity Legal Foundation, Biodiversity Associates, Center for Native Ecosystems, and Wyoming Outdoor Council filed a complaint in the U.S. District Court of Colorado alleging that the Service failed to make a timely final listing determination and critical habitat designation for *Yermo xanthocephalus* (*Biodiversity Legal Foundation* v. *Norton,* 01–B–2204 District of Colorado). The Court approved a settlement agreement on February 28, 2002, which included a March 8, 2003, date for submission of proposed critical habitat for *Y. xanthocephalus* to the **Federal Register** for publication and a March 8, 2004, date for submission of final critical habitat for *Y. xanthocephalus* to the **Federal Register**.

After a review of the best scientific data available and all comments received in response to the proposed rule, we published a final rule on March 14, 2002, designating *Yermo xanthocephalus* as threatened

throughout its range (67 FR 11442). We did not designate critical habitat at that time. However, we reevaluated our prudency determination under the standards mandated by various court decisions and found that designation of critical habitat for *Y. xanthocephalus* was prudent. We elected to list *Y. xanthocephalus* as threatened without designation of critical habitat to allow us to concentrate limited resources on other listing actions that needed to be addressed, while allowing us to invoke the protections needed for the conservation of this species without further delay. We committed to prepare a critical habitat designation in the future when our available resources and priorities would allow.

Critical Habitat

Critical habitat is defined in section 3 of the Act as: (i) The specific areas within the geographical area occupied by a species, at the time it is listed in accordance with the Act, on which are found those physical or biological features (I) essential to the conservation of the species and (II) that may require special management considerations or protection; and (ii) specific areas outside the geographical area occupied by a species at the time it is listed, upon a determination that such areas are essential for the conservation of the species. ''Conservation'' means the use of all methods and procedures needed to bring an endangered or threatened species to the point at which listing under the Act is no longer necessary.

Critical habitat receives protection under section 7 of the Act through the prohibition against destruction or adverse modification with regard to actions carried out, funded, permitted, or authorized by a Federal agency. Section 7 also requires conferences on Federal actions that are likely to result in the destruction or adverse modification of proposed critical habitat. In our regulations at 50 CFR 402.02, we define destruction or adverse modification as ''a direct or indirect alteration that appreciably diminishes the value of critical habitat for both the survival and recovery of a listed species. Such alterations include, but are not limited to: alterations adversely modifying any of those physical or biological features that were the basis for determining the habitat to be critical.'' However, in a March 15, 2001, decision of the United States Court of Appeals for the Fifth Circuit (*Sierra Club* v. *U.S. Fish and Wildlife Service et al.*, 245 F.3d 434), the Court found our definition of destruction or adverse modification to be invalid. In response to this decision, we are reviewing the regulatory definition of adverse modification in relation to the conservation of the species.

Aside from the added protection that may be provided under section 7, the Act does not provide other forms of protection to lands designated as critical habitat. However, the designation of critical habitat provides benefits to the species in other ways. Designation of critical habitat allows for a better focus of conservation efforts by identifying those areas that contain the primary constituent elements (physical and biological features) essential to the conservation of the species. The designation alerts public land management agencies to the importance of the area for conservation of the species. Additionally, designation of critical habitat allows for long-term planning that will facilitate the conservation needs of the species.

To be included in a critical habitat designation, the habitat must first be ''essential to the conservation of the species.'' Critical habitat designations identify, to the extent known using the best scientific and commercial data available, habitat areas that provide essential life cycle needs of the species (*i.e.*, areas on which are found the primary constituent elements, as defined at 50 CFR 424.12(b)).

Within the geographic area occupied by the species, we will designate only areas currently known to be essential. Essential areas should already have the features and habitat characteristics that are necessary to sustain the species. We will not speculate about what areas might be found to be essential if better information became available, or what areas may become essential over time. If the information available at the time of designation does not show that an area provides essential life cycle needs of the species, then the area should not be included in the critical habitat designation. Within the geographic area occupied by the species, we will not designate areas that do not now have the primary constituent elements, as defined at 50 CFR 424.12(b), that provide essential life cycle needs of the species.

Our regulations state that, ''The Secretary shall designate as critical habitat areas outside the geographic area presently occupied by a species only when a designation limited to its present range would be inadequate to ensure the conservation of the species,'' (50 CFR 424.12(e)). Accordingly, unless the best available scientific data do not demonstrate that the conservation needs of the species require it, we will not designate critical habitat in areas outside the geographic area occupied by the species.

Our Policy on Information Standards Under the Endangered Species Act, published in the **Federal Register** on July 1, 1994 (59 FR 34271), provides criteria, establishes procedures, and provides guidance to ensure that our decisions represent the best scientific and commercial data available. It requires Service biologists, to the extent consistent with the Act, and with the use of the best scientific and commercial data available, to use primary and original sources of information as the basis for recommendations to designate critical habitat. When determining which areas are critical habitat, a primary source of information should, at a minimum, be the listing package for the species. Additional information may be obtained from a recovery plan, articles in peer-reviewed journals, conservation plans developed by States and counties, scientific status surveys and studies, biological assessments, unpublished materials, and expert opinion.

Habitat is often dynamic, and species may move from one area to another over time. Furthermore, we recognize that designation of critical habitat may not include all of the habitat areas that may eventually be determined to be necessary for the recovery of the species. For these reasons, all should understand that critical habitat designations do not signal that habitat outside the designation is unimportant or may not be required for recovery. Areas outside the critical habitat designation will continue to be subject to conservation actions that may be implemented under section 7(a)(1) and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the section 9 take prohibition, as determined on the basis of the best available information at the time of the action. We specifically anticipate that federally funded or assisted projects affecting listed species outside their designated critical habitat areas may still result in jeopardy findings in some cases. Similarly, critical habitat designations made on the basis of the best available information at the time of designation will not control the direction and substance of future recovery plans, habitat conservation plans, or other species conservation planning efforts if new information available to these planning efforts calls for a different outcome.

Methods

In determining areas that are essential to conserve *Yermo xanthocephalus,* we used the best scientific information

available, as required by the Act and regulations (section 4(b)(2) and 50 CFR 424.12). We reviewed available information that pertains to the habitat requirements of this species, including information from the final rule listing the species as threatened (67 FR 11442), data from research and survey observations at the known population site, status reports compiled by the Wyoming Natural Diversity Database, the BLM's Resource Management Plan/Environmental Impact Statement for the Lander Resource Area (1986), Geological Survey Bulletins regarding the geology of central Wyoming and the Beaver Rim area, data regarding soils at the known population site, and discussions with botanical experts and BLM employees.

We mapped critical habitat based on U.S. Geological Survey 7.5″ quadrangle maps (Dishpan Butte and Sweetwater Station, Wyoming). We included the areas occupied by the subpopulations of *Yermo xanthocephalus* based upon existing maps of the subpopulations, as well as site visits by Service and BLM employees. We included adjacent areas of suitable soils and vegetative communities to allow for maintenance of the seed bank and dispersal. Additionally, we identified areas with topographic features (outcroppings, cliffs, and hills) influencing the microscale dynamics of local winds, erosional processes, and hydrologic processes needed to maintain the integrity of the shallow deflation hollows providing *Y. xanthocephalus* habitat, as well as the sheet wash that provides increased moisture to the habitat. We believe these areas are necessary because of the unstable nature of the landscape (Bynum 1993) and the more mesic nature of the hollows than the surrounding arid landscape (R. Scott, Central Wyoming College, pers. comm. 2002). We delineated the boundary of this area using section lines and quarter-section lines where feasible, in order to facilitate BLM management and enforcement. This designation will also reduce the likelihood that extant populations would be identified and vandalized.

Primary Constituent Elements

In accordance with section 3(5)(A)(i) of the Act and regulations at 50 CFR 424.12, in determining which areas to propose as critical habitat, we must consider those physical and biological features (primary constituent elements) that are essential to the conservation of the species, and that may require special management considerations or protection. These include, but are not limited to: space for individual and population growth, and for normal behavior; food, water, air, light, minerals, or other nutritional or physiological requirements; cover or shelter; sites for breeding, reproduction, rearing of offspring; and habitats that are protected from disturbance or are representative of the historic geographical and ecological distributions of a species. The area proposed as critical habitat for *Yermo xanthocephalus* is within the geographical area presently occupied by the species and contains these physical or biological features (primary constituent elements) essential for the conservation of the species.

Based on our knowledge to date, the primary constituent elements for *Yermo xanthocephalus* consist of, but are not limited to:

(1) Recent soils derived from sandstones and limestones of the Split Rock Formation at its junction with the White River Formation. These are shallow, loamy soils of the Entisol order that can be classified as coarse-loamy over sandy-skeletal, mixed, Lithic Torriorthent. The surface stratum has little organic matter and subsurface layers show no accumulation of humus, clay, gypsum, salts, or carbonates.

(2) Plant communities associated with *Yermo xanthocephalus* that include, but may not be limited to, sparsely-vegetated cushion plant communities with scattered clumps of *Oryzopsis hymenoides* (Indian ricegrass) between 2,043 and 2,073 m (6,700 and 6,800 ft) in Fremont County, Wyoming. Species common to these communities include *Arenaria hookeri* (Hooker's sandwort), *Astragalus kentrophyta* (thistle milkvetch), *Hymenoxys acaulis* (stemless hymenoxy), and *Phlox muscoides* (squarestem phlox). These cushion-plant communities also contain natural openings.

(3) Topographic features/relief (outcroppings, cliffs, and hills) and physical processes, particularly hydrologic processes, that maintain the shape and orientation of the hollows characteristic of *Yermo xanthocephalus* habitat (through microscale dynamics of local winds and erosion) and maintain moisture below the surface of the ground (through sheet wash from the adjacent outcroppings, cliffs, and hills).

Criteria Used To Identify Critical Habitat

We identified critical habitat essential for the conservation of *Yermo xanthocephalus* in the only area where it is known to occur. There are no known historic locations for this species. While we acknowledge the high degree of threat that arises from chance catastrophic events given the limited geographic distribution of this species, we find no compelling evidence that the plant ever existed at other locations. We believe conservation of the species can be achieved through management of threats to the population within this proposed critical habitat.

Given the clustered distribution pattern of *Yermo xanthocephalus* and our assumption that dispersal distances are short and possibly fostered by water erosion, a limited amount of critical habitat is essential for maintenance of the seed bank and dispersal. Additionally, the persistence of the species requires some surrounding habitat to maintain the ecological processes that allow the population and the primary constituent elements to persist.

Even though we did not propose sites other than where the population is currently known to occur, we do not mean to imply that habitat outside the designation is unimportant or may not be required for recovery of the species. Areas that support newly discovered populations in the future, but are outside the critical habitat designation, will continue to be subject to conservation actions that may be implemented under section 7(a)(1) of the Act and to the regulatory protections afforded by the section 7(a)(2) jeopardy standard and the prohibitions of section 9 of the Act, as determined on the basis of best available information at the time an action is proposed.

Critical Habitat Proposal

The proposed critical habitat area described below constitutes our best assessment at this time of the area essential for the conservation of *Yermo xanthocephalus.* The site includes the only known location where the species currently occurs and, as such, is essential.

The proposed critical habitat is approximately 146 ha (360 ac) of Federal lands managed by BLM in the Beaver Rim area approximately 10 km (6 mi) north of Sweetwater Station in southern Fremont County, Wyoming. Within this area, *Yermo xanthocephalus* occurs in sparsely vegetated cushion-plant communities associated with shallow soils on low slopes, rim margins, colluvial fans, and bottoms within deflation hollows. Additionally, as discussed previously, we included areas supporting topographic features (outcroppings, cliffs, and hills) influencing the microscale dynamics of local winds, erosional processes, and hydrologic processes needed to maintain the integrity of the shallow deflation hollows providing *Y. xanthocephalus* habitat, as well as the

sheet wash that provides increased moisture to the habitat. Within the critical habitat, *Y. xanthocephalus* occurs in 3 subpopulations with a total population size of 11,967 plants in 2001 (R. Scott, Central Wyoming College, pers. comm. 2001). Dispersal from these subpopulations is limited and frequently occurs along colluvial washes.

Effects of Critical Habitat Designation

Section 7 Consultation

Section 7(a) of the Act requires Federal agencies, including the Service, to ensure that actions they fund, authorize, or carry out do not destroy or adversely modify critical habitat to the extent that the action appreciably diminishes the value of the critical habitat for the survival and recovery of the species. Individuals, organizations, States, local governments, and other non-Federal entities are affected by the designation of critical habitat only if their actions occur on Federal lands, require a Federal permit, license, or other authorization, or involve Federal funding.

Section 7(a) of the Act requires Federal agencies, including the Service, to evaluate their actions with respect to any species that is proposed or listed as endangered or threatened and with respect to its critical habitat, if any is designated or proposed. Regulations implementing this interagency cooperation provision of the Act are codified at 50 CFR part 402. Section 7(a)(4) requires Federal agencies to confer with us on any action that is likely to jeopardize the continued existence of a proposed species or result in destruction or adverse modification of proposed critical habitat. Conference reports provide conservation recommendations to assist the action agency in eliminating conflicts that may be caused by the proposed action. The conservation recommendations in a conference report are advisory.

We may issue a formal conference report, if requested by the Federal action agency. Formal conference reports include an opinion that is prepared according to 50 CFR 402.14, as if the species was listed or critical habitat designated. We may adopt the formal conference report as the biological opinion when the species is listed or critical habitat designated, if no substantial new information or changes in the action alter the content of the opinion (*see* 50 CFR 402.10(d)).

If a species is listed or critical habitat is designated, section 7(a)(2) requires Federal agencies to ensure that activities they authorize, fund, or carry out are not likely to jeopardize the continued existence of such a species or to destroy or adversely modify its critical habitat. If a Federal action may affect a listed species or its critical habitat, the responsible Federal agency (action agency) must enter into consultation with us. Through this consultation, we would ensure that the permitted actions do not destroy or adversely modify critical habitat.

When we issue a biological opinion concluding that a project is likely to result in the destruction or adverse modification of critical habitat, we also provide reasonable and prudent alternatives to the project, if any are identifiable. ''Reasonable and prudent alternatives'' are defined at 50 CFR 402.02 as alternative actions identified during consultation that can be implemented in a manner consistent with the intended purpose of the action, that are consistent with the scope of the Federal agency's legal authority and jurisdiction, that are economically and technologically feasible, and that the Director believes would avoid the destruction or adverse modification of critical habitat. Reasonable and prudent alternatives can vary from slight project modifications to extensive redesign or relocation of the project. Costs associated with implementing a reasonable and prudent alternative are similarly variable.

Regulations at 50 CFR 402.16 require Federal agencies to reinitiate consultation on previously reviewed actions in instances where critical habitat is subsequently designated, and the Federal agency has retained discretionary involvement or control over the action or such discretionary involvement or control is authorized by law. Consequently, some Federal agencies may request reinitiation of consultation or conference with us on actions for which formal consultation has been completed, if those actions may affect designated critical habitat or adversely modify or destroy proposed critical habitat.

Activities on Federal lands that may affect *Yermo xanthocephalus* or its critical habitat will require section 7 consultation. Federal actions not affecting listed species or critical habitat do not require section 7 consultation.

Section 4(b)(8) of the Act requires us to briefly evaluate and describe in any proposed or final regulation that designates critical habitat those activities involving a Federal action that may destroy or adversely modify such habitat, or that may be affected by such designation. Activities that, when carried out, funded, or authorized by a Federal agency, may directly or indirectly destroy or adversely modify critical habitat or may be affected by the designation include, but are not limited to:

(1) Activities that have the potential to appreciably degrade or destroy *Yermo xanthocephalus* habitat (and its PCEs), including mining, oil and gas exploration and development, herbicide use, intensive livestock grazing, clearing, discing, farming, residential or commercial development, off-road vehicle use, and heavy recreational use;

(2) Alteration of existing hydrology by lowering the groundwater table or redirection of sheet flow from areas adjacent to deflation hollows;

(3) Compaction of soil through the establishment of trails or roads;

(4) Activities that foster the introduction of non-native vegetation, particularly noxious weeds, or create conditions that encourage the growth of non-natives. These activities could include, but are not limited to: irrigation, supplemental feeding of livestock, and ground disturbance associated with pipelines, roads, and other soil-disturbing activities; and

(5) Appreciably decreasing habitat value or quality through indirect effects (*e.g.*, construction of fencing along the perimeter of the critical habitat leading to cattle congregation at the fence and resultant focused disturbance, erosion, and changes to drainage patterns, soil stability, and vegetative community composition).

If you have questions regarding whether specific activities will constitute adverse modification of critical habitat, contact the Field Supervisor, Wyoming Field Office, U.S. Fish and Wildlife Service (*see* **ADDRESSES** section). Requests for copies of the regulations on listed wildlife, and inquiries about prohibitions and permits may be addressed to the U.S. Fish and Wildlife Service, Ecological Services, P.O. Box 25486, DFC, Denver, Colorado 80225–0486 (telephone: 303–236–7400; facsimile: 303–236–0027).

Economic Analysis

Section 4(b)(2) of the Act requires us to designate critical habitat on the basis of the best scientific and commercial information available, and to consider the economic and other relevant impacts of designating a particular area as critical habitat. We may exclude areas from critical habitat upon a determination that the benefits of such exclusions outweigh the benefits of specifying such areas as critical habitat. We cannot exclude such areas from critical habitat when such exclusion will result in the extinction of the species. We will conduct an analysis of

the economic impacts of designating the specific proposed area as critical habitat prior to a final determination. When completed, we will announce the availability of the draft economic analysis with a notice in the **Federal Register**, and we will open a public comment period on the draft economic analysis and proposed rule at that time.

Public Comments Solicited

We intend that any final action resulting from this proposal be as accurate and effective as possible. Therefore, we solicit comments or suggestions from the public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of designation will outweigh any threats to the species due to designation;

(2) Specific information on the amount and distribution of *Yermo xanthocephalus* habitat, and what habitat is essential to the conservation of the species and why;

(3) Land use practices and current or planned activities in the subject area and their possible impacts on proposed critical habitat;

(4) Any foreseeable economic or other impacts resulting from the proposed designation of critical habitat, in particular, any impacts on small entities or families;

(5) Economic and other values associated with designating critical habitat for *Yermo xanthocephalus,* such as those derived from non-consumptive uses (*e.g.*, hiking, camping, bird-watching, enhanced watershed protection, improved air quality, increased soil retention, ''existence values,'' and reductions in administrative costs); and

(6) Whether our approach to critical habitat designation could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concern and comments.

If you wish to comment on this proposed rule, you may submit your comments and materials by any one of several methods (*see* **ADDRESSES** section). If submitting comments by electronic format, please submit them in ASCII file format and avoid the use of special characters and encryption. Please include your name and return e-mail address in your e-mail message. Please note that the e-mail address will be closed out at the termination of the public comment period. If you do not receive confirmation from the system that we have received your message, contact us directly by calling our Wyoming Field Office (*see* **FOR FURTHER INFORMATION CONTACT** section).

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this request prominently at the beginning of your comment. However, we will not consider anonymous comments. To the extent consistent with applicable law, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be available for public inspection, by appointment, during normal business hours at the above address (*see* **ADDRESSES** section).

Peer Review

In accordance with our policy published on July 1, 1994 (59 FR 34270), we will seek the expert opinions of at least three appropriate and independent specialists regarding this proposed rule. The purpose of such review is to ensure that our critical habitat designation is based on scientifically sound data, assumptions, and analyses. We will send these peer reviewers copies of this proposed rule immediately following publication in the **Federal Register**. We will invite these peer reviewers to comment, during the public comment period, on the specific assumptions and conclusions regarding the proposed designation of critical habitat.

We will consider all comments and information received during the public comment period on this proposed rule during preparation of a final rulemaking. Accordingly, the final decision may differ from this proposal.

Public Hearings

The Act provides for one or more public hearings on this proposal, if requested. Requests for public hearings must be made at least 15 days prior to the close of the public comment period. We will schedule public hearings on this proposal, if any are requested, and announce the dates, times, and places of those hearings in the **Federal Register** and local newspapers at least 15 days prior to the first hearing.

Clarity of the Rule

Executive Order 12866 requires each agency to write regulations/notices that are easy to understand. We invite your comments on how to make this proposed rule easier to understand including answers to questions such as the following: (1) Are the requirements in the proposed rule clearly stated? (2) Does the proposed rule contain technical language or jargon that interferes with the clarity? (3) Does the format of the proposed rule (grouping and order of sections, use of headings, paragraphing, etc.) aid or reduce its clarity? (4) Is the description of the proposed rule in the **SUPPLEMENTARY INFORMATION** section of the preamble helpful in understanding the notice? (5) What else could we do to make the proposed rule easier to understand?

Send comments that concern how we could make this notice easier to understand to: Office of Regulatory Affairs, Department of the Interior, Room 7229, 1849 C Street, NW., Washington, DC 20240. You also may e-mail your comments to this address: *Execsec@ios.doi.gov.*

Required Determinations

Regulatory Planning and Review

In accordance with Executive Order 12866, the Office of Management and Budget (OMB) has determined that this document is not a significant rule and therefore OMB is not required to review it. We are preparing a draft analysis of this proposed action, which will be available for public comment, to determine the economic consequences of designating the specific area as critical habitat. The availability of the draft economic analysis will be announced in the **Federal Register** and in local newspapers so that it is available for public review and comments.

Regulatory Flexibility Act

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*, as amended by the Small Business Regulatory Enforcement Fairness Act (SBREFA) of 1996), whenever an agency is required to publish a notice of rulemaking for any proposed or final rule, it must prepare and make available for public comment a regulatory flexibility analysis that describes the effect of the rule on small entities (*i.e.*, small businesses, small

organizations, and small government jurisdictions). However, no regulatory flexibility analysis is required if the head of an agency certifies the rule will not have a significant economic impact on a substantial number of small entities. The SBREFA amended the Regulatory Flexibility Act to require Federal agencies to provide a statement of the factual basis for certifying that a rule will not have a significant economic impact on a substantial number of small entities.

The area we are proposing as critical habitat is already occupied by *Yermo xanthocephalus.* As a result, Federal agencies funding, permitting, or implementing activities in this area are already required to consult with us under section 7 of the Act, to avoid jeopardizing the continued existence of this species. While the designation of critical habitat will require that agencies ensure, through section 7 consultation, that their activities do not destroy or adversely modify critical habitat, we do not believe this will result in any additional regulatory burden on the Federal agencies or their applicants. As a result, this proposed rule, if finalized, would not likely result in a significant economic burden on Federal agencies or their applicants. However, the economic analysis will provide the details needed prior to certifying that this proposed rule is not expected to have a significant adverse impact on a substantial number of small entities, with no need for a regulatory flexibility analysis.

Energy Supply, Distribution or Use (Executive Order 13211)

On May 18, 2001, the President issued an Executive Order (13211) which applies to regulations that significantly affect energy supply, distribution, and use. Executive Order 13211 requires agencies to prepare Statements of Energy Effects when undertaking certain actions. Because this proposed rule is not expected to significantly affect energy supplies, distribution, or use, this action is not a significant energy action and no Statement of Energy Effects is required.

Unfunded Mandates Reform Act (2 U.S.C. 1501 et seq.)

In accordance with the Unfunded Mandates Reform Act (2 U.S.C. 1501 *et seq.*), we will use the economic analysis to further evaluate this situation.

Takings

In accordance with Executive Order 12630, the rule does not have significant takings implications. A takings implication assessment is not required. The rule will not increase or decrease current restrictions on private property concerning *Yermo xanthocephalus* because all of the critical habitat designated is on Federal land. Due to current public knowledge of the species' protection, and the fact that the plant receives protection through section 9 of the Act both within and outside of the designated areas, we do not anticipate that property values will be affected by the critical habitat designation.

Federalism

In accordance with Executive Order 13132, the rule does not have significant Federalism effects. A Federalism assessment is not required. In keeping with Department of the Interior policy, we requested information from, and coordinated development of this critical habitat designation with, appropriate State resource agencies in Wyoming. The designation of critical habitat within the geographic range occupied by *Yermo xanthocephalus* imposes no additional restrictions to those currently in place and, therefore, has little additional impact on State and local governments and their activities. The designation may have some benefit to these governments in that the area essential to the conservation of the species is more clearly defined, and the primary constituent elements of the habitat necessary to the conservation of the species are specifically identified. While defining the area essential to the conservation of *Y. xanthocephalus* and identifying primary constituent elements does not alter where and what federally sponsored activities may occur, this information may assist these local governments in long-range planning (rather than waiting for case-by-case section 7 consultations to occur).

Civil Justice Reform

In accordance with Executive Order 12988, the Office of the Solicitor has determined that the rule does not unduly burden the judicial system and meets the requirements of sections 3(a) and 3(b)(2) of the Order. We are proposing to designate critical habitat in accordance with the provisions of the Act. The rule uses standard property descriptions and identifies the primary constituent elements within the designated area to assist the public in understanding the habitat needs of *Yermo xanthocephalus.*

Paperwork Reduction Act of 1995 (44 U.S.C. 3501 et seq.)

This proposed rule does not contain any information collection requirements for which OMB approval under the Paperwork Reduction Act is required. An agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a valid OMB Control Number.

National Environmental Policy Act

Our position is that, outside the Tenth Circuit, we do not need to prepare environmental analyses as defined by the National Environmental Policy Act (NEPA) in connection with designating critical habitat under the Act. We published a notice outlining our reasons for this determination in the **Federal Register** on October 25, 1983 (48 FR 49244). This assertion was upheld in the courts of the Ninth Circuit (*Douglas County* v. *Babbitt,* 48 F .3d 1495 (Ninth Cir. Ore. 1995), cert. denied 116 S. Ct. 698 (1996)). However, when the range of the species includes States within the Tenth Circuit, pursuant to the Tenth Circuit ruling in *Catron County Board of Commissioners* v. *U.S. Fish and Wildlife Service,* 75 F .3d 1429 (Tenth Cir. 1996), we will complete a NEPA analysis. The range of *Yermo xanthocephalus* includes States within the Tenth Circuit; therefore, we are completing an Environmental Assessment and will announce its availability in the **Federal Register**.

Government-to-Government Relationship with Tribes

In accordance with the President's memorandum of April 29, 1994, ''Government-to-Government Relations with Native American Tribal Governments'' (59 FR 22951), Executive Order 13175, and 512 DM 2, we readily acknowledge our responsibility to communicate meaningfully with recognized Federal Tribes on a government-to-government basis. We have determined that there are no Tribal lands essential for the conservation of *Yermo xanthocephalus* because these lands do not support populations, or provide essential habitat. Therefore, critical habitat for *Y. xanthocephalus* has not been proposed on Tribal lands.

References Cited

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Bynum, M. 1993. Soils 5120 Term Project. Unpublished soil survey prepared for Dr. Larry Munn, University of Wyoming. 7pp.

Dorn, R.D. 1991. *Yermo xanthocephalus* (Asteraceae: Senecioneae): A New genus and Species from Wyoming. Madrono 38(3):198–201.

Fertig, W. 1995. Status Report on *Yermo xanthocephalus* in central Wyoming. Wyoming Natural Diversity Database Report to the BLM, Wyoming State Office and Rawlins District. 46pp.

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Love, J.D. 1961. Geological Survey Bulletin 112: Split Rock Formation (Miocene) and moonstone Formation (Pliocene) in central Wyoming. Contributions to General Geology. 1–I. United States Government Printing Office, Washington, DC.

Opler, P.A., H. Pavulaan, and R.E. Stanford (coordinators). 1995. Butterflies of North America. Jamestown, ND: Northern Prairie Wildlife Research Center Home Page. *http://www.npwrc.usgs.gov/resource/distr/lepid/bflyusa/bflyusa.htm* (Version 26JUN2002).

Scott, R.W. 2000. Field Studies on *Yermo xanthocephalus* Dorn: BLM Cooperative Agreement No. KAA000003, Final Report. Department of Biology, Central Wyoming College. 13pp.

Van Houten, F.B. 1964. Tertiary Geology of the Beaver Rim Area Fremont and Natrona Counties, Wyoming: Geological Survey Bulletin 1164. United States Government Printing Office, Washington, DC.

Author

The primary author of this proposed rule is Mary E. Jennings (*see* **ADDRESSES** section).

List of Subjects in 50 CFR Part 17

Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Proposed Regulation Promulgation

Accordingly, we propose to amend part 17, subchapter B of chapter I, title 50 of the Code of Federal Regulations as set forth below:

PART 17—[AMENDED]

1. The authority citation for part 17 continues to read as follows:

Authority: 16 U.S.C. 1361–1407; 16 U.S.C. 1531–1544; 16 U.S.C. 4201–4245; Pub. L. 99–625, 100 Stat. 3500; unless otherwise noted.

2. In § 17.12(h), revise the entry for *Yermo xanthocephalus* under ''FLOWERING PLANTS'' to read as follows:

§ 17.12 Endangered and threatened plants.

* * * * *

(h) * * *

Species		Historic range	Family	Status	When listed	Critical habitat	Special rules
Scientific name	Common name						
Flowering plants							
*	*	*	*	*	*		*
Yermo xanthocephalus.	Desert yellowhead ..	U.S.A. (WY)	Asteraceae—Sunflower.	T	723	17.96(a)	NA
*	*	*	*	*	*		*

3. In § 17.96, amend paragraph (a) by adding an entry for *Yermo xanthocephalus* in alphabetical order under Asteraceae to read as follows:

§ 17.96 Critical habitat—plants.

(a) * * *

Family Asteraceae: *Yermo xanthocephalus* (Desert yellowhead)

(1) Critical habitat unit is depicted for Fremont County, Wyoming, on the map below.

(2) The primary constituent elements of critical habitat for *Yermo xanthocephalus* are those habitat components that are essential for the primary needs of the species. Based upon our current knowledge of this species, the primary constituent elements include, but are not limited to:

(i) Recent soils derived from sandstones and limestones of the Split Rock Formation at its junction with the White River Formation. These are shallow, loamy soils of the Entisol order that can be classified as coarse-loamy over sandy-skeletal, mixed, Lithic Torriorthent. The surface stratum has little organic matter and subsurface layers show no accumulation of humus, clay, gypsum, salts, or carbonates.

(ii) Plant communities associated with *Yermo xanthocephalus* that include, but may not be limited to, sparsely vegetated cushion-plant communities with scattered clumps of *Oryzopsis hymenoides* (Indian ricegrass) between 2,043 and 2,073 m (6,700 and 6,800 ft) in Fremont County, Wyoming. Species common to these communities include *Arenaria hookeri* (Hooker's sandwort), *Astragalus kentrophyta* (thistle milkvetch), *Hymenoxys acaulis* (stemless hymenoxy), and *Phlox muscoides* (squarestem phlox). These cushion-plant communities also contain natural openings.

(iii) Topographic features/relief and physical processes, particularly hydrologic processes, that maintain the shape and orientation of the hollows characteristic of *Yermo xanthocephalus* and maintain moisture below the surface of the ground.

(3) The critical habitat unit occurs entirely in Fremont County, Wyoming.

(i) From U.S. Geological Survey 7.5″ quadrangle maps Dishpan Butte and Sweetwater Station, Wyoming. T. 31 N., R. 95 W., SW ¼ sec. 27, NW ¼ sec. 34, and W ½ W ½ NE ¼ sec. 34.

(ii) Map follows:

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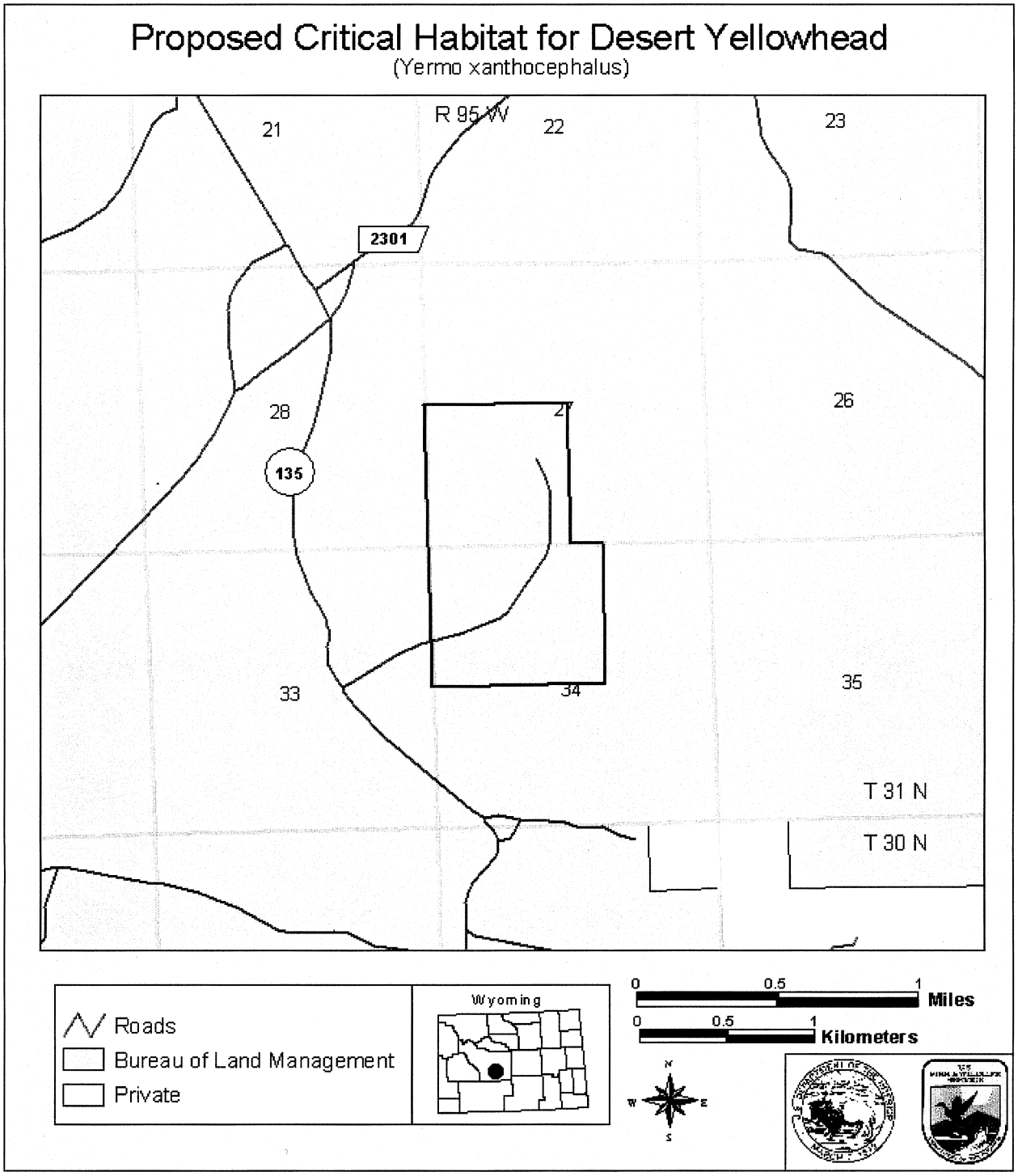

DISCLAIMER
This map is a graphical representation of (Yermo xanthocephalus) critical habitat and is provided for illustrative purposes only. The map and GIS vector files used to create this map are not the definitive source for determining critical habitat boundaries. While the Service makes every effort to represent the critical habitat shown on this map as completely and accurately as possible (given existing time, resource, data and display constraints), the USFWS gives no warranty, expressed or implied, as to the accuracy, reliability, or completeness of these data.

* * * * *

Dated: March 6, 2003.

Craig Manson,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 03–6131 Filed 3–13–03; 8:45 am]

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DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

50 CFR Part 17

RIN 1018–AI26

Endangered and Threatened Wildlife and Plants; Critical Habitat Designation for Four Vernal Pool Crustaceans and Eleven Vernal Pool Plants in California and Southern Oregon

AGENCY: Fish and Wildlife Service, Interior.

ACTION: Proposed rule; reopening of the comment period.

SUMMARY: We, the U.S. Fish and Wildlife Service (Service), announce the reopening of the comment period for the proposed rule and economic analysis to designate critical habitat pursuant to the Endangered Species Act of 1973, as amended (Act), for four vernal pool crustaceans and eleven vernal pool plants in 36 counties in California and one county in Oregon. We are reopening the comment period for the proposed rule and the draft economic analysis to allow interested parties additional time to submit comments and information to us for our consideration in making the final determination of critical habitat for the 15 vernal pool species. Comments previously submitted need not be resubmitted as they will be incorporated into the public record as part of this re-opening of the comment period, and will be fully considered in the final rule.

DATES: We will accept comments on the proposed critical habitat designation and the economic analysis until March 28, 2003.

ADDRESSES: Written comments and information should be submitted to Wayne White, Field Supervisor, Sacramento Fish and Wildlife Office, U.S. Fish and Wildlife Service, 2800 Cottage, Room W–2605, Sacramento, CA 95825. Written comments may also be sent by fax to 916/414–6710 or hand-delivered to our Sacramento Fish and Wildlife Office at the above address. You may also send comments by electronic mail (e-mail) to *fw1_vernalpool@fws.gov*.

You may view comments and materials received , as well as supporting documentation used in the preparation of this proposed rule, by appointment, during normal business hours in the U.S. Fish and Wildlife Service's Sacramento Fish and Wildlife Office at the above address. You may obtain copies of the proposed rule and the draft economic analysis from the above address, by calling (916) 414–6600, or from our Web site at *http://sacramento.fws.gov/*.

FOR FURTHER INFORMATION CONTACT: Arnold Roessler or Susan Moore, at the Sacramento Fish and Wildlife Office address above (telephone (916) 414–6600; facsimile (916) 414–6710).

SUPPLEMENTARY INFORMATION:

Background

On September 24, 2002, we published a proposed rule to designate critical habitat, pursuant to the Endangered Species Act of 1973, as amended (Act), for four vernal pool crustaceans and eleven vernal pool plants (67 FR 59884). The four vernal pool crustaceans involved in this critical habitat designation are the Conservancy fairy shrimp (*Branchinecta conservatio*), longhorn fairy shrimp (*Branchinecta longiantenna*), vernal pool fairy shrimp (*Branchinecta lynchi*) and vernal pool tadpole shrimp (*Lepidurus packardi*). The eleven vernal pool plant species are Butte County meadowfoam (*Limnanthes floccosa* ssp. *californica*), Contra Costa goldfields (*Lasthenia conjugens*), Hoover's spurge (*Chamaesyce hooveri*), succulent (or fleshy) owl's-clover (*Castilleja campestris* ssp. *succulenta*), Colusa grass (*Neostapfia colusana*), Greene's tuctoria (*Tuctoria greenei*), hairy Orcutt grass (*Orcuttia pilosa*), Sacramento Orcutt grass (*Orcuttia viscida*), San Joaquin Valley Orcutt grass (*Orcuttia inaequalis*), slender Orcutt grass (*Orcuttia tenuis*), and Solano grass (*Tuctoria mucronata*). We proposed a total of 128 units of critical habitat for these 15 species, totaling approximately 672,920 hectares (ha) (1,662,762 acres (ac)) in 36 counties in California and one county in Oregon. All the species listed above live in vernal pools (shallow depressions that hold water seasonally), swales (shallow drainages that carry water seasonally), and ephemeral freshwater habitats. None are known to occur in riverine waters, marine waters, or other permanent bodies of water. The vernal pool habitats of these species have a discontinuous distribution west of the Sierra Nevada that extends from southern Oregon through California into northern Baja California, Mexico. The species have all adapted to the generally mild climate and seasonal periods of inundation and drying which help make the vernal pool ecosystems of California and southern Oregon unique. Critical habitat receives protection from destruction or adverse modification through required consultation under section 7 of the Act with regards to actions carried out, funded, or authorized by a Federal agency. Section 4(b)(2) of the Act requires that the Secretary of the Interior shall designate or revise critical habitat based upon the best scientific and commercial data available, after taking into consideration the economic impact of specifying any particular area as critical habitat.

The public comment period for the September 24, 2002, proposal originally closed on November 25, 2002, and was extended by the November 21, 2002, notice of availability of the draft economic analysis to close on December 23, 2002. The draft economic analysis estimates the foreseeable economic impacts of the critical habitat designation on government agencies and private businesses and individuals. The Service will not make any final decisions about exclusions based on economic impact, until it has obtained public comment on the economic analysis and produced an addendum to the economic analysis containing its final conclusions. The Service is interested in comments from the public on the economic analysis, on whether any of the areas identified in the economic analysis as having economic effects should be excluded for economic reasons, and whether those or any other areas should be excluded for other reasons.

For further information regarding background biological information on the 15 vernal pool species, please refer to our proposed rule published in the **Federal Register** on September 24, 2002, (67 FR 59884).

Public Comments Solicited

We solicit additional information and comments that may assist us in making a final decision on the proposed rule to designate critical habitat for the four vernal pool crustaceans and eleven vernal pool plants. We intend that any final action resulting from our proposal will be as accurate and effective as possible. Therefore, we are reopening the comment period to solicit additional information from the general public, other concerned governmental agencies, the scientific community, industry, or any other interested party concerning this proposed rule. We particularly seek comments concerning:

(1) The reasons why any habitat should or should not be determined to be critical habitat as provided by section 4 of the Act, including whether the benefits of designation will outweigh any threats to the species due to designation and whether areas under consideration require additional special management;

(2) Specific information on the amount and distribution of any of the vernal pool crustaceans or vernal pool plants and what habitat is essential to the conservation of these species and why;

(3) Land use designations and current or planned activities in the subject areas and their possible impacts on proposed critical habitat; in particular, in Oregon, we seek information related to potential of selected parcels to contribute to the species recovery, considering their zoning, adjacent land uses, watershed integrity, and potential for edge effects (related to shape of parcel);

(4) Any foreseeable economic or other impacts resulting from the proposed designation of critical habitat, in particular, any impacts on small entities or families;

(5) Economic and other values associated with designating critical habitat for vernal pool crustaceans and vernal pool plants such as those derived from non-consumptive uses (*e.g.*, hiking, camping, bird-watching, enhanced watershed protection, improved air quality, increased soil retention, ''existence values,'' and reductions in administrative costs);

(6) Whether any areas should be excluded pursuant to section 4(b)(2);

(7) Whether our approach to critical habitat designation could be improved or modified in any way to provide for greater public participation and understanding, or to assist us in accommodating public concern and comments; and

(8) Assumptions reflected in the economic analysis regarding land use practices and current, planned, or reasonably foreseeable activities in the subject areas, including comments or information relating to the potential effects that the designation could have on private landowners as a result of actual or foreseeable State and local government responses due to the California Environmental Quality Act.

If you wish to comment on this proposed rule, you may submit your comments and materials by any one of several methods (*see* **ADDRESSES**). Please submit electronic mail comments as an ASCII file and avoid the use of special characters and any form of encryption. Please also include ''Attn: Vernal Pool Critical Habitat'' and your name and return address in your electronic message. Please note that the electronic address *fw1_vernalpool@fws.gov* will be closed out at the termination of the public comment period. If you do not receive a confirmation from the system that we have received your electronic message, contact us directly by calling our Sacramento Fish and Wildlife Office at phone number (916) 414–6600.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the rulemaking record, which we will honor to the extent allowable by law. In some circumstances, we would withhold from the rulemaking record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. However, we will not consider anonymous comments. To the extent consistent with applicable law, we will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety. Comments and materials received will be made available for public inspection, by appointment, during normal business hours at the above address.

The comment period, which originally closed on December 23, 2002 (67 FR 70202), will now close on the date specified above in the **DATES** section.

Author

The primary author of this notice is Susan Moore, (*see* **ADDRESSES** section).

Authority: The authority for this action is the Endangered Species Act of 1973 (16 U.S.C. 1531 *et seq.*).

Dated: March 7, 2003.

Craig Manson,

Assistant Secretary for Fish and Wildlife and Parks.

[FR Doc. 03–6370 Filed 3–12–03; 4:45 pm]

BILLING CODE 4310–55–P

Notices

Federal Register
Vol. 68, No. 50
Friday, March 14, 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

Food Safety and Inspection Service

[Docket No. 03–007N]

Codex Alimentarius: 31st Session of the Codex Committee on Food Labelling

AGENCY: Office of the Under Secretary for Food Safety.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Office of the Under Secretary for Food Safety, U.S. Department of Agriculture (USDA), and the Food and Drug Administration (FDA), Department of Health and Human Services, are sponsoring a public meeting on March 20, 2003, to provide information and receive public comments on agenda items that will be discussed at the 31st Session of the Codex Committee on Food Labelling (CCFL), which will be held in Ottawa, Canada, on April 28–May 2, 2003. USDA and FDA recognize the importance of providing interested parties the opportunity to obtain background information on the CCFL of the Codex Alimentarius Commission (Codex) and to address items on the Agenda for the 31st Session of the CCFL.

DATES: The public meeting is scheduled for Thursday, March 20, 2003, from 1 p.m. to 4:30 p.m.

ADDRESSES: The public meeting will be held in the Auditorium, Harvey W. Wiley Federal Building, 5100 Paint Branch Parkway, College Park, MD. To receive copies of the documents referenced in this notice, contact the FSIS Docket Clerk, U.S. Department of Agriculture, Food Safety and Inspection Service, Room 102, Cotton Annex, 300 12th Street, SW., Washington, DC 20250–3700. The documents will also be accessible via the World Wide Web at the following address: *http://www.codexalimentarius.net/current.asp*.

If you have comments, please send an original and two copies to the FSIS Docket Clerk and reference Docket Number 03–007N. All comments submitted will be available for public inspection in the Docket Clerk's Office between 8:30 a.m. and 4:30 p.m., Monday through Friday.

To gain admittance to this meeting, individuals should preregister. All registrants will need to present a photo ID for entrance into the Auditorium. To pre-register, please contact Ms. Theresa Thomas, at (301) 436–1967 or (301) 436–2636 (fax).

FOR FURTHER INFORMATION CONTACT: Ellen Matten, International Issues Analyst, U.S. Codex Office, Food Safety and Inspection Service, Room 4861, South Building, 1400 Independence Avenue SW., Washington, DC 20250; Phone: (202) 205–7760, Fax: (202) 720–3157.

SUPPLEMENTARY INFORMATION:

Background

Codex was established in 1962 by two United Nations organizations, the Food and Agriculture Organization (FAO) and the World Health Organization (WHO). Codex is the major international organization for protecting the health and economic interests of consumers and encouraging fair international trade in food. Through adoption of food standards, codes of practice, and other guidelines developed by its committees, and by promoting their adoption and implementation by governments, Codex seeks to ensure that the world's food supply is sound, wholesome, free from adulteration, and properly labeled. In the United States, USDA, FDA, and the Environmental Protection Agency manage and carry out U.S. Codex activities.

The CCFL drafts labeling provisions that are applicable to all foods; considers, amends if necessary, and endorses specific provisions on labeling of draft standards, codes of practice, and guidelines prepared by other Codex committees; studies specific labeling problems assigned to it by the Commission; and studies problems associated with the advertisement of food, with particular reference to claims and misleading descriptions. The CCFL is chaired by Canada.

Issues To Be Discussed at the Public Meeting

The provisional agenda items to be discussed during the public meeting:

1. Adoption of the Agenda.
2. Matters referred by the Codex Alimentarius Commission and other Codex Committees.
3. Consideration of Labelling Provisions in the Draft Codex Standards.
4. Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods (Class names).*
5. Draft Amendment to the *Guidelines on Nutrition Labelling* (Section 3.2 Listing of Nutrients).
6. Draft *Guidelines for the Use of Health and Nutrition Claims.*
7. (a.) Draft Recommendations for the *Labelling of Foods obtained through Certain Techniques of Genetic Modification/Genetic Engineering* (Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods): Definitions.*

   (b.) Proposed Draft Recommendations for the *Labelling of Foods obtained through Certain Techniques of Genetic Modification/Genetic Engineering* (Proposed Draft Guidelines for the *Labelling of Foods and Food Ingredients Obtained through Certain Techniques of Genetic Modification/Engineering): Labelling Provisions.*
8. *Guidelines for the Production, Processing, Labelling and Marketing of Organically Produced Foods.*

   Proposed Draft Revised Sections:

   (a) Section 5—Criteria, and

   (b) Annex 2—Permitted Substances.
9. Proposed Draft Amendment to the *General Standard for the Labelling of Prepackaged Foods: Quantitative Declaration of Ingredients.*
10. Consideration of Country of Origin Labelling.
11. Consideration of Food Labelling and Traceability.
12. Discussion *Paper on Misleading Claims.*

Each issue listed will be fully described in documents distributed, or to be distributed, by the Canadian Secretariat to the Meeting. Members of the public may access or request copies of these documents (*see* **ADDRESSES**).

Public Meeting

At the March 20th public meeting, the agenda items will be described, discussed, and attendees will have an opportunity to pose questions and offer

comments. Written comments may be offered at the meeting or sent to the FSIS Docket Room (*see* **ADDRESSES**). Written comments should state that they relate to activities of the 31st CCFL.

Additional Information

Pursuant to Departmental Regulation 4300–4, ''Civil Rights Impact Analysis,'' dated September 22, 1993, FSIS has considered the potential civil rights impact of this notice on minorities, women, and persons with disabilities.

Therefore, to ensure that these groups and others are made aware of this meeting, FSIS will announce it and provide copies of the **Federal Register** publication in the FSIS Constituent Update. FSIS provides a weekly FSIS Constituent Update, which is communicated via Listserv, a free e-mail subscription service. In addition, the update is available on line through the Internet at *http://www.fsis.usda.gov.* The update is used to provide information regarding FSIS policies, procedures, regulations, **Federal Register** notices, FSIS public meetings, recalls, and any other types of information that could affect or would be of interest to our constituents and stakeholders. The constituent Listserv consists of industry, trade, and farm groups, consumer interest groups, allied health professionals, scientific professionals, and other individuals who have requested to be included. Through the Listserv and Web page, FSIS is able to provide information to a much broader, more diverse audience. For more information, contact the Congressional and Public Affairs Office at (202) 720–9113.

To be added to the free e-mail subscription service (Listserv), go to the ''Constituent Update'' page on the FSIS Web site at *http://www.fsis.usda.gov/oa/update/update.htm.*

Click on the ''Subscribe to the Constituent Update Listserv'' link, then fill out and submit the form.

Done at Washington, DC, on March 7, 2003.

F. Edward Scarbrough,

U.S. Manager for Codex Alimentarius.

[FR Doc. 03–6122 Filed 3–13–03; 8:45 am]

BILLING CODE 3410–DM–P

DEPARTMENT OF AGRICULTURE

Forest Service

Helena National Forest Travel Plan, Helena National Forest, Broadwater, Lewis & Clark, Meagher, and Powell Counties, MT

AGENCY: Forest Service, USDA.

ACTION: Cancellation notice.

SUMMARY: On December 1, 2000, a Notice of Intent (NOI) to prepare an environmental impact statement called the Helena National Forest Travel Plan was published in the 65 FR 75236. This NOI is hereby rescinded due to elapsed time since the appearance of the NOI in the **Federal Register** and changed scope of the proposal.

FOR FURTHER INFORMATION CONTACT: Chuck Neal, Travel Plan Coordinator, Helena National Forest, 2880 Skyway Drive, Helena MT 59601, phone 406–449–5201.

Dated: March 7, 2003.

Allen L. Christophersen,

Deputy Forest Supervisor.

[FR Doc. 03–6042 Filed 3–13–03; 8:45 am]

BILLING CODE 3410–11–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List Addition and Deletions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Additions to and Deletions from Procurement List.

SUMMARY: This action adds to the Procurement List a service to be furnished by a nonprofit agency employing persons who are blind or have other severe disabilities, and deletes from the Procurement List a product and a service previously furnished by such agencies.

EFFECTIVE DATE: April 13, 2003.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, (703) 603–7740.

SUPPLEMENTARY INFORMATION: Addition: On January 10, 2003, the Committee for Purchase From People Who Are Blind or Severely Disabled published notice (68 FR 1434) of proposed additions to the Procurement List. After consideration of the material presented to it concerning capability of qualified nonprofit agencies to provide the service and impact of the addition on the current or most recent contractor, the Committee has determined that the service listed below is suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the service to the Government.

2. The action will result in authorizing small entities to furnish the service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the service proposed for addition to the Procurement List.

Accordingly, the following service is added to the Procurement List:

Service: Service Type/Location: Janitorial/Custodial, U.S. Coast Guard Cutter Aspen, Yerba Buena Island, San Francisco, California.

NPA: Toolworks, Inc., San Francisco, California.

Contract Activity: U.S. Coast Guard Integrated Support Command, Alameda, California.

Deletions:

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. The action may not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. The action may result in authorizing small entities to furnish the product and service to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the product and service deleted from the Procurement List.

After consideration of the relevant matter presented, the committee has determined that the product and service listed below are no longer suitable for procurement by the Federal Government under 41 U.S.C. 46–48c and 41 CFR 51–2.4.

Accordingly, the following product and service are deleted from the Procurement List:

Product: Product/NSN: Brush, Tooth Brush Style, 7920–00–900–3577.

NPA: None currently authorized.

Contract Activity: GSA, Southwest Supply Center, Fort Worth, Texas.

Service: Service Type/Location: Janitorial/Custodial, U.S. Courthouse and Customhouse, Toledo, Ohio.

NPA: ContracTech, Inc., Toledo, Ohio.
Contract Activity: GSA, Public Buildings Service, Great Lakes Region.

Sheryl D. Kennerly,
Director, Information Management.
[FR Doc. 03–6168 Filed 3–13–03; 8:45 am]
BILLING CODE 6353–01–P

COMMITTEE FOR PURCHASE FROM PEOPLE WHO ARE BLIND OR SEVERELY DISABLED

Procurement List; Proposed Additions and Deletions

AGENCY: Committee for Purchase from People Who Are Blind or Severely Disabled.

ACTION: Proposed additions to and deletions from Procurement List.

SUMMARY: The Committee is proposing to add to the Procurement List products and services to be furnished by nonprofit agencies employing persons who are blind or have other severe disabilities, and to delete products previously furnished by such agencies.

Comments Must Be Received on or Before: April 13, 2003.

ADDRESSES: Committee for Purchase From People Who Are Blind or Severely Disabled, Jefferson Plaza 2, Suite 10800, 1421 Jefferson Davis Highway, Arlington, Virginia 22202–3259.

FOR FURTHER INFORMATION CONTACT: Sheryl D. Kennerly, (703) 603–7740.

SUPPLEMENTARY INFORMATION: This notice is published pursuant to 41 U.S.C. 47(a)(2) and 41 CFR 51–2.3. Its purpose is to provide interested persons an opportunity to submit comments on the proposed actions.

Additions

If the Committee approves the proposed additions, the entities of the Federal Government identified in this notice for each product or service will be required to procure the products and services listed below from nonprofit agencies employing persons who are blind or have other severe disabilities.

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities other than the small organizations that will furnish the products and services to the Government.

2. If approved, the action will result in authorizing small entities to furnish the products and services to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products and services proposed for addition to the Procurement List. Comments on this certification are invited. Commenters should identify the statement(s) underlying the certification on which they are providing additional information.

The following products and services are proposed for addition to the Procurement List for production by the nonprofit agencies listed:

Products

Product/NSN: Casters, Rigid and Swivel,
5340–05–000–5758,
5340–05–000–5759.
NPA: Rauch Rehabilitation and Developmental Services, Inc., New Albany, Indiana.
Contract Activity: U.S. Postal Service, Topeka, Kansas.

Services

Service Type/Location: Administrative, Mail/Messenger and Warehouse Service, Federal Highway Administration, Eastern Federal Lands Highway Division, Sterling, Virginia.
NPA: Anchor Mental Health Association (Anchor Services Workshop), Washington, DC.
Contract Activity: Federal Highway Administration, Sterling, Virginia.
Service Type/Location: Landscaping Service, Department of Justice, Bureau of Prisons, Washington, DC.
NPA: Davis Memorial Goodwill Industries, Washington, DC.
Contract Activity: Department of Justice, Bureau of Prisons, Washington, DC.

Deletions

I certify that the following action will not have a significant impact on a substantial number of small entities. The major factors considered for this certification were:

1. If approved, the action will not result in any additional reporting, recordkeeping or other compliance requirements for small entities.

2. If approved, the action will result in authorizing small entities to furnish the products to the Government.

3. There are no known regulatory alternatives which would accomplish the objectives of the Javits-Wagner-O'Day Act (41 U.S.C. 46–48c) in connection with the products proposed for deletion from the Procurement List.

The following products are proposed for deletion from the Procurement List:

Products

Product/NSN: Case, Plotting Board, 1220–01–055–6137.
NPA: North Bay Rehabilitation Services, Inc., Rohnert Park, California.
Contract Activity: Department of the Army, Rock Island, Illinois.
Product/NSN: Patient Utility Kit, 6530–01–166–3499.
NPA: CCI Enterprises, Inc., Milwaukie, Oregon.
Contract Activity: Defense Supply Center Philadelphia, Philadelphia, PA.

Sheryl D. Kennerly,
Director, Information Management.
[FR Doc. 03–6169 Filed 3–13–03; 8:45 am]
BILLING CODE 6353–01–P

COMMISSION ON CIVIL RIGHTS

Sunshine Act Meeting Notice

AGENCY: Commission on Civil Rights.

DATES AND TIME: Friday, March 21, 2003, 9:30 a.m.

PLACE: U.S. Commission on Civil Rights, 624 Ninth Street, NW., Room 540, Washington, DC 20425.

STATUS:

Agenda

I. Approval of Agenda
II. Approval of Minutes of February 7, 2003 Meeting
III. Announcements
IV. Staff Director's Report
V. State Advisory Committee Appointments for Minnesota and Interim Appointment for Illinois
VI. Future Agenda Items
10:30 a.m. Presentation on Civil Rights Issues Affecting the Latino Community in the District of Columbia

FOR FURTHER INFORMATION CONTACT: Les Jin, Press and Communications, (202) 376–7700.

Debra A. Carr,
Deputy General Counsel.
[FR Doc. 03–6290 Filed 3–12–03; 12:29 pm]
BILLING CODE 6335–01–M

DEPARTMENT OF COMMERCE

International Trade Administration

University of Chicago; Notice of Decision on Application for Duty-Free Entry of Electron Microscope

This is a decision pursuant to section 6(c) of the Educational, Scientific, and

Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW., Washington, DC.

Docket Number: 02–052. *Applicant:* University of Chicago, Chicago, IL 60637. *Instrument:* Electron Microscope, Model Tecnai G2 F30 S–TWIN. *Manufacturer:* FEI Company, The Netherlands. *Intended Use:* See notice at 68 FR 6415, February 7, 2003. *Order Date:* December 12, 2002.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as the instrument is intended to be used, was being manufactured in the United States at the time the instrument was ordered. *Reasons:* The foreign instrument is a conventional transmission electron microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States at the time of order of the instrument.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 03–6182 Filed 3–13–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

University of Missouri—Kansas City; Notice of Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR part 301). Related records can be viewed between 8:30 a.m. and 5 p.m. in Suite 4100W, U.S. Department of Commerce, Franklin Court Building, 1099 14th Street, NW., Washington, DC.

Docket Number: 03–001. *Applicant:* University of Missouri, Kansas City, MO 64108. *Instrument:* (2) each Scanning Acoustic Microscopes, Models SAM 2000 and WINSAM 100. Manufacturer: Kramer Scientific Instruments GmbH, Germany. *Intended Use:* See notice at 68 FR 6415, February 7, 2003.

Comments: None received. *Decision:* Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States. *Reasons:* The foreign instrument provides: (1) Resolution to 0.1 μm, (2) operation at frequencies to 2 GHz and (3) analysis of surface waves by the V(z)-curve technique for acoustic subsurface analysis of novel dental materials and composites. The National Institutes of Health advises in its memorandum of January 29, 2003 that (1) these capabilities are pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

Gerald A. Zerdy,

Program Manager, Statutory Import Programs Staff.

[FR Doc. 03–6183 Filed 3–13–03; 8:45 am]

BILLING CODE 3510–DS–P

DEPARTMENT OF COMMERCE

International Trade Administration

Overseas Trade Missions

AGENCY: International Trade Administration, Department of Commerce.

ACTION: Notice.

SUMMARY: The Department of Commerce invites U.S. companies to participate in the below listed overseas trade missions. For a more complete description, obtain a copy of the mission statement from the contact officer indicated for each individual mission below.

Asian Infrastructure Trade Mission

Istanbul, Turkey, May 19–23, 2003, Recruitment closes April 21, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. Raj Dheer, U.S. Department of Commerce, telephone (202) 482–0111, or e-mail to *Raj.Dheer@mail.doc.gov.*

Electric Power Mission to Vietnam and Thailand

Hanoi, Ho Chi Minh City and Bangkok, June 21–25, 2003, Recruitment closes April 15, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. Andrew Collier, U.S. Department of Commerce, telephone (202) 482–0680, or e-mail to *Andrew_Collier@ita.doc.gov.*

Manufacturing Trade Mission to Mexico

Guadalajara, Monterrey and Mexico City, June 22–28, 2003, Recruitment closes April 30, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Yvonne Jackson, U.S. Department of Commerce, telephone (202) 482–2675, or e-mail to *Yvonne.Jackson@mail.doc.gov.*

Food Processing and Packaging Mission to Vietnam and Thailand

Hanoi, Ho Chi Minh City and Bangkok, August 11–15, 2003, Recruitment closes June 27, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Monica McFarlane, U.S. Department of Commerce, telephone (202) 482–3364, or e-mail to *Monica.McFarlane@mail.doc.gov.*

Healthcare Technologies Trade Mission to the United Kingdom and Ireland

London and Dublin, September 5–19, 2003, Recruitment closes May 30, 2003.

FOR FURTHER INFORMATION CONTACT: Mr. Bill Kutson, U.S. Department of Commerce, telephone (202) 482–2839, or e-mail to *William.Kutson@mail.doc.gov.*

Oil and Gas Equipment and Services Mission to Kazakhstan

Astana, Atyrau and Almaty, October 2–10, 2003, Recruitment closes on June 30, 2003.

FOR FURTHER INFORMATION CONTACT: Ms. Rachel Halpern, U.S. Department of Commerce, telephone (202) 482–4423, or e-mail to *Rachel.Halpern@mail.doc.gov.*

Recruitment and selection of private sector participants for these trade missions will be conducted according to the Statement of Policy Governing Department of Commerce Overseas Trade Missions dated March 3, 1997.

FOR FURTHER INFORMATION CONTACT: Mr. Thomas Nisbet, U.S. Department of Commerce, telephone (202) 482–5657, or e-mail *Tom_Nisbet@ita.doc.gov.*

Dated: March 10, 2003.

Thomas H. Nisbet,

Director, Export Promotion Coordination, Office of Planning, Coordination and Management.

[FR Doc. 03–6134 Filed 3–13–03; 8:45 am]

BILLING CODE 3510–DR–P

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 031003F]

Endangered and Threatened Species; Take of Anadromous Fish

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

ACTION: Applications for scientific research permits (1140, 1156, 1205, 1410) and permit modifications (1309, 1315).

SUMMARY: Notice is hereby given that NOAA Fisheries received four scientific research permit applications and two applications to modify existing permits related to Pacific salmon and steelhead. All of the proposed research is intended to increase knowledge of species listed under the Endangered Species Act (ESA) and to help guide management and conservation efforts.

DATES: Comments or requests for a public hearing on the applications or modification requests must be received no later than 5 p.m. Pacific daylight savings time on April 14, 2003.

ADDRESSES: Written comments on the applications or modification requests should be sent to Protected Resources Division, NOAA Fisheries, F/NWO3, 525 NE Oregon Street, Suite 500, Portland, OR 97232–2737. Comments may also be sent via fax to 503–230–5435. Comments will not be accepted if submitted via e-mail or the internet.

FOR FURTHER INFORMATION CONTACT: Garth Griffin, Portland, OR (ph: 503–231–2005, Fax: 503–230–5435, e-mail: Garth.Griffin@noaa.gov). Permit applications are available at http://www.nwr.noaa.gov.

SUPPLEMENTARY INFORMATION:

Species Covered in This Notice

The following listed species and evolutionarily significant units (ESUs) are covered in this notice:

Sockeye salmon (*Oncorhynchus nerka*): endangered Snake River (SnR); threatened Ozette Lake.

Chinook salmon (O. *tshawytscha*): endangered naturally produced and artificially propagated upper Columbia River (UCR) spring-run; threatened naturally produced and artificially propagated SnR spring/summer (S/S); threatened SnR fall; threatened lower Columbia River (LCR); threatened upper Willamette River (UWR); threatened naturally produced and artificially propagated Puget Sound.

Chum salmon (*O. keta*): threatened Columbia River (CR); threatened Hood Canal summer-run.

Steelhead (*O. mykiss*): endangered naturally produced and artificially propagated UCR; threatened SnR; threatened middle Columbia River (MCR); threatened LCR.

Authority

Scientific research permits are issued in accordance with section 10(a)(1)(A) of the ESA (16 U.S.C. 1531 et. seq) and Federal regulations governing listed fish and wildlife permits (50CFR 222–226). NOAA Fisheries issues permits and modifications based on findings that such permits and modifications: (1) are applied for in good faith; (2) if granted and exercised, would not operate to the disadvantage of the listed species that are the subject of the permit; and (3) are consistent with the purposes and policy of section 2 of the ESA. Authority to take listed species is subject to conditions set forth in the permits and modifications.

Anyone requesting a hearing on an permit or modification application listed in this document should set out the specific reasons why a hearing would be appropriate (see **ADDRESSES**). The holding of such hearing is at the discretion of the Assistant Administrator for Fisheries, NOAA.

Permit Applications Received

Permit 1140

The Northwest Fisheries Science Center (NWFSC), NOAA Fisheries in Seattle, WA requests a 5–year permit for three studies that will have annual take of juvenile threatened OC coho salmon; juvenile threatened CR chum salmon; juvenile endangered SnR sockeye salmon; juvenile threatened naturally produced and artificially-propagated SnR S/S chinook salmon; juvenile threatened SnR fall chinook salmon; juvenile threatened LCR chinook salmon; juvenile threatened UWR chinook salmon; juvenile endangered naturally produced and artificially propagated UCR spring chinook salmon; juvenile threatened naturally produced and artificially propagated PS chinook salmon; juvenile threatened SnR steelhead; juvenile threatened LCR steelhead; juvenile threatened MCR steelhead; juvenile endangered naturally produced and artificially propagated UCR steelhead; and juvenile threatened UWR steelhead.

Study 1. The NWFSC would take listed juvenile salmon and steelhead while conducting research that will assess the relationship between environmental variables, selected anthropogenic stresses, and bacterial and parasitic pathogens on disease-induced mortality in juvenile salmon in selected coastal estuaries and nearshore areas in Oregon and Washington. In addition, the NWFSC proposes to gather additional site-specific information in the Lower Columbia River to (1) determine contaminant concentrations in fish, (2) understand bioaccumulation in juvenile salmon and determine site-specific factors, (3) analyze for the presence of physiological biomarkers, and to (4) investigate the presence of indicators of exposure to environmental estrogens. The NWFSC would collect samples with seines or high speed rope trawls, and requests authorization to lethally take salmon for pathogen prevalence and intensity, biochemical composition, histopathological attributes, and stomach content analyses.

Study 2. The NWFSC would take listed juvenile PS chinook salmon while conducting research activities in the Duwamish waterway in the state of Washington. The NWFSC will investigate salmon exposure to contaminants and evaluate the extent of river contamination to determine what actions will be necessary to mitigate future exposure. Beach seines will be used to catch juvenile threatened PS chinook salmon. The NWFSC also would collect samples with high speed rope trawls and it requests authorization to lethally take salmon for contaminant analysis.

Study 3. The NWFSC would take juvenile PS chinook salmon associated with an assessment and monitoring program designed to (1) characterize the estuarine ecology of existing life history types of chinook salmon, (2) evaluate the performance of estuarine habitat restoration actions, and (3) evaluate the effects of shoreline alterations on nearshore fishes. Sampling will occur in Seattle, WA estuarine nearshore areas. The NWFSC would collect listed salmon with beach seines, enclosure nets, surface trawl nets, and block/fyke nets, sample the fish for biological data and stomach contents using non-lethal evacuation, and then release them. In addition, the NWFSC requests authorization to lethally take salmon for histopathological attributes and otolith stomach content analyses.

Permit 1156

The U.S. Environmental Protection Agency (EPA) in Corvallis, Oregon (OR) requests a 5–year permit for annual take of juvenile and adult threatened LCR steelhead; threatened MCR steelhead; endangered naturally-produced and artificially propagated UCR steelhead;

threatened SnR steelhead; threatened UWR steelhead; threatened SnR (S/S) chinook salmon; threatened SnR fall chinook salmon; threatened LCR chinook salmon; threatened UWR chinook salmon; endangered naturally produced and artificially propagated UCR spring chinook salmon; threatened naturally produced and artificially propagated PS chinook salmon; threatened OC coho salmon; and threatened SONCC coho salmon associated with research designed to assess species status and trends in randomly selected river systems in Oregon, Washington, and Idaho. The EPA intends to conduct annual surveys for fish, macroinvertebrate, algae, and microbial assemblages as well as physical and chemical habitat conditions in randomly selected river-systems in Oregon, Washington, and Idaho. Listed fish will be captured by electrofishing (using backpack or raft-mounted gear), sampled for biological information, and released. The research will benefit the listed species by providing baseline information about water quality in the study areas and will also support enforcement of the Clean Water Act in those river systems where listed fish are present. Dynamac Corporation, U.S. Geological Survey Biological Resources Division, Idaho Department of Environmental Quality, and Washington Department of Ecology will be cooperators in the proposed EPA research. The EPA requests the cooperators' biologists be authorized as agents of the EPA in conducting the research.

Permit 1205

The Oregon Department of Environmental Quality (ODEQ) in Portland, OR requests a 5–year permit for annual take of juvenile threatened SnR (S/S) chinook salmon; SnR fall chinook salmon; and SONCC coho salmon associated with research designed to assess the condition of randomly selected streams in Southwestern and Northeastern Oregon. The research involves stream vertebrate surveys that are part of a monitoring program that evaluates the chemical, biological, and habitat conditions of streams on a regional basis. ODEQ's research implements the Oregon Plan and is coordinated with the Oregon Department of Fish and Wildlife and the EPA. ODEQ would capture listed juvenile salmonids using backpack electrofishing, sample them for biological information, and release them. The research will benefit the listed species by providing baseline information to support enforcement of the Clean Water Act in freshwater river systems where listed fish are present.

Permit 1410

The NNWFSC in Seattle, WA requests a 5–year permit for annual take of adult and juvenile listed fish. The NWFSC proposes to investigate the distribution, abundance, condition and health of juvenile salmon in relation to physical and biological oceanographic conditions in the Columbia River plume and surrounding ocean environment to better understand factors controlling estuarine and marine survival. The study will provide information to help predict and forecast survival potential as a function of easily measured indices of plume and ocean conditions. Further, the information will help hydropower operators develop a set of hydropower management scenarios that could benefit survival, growth, and health of juvenile salmon by changing the dynamics of the Columbia River plume. Listed fish will be collected with purse seines and trawl nets, sampled for biological data, and released. The NWFSC also requests authorization to lethally take salmon for endocrine assessments, genetic stock identification, pathogen prevalence and intensity, otolith and stomach content analysis, and histopathological attributes.

Modification Requests

Permit 1309–Modification 2

The King County Department of Natural Resources and Parks (KCDNRP) in Seattle, WA requests a modification to permit 1309 for increased annual take of juvenile threatened naturally produced PS chinook salmon associated with its current study examining the behavior of juvenile chinook and other salmonids in the Green and Duwamish Rivers and adjacent nearshore areas in the State of Washington. The study will provide information about natural chinook salmon growth, timing of migration, feeding, life history types and interactions with hatchery salmon. Resource managers will use the information to take short-term conservation measures as well as to establish a baseline to gauge the long-term effectiveness of ESA recovery actions. In addition, the KCDNR requests authorization to lethally take PS chinook salmon for otolith and diet analysis and to capture listed fish using a screw trap.

Permit 1315–Modification 2

The U.S. Army Corp of Engineers Seattle District (COE) requests a modification to permit 1315, which authorizes annual take of PS chinook salmon under several studies. The COE is proposing to micro-acoustic tag naturally produced PS chinook salmon associated with an ongoing investigation of fish passage conditions at the large lock chamber of the Hiram M. Chittenden Locks and Lake Washington Ship Canal in the State of Washington. The study will identify effects on salmonids in the Lake Washington Basin and help researchers (1) identify limiting factors contributing to smolt survival, (2) develop smolt survival estimates, and (3) assess restoration measures to improve smolt survival.

Further, the COE is requesting annual take of juvenile naturally produced PS chinook salmon associated with a new study which will provide it and the city of Seattle with information on salmonid nearshore habitat use in Lake Washington and the Lake Washington Ship Canal. The information will help (1) determine the relationship between habitat use and shoreline development, (2) guide the city's habitat restoration efforts to improve habitat conditions, (3) help predict the effects of modifications to salmonid habitat, and (4) and aid Lake Washington area municipalities with their shoreline management programs. Listed fish would be captured by beach seine, anesthetized, sampled for biological information and stomach contents using non-lethal evacuation, tagged/marked, and released.

This notice is provided pursuant to section 10(c) of the ESA. NOAA Fisheries will evaluate the applications and modification requests, associated documents, and any comments submitted to determine whether the applications and modification requests meet the requirements of section 10(a) of the ESA and Federal regulations. NOAA will not make any final determinations until after the end of the 30–day comment period. NOAA Fisheries will publish notice of its final action in the **Federal Register**.

Dated: March 11, 2003.

Barbara Schroeder,

Acting Chief, Endangered Species Division, Office of Protected Resources, National Marine Fisheries Service.

[FR Doc. 03–6199 Filed 3–13–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

[I.D. 021903B]

RIN 0648–AQ24

Fisheries of the Caribbean, Gulf of Mexico, and South Atlantic; Reef Fish Fishery of the Gulf of Mexico; Rebuilding Plan for Greater Amberjack in the Gulf of Mexico

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

ACTION: Notice of availability of a Secretarial amendment; request for comments.

SUMMARY: NMFS announces that the Secretary of Commerce (Secretary), acting through the Gulf of Mexico Fishery Management Council (Council), has prepared Secretarial Amendment 2 to the Reef Fish Fishery Management Plan (Secretarial Amendment 2) that would establish a 10–year stock rebuilding plan for greater amberjack in the Gulf of Mexico. The rebuilding plan consists of a series of 3–year management goals and the associated management measures and actions necessary to achieve those goals, as determined by the status of the stock during each of the 3–year intervals. Secretarial Amendment 2 also establishes biomass-based stock rebuilding targets and thresholds (i.e., maximum sustainable yield (MSY), optimum yield (OY), maximum fishing mortality threshold (MFMT), and minimum stock size threshold (MSST)), consistent with the requirements of the Sustainable Fisheries Act of 1996 (SFA). The intended effect of Secretarial Amendment 2 is to prevent overfishing and rebuild the greater amberjack resource consistent with the requirements of the Magnuson-Stevens Fishery Conservation and Management Act (Magnuson-Stevens Act) while minimizing, to the extent practicable, adverse economic impacts on all users of the resource and the affected fishing communities.

DATES: Comments must be received no later than 4:30 p.m., eastern time, on May 13, 2003.

ADDRESSES: Written comments on Secretarial Amendment 2 must be sent to Phil Steele, Southeast Regional Office, NMFS, 9721 Executive Center Drive N., St. Petersburg, FL 33702. Comments may also be sent via fax to 727–570–5583. Comments will not be accepted if submitted via e-mail or Internet.

Requests for copies of Secretarial Amendment 2, which includes an environmental assessment and a regulatory impact review (RIR) should be sent to the Gulf of Mexico Fishery Management Council, 3018 U.S. Highway 301 North, Suite 1000, Tampa, FL 33619–2266; telephone: 813–228–2815; fax: 813–225–7015; e-mail: *gulf.council@noaa.gov*.

FOR FURTHER INFORMATION CONTACT: Phil Steele, telephone: 727–570–5305, fax: 727–570–5583, e-mail: *Phil.Steele@noaa.gov*.

SUPPLEMENTARY INFORMATION: The reef fish fishery in the exclusive economic zone of the Gulf of Mexico is managed under the Fishery Management Plan for the Reef Fish Resources of the Gulf of Mexico (FMP). The FMP was prepared by the Council, and is implemented under the authority of the Magnuson-Stevens Act by regulations at 50 CFR part 622.

Background

The greater amberjack resource in the Gulf of Mexico was declared overfished by NMFS on February 9, 2001. This determination was based on the 2000 greater amberjack stock assessment (using data through 1998) conducted by the NMFS Southeast Fisheries Science Center and the December 2000 Report of the Reef Fish Stock Assessment Panel (RFSAP). The results of several analyses indicated that the stock biomass was below the level needed to sustain harvest at MSY, with the best estimate indicating that the stock biomass was at less than half the biomass needed to sustain MSY, which is below the minimum level allowed under the 1998 NMFS National Standard Guidelines.

Further, the RFSAP concluded in its December 2000 report that the greater amberjack stock may not be experiencing overfishing if regulations previously implemented by the Council, but not factored into the 2000 stock assessment, have reduced fishing mortality. These regulations include: (1) an annual Gulf-wide closed season for greater amberjack from March through May (implemented in 1998); (2) a reduced bag limit for greater amberjack, from three to one fish per person (implemented in 1997); and (3) bag and size limits for lesser amberjack and for banded rudderfish, which are often mistaken for greater amberjack (implemented in 1999). NMFS concurred with this conclusion, stating in the February 9, 2001, letter to the Council that ''the Gulf of Mexico greater amberjack stock is overfished, but is not experiencing overfishing.'' A 2002 analysis, which incorporated recent landings data through the year 2000, indicated that overfishing had indeed been halted. Because overfishing has been halted, and because recent landings have been below levels required to rebuild the stock within a 10–year time frame, the rebuilding plan alternatives considered in this document do not contain additional management measures to further reduce fishing mortality.

Currently, the FMP requires that overfished stocks be restored to a level of 20 percent transitional spawning potential ratio within a time period equal to one and one-half times the average time it would take a year class in an unfished population to replace itself, also known as the generation time. However, in order to comply with the requirements of the Magnuson-Stevens Act, as amended by the Sustainable Fisheries Act, new biomass-based targets and recovery time frame parameters need to be implemented.

This Secretarial Amendment proposes to establish these new biomass-based targets and thresholds for greater amberjack, as well as a schedule to rebuild the stock to a non-overfished level within 10 years. Proposed actions in the amendment include setting total allowable catch (TAC) for 3–year intervals with TAC being set at the yield associated with year one of the 3–year interval from the constant F40% rebuilding stream. Proposed TAC will be 2.9 million lb (1.3 million kg) for the years 2003–2005, 5.2 million lb (2.4 million kg) for years 2006–2008, 7.0 million lb (3.2 million kg) for years 2009–2011, and 7.9 million lb (3.6 million kg) for 2012. Additionally, the amendment contains definitions of MSY and OY and adds new stock status determination criteria regarding definitions of ''overfished'' (minimum stock size threshold) and ''overfishing'' (maximum fishing mortality threshold). The amendment proposes no changes to the current fishing regulations for greater amberjack.

Procedural Aspects of Secretarial Amendment 2

The Council has proposed Secretarial Amendment 2 for NMFS' review, approval, and implementation. However, neither the proposed biomass-based stock rebuilding targets and thresholds nor the initial phase (2003–2005) of the greater amberjack rebuilding plan involve changes to the regulations; therefore, no proposed or final rule is required at this time. NMFS' decision to adopt Secretarial Amendment 2 will be based on

consideration of comments, recommendations, views, and information received during the comment period on this notice of availability. After consideration of these factors, NMFS will publish a notice of agency action in the **Federal Register** announcing the agency's decision to approve, partially approve, or disapprove Secretarial Amendment 2 and the associated rationale. If approved, the provisions of Secretarial Amendment 2 would not be specified in regulations but would be considered to be amendments to the FMP. To the extent that management measures resulting from the rebuilding plan after 2005, or any that might result from routine monitoring prior to 2005, require changes to the regulations, such changes would be implemented via plan amendment or regulatory amendment with associated proposed rules, public comment, and final rules.

Consideration of Public Comments

Public comments received by 4:30 p.m. eastern time, on May 13, 2003 will be considered by NMFS in the approval/disapproval decision regarding Secretarial Amendment 2.

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

Dated: March 10, 2003.

Richard W. Surdi,

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

[FR Doc. 03–6197 Filed 3–13–03; 8:45 am]

BILLING CODE 3510–22–S

DEPARTMENT OF ENERGY

Renewable Energy Development On Tribal Lands

AGENCY: Golden Field Office, U.S. Department of Energy.

ACTION: Notice of issuance of solicitation for financial assistance applications number DE–PS36–03GO93002.

SUMMARY: The U.S. Department of Energy (DOE), pursuant to the DOE Financial Assistance Rules, 10 CFR 600.8, is announcing its intention to solicit applications for the development of renewable energy on Tribal lands. Under the solicitation, DOE is soliciting applications for financial assistance from Federally-recognized Tribes or Alaskan Native Corporations (hereafter referred to as ''Tribes'') to either: (1) Conduct feasibility studies for the development of economically sustainable renewable energy installations on Tribal Lands; or (2) implement sustainable renewable energy development projects.

DATES: Issuance of the solicitation is planned for early March 2003.

ADDRESSES: To obtain a copy of the solicitation, once issued, interested parties should access the DOE Golden Field Office Home Page at *http://www.golden.doe.gov/businessopportunities.html,* click on ''Solicitations,'' and then access the solicitation number identified above. The DOE Golden Field Office Home Page will provide a link to the solicitation synopsis in the Industry Interactive Procurement System (IIPS) Web site and provides instructions on using IIPS. The solicitation will be available directly through IIPS at *http://e-center.doe.gov* by browsing opportunities by Contract Activity, for those solicitations issued by the Golden Field Office. To be notified when the solicitation is issued, join the Solicitation Mailing List specific to this notice through IIPS. DOE will not issue paper copies of the solicitation. For questions regarding the operation of IIPS, contact the IIPS Help Desk at *IIPS_HelpDesk@e-center.doe.gov* or at (800) 683–0751.

FOR FURTHER INFORMATION CONTACT: Tammie Lawler, Contract Specialist, via facsimile at 303–275–4788 or electronically at *tribalgo93002@go.doe.gov.* Responses to questions will be made by amendment to the solicitation and posted on the DOE Industry Interactive Procurement System (IIPS) Web site.

SUPPLEMENTARY INFORMATION: DOE's Tribal Energy Program promotes tribal energy self-sufficiency and fosters employment and economic development on Tribal Lands through financial assistance to Native American Tribes and Alaskan Native Corporations for feasibility studies and renewable energy development projects. Under this solicitation, DOE will be soliciting applications for financial assistance from Federally-recognized Tribes or Alaskan Native Corporations (hereafter referred to as ''Tribes'') to either: (1) Conduct feasibility studies for the development of economically sustainable renewable energy installations on Tribal Lands; or (2) implement sustainable renewable energy development projects.

Eligible technologies under this solicitation include, but are not limited to the following: photovoltaic (solar electric), concentrating solar power, solar thermal systems (*i.e.*, active or passive solar technologies for space or water heating, or power generation technologies), wind, biomass power, hydro, geothermal electric generation, geothermal resources for direct heating and cooling applications, and other renewable hybrid systems. Applications may include, but are not limited to, the use of renewable energy for: direct electrical generation, building uses, water pumping, or other grid connected or off-grid power uses.

DOE will only consider applications from Federally-recognized Tribes on whose Tribal Lands the project will be located. Applications from a consortium will be accepted but must be submitted by a single Tribe representing the consortium. A Statement of Commitment from an authorized representative of the Tribe (Chief, Governor, President, Chairperson or other representative able to commit the Tribe), that includes a Statement of Commitment from each participant will be required as part of the application. For Development Project Applications, a Tribal Council Resolution or a commitment and a plan to obtain a Resolution is required. Awards under this solicitation will be grants or cooperative agreements with terms of one to three years depending on the type and scope of the proposed project. Subject to funding availability, the total DOE funding available under this solicitation is estimated at between $2,000,000 to $3,000,000. DOE anticipates selecting 5 to 10 Renewable Energy Feasibility Study Applications and 3 to 5 Renewable Energy Development Project Applications for negotiation toward award. No cost share is required in order to be considered for feasibility study awards under this solicitation. For development projects, a minimum cost share of 20% of total project costs (DOE funds plus Cost Share) is required to be considered for award. Solicitation number DE–PS36–03GO93002 will include complete information including technical aspects, funding, application preparation instructions, evaluation criteria, and other factors that will be considered when selecting applications for funding. Issuance of the solicitation is planned for early March 2003, with applications due approximately 60 days after the solicitation has been issued. Information on Financial Assistance Regulations (10 CFR 600), proposal forms, award format, or post award forms can be obtained through the DOE Golden Field Office Home Page *http://www.golden.doe.gov/businessopportunities.html.*

Issued in Golden, Colorado, on March 4, 2003.

Jerry L. Zimmer,

Director, Office of Acquisition and Financial Assistance.

[FR Doc. 03–6167 Filed 3–13–03; 8:45 am]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

Office of Energy Efficiency and Renewable Energy

State Energy Advisory Board Meeting

AGENCY: Department of Energy.

ACTION: Notice of open meeting.

SUMMARY: This notice announces a meeting of the State Energy Advisory Board. Federal Advisory Committee Act (Pub. L. 92–463; 86 Stat. 770) requires that public notice be announced in the **Federal Register**.

DATES: March 17, 2003, from 8 a.m. to 5 p.m., and March 18, 2003, from 8 a.m. to 1 p.m.

ADDRESSES: Washington Marriott Hotel, 1221 22nd Street, NW., Washington, DC 20037.

FOR FURTHER INFORMATION CONTACT: William J. Raup, Office of Planning, Budget, and Outreach, Energy Efficiency and Renewable Energy, U.S. Department of Energy (DOE), Washington, DC 20585, Telephone 202/586–2214.

SUPPLEMENTARY INFORMATION:

Purpose of the Board: To make recommendations to the Assistant Secretary for Energy Efficiency and Renewable Energy regarding goals and objectives and programmatic and administrative policies, and to otherwise carry out the Board's responsibilities as designated in the State Energy Efficiency Programs Improvement Act of 1990 (Pub. L. 101–440).

Tentative Agenda:

- STEAB Committee updates
- STEAB Annual Report Update
- State Success Stories
- Discussion Sessions with the Office of Energy Efficiency and Renewable Energy, USDOE Staff
- STEAB Presentations on SEP metrics to EERE staff and Office of Management and Budget Staff
- Public Comment Period

Public Participation: The meeting is open to the public. Written statements may be filed with the Board either before or after the meeting. Members of the public who wish to make oral statements pertaining to agenda items should contact William J. Raup at the address or telephone number listed above. The Chair of the Board is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. This notice is being published less than 15 days before the date of the meeting due to the late resolution of programmatic issues.

Minutes: The minutes of the meeting will be available for public review and copying within 60 days at the Freedom of Information Public Reading Room, 1E–190, Forrestal Building, 1000 Independence Avenue, SW., Washington, DC, between 9 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

Issued in Washington, DC, on March 12, 2003.

Rachel Samuel,

Deputy Advisory Committee Management Officer.

[FR Doc. 03–6328 Filed 3–12–03; 2:53 pm]

BILLING CODE 6450–01–P

DEPARTMENT OF ENERGY

[Solicitation Number DE–SC04–2003AL68471]

National Nuclear Security Administration; Availability of Solicitation for Research and Development for Reduction in Parasitic Energy Losses in Class 3–8 Trucks

AGENCY: National Nuclear Security Administration, Department of Energy.

ACTION: Notice of availability of solicitation.

SUMMARY: The National Nuclear Security Administration (NNSA) Service Center, Albuquerque, NM, is seeking applications for energy efficiency improvements and emissions reduction. Through this solicitation, NNSA seeks to improve the energy efficiency and emissions performance of Class 1–8 trucks through the use of advanced diesel engines, emission control technologies, hybrid electric propulsion systems, and reduction of parasitic energy losses. This solicitation primarily addresses the parasitic (non engine) energy losses that account for about 45% of the total losses in class 7–8 on-highway trucks, and various amounts in class 3–6 trucks, depending on their duty cycle. A NNSA technical panel will perform a scientific and engineering evaluation of each responsive application to determine the merit of the approach. NNSA anticipates issuing one or more financial assistance instruments from this solicitation. Funding in the amount of $2,000,000 for the first year period is anticipated to be available. Cost sharing of 50% by the applicant is required.

DATES: Applications are to be received no later than 4 p.m. local prevailing time on May 1, 2003. Any application received after the due date and time will not be evaluated.

FOR FURTHER INFORMATION CONTACT: Erwin E. Fragua, Contract Specialist, NNSA/OBS, at (505) 845–6442 or by e-mail at *efragua@doeal.gov.*

SUPPLEMENTARY INFORMATION: The solicitation will be available on the Internet on or about March 10, 2003 at the following Web site: *http://e-center.doe.gov.* Applications must be prepared and submitted in accordance with the instructions and forms contained in the solicitation. For profit and not-for-profit organizations, state and local governments, Indian tribes, and institutions of higher learning are eligible for awards under this solicitation. Teaming arrangements, led by an industrial partner, are required, especially among tractor and trailer manufacturers, engine manufacturers, and component suppliers to take advantage of the best complementary technologies available. The solicitation number for this action is DE–SC04–2003AL68471.

Issued in Albuquerque, New Mexico, March 4, 2003.

William L. McCullough,

Contracting Officer, Acquisition and Financial Assistance Department, NNSA Service Center.

[FR Doc. 03–6166 Filed 3–13–03; 8:45 am]

BILLING CODE 6450–01–P

ENVIRONMENTAL PROTECTION AGENCY

[Docket ID No. OW–2003–0013; FRL–7464–9]

Agency Information Collection Activities: Title IV of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002: Drinking Water Security and Safety (Act); 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 Notice announces that the following Information Collection Request (ICR) will be forwarded to the Office of Management and Budget (OMB) for review and approval: Information Collection Request for Title IV of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002: Drinking Water Security and Safety (Act). Today's notice invites comment on EPA's proposed ICR. EPA also solicits comment on its intention to seek an emergency clearance from OMB to begin collecting data from community water systems (CWS) that are required to comply with the Act.

DATES: The Agency requests comments on today's notice. Comments must be received or postmarked by midnight March 24, 2003. If EPA does not receive adverse comments on or before this date regarding EPA's request for emergency clearance, EPA intends to seek a 180-day emergency clearance from OMB to begin collecting information from CWSs.

ADDRESSES: Follow the detailed instructions in **SUPPLEMENTARY INFORMATION.**

FOR FURTHER INFORMATION CONTACT: For more information, or to obtain a copy of the draft Public Health Security and Bioterrorism Preparedness and Response Act ICR without charge, please contact Roy Rathbun, U.S. EPA, Office of Groundwater and Drinking Water (4601M), 1200 Pennsylvania Ave, NW; Washington DC 20460. Phone: (202) 564–9932; fax (202) 564–3753; E-mail: *rathbun.roy@epa.gov.*

SUPPLEMENTARY INFORMATION:

I. General Information

A. Who Is Affected by This Action?

Entities affected by this action are community water systems (CWSs) that serve a population greater than 3,300 persons. A CWS means a public water system which serves at least 15 service connections used by year-round residents or regularly serves at least 25 year-round residents.

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–2003–0013. 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 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 material, please call (202) 566–2426 to schedule an appointment.

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 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. 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.

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 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.

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. Once in the system, select ''search,'' and then key in Docket ID No. OW–2003–0013. 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–2003–0013. 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 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 an original and three copies of your comments and any enclosures to: Water Docket, Environmental Protection Agency, Mail Code 4101T, 1200 Pennsylvania Ave., NW, Washington, DC, 20460, Attention Docket No. OW–2003–0013.

3. By Hand Delivery or Courier. Deliver your comments to: Water Docket, Environmental Protection Agency, EPA West, Room B102, 1301 Constitution Ave., NW., Washington DC, Attention Docket ID No. OW–2003–0013. Such deliveries are only accepted during the Docket's normal hours of operation as identified in section I.B.1

D. 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 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 your estimate.
5. Provide specific examples to illustrate your concerns.
6. Offer alternatives.
7. Make sure to submit your comments by the comment period deadline identified.
8. To ensure proper receipt by EPA, identify the appropriate docket identification number in the subject line on the first page of your response. It would also be helpful if you provided the name, date, and **Federal Register** citation related to your comments.

E. Title: Title IV of the Public Health Security and Bioterrorism Preparedness and Response Act of 2002: Drinking Water Security and Safety EPA ICR Number 2103.01. This is a request for a new information collection, and a notification that EPA will seek an emergency clearance from OMB to begin collecting information.

F. Abstract: Title IV of the *Public Health Security and Bioterrorism Preparedness and Response Act of 2002* (Pub. L. 107–188) (Act) amends the Safe Drinking Water Act (SDWA). The Act requires each community water system (CWS) serving a population of more than 3,300 people to conduct a vulnerability assessment of its water system and to prepare or revise an emergency response plan that incorporates the results of the vulnerability assessment. EPA will use the information collected under this ICR to determine whether CWSs have conducted vulnerability assessments and prepared or revised emergency response plans in compliance with the Act.

Primary users of the information collected under this ICR include the EPA Office of Ground Water and Drinking Water, EPA Regional Administrators, and CWSs. EPA will comply with the Bioterrorism Act, which strictly limits the use of some of this 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.

G. Burden Statement: The annual public reporting and recordkeeping burden for this collection of information is estimated to average 117.9 hours per response. 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: Community water systems serving populations greater than 3,300 persons.

Estimated Number of Respondents: 8,487 systems.

Frequency of Response: Varies based on statutory schedule and system size.

Estimated Total Annual Hour Burden: 2,652,392 hours.

Estimated Total Annual Cost: $156,540,365; includes $82,211 O&M costs and $0 capital and startup costs.

Dated: March 6, 2003.

Peter E. Shanaghan,

Acting Director, Office of Ground Water and Drinking Water.

[FR Doc. 03–6193 Filed 3–13–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6338–4]

Environmental Impact Statements; Notice of Availability

Responsible Agency: Office of Federal Activities, General Information, (202) 564–7167 or *http://www.epa.gov/compliance/nepa/*

Weekly receipt of Environmental Impact Statements filed March 3, 2003, through March 7, 2003, pursuant to 40 CFR 1506.9.

EIS No. 030088, Final EIS, NPS, AZ, Tonto National Monument, General Management Plan, New Administrative Facility Construction within the Monument Boundaries, Implementation, AZ, Wait Period Ends: April 14, 2003, Contact: Lee Baiza (928) 467–2241. This document is available on the Internet at: *http://planning.nps.gov/plans.cfm.*

EIS No. 030089, Final EIS, COE, TX, North Padre Island Storm Damage Reduction and Environmental Restoration Project, Construction of a Channel between the Laquna Madre and the Gulf of Mexico across North Padre Island referred to as Packery Channel Project, Nueces County, IL, Wait Period Ends: April 14, 2003, Contact: Carolyn Murphy (409) 766–3044.

EIS No. 030090, Final EIS, AFS, AZ, Flagstaff/Lake Mary Ecosystem Analyses Area, Amendment to the Coconino Forest Plan, Implementation, Coconino National Forest, Peaks and Mormon Lake Ranger Districts, Coconino County, AZ, Wait Period Ends: April 14, 2003, Contact: Debbie Kill (928) 526–0866. This document is available on the Internet at: *http://www.fs.fed.us/r3/coconino/nepa.*

EIS No. 030091, Draft EIS, AFS, CA, Silver Pearl Land Exchange Project, Proposal to Exchange 2,153 Acres of National Forest System (NFS) Land for up to 3,963 Acres of Sierra Pacific Industries Land (SPI) Land, within the boundary of Eldorado National Forest, Eldorado and Placer County, CA, Comment Period Ends: April 28, 2003, Contact: Elaine Gee (530) 333–5568.

EIS No. 030092, Draft EIS, COE, FL, Miami Harbor Navigation Improvements Project, To Study the Feasibility of Widening and Deepening Portions of the Port, Miami-Dade County, FL, Comment Period Ends: May 4, 2003, Contact: Terri Jordan (904) 232–1817.

EIS No. 030093, Draft EIS, BLM, CO, Gunnison Gorge National

Conservation Area Resource Management Plan, Implementation, Montrose and Delta Counties, CO, Comment Period Ends: June 16, 2003, Contact: Bill Bottomly (970) 240–5337. This document is available on the Internet at: *http://www.gunnison-gorge-eis.com.*

EIS No. 030094, Draft EIS, EPA, AK, Pogo Gold Mine Project, Construct and Operate an Underground Mine, NPDES and U.S. Army COE Section 404 Permits, Goodpaster River Valley, Delta Junction, AK, Comment Period Ends: May 13, 2003, Contact: Hanh Gold (206) 553–0171. This document is available on the Internet at: *http://www.pogomineeis.com.*

EIS No. 030095, Draft EIS, FRC, CA, El Dorado Hydroelectric Project, Application for a New License, South Fork of the American River Basin, and Truckee River Basin, (FERC NO. 184–065) (FERC NO. 184–065), EL Dorada National Forest, Lake Tahoe Basin Management Unit, Alpine, Amador and EL Dorada Counties, CA, Comment Period Ends: April 28, 2003, Contact: Susan O'Brien (202) 502–8449.

EIS No. 030096, Draft EIS, BLM, NV, Black Rock Desert—High Rock Canyon Emigrant Trails National Conservation Area (NCA) and Associated Wilderness, and Other Contiguous Lands, Resource Management Plan, Implementation, Great Basin, NV, Comment Period Ends: June 16, 2003, Contact: Ester Hutchison (775) 623–1523. This document is available on the Internet at: *http://www.BlackRockHighRock.org.*

Amended Notices

EIS No. 030080, Draft EIS, AFS, SC, Sumter National Forest Revised Land and Resource Management Plan, Implementation, Oconee, Chester, Fairfield, Laurens, Newberry, Union-Abbeville, Edgefield, Greenwood, McCormick and Saluda Counties, SC, Comment Period Ends: June 21, 2003, Contact: Jerome Thomas (803) 561–4000. Revision of FR Notice Published on 3/7/2003: Correction to Comment Period from 4/21/2003 to 6/21/2003.

Dated: March 11, 2003.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 03–6195 Filed 3–13–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[ER–FRL–6638–5]

Environmental Impact Statements and Regulations; Availability of EPA Comments

Availability of EPA comments prepared pursuant to the Environmental Review Process (ERP), under section 309 of the Clean Air Act and section 102(2)(c) of the National Environmental Policy Act as amended. Requests for copies of EPA comments can be directed to the Office of Federal Activities at (202) 564–7153.

An explanation of the ratings assigned to draft environmental impact statements (EISs) was published in the **Federal Register** dated April 12, 2003 (67 FR 17992).

Draft EISs

ERP No. D–AFS–J65372–CO Rating EC2, Trout-West Hazardous Fuels Reduction Project, Proposed Action to Reduce Fuels, Pike-San Isabel National Forest, Trout and West Creek Watersheds, Teller, El Paso and Douglas Counties, CO.

Summary: EPA expressed environmental concerns about impacts to aquatic resources, including 303(d)-listed streams. EPA recommended mitigation measures to improve impaired conditions in these streams with protecting structures and allowing timber harvest and other fuels treatment in designated high-value management areas.

ERP No. D–AFS–L65410–ID Rating EC2, Gaylord North Timber Sale Project, Harvesting Timber, Council Ranger District, Payette National Forest, Adam County, ID.

Summary: EPA expressed environmental concerns with the lack of substantive differences between the alternatives and that road closures and decommissioning should better meet Forest Plan road density standards for wildlife. EPA requested the FEIS include more detail on the management of closed roads and present a clearer analysis of cumulative impacts including comparison of predicted impacts to established resource threshold.

ERP No. D–NPS–L65413–WA Rating NS, Fort Vancouver National Historic Site, General Management Plan and Development Concept Plans, Implementation, Oregon County, WA.

Summary: EPA Region 10 used a screening tool to conduct a limited review of this action. Based upon the screen, EPA does not foresee having any environmental objections to the proposed project.

Final EISs

ERP No. F–AFS–D65014–00, American Electirc Power 765 kV Transmission Line Construction, Operation and Maintenance, Wyoming Station to Cloverdale Station, Special Use Permit Issuance and Right-of-Way Grants Federal and Non-Federal Lands, George Washington and Jefferson National Forests, several counties, WV and VA.

Summary: EPA expressed environmental concerns from impacts to water quality and natural resources on federal lands from construction and maintenance of 11 miles of transmission line. Described measures to avoid and minimize impacts should continue through the final stages of the project.

ERP No. F–SFW–L02029–AK, Swanson River Satellites Natural Gas Exploration and Development Project, Evaluation of a Right-of-Way Permit Application and U.S. Army COE Section 404 and NPDES Permits Issuance, Kenai National Wildlife Refuge, Kenai Peninsula, AK.

Summary: No formal comment letter was sent to the preparing agency.

ERP No. FS–BLM–K67011–NV, Betze-Post Project, Updated Information concerning Dewatering Operations and Additional Underground Pipeline Construction, Elko and Eureka Counties, NV.

Summary: EPA expressed continuing environmental concerns regarding the potential ecological risks to biological resources from the project and adverse impacts to water quality, including levels of selenium. EPA recommended additional analysis of cumulative impacts and additional mitigation measures.

Dated: March 11, 2003.

Joseph C. Montgomery,

Director, NEPA Compliance Division, Office of Federal Activities.

[FR Doc. 03–6196 Filed 3–13–03; 8:45 am]

BILLING CODE 6560–50–P

ENVIRONMENTAL PROTECTION AGENCY

[OPPT 2003–0009; FRL–7298—3]

Forum on State and Tribal Toxics Action; Notice of Public Meetings

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice.

SUMMARY: EPA is announcing the spring meeting of the Forum on State and

Tribal Toxics Action (FOSTTA) to collaborate on environmental protection and chemical and prevention issues. The Chemical Information and Management, Pollution Prevention, and Tribal Affairs Projects, components of FOSTTA, will hold meetings March 25–26, 2003. The meetings are being held in conjunction with the Office of Prevention, Pesticides and Toxic Substances (OPPTS) Regional Division Directors meeting. This notice announces the location and times for the meetings and sets forth some tentative agenda topics. EPA invites all interested parties to attend the public meetings.

DATES: The three projects will meet concurrently March 25, 2003, from 8:30 a.m. to 5 p.m., and March 26, 2003, from 8 a.m. to noon. A plenary session is being planned for the participants on Tuesday, March 26, 2003, from 1 p.m. to 3:15 p.m. Joint sessions will be held for the projects and the respective Regional Division Directors. Requests to participate in the spring FOSTTA meeting, identified by docket ID number OPPT–2003–0009, must be received by EPA on or before March 21, 2003.

ADDRESSES: The meetings will be held at the Western Tabor Center, 1672 Lawrence Street, Denver, Colorado.

Requests to participate in the meeting may be submitted to Christine Eppstein, listed under **FOR FURTHER INFORMATION CONTACT**. Follow the detailed instructions as provided in Unit III. of the **SUPPLEMENTARY INFORMATION**.

FOR FURTHER INFORMATION CONTACT: *For general information contact*: Barbara Cunningham, Acting Director, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 554–1404; e-mail address: TSCA-Hotline@epa.gov.

For technical information contact: Darlene Harrod, Environmental Assistance Division (7408M), Office of Pollution Prevention and Toxics, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460–0001; telephone number: (202) 564–8814; fax number: (202) 564–8813; e-mail address: harrod.darlene@epa.gov.

Christine Eppstein, Environmental Council of the States, 444 North Capitol Street, NW., Suite 445, Washington, DC 20001; telephone number: (202) 624–3661; fax number: (202) 624–3666; e-mail address: ceppstein@sso.org.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this Action Apply to Me?

You may be potentially affected by this action if you are interested in FOSTTA and hearing more about the perspectives of the States and Tribes on EPA programs and information exchange regarding important issues related to human health and environmental exposure to toxics. Potentially affected entities may include, but are not limited to:

- States and federally recognized Tribes.
- State, Federal, and local environmental and public health organizations.
- Chemical trade associations.

The listing is not intended to be exhaustive, but rather provides a guide for readers regarding entities likely to be affected by this action. If you have any questions regarding the applicability of this action to a particular entity, consult the technical persons listed under **FOR FURTHER INFORMATION CONTACT**.

B. How Can I Get Copies of this Document and Other Related Documents?

1. *Docket*. EPA has established an official public docket for this action under docket ID number OPPT–2003–0009. 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 EPA Docket Center, Rm. B102-Reading Room, EPA West, 1301 Constitution Ave., NW., Washington, DC. The EPA Docket Center is open from 8:30 a.m. to 4:30 p.m., Monday through Friday, excluding legal holidays. The EPA Docket Center Reading Room telephone number is (202) 566–1744 and the telephone number for the OPPT Docket, which is located in EPA Docket Center, is (202) 566–0280.

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. 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.

II. How Can I Request to Participate in this Meeting?

You may submit a request to participate in this meeting to Christine Eppstein, the technical person listed under **FOR FURTHER INFORMATION CONTACT**. Do not submit any information in your request that is considered CBI. Requests to participate in the meeting, identified by docket ID number OPPT–2003–0009, must be received on or before March 21, 2003.

III. Background

The Toxic Substances Control Act, 15 U.S.C. 2609, authorizes EPA and other Federal agencies to establish and coordinate a system for exchange among Federal, State, and local authorities of research and development results respecting toxic chemical substances and mixtures, including a system to facilitate and promote the development of standard data format and analysis and consistent testing procedures. Through FOSTTA, the Chemical Information and Management Project (CIMP) focuses on EPA's chemical program and works to develop a more coordinated effort involving Federal, State, and Tribal agencies. The Pollution Prevention Project (P2) promotes the prevention ethic across society, helping companies incorporate P2 approaches and techniques and integrating P2 into mainstream environmental activities at both the Federal level and among the States. The Tribal Affairs Project TAP concentrates on chemical and prevention issues that are most relevant to the Tribes, including lead control and abatement, Tribal traditional/subsistence lifeways, and hazard communications and outreach. FOSTTA's vision is to reinvigorate the projects, focus on major policy-level issues, recruit more senior State and Tribal leaders, increase outreach to all 50 States and some 560 federally recognized Tribes, and vigorously seek ways to engage the States and Tribes in ongoing substantive discussions on complex and oftentimes controversial environmental issues that States and Tribes resolve at their respective levels of government. In January 2002, the Environmental Council of the States (ECOS), in cooperation with the

National Tribal Environmental Council (NTEC), was awarded the new FOSTTA cooperative agreement. ECOS, NTEC, and EPA's Office of Pollution Prevention and Toxics (OPPT) are co-sponsoring the meetings. As part of a cooperative agreement, ECOS facilitates ongoing efforts of the State and Tribal leaders and OPPT to increase understanding and improve collaboration on toxics and pollution prevention issues and to continue a dialogue on how federal environmental programs can best be implemented among the States, Tribes, and EPA.

IV. The Meeting

In the interest of time and efficiency, the meetings are structured to provide maximum opportunity for State, Tribal, and EPA participants to discuss items on the predetermined agenda. At the discretion of the chair, an effort will be made to accommodate participation by observers attending the proceedings. The FOSTTA representatives and EPA will collaborate on environmental protection and chemical and prevention issues. The tentative agenda items identified by the States and the Tribes follow:

1. High production volume data (CIMP).
2. Environmental indicators (CIMP).
3. Impact of State budget cuts on pollution prevention programs (P2).
4. EPA's resource conservation challenge (P2).
5. OPPTS Tribal strategy (TAP).
6. Lead issues (TAP).

Stephen L. Johnson, Assistant Administrator, for the Office of Prevention, Pesticides and Toxic Substances, will be a speaker at the plenary session.

List of Subjects

Environmental protection, Chemicals, Pollution prevention.

Dated: March 7, 2003.

Clarence O. Lewis, III

Acting Director, Environmental Assistance Division, Office of Pollution Prevention and Toxics.

[FR Doc 03–6300 Filed 3–12–03; 1:03 pm]

BILLING CODE 6560–50–S

ENVIRONMENTAL PROTECTION AGENCY

[FRL–7466–8]

Clinch and Powell Valley Watershed Ecological Risk Assessment

AGENCY: Environmental Protection Agency.

ACTION: Notice of availability of final document.

SUMMARY: The U.S. Environmental Protection Agency (EPA) announces the availability of a final document, *Clinch and Powell Valley Watershed Ecological Risk Assessment* (EPA/600/R–01/050, September 2002), prepared as a collaborative effort between the National Center for Environmental Assessment—Washington (NCEA–W) within EPA's Office of Research and Development, The Nature Conservancy, the U.S. Fish and Wildlife Service, the Tennessee Valley Authority, and other organizations. This watershed ecological risk assessment was developed to help protect the native mussels and fish of the Clinch and Powell Valley watershed. The report is based on the *Guidelines for Ecological Risk Assessment* (U.S. EPA, 1998) and advice and support from NCEA, while exercising the necessary flexibility to implement the risk assessment approach at the watershed scale. The document includes brief descriptions of the process that the workgroup followed and the major analyses performed.

ADDRESSES: The document is available electronically from the NCEA Web site (*http://www.epa.gov/ncea*) under *Selected Topics, Watershed Assessment.* A limited number of copies will be available from EPA's National Service Center for Environmental Publications (NSCEP), P.O. Box 42419, Cincinnati, OH 45242; telephone: 1–800–490–9198 or 513–489–8190; facsimile 513–489–8695. Please provide your name and mailing address and the title and EPA number when ordering from NSCEP. Documents also may be ordered via the Internet at *http://www.epa.gov/NCEPIhome/orderpub.html.* Paper copies may be purchased from the National Technical Information Service (NTIS) in Springfield, VA (1–800–553-NTIS[6847] or 703–605–6000; facsimile 703–321–8547). Please provide the number, PB2003–101118, when ordering this document from NTIS.

FOR FURTHER INFORMATION CONTACT: For further information, please contact Victor Serveiss, National Center for Environmental Assessment (8623D), U.S. Environmental Protection Agency, Washington, DC 20460; telephone: 202–564–3251; facsimile: 202–565–0076; e-mail: *serveiss.victor@epa.gov.*

Dated: March 6, 2003.

George Alapas,

Acting Director, National Center for Environmental Assessment.

[FR Doc. 03–6194 Filed 3–13–03; 8:45 am]

BILLING CODE 6560–50–P

FEDERAL COMMUNICATIONS COMMISSION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission

March 6, 2003.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a currently valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (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 estimate; (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.

DATES: Written comments should be submitted on or before April 14, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Judith Boley Herman, Federal Communications Commission, Room 1–C804, 445 12th Street, SW., DC 20554 or via the Internet to *jboley@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s), contact Judith Boley Herman at 202–418–0214 or via the Internet at *jboley@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control No.: 3060–0395.

Title: The ARMIS USOA Report (ARMIS Report 43–02); the ARMIS Service Quality Report (ARMIS Report 43–05); and the ARMIS Infrastructure Report (ARMIS Report 43–07).

Report Nos: FCC Reports 43–02, 43–05 and 43–07.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 49.

Estimated Time Per Response: 5.7–844 hours.

Frequency of Response: Annual reporting requirements and recordkeeping requirement.

Total Annual Burden: 23,677 hours.

Total Annual Cost: N/A.

Needs and Uses: The USOA Report proves the annual results of the carriers' activities for each account of the Uniform System of Accounts. The Service Quality Report provides service quality information in the areas of interexchange access service, installation and repair intervals, local service installation and repair intervals, trunk blockage, and total switch downtime for price cap carriers. The Infrastructure Report provides switch deployment and capabilities data. For the FCC Report 43–02 the Commission extended the effective date of the changes to the Part 32 chart of accounts to January 1, 2003 and thus the revision to ARMIS 43–02 shall be effective with the April 1, 2004 filings. There were no changes to ARMIS 43–05. ARMIS 43–07 the Commission proposed to eliminate the collection of outdated information and to collect information on newer technologies on Table I. As a result of the Phase 2 Report and Order, the Commission eliminated eight rows related to electromechanical switches; 12 rows related to analog and digital stored-program control; eight rows related to equal access and touch tone; and 17 rows related to Signaling System 7 and integrated services digital network. Among other eliminated reporting requirements, the Commission proposed and eliminated Tables III and IV because Table III information is no longer significant and Table IV information is available in other ARMIS reports or can be generated by reference to other ARMIS reports.

OMB Control No.: 3060–0496.

Title: The ARMIS Operating Data Report.

Report No: FCC Report 43–08.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 53.

Estimated Time Per Response: 139 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 7,367 hours.

Total Annual Cost: N/A.

Needs and Uses: The Operating Data Report collects annual statistical data in a consistent format that is essential for the Commission to monitor network growth, usage, and reliability. The Commission proposed to eliminate the reporting requirements in Table I–A. Pending further exploration of alternative means of gathering information, the Commission only eliminated columns J, K, L and M because little, if any, data are reported for these categories. The Commission proposed to eliminate columns be, bj, and bm of Table 1–B due to changes in technology. For Table II, the Commission proposed to eliminate the distinction between analog and digital by eliminating columns cf, cg, and ch. Finally, the Commission proposed to make extensive structural changes to Table III to remove data no longer required, and to reflect current access line category structure. Further, we are correcting the number of carriers filing this ARMIS report.

OMB Control No.: 3060–0511.

Title: The ARMIS Access Report.

Report No: FCC Report 43–04.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 84.

Estimated Time Per Response: 157 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 13,188 hours.

Total Annual Cost: N/A.

Needs and Uses: The ARMIS Access Report is needed to administer the Commission's accounting, jurisdictional separations and access charge rule; to analyze revenue requirements and rates of return, and to collect financial data from Tier 1 incumbent local exchange carriers. This information collection has been revised to eliminate the obligation of mid-sized carriers to file the ARMIS 43–04 report on April 1, 2002. That change was approved in a previous OMB filing. The Commission is re-estimating the number of carriers filing this ARMIS report from 121 to 84 respondents given that a number of study areas have been sold or dissolved over the years.

OMB Control No.: 3060–0512.

Title: The ARMIS Annual Summary Report.

Report No: FCC Report 43–01.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 115.

Estimated Time Per Response: 93 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 10,695 hours.

Total Annual Cost: N/A.

Needs and Uses: The Annual Summary Report contains financial and operating data and is used to monitor the incumbent local exchange carrier industry and to perform routine analyses of costs and revenues on behalf of the Commission. The Commission eliminated the distinction between ''SNFA and Intra-co Adjustments'' and ''Other Adjustments'' and combining these columns into one column entitled ''Adjustments''. The Commission also proposed eliminating the requirement to file Table II. Because the elimination of Table II was not feasible due to other streamlining adopted for the mid-sized carriers, the Commission did not adopt the elimination of Table II but eliminated the Common Line Minutes of Use (rows 2010, 2020, 2030 and 2040). In addition, the Commission also provided the accounts and data that are necessary and must be maintained and reported in ARMIS to calculate just and reasonable pole, duct, conduit, and right-of-way attachment rates pursuant to Section 224 of the Communications Act. Table III is the Pole and Conduit Rental Calculation table for Class A carriers. Further, we are correcting the number of carriers filing this ARMIS report from 121 and 115 given that a number of study areas have been sold or dissolved over the years.

OMB Control No.: 3060–0513.

Title: The ARMIS Joint Cost Report.

Report No: FCC Report 43–03.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 85.

Estimated Time Per Response: 76 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 6,460 hours.

Total Annual Cost: N/A.

Needs and Uses: The Joint Cost Report is needed to administer our joint cost rules (Part 64) and to analyze data in order to prevent cross-subsidization of nonregulated operations by the regulated operations of Tier 1 carriers. The Commission proposed to reduce the number of columns currently reported by eliminating the distinction between ''SNFA and Intra-co Adjustments'' and ''Other Adjustments'' and combining these columns into one column. The Commission approved the proposal to combine the two columns based on its determination that it does not appear to be a significant regulatory need to retain the ''SNFA and Intra-co Adjustment'' columns. Further, we are correcting the number of carriers filing this ARMIS

report from 121 to 85 given that a number of study areas have been sold or dissolved over the years.

OMB Control No.: 3060–0763.

Title: The ARMIS Customer Satisfaction Report.

Report No: FCC Report 43–06.

Type of Review: Revision of a currently approved collection.

Respondents: Business or other for-profit.

Number of Respondents: 7.

Estimated Time Per Response: 720 hours.

Frequency of Response: Annual reporting requirement.

Total Annual Burden: 5,040 hours.

Total Annual Cost: N/A.

Needs and Uses: The Customer Satisfaction Report reflects the results of customer satisfaction based on surveys conducted by individual carriers from their customers. The Commission is re-estimating the number of carriers filing this report. No other changes have been made. The information contained in this report provides the necessary detail to enable the Commission to fulfill its regulatory responsibilities.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–6143 Filed 3–13–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISION

Notice of Public Information Collection(s) Being Reviewed by the Federal Communications Commission for Extension Under Delegated Authority 5 CFR 1320 Authority, Comments Requested

March 6, 2003.

SUMMARY: The Federal Communications Commission, as part of its continuing effort to reduce paperwork burden invites the general public and other Federal agencies to take this opportunity to comment on the following information collection(s), as required by the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor a collection of information unless it displays a current valid control number. No person shall be subject to any penalty for failing to comply with a collection of information subject to the Paperwork Reduction Act (PRA) that does not display a valid control number. Comments are requested concerning (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 estimate; (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.

DATES: Written comments should be submitted on or before May 13, 2003. If you anticipate that you will be submitting comments, but find it difficult to do so within the period of time allowed by this notice, you should advise the contact listed below as soon as possible.

ADDRESSES: Direct all comments to Les Smith, Federal Communications Commission, Room 1–A804, 445 12th Street, SW., Washington, DC 20554, or via the Internet to *lesmith@fcc.gov.*

FOR FURTHER INFORMATION CONTACT: For additional information or copies of the information collection(s) contact Les Smith at 202–418–0217 or via the Internet at *lesmith@fcc.gov.*

SUPPLEMENTARY INFORMATION:

OMB Control Number: 3060–0250.

Title: Section 74.784, Rebroadcasts.

Form Number: N/A.

Type of Review: Extension of a currently approved collection.

Respondents: Business and other for-profit entities; State, Local or Tribal Government.

Number of Respondents: 1,080.

Estimated Time Per Response: 1 hour.

Frequency of Response: On occasion reporting requirements.

Total Annual Burden: 1,080 hours.

Total Annual Costs: $0.00.

Needs and Uses: 47 CFR 73.1560 requires licensees of low power and TV translator stations to notify the FCC when rebroadcasting programs or signals of another station and to certify that written consent has been obtained from originating station. Data are used by FCC staff to ensure compliance with Section 325(a) of the Communications Act, as amended.

OMB Control Number: 3060–0466.

Title: Section 74.1283, Station Identification.

Form Number: N/A.

Type of Review: Extension of currently approved collection.

Respondents: Business or other for-profit entities.

Number of Respondents: 200.

Estimated Time per Response: 2 hours.

Frequency of Response: Recordkeeping; On occasion reporting requirement.

Total annual burden: 400 hours.

Total Annual Costs: $0.00.

Needs and Uses: 47 CFR 74.1283(c)(1) requires FM translator stations whose station identification is made by the primary station to furnish current information on the translator's call letters and location. This information is kept in the primary station's files. This information is used to contact the translator licensee in the event of malfunction of the translator.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–6144 Filed 3–13–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collections Approved by Office of Management and Budget

March 6, 2003.

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collections pursuant to the Paperwork Reduction Act of 1995, Public Law 104–13. An agency may not conduct or sponsor and a person is not required to respond to a collection of information unless it displays a currently valid control number. For further information contact Paul J. Laurenzano, Federal Communications Commission, (202) 418–1359 or via the Internet at *plaurenz@fcc.gov.*

OMB Control No.: 3060–0715.

Expiration Date: 02/28/2006.

Title: Telecommunications Carriers' Use of Customer Proprietary Network Information (CPNI) and Other Customer Information, CC Docket No. 96–115.

Form No.: N/A.

Estimated Annual Burden: 4,832 responses; 672,808 total annual hours; $229,520,000 cost burden; 139.2 hours per respondent.

Needs and Uses: The requirements implement the statutory obligations of section 222 of the Telecommunications Act of 1996. Among other things, carriers are permitted to use, disclose, or permit access to CPNI, without customer approval, under certain conditions.

Many uses of CPNI require either opt-in or opt-out customer approval, depending upon the entity using the CPNI and the purpose for which it is used.

OMB Control No.: 3060–1009.

Expiration Date: 02/28/2006.

Title: Telecommunications Reporting Worksheet, CC Docket No. 96–45.

Form No.: 499, 499–A, 499–Q, 499–M.

Estimated Annual Burden: 1 responses; 1 total annual hours; 1 hour per response.

Needs and Uses: Pursuant to the Communications Act of 1934, as amended, telecommunications carriers (and certain other providers of telecommunications services) must contribute to the support and cost recovery mechanisms for telecommunications relay services, numbering administration, number portability, and universal service. The Commission is seeking comment on three connection-based proposals to futher refine the record in the proceeding to revisit its universal service contribution methodology. If adopted, the proposals may entail altering the current reporting requirements to which interstate telecommunications carriers are subject under Part 54 of the Commission's rules.

OMB Control No.: 3060–0147.

Expiration Date: 02/28/2006.

Title: Section 64.804—Extension of Unsecured Credit for Interstate and Foreign Communication Services to Candidates for Federal Office.

Form No.: N/A.

Estimated Annual Burden: 13 responses; 104 total annual hours; 8 hours per response.

Needs and Uses: Communications common carriers with operating revenues exceeding $1 million who extend unsecured credit to a candidate or person on behalf of such candidates for Federal office must file with the FCC a report including due and outstanding balances. The information is used for monitoring purposes.

OMB Control No.: 3060–0076.

Expiration Date: 02/28/2006.

Title: Annual Employment Report for Common Carriers.

Form No.: FCC–395.

Estimated Annual Burden: 4,000 responses; 4,000 total annual burden hours; 1 hour per response.

Needs and Uses: The Annual Employment Report is submitted by certain common carrier licensees and permittees. The Information contained in the report is intended to assess compliance with equal employment opportunity requirements. The reports have been used by the FCC, Congress, the U.S. Commission on Civil Rights, EEOC, NTIA, public interest groups and carrier representatives.

OMB Control No.: 3060–0989.

Expiration Date: 11/30/2005.

Title: Procedures for Applicants Requiring Section 214 Authorization for Domestic Interstate Transmission Lines Aquired Through Corporate Control, 47 CFR Sections 63.01, 63.03 and 63.04.

Form No.: N/A.

Estimated Annual Burden: 35 responses; 1,655 total annual hours; $20,000 cost burden; 3–60 hours per response.

Needs and Uses: Report and Order (CC Docket No. 01–150) provides presumptive Streamlining categories, allows for joint applications for international and domestic transfers of control, clarifies confusion about content of applications, provides timelines for streamlined transaction review, provides a pro forma transaction process, allows asset acquisitions to be treated as transfers of control and deletes obsolete sections of the Commission's rules. The information will be used to ensure that applicants comply with the requirements of 47 U.S.C. Section 214.

OMB Control No.: 3060–0519.

Expiration Date: 11/30/2005.

Title: Rules and Regulations Implementing the Telephone Consumer Protection Act of 1991 (CC Docket No. 92–06).

Form No.: N/A.

Estimated Annual Burden: 30,000 responses; 1,653,600 total annual hours; 55.1 hours per response.

Needs and Uses: Parts 64 and 68 of the Commission's rules contain procedures for avoiding unwanted telephone solicitations to residences, and to regulate the use of automatic telephone dialing systems, artificial or prerecorded voice messages, and telephone facsimile machines. The Commission believes that the recordkeeping requirement is the best means of preventing unwanted telephone solicitations.

OMB Control No.: 3060–0513.

Expiration Date: 12/31/2005.

Title: ARMIS Joint Cost Report.

Form No.: FCC 43–03.

Estimated Annual Burden: 121 responses; 10,043 total annual hours; 83 hours per response.

Needs and Uses: The Joint Cost Report is needed to administer our joint cost rules (Part 64), and to analyze data in order to prevent cross-subsidization of non-regulated operations by the regulated operations of Tier 1 carriers.

OMB Control No.: 3060–0511.

Expiration Date: 12/21/2005.

Title: ARMIS Access Report.

Form No.: FCC 43–04.

Estimated Annual Burden: 121 responses; 18,997 total annual hours; 157 hours per respondent.

Needs and Uses: The Access Report is needed to administer the Commission's accounting, jurisdicational separations and access charge rule; to analyze revenue requirements and rates of return, and to collect financial data from Tier 1 incumbent local exchange carriers.

OMB Control No.: 3060–0395.

Expiration Date: 12/31/2005.

Title: The Armis USOA Report (ARMIS Report 43–02); The ARMIS Service Quality Report (ARMIS Report 43–05); and the ARMIS Infrastructure Report (ARMIS Report 43–07).

Form No.: FCC 43–02, FCC 43–05, FCC 43–07.

Estimated Annual Burden: 50 responses; 26,446 total annual hours; 529 hours per response.

Needs and Uses: The USOA Report provides the annual results of the carriers' activities for each account of the Uniform System of Accounts. The Service Quality Report provides service quality information in the areas of interexchange access service, installation and repair intervals, local service installation and repair intervals, trunk blockage, and total switch downtime for price cap carriers. The Infrastructure Report provides switch deployment and capabilities data.

OMB Control No.: 3060–0793.

Expiration Date: 10/31/2005.

Title: Federal-State Joint Board on Universal Service, CC Docket No. 96–45, Procedures For Self Certifying as a Rural Carrier.

Form No.: N/A.

Estimated Annual Burden: 10 responses; 10 total annual hours; 1 hour per response.

Needs and Uses: In the Tenth Report and Order, the Commission adopted proposals that carriers serving study areas with fewer than 100,000 access lines that already have certified their rural status need not re-certify for purposes of receiving support beginning January 1, 2000, and need only file thereafter if their status changes. Further, carriers serving more than 100,000 access lines need to file rural certifications for their year 2001 status has changed.

OMB Control No.: 3060–0855.

Expiration Date: 10/31/2005.

Title: Telecommunications Reporting Worksheet, CC Docket No. 96–45.

Form No.: FCC 499, FCC 499–A, FCC 499–Q.

Estimated Annual Burden: 14,300 responses; 106,287 total annual hours; $18,000 cost burden; 7.5 hours per respondent.

Needs and Uses: Pursuant to the Communications Act of 1934, as amended, telecommunications carriers (and certain other providers of telecommunications services) must contribute to the support and cost recovery mechanisms for

telecommunications relay services, numbering administration, number portability, and universal service. The Commission modified the existing methodology used to assess contributions that carriers make to the federal universal servcie support mechanisms.

The modifications adopted, will entail altering to the current revenue reporting requirements to which interstate telecom. carriers are subject under part 54 of the Commission's rules.

OMB Control No.: 3060–0770.

Expiration Date: 12/31/2005.

Title: Price Cap Performance Review for Local Exchange Carriers, CC Docket No. 94–1 (New Services).

Form No.: N/A.

Estimated Annual Burden: 26 responses; 130 total annual hours; 5 hours per response.

Needs and Uses: The Commission permits price cap LECs to introduce new services on a streamlined basis, without prior approval. The Commission modified the rules to eliminate the public interest showing required by 69.4(g) and to eliminate the new services test (except in the case of loop-based new services) required under sections 61.49(f) and (g). The information is needed by the Commission to carry out its mandate.

OMB Control No.: 3060–0704.

Expiration Date: 12/31/2005.

Title: Policy and Rules Concerning the Interstate, Interexchange Marketplace; Implementation of Section 254 (g) of the Communications Act of 1934, as amended, CC Docket No. 96–6.

Form No.: N/A.

Estimated Annual Burden: 519 responses; 158,971 total annual hours; $435,000 cost burden; 306.3 hours per response.

Needs and Uses: In the Second Order on Reconsideration issued in CC Docket No. 96–61, the Commission reinstates the public disclosure requirement and also requires that nondominant interexchange carriers that have Internet websites pass this information on-line in a timely and easily accessible manner. These carriers also continue to be required to file annual certifications pursuant to section 254(g); maintain price and service information; and are forborned from filing certain tariffs.

OMB Control No.: 3060–0760.

Expiration Date: 12/31/2005.

Title: Access Charge Reform, CC Docket No. 96–262 (First Report and Order); Second Order on Reconsideration and Memorandum Opinion and Order, and Fifth Report and Order.

Form No.: N/A.

Estimated Annual Burden: 14 responses; 57,127 total annual hours; $8,000 cost burden; 4,080.5 hours per response.

Needs and Uses: The Commission provides detailed rules for implementing the market-based approach, pursuant to which price cap LECs would receive pricing flexibility in the provision of interstate access services as competition for those services develops. The Order grants immediate pricing flexibility to price cap LECs in the form of streamlined introduction of new services, geographic deaveraging of rates for services in the trunking basket, and removal of certain interstate interexchange services from price cap regulation, while providing for additional pricing flexibility upon certain showings. A FNPRM seeks additional flexibility.

Federal Communications Commission.

Marlene H. Dortch,

Secretary.

[FR Doc. 03–6145 Filed 3–13–03; 8:45 am]

BILLING CODE 6712–01–P

FEDERAL DEPOSIT INSURANCE CORPORATION

Notice of Agency Meeting

Pursuant to the provisions of the ''Government in the Sunshine Act'' (5 U.S.C. 552b), notice is hereby given that at 10:03 a.m. on Tuesday, March 11, 2003, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to consider matters relating to the Corporation's resolution, corporate, and enforcement activities.

In calling the meeting, the Board determined, on motion of Director James E. Gilleran (Director, Office of Thrift Supervision), seconded by Ms. Julie L. Williams, acting in the place and stead of Director John D. Hawke, Jr. (Comptroller of the Currency), concurred in by Vice Chairman John M. Reich, and Chairman Donald E. Powell, that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no notice earlier than March 7, 2003, of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting by authority of subsections (c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the ''Government in the Sunshine Act'' (5 U.S.C. 552b(c)(2), (c)(4), (c)(6), (c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in the Board Room of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: March 11, 2003.

Valerie J. Best,

Assistant Executive Secretary.

[FR Doc. 03–6277 Filed 3–12–03; 10:44 am]

BILLING CODE 6714–01–M

FEDERAL ELECTION COMMISSION

Sunshine Act Notices

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.

The following item has been withdrawn from the agenda:

Notice of proposed rulemaking on public funding of presidential primary and general election candidates and conventions.

FOR MORE INFORMATION CONTACT: Ron Harris, Press Officer, Telephone (202) 694–1220.

Mary W. Dove,

Secretary of the Commission.

[FR Doc. 03–6348 Filed 3–12–03; 3:26 pm]

BILLING CODE 6715–01–M

FEDERAL RESERVE SYSTEM

Formations of, Acquisitions by, and Mergers of Bank Holding Companies

The companies listed in this notice have applied to the Board for approval, pursuant to the Bank Holding Company Act of 1956 (12 U.S.C. 1841 *et seq.*) (BHC Act), Regulation Y (12 CFR Part 225), and all other applicable statutes and regulations to become a bank holding company and/or to acquire the assets or the ownership of, control of, or the power to vote shares of a bank or bank holding company and all of the banks and nonbanking companies owned by the bank holding company, including the companies listed below.

The applications listed below, as well as other related filings required by the Board, are available for immediate inspection at the Federal Reserve Bank indicated. The application also will be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the standards enumerated in the BHC Act (12 U.S.C. 1842(c)). If the proposal also involves the acquisition of a nonbanking company, the review also includes whether the acquisition of the

nonbanking company complies with the standards in section 4 of the BHC Act (12 U.S.C. 1843). Unless otherwise noted, nonbanking activities will be conducted throughout the United States. Additional information on all bank holding companies may be obtained from the National Information Center website at www.ffiec.gov/nic/.

Unless otherwise noted, comments regarding each of these applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than April 7, 2003.

A. Federal Reserve Bank of St. Louis (Randall C. Sumner, Vice President) 411 Locust Street, St. Louis, Missouri 63166-2034:

1. Security First Bancshares, Inc., O'Fallon, Illinois; to become a bank holding company by acquiring at least 68 percent of the voting shares of Bank of O'Fallon, O'Fallon, Illinois.

Board of Governors of the Federal Reserve System, March 10, 2003.

Robert deV. Frierson,

Deputy Secretary of the Board.

[FR Doc. 03–6156 Filed 3–13–03; 8:45 am]

BILLING CODE 6210–01–S

GENERAL SERVICES ADMINISTRATION

Office of Management Services; Revision of SF 1444, Request for Authorization of Additional Classification and Rate

AGENCY: Office of Management Services, GSA.

ACTION: Notice.

SUMMARY: The General Services Administration (GSA), Office of Governmentwide Policy revised the SF 1444, Request for Authorization of Additional Classification and Rate to:

a. Update the reporting burden statement due to a reorganization;

b. Revise the instructions for copy distribution; and

c. Make authorized for local reproduction. The form is now a single cutsheet instead of a 5 part set.

Since this form is now authorized for local reproduction, you can obtain the updated camera copy in two ways:

On the internet. Address: *http://www.gsa.gov/forms;* or from Forms-CAP, Attn.: Barbara Williams, (202) 501–0581.

The Federal Acquisition Regulation will reflect this change at a later date.

FOR FURTHER INFORMATION CONTACT: Ms. Barbara Williams, General Services Administration, (202) 501–0581.

Effective March 14, 2003.

Dated: March 4, 2003.

Barbara M. Williams,

Deputy Standard and Optional Forms Management Officer, General Services Administration.

[FR Doc. 03–6125 Filed 3–13–03; 8:45 am]

BILLING CODE 6820–34–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–368/R144, CMS–R–240, and CMS–566]

Agency Information Collection Activities: Proposed Collection; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA)), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

(1) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicaid Drug Rebate; *Form No.:* CMS–368/R144 (OMB# 0938–0582); *Use:* Section 1927 requires State Medicaid agencies to report to drug manufacturers and CMS on the drug utilization for their State and the amount of rebate to be paid by the manufacturer; *Frequency:* Quarterly; *Affected Public:* State, local, or tribal government; *Number of Respondents:* 51; *Total Annual Responses:* 204; *Total Annual Hours:* 6,125.

(2) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Prospective Payments for Hospital Outpatient Services and Supporting Regulations in 42 CFR 413.24, 413.65, and 419.42; *Form No.:* CMS–R–240 (OMB# 0938–0798); *Use:* As required by sections 4521, 4522, and 4523 of the Balanced Budget Act of 1997, HCFA–1005FC eliminates the formula driven overpayment for certain outpatient hospital services, extends reductions in payment for costs of hospital outpatient services, and establishes in regulations a prospective payment system for hospital outpatient services. The rule also establishes in regulations the requirements for designating certain entities as provider-based or as a department of a hospital; *Frequency:* Other—as needed; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 750; *Total Annual Responses:* 2,272; *Total Annual Hours:* 41,063.

(3) *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Medicare Managed Care Disenrollment Form; *Form No.:* CMS–566 (0938–0507); *Use:* This form provides Medicare beneficiaries the option to disenroll from their Medicare managed care plan through a neutral third party. CMS and SSA have established an agreement via a formal Memorandum of Understanding for SSA to process beneficiary disenrollments from Medicare managed care plans. Prior to 1999, the Social Security Act provided Medicare beneficiaries enrolled in Medicare managed care plans with the option of disenrolling from the plan at a Social Security Field Office; however, section 4001 of the Balanced Budget Act of 1997 amended the Social Security Act, removing this requirement from the statute; *Frequency:* On Occasion; *Affected Public:* Individuals or Households, Business or other for-profit, Not-for-profit institutions, and Federal Government; *Number of Respondents:* 85,000; *Total Annual Responses:* 85,000; *Total Annual Hours:* 2,805.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS's Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or E-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed

within 60 days of this notice directly to the CMS Paperwork Clearance Officer designated at the following address: CMS, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances, *Attention:* Dawn Willinghan, Room N2–14–26, 7500 Security Boulevard, Baltimore, Maryland 21244–1850.

Dated: March 6, 2003.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Strategic Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–6139 Filed 3–13–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Medicare and Medicaid Services

[Document Identifier: CMS–R–205, CMS–R–206, CMS–R–228, CMS–10050, CMS–R–262, and CMS–10080]

Agency Information Collection Activities: Submission for OMB Review; Comment Request

AGENCY: Centers for Medicare and Medicaid Services.

In compliance with the requirement of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Centers for Medicare and Medicaid Services (CMS) (formerly known as the Health Care Financing Administration (HCFA), Department of Health and Human Services, is publishing the following summary of proposed collections for public comment. Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

1. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Referenced in HIPAA, Title 1, for the Individual Market, Supporting regulations at 45 CFR 148.120, 148.122, 148.124, 148.126, and 148.128, and Forms/instructions; *Form No.:* CMS–R–205 (OMB# 0938–0703); *Use:* Information collection requirements (ICRs) will ensure that issuers in the individual market comply with Title 1 of the Health Insurance Portability and Accountability Act, provide individuals with certificates of coverage necessary to demonstrate prior creditable coverage and file documentation with CMS for review in a Federal direct enforcement state. ICRs will also ensure States' flexibility to implement state alternative mechanisms; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Individuals or households, Not-for-profit institutions, Federal government, and State, local, or tribal government; *Number of Respondents:* 1,041; *Total Annual Responses:* 3,242,500; *Total Annual Hours:* 914,347.

2. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Information Collection Requirements Referenced in HIPAA, Title 1, for the Group Market and Supporting Regulations at 45 CFR 146.111, 146.115, 146.117, 146.150, 146.152, 146.160, and 146.180, and Forms/instructions; *Form No.:* CMS–R–206 (OMB# 0938–0702); *Use:* Information collection requirements (ICRs) will ensure that issuers in the group market comply with Title 1 of the Health Insurance Portability and Accountability Act, including providing individuals with certificates of creditable coverage, notifying individuals about their status with respect to pre-existing condition exclusions, and giving them special enrollment rights to which they are entitled and that states and the Federal government have the flexibility necessary to enforce HIPAA; *Frequency:* On occasion; *Affected Public:* Business or other for-profit, Individuals or households, Not-for-profit institutions, Federal government, and State, local, or tribal government; *Number of Respondents:* 2,080; *Total Annual Responses:* 43,003,297; *Total Annual Hours:* 2,652,282.

3. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* Adjusted Community Rate (ACR) Proposal Medicare+Choice; *Form No.:* CMS–R–228 (OMB# 0938–0742); *Use:* Under part C of the Social Security Act, a Medicare+Choice (M+C) organization is required to offer a benefit package that is approved and priced properly to all Medicare beneficiaries residing in the service area. This form is used by M+C organizations to price its benefit packages; *Frequency:* Annually; *Affected Public:* Business or other for-profit, and Not-for-profit institutions; *Number of Respondents:* 600; *Total Annual Responses:* 600; *Total Annual Hours:* 57,000.

4. *Type of Information Collection Request:* Extension of a currently approved collection; *Title of Information Collection:* Survey of Newly Eligible Medicare Beneficiaries; *Form No.:* CMS–10050 (OMB# 0938–0869); *Use:* It is not enough to merely mail information about the Medicare program to each beneficiary. We need to know not only that the beneficiary got the information, but that they understood the information and are able to use it in making choices about their Medicare participation. To this end, CMS must have measure(s) over time of what beneficiaries know and understand about the Medicare program now to be able to quantify and attribute any changes to their understanding or behavior to information/education initiatives. Measuring beneficiary information needs and knowledge over time will help us to evaluate the impact of information/education and other initiatives as well as to understand how the population is changing apart from such initiatives.; *Frequency:* Monthly; *Affected Public:* Individuals or Households; *Number of Respondents:* 3600; *Total Annual Responses:* 3600; *Total Annual Hours:* 1080.

5. *Type of Information Collection Request:* Revision of a currently approved collection; *Title of Information Collection:* The Adjusted Community Rate Proposal (ACRP) Medicare+Choice (M+C) Plan Benefit Package (PBP) and Supporting Regulations in 42 CFR 417.401, 422.1–422.10, 422.50–422.80; *Form No.:* CMS–R–262 (OMB# 0938–0763); *Use:* Under part C of the Social Security Act, a Medicare+Choice (M+C) organization is required to offer at least one plan benefit package that is approved and priced properly to all Medicare beneficiaries residing in the service area. This software is used by M+C organizations to describe their plan benefit package(s).; *Frequency:* Annually and as required by new legislation; *Affected Public:* Business or other for-profit and Not-for-profit institutions; *Number of Respondents:* 200; *Total Annual Responses:* 200; *Total Annual Hours:* 600.

6. *Type of Information Collection Request:* New Collection; *Title of Information Collection:* Publications Use Study; *Form No.:* CMS–10080 (OMB# 0938–NEW); *Use:* CMS/CBC needs to conduct this research to evaluate how CMS meets beneficiaries'

informational needs about health care benefits and choices, as directed by the Balanced Budget Act of 1997. This telephone survey will gather data on publications users' demographics, usage patterns, and attitudes toward Medicare publications. Research findings will support the improvement of a dissemination of Medicare publications; *Frequency:* Quarterly; *Affected Public:* Individuals or Households; *Number of Respondents:* 3,000; *Total Annual Responses:* 3,000; *Total Annual Hours:* 850.

To obtain copies of the supporting statement and any related forms for the proposed paperwork collections referenced above, access CMS Web site address at *http://cms.hhs.gov/regulations/pra/default.asp,* or e-mail your request, including your address, phone number, OMB number, and CMS document identifier, to *Paperwork@hcfa.gov,* or call the Reports Clearance Office on (410) 786–1326. Written comments and recommendations for the proposed information collections must be mailed within 30 days of this notice directly to the OMB desk officer: OMB Human Resources and Housing Branch, Attention: Brenda Aguilar, New Executive Office Building, Room 10235, Washington, DC 20503.

Dated: March 6, 2003.

John P. Burke, III,

Paperwork Reduction Act Team Leader, CMS Reports Clearance Officer, Office of Strategic Operations and Regulatory Affairs, Division of Regulations Development and Issuances.

[FR Doc. 03–6140 Filed 3–13–03; 8:45 am]

BILLING CODE 4120–03–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Native Employment Works (NEW) Program Plan Guidance and Program Report.

OMB No.: 0970–0174.

Description: The Native Employment Works (NEW) program plan is the application for NEW program funding. As approved by the Department of Health and Human Services (HHS), it documents how the grantee will carry out its NEW program. The NEW program plan guidance specifies the information needed to complete a NEW program plan and explains the process for plan submission every third year.

The NEW program report provides information on the activities and accomplishments of grantees' NEW programs. The NEW program report and instructions specify the program data that NEW grantees report annually.

Respondents: Federally-recognized Indian tribes and tribal organizations that are NEW program grantees.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours (annually)
NEW program plan guidance	26	One, every 3 years	30	780
NEW program report	53	One, annually	15	795
Estimated Total Annual Burden Hours	1,575			

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 10, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–6149 Filed 3–13–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Adoption and Foster Care Analysis and Reporting System for title IV–B and title IV–E.

OMB No.: 0980–0267.

Description: Section 479 of title IV–E of the Social Security Act directs States to establish and implement an adoption and foster care reporting system. The data are used for a number of purposes, including responding to Congressional requests for current data on children in foster care or those who have been adopted; responding to questions and requests from other Federal departments and agencies; trend analyses and short and long-term planning; targeting areas for greater or potential technical assistance efforts; and determining and assessing outcomes for children and families.

Respondents: States, District of Columbia and Puerto Rico.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
AFCARS (Electronic Format)	52	2	3,316	344,864

Additional Information

Copies of the proposed collection may be obtained by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register.** Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 10, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–6150 Filed 3–13–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Head Start Impact Study.

OMB No.: 0970–0229.

Description: The Administration on Children, Youth and Families (ACYF), Administration for Children and Families (ACF) of the Department of Health and Human Services (DHHS) is requesting comments on plans to conduct the Head Start Impact Study. This study is being conducted under contract with Westat, Inc. (with the Urban Institute, American Institutes for Research, and Decision Information Resources as their subcontractors) (#282–00–0022) to collect information for determining, on a national basis, how Head Start affects the school readiness of children participating in the program as compared to children not enrolled in Head Start and to determine under which conditions Head Start works best and for which children.

The Head Start Impact Study is a longitudinal study that will involve approximately 5,000 first time enrolled three- and four-year old preschool children across an estimated 90 nationally representative grantee/delegate agencies (in communities where there are more eligible children and families than can be served by the program). Data collection for the full-scale study began in fall 2002 and extends through spring 2006, with child assessments conducted in the fall and spring of the Head Start years and in the spring of the kindergarten and first grade years, and parent interviews conducted in the fall and spring of each year. Interviews/surveys with program staff/care providers, and quality of care assessments will be conducted in the spring of each year. This schedule of data collection is necessitated by the mandate in Head Start's 1998 reauthorization (Coats Human Services Amendments of 1998, Pub. L. 05–285) that DHHS conduct research to determine, on a national level, the impact of Head Start on the children it serves.

A field test of instruments and procedures was conducted during fall 2001 and spring 2002. The field test involved approximately 450 first time enrolled three-and four-year old preschool children across eight grantee/delegate agencies representing different community contexts.

Respondents: Individuals or Households, Head Start Agencies, School Districts, and other Child Care Providers.

Annual Burden Estimates: Estimated Response Burden for Respondents to the Head Start Impact Study—fall 2002, spring 2003, fall 2003, spring 2004, spring 2005, fall 2005, and spring 2006.

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Year 1 (fall 2002):				
Parent Interviews	5,111	1	1.00	5,111
Child Assessments	5,111	1	0.9166	4,685
Year 1 (spring 2003):				
Parent Interviews	4,599	1	1.00	4,599
Father Questionnaire	4,599	1	0.50	2,300
Child Assessments	4,599	1	0.9166	4,216
Teacher/Provider Ratings	966	5	0.833	403
Center Directors/Principals	368	1	0.25	92
Classroom Teachers	736	1	0.50	368
Other Care Providers	230	1	0.50	115
Year 2 (fall 2003):				
Parent Interviews	4,139	1	1.00	4,139
Child Assessments	2,287	1	0.9166	2,096
Year 2 (spring 2004):				
Parent Interviews	3,910	1	1.00	3,910
Child Assessments	3,910	1	0.9166	3,584
Teacher/Provider Ratings	803	5	0.833	335
Center Directors/Principals	349	1	0.25	87
Classroom Teachers	700	1	0.50	350
Other Care Providers	103	1	0.50	52
Year 3 (fall 2004):				
Parent Interviews	3,519	1	1.00	3,519
Year 3 (spring 2005):				
Parent Interviews	3,519	1	1.00	3,519
Child Assessments	3,519	1	0.9166	3,226

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Teacher Ratings	704	5	0.0833	293
Principals	352	1	0.25	88
Classroom Teachers	704	1	0.50	352
Year 4 (fall 2005):				
Parent Interviews	1,667	1	1.00	1,667
Year 4 (spring 2006):				
Parent Interviews	1,667	1	1.00	1,667
Child Assessments	1,667	1	0.9166	1,528
Teacher Ratings	333	5	0.0833	139
Principals	167	1	0.25	42
Classroom Teachers	333	1	0.50	167
Estimated Total Annual Burden Hours				13,162

Note The 13,745 Total Annual Burden Hours is based on an average of 2003–03, 2003–04, 2004–05, and 2005–06 estimated burden hours.

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 175th Street, NW., Washington, DC 20503, *Attn:* Desk Officer for ACF.

March 10, 2003.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 03–6151 Filed 3–13–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Submission for OMB Review; Comment Request

Title: Federal Parent Locator Service.

OMB No.: 0970–0142.

Description: State and local child support enforcement agencies may request that the Federal Parent Locator Service (FPLS) assist in locating parents in order to establish or enforce child support. The FPLS serves as a conduit between child support enforcement offices and Federal and state agencies by conducting weekly, biweekly, or monthly matches of the collected information with various agencies and distributing the information back to the requesting state or local child support office.

Respondents: State and local IV–D child support offices.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response (hour)	Total burden hours
FPLS submissions	5	24	1	120
Estimated Total Annual Burden Hours				120

Additional Information

Copies of the proposed collection may be obtained by writing to The Administration for Children and Families, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer.

OMB Comment

OMB is required to make a decision concerning the collection of information between 30 and 60 days after publication of this document in the **Federal Register**. Therefore, a comment is best assured of having its full effect if OMB receives it within 30 days of publication. Written comments and recommendations for the proposed information collection should be sent directly to the following: Office of Management and Budget, Paperwork Reduction Project, 725 17th Street, NW., Washington, DC 20503, Attn: Desk Officer for ACF.

Dated: March 10, 2003.

Bob Sargis,

Reports Clearance Officer.

[FR Doc. 03–6152 Filed 3–13–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Administration for Children and Families

Proposed Information Collection Activity; Comment Request

Proposed Projects

Title: Child Care and Development Fund Annual Aggregate Report.

OMB No.: 0970–0150.

Description: Section 658K of the Child Care and Development Block Grant Act of 1990 (Pub. L. 101–508, 42 U.S.C. 9858) requires that States and

Territories submit annual aggregate data on the children and families receiving direct services under the Child Care and Development Fund. The implementing regulations for the statutorily required reporting are at 45 CFR 98.70. Annual aggregate reports include data elements represented in the ACF–800. Aggregate data is used to determine the scope, type, and methods of child care delivery. This provides ACF with the information necessary to make reports to Congress, address national child care needs, offer technical assistance to grantees, meet performance measures, and conduct research. Consistent with the statute and regulations, ACF requests extension of the ACF–800.

Respondents: States, the District of Columbia, and Territories including Puerto Rico, Guam, the Virgin Islands, American Samoa, and the Northern Marianna Islands.

Annual Burden Estimates

Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
ACF–800	56	1	40	2,240

Estimated Total Annual Burden Hours:

In compliance with the requirements of section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995, the Administration for Children and Families is soliciting public comment on the specific aspects of the information collection described above. Copies of the proposed collection of information can be obtained and comments may be forwarded by writing to the Administration for Children and Families, Office of Administration, Office of Information Services, 370 L'Enfant Promenade, SW., Washington, DC 20447, Attn: ACF Reports Clearance Officer. All requests should be identified by the title of the information collection.

The Department specifically requests comments on: (a) Whether the proposed collection of information is necessary to 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) 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 within 60 days of this publication.

Dated: March 10, 2003.

Robert Sargis,

Reports Clearance Officer.

[FR Doc. 03–6153 Filed 3–31–03; 8:45 am]

BILLING CODE 4184–01–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of Inspector General

Program Exclusions: February 2003

AGENCY: Office of Inspector General, HHS.

ACTION: Notice of program exclusions.

During the month of February 2003, the HHS Office of Inspector General imposed exclusions in the cases set forth below. When an exclusions is imposed, no program payment is made to anyone for any items or services (other than an emergency item or service not provided in a hospital emergency room) furnished, ordered or prescribed by an excluded party under the Medicare, Medicaid, and all Federal Health Care programs. In addition, no program payment is made to any business or facility, *e.g.*, a hospital, that submits bills for payment for items or services provided by an excluded party. Program beneficiaries remain free to decide for themselves whether they will continue to use the services of an excluded party even though no program payments will be made for items and services provided by that excluded party. The exclusions have national effect and also apply to all Executive Branch procurement and non-procurement programs and activities.

Subject city, state	Effective date
PROGRAM-RELATED CONVICTIONS	
ALMAZAN, ABNER LA CANADA, CA	03/20/2003
ARCHER, MICHELE PHILADELPHIA, PA	03/20/2003
BOGUSLAVSKY, ELLEN E ELMHURST, NY	03/20/2003
BUTLER, LAURA A CASCO, ME	03/20/2003
CALPO, EPIFANIA DIRECTO JACOB UNION CITY, CA	03/20/2003
CASILLAS, ALFREDO MIAMI, FL	03/20/2003
DANIELS, HERBERT A YANKTON, SD	03/20/2003
DBB, INC TAMPA, FL	03/20/2003
DICHIARA, JOSEPH A JAMESTOWN, NY	03/20/2003
DIRECTO, ELIZABETH BASA NORCO, CA	03/20/2003
HUTCHINSON, MICHAEL LOMPOC, CA	03/20/2003
JONES, CHARLES ALDEN SEATTLE, WA	03/20/2003
JONES, BENJAMIN MCKENNY SEATTLE, WA	03/20/2003
KAMNA, BARBARA LOUISE WILSONVILLE, OR	03/20/2003
MKHITARIAN, OVAKIM LOS ANGELES, CA	03/20/2003
PEREZ, PEDRO AGUSTIN MIAMI, FL	10/02/2001
REGIL, ODALYS MIAMI, FL	03/20/2003
SEMIDEY-ROMAN, ROCIO YAUCO, PR	03/20/2003
TRANMER, DEBBIE POCATELLO, ID	03/20/2003
WALL, MITCHELL WARREN, ME	03/20/2003
WARD, DANIEL F WESTWOOD, KS	03/20/2003
WILLIAMS, ROGER FISHKILL, NY	03/20/2003
WORTHINGTON, WINSTON HALL KNOXVILLE, TN	03/20/2003
ZAKRZESKI, PAUL SHREWSBURY, PA	03/20/2003
FELONY CONVICTION FOR HEALTH CARE FRAUD	
BOWIE, CHARLES DOUGLAS JR BALTIMORE, MD	03/20/2003
MALISCH, ANNETTE RENEE SIOUX CITY, IA	03/20/2003
MCQUAITE, JEFFREY T HOLLAND, PA	03/20/2003
FELONY CONTROL SUBSTANCE CONVICTIONS	
ACOSTA, ARMANDO M	03/20/2003

Subject city, state	Effective date
LEXINGTON, KY	
BATEMAN, AMY MICHELLE ... LOOGOOTEE, IN	03/20/2003
CARRILLO, BRENDA RENEE CAMARILLO, CA	03/20/2003
CARSON, KATHERINE R ..... MENTOR, OH	03/20/2003
CLOUTIER, ROBERT M ..... SALEM, MA	03/20/2003
EDMONDS, NORMA LYNN ..... APPLE VALLEY, CA	03/20/2003
FELTMAN, HILLARY ANN ..... LUFKIN, TX	03/20/2003
MCGLAMERY, DAVID A ..... GRANTSVILLE, UT	03/20/2003
MORGIA, KIMBERLY ANNE .... YORK, NE	03/20/2003
PULLIAM, TIMOTHY W ..... TALLADEGA, AL	03/20/2003
RILEY, BRIDGETT ..... LINDENWOLD, NJ	03/20/2003
TURNER, DIANE C ..... CASPER, WY	03/20/2003
PATIENT ABUSE/NEGLECT CONVICTIONS	
DANIELS, CAROLE ..... BRUCE, MS	03/20/2003
DEBOUVIER, JUDE JOSEPH BOULDER, CO	03/20/2003
GRAY, JACCI LYNN ..... MCLOUD, OK	03/20/2003
RITCH, SHERRY L ..... BALTIMORE, MD	03/20/2003
SANDERS, KENDALL ..... JESSUP, MD	03/20/2003
SPOERRY, FLOYD DEAN ..... DEXTER, IA	03/20/2003
SPRAGUE, CHAD E ..... W RUTLAND, VT	03/20/2003
WATT, JAMES S ..... RUTHER GLEN, VA	03/20/2003
CONVICTION—OBSTRUCTION OF AN INVESTIGATION	
FRYMIRE, MARY KATHRYN ... MARQUAND, MO	03/20/2003
LICENSE REVOCATION/SUSPENSION/ SURRENDERED	
ALVORD, MARSHA DIANE ..... ROY, UT	03/20/2003
ARAGON, MICHAEL ANTHONY ..... WESTMINSTER, CA	03/20/2003
BAIN-CHARIF, BEVERLY ..... WINDSOR ONTARIO,	03/20/2003
BANKS, KATHY LEE ..... EDGEWOOD, NM	03/20/2003
BECKER, DONALD EUGENE BLACKWELL, OK	03/20/2003
BERG, JULIE ANNE ..... SALT LAKE CITY, UT	03/20/2003
BEYERLE, CLINTON D ..... SAN FERNANDO, CA	03/20/2003
BOWMAN, JOYCE L ..... CEDAR FALLS, IA	03/20/2003
BRAICK, SALIM MANSOUR .... UTICA, NY	03/20/2003
BROWN, CINDY MARIE ..... YUMA, AZ	03/20/2003
BUERLEN, RACHEL H ..... RUTLAND, MA	03/20/2003
CHILDS, KRIS A ..... PHOENIX, AZ	03/20/2003
COLE, KIM L ..... WILLIAMSBURG, VA	03/20/2003
CORLEY, EDNA M ..... CHICAGO, IL	03/20/2003
COSTILOE, WANDA JUNE ..... OAKDALE, PA	03/20/2003
DAVIDSON HINES, KELLY DAWN ..... IDABEL, OK	03/20/2003
DOTTLE, MAUREEN DUNCAN GIBSONIA, PA	03/20/2003
DUMOND, CRAIG B ..... ALBANY, NY	03/20/2003
ELLIS-BALES, THERESA ..... BALTIMORE, MD	03/20/2003
GERMAN, TIMOTHY ROWLEY PHOENIX, AZ	03/20/2003
GOLIN, MARK M ..... RIDGEWOOD, NJ	03/20/2003
HARDY, MICHELLE D ..... BALTIMORE, MD	03/20/2003
HOWESA, PATSY A ..... SCOTTSDALE, AZ	03/20/2003
HUNT, MALETA D ..... TUCSON, AZ	03/20/2003
IVEY, VARNER JEAN ..... FRANKLIN, VA	03/20/2003
JAKUBIAK, PAUL J ..... WILLIAMSTON, MI	03/20/2003
JAMES, CORNELIUS W ..... GLENDALE, AZ	03/20/2003
JARROLD, DENISE M ..... PHOENIX, AZ	03/20/2003
JONES, NAOMI ..... DUNCANSVILLE, PA	03/20/2003
JONES, DAVID W ..... NEWARK, NJ	03/20/2003
KANTOR, HOWARD L ..... LAKE OSWEGO, OR	03/20/2003
KILZER, MARYANN A ..... OMAHA, NE	03/20/2003
KRELL, TRACY A ..... BLUE ISLAND, IL	03/20/2003
LATHAM, BRIAN ..... TEXARKANA, TX	03/20/2003
LEE, NAM HOON ..... LOS ANGELES, CA	03/20/2003
LINNELL, CHRISTINA JOYCE SAN LORENZO, CA	03/20/2003
MACGINNIS, STEPHEN D ..... OXFORD, MA	03/20/2003
MALLORY, CHARLES DOUGLAS ..... VIRGINIA BEACH, VA	03/20/2003
MCCAFFERTY-MATTIA, MAUREEN C ..... NORTH HAVEN, CT	03/20/2003
MCCARTHY, THOMAS A ..... MACUNGIE, PA	03/20/2003
MCGEE, JULIE L ..... E GREENWICH, RI	03/20/2003
MCGEE-RUSSELL, PATRICK M ..... SANTA FE, NM	03/20/2003
MITCHELL, SHANN RANAE .... ANCHORAGE, AK	03/20/2003
MONDOCK, PENNY ANN ..... BOSWELL, PA	03/20/2003
MORENO, BRENDA A ..... CHANDLER, AZ	03/20/2003
O'MEARA, RICHARD DON ..... DRAPER, UT	03/20/2003
PACKEY, DARREL ROWAN ... PITTSBURGH, PA	03/20/2003
PAINTER, BRENDA LYNN ..... GLENDALE, AZ	03/20/2003
PEAK, DOROTHEA JOY ..... SALT LAKE CITY, UT	03/20/2003
PEREZ, ANDREW M ..... PHOENIX, AZ	03/20/2003
PERRYMAN, BRET A ..... LINCOLNVILLE, ME	03/20/2003
PHILLIPS, DAVID CHAFFEE ... ROSSFORD, OH	03/20/2003
RECKARD, NANCY ANN ..... TEMPE, AZ	03/20/2003
RICKARD, VERNON DAVID .... SONORA, CA	03/20/2003
ROSE, JAMES TIMOTHY ..... HOUSTON, TX	03/20/2003
SCHLOSSER, MICHAEL S ..... OGDEN, UT	03/20/2003
SCHMUTZ, GEORGE DAVID .. WARSAW, MO	03/20/2003
SMETTLER, KIM ..... HAYWARD, CA	03/20/2003
STADIEM, JACQUELINE WILLIAMS ..... CARLSBAD, CA	03/20/2003
THOMAS, SCOTT A ..... ANCHORAGE, AK	03/20/2003
WEST, LINDA MACFADDEN ... TUCSON, AZ	03/20/2003
WOODWARD, JEROME P ..... ROCHESTER, NY	03/20/2003
YORK, BETTY JEAN ..... CHANDLER, AZ	03/20/2003
YU, BONITO CHUA ..... S SAN FRANCISCO, CA	03/20/2003
FRAUD/KICKBACKS	
MOORE, JOHN T ..... NORWALK, CT	08/05/2002
OWNED/CONTROLLED BY CONVICTED ENTITIES	
A-COMMUNITY HOME HEALTH, INC ..... MIAMI, FL	03/20/2003
CLASSIC COMFORT, INC ..... RESEDA, CA	03/20/2003
IDEAL COUNTRY PL & SCHOOL ..... MIAMI, FL	03/20/2003
MEDICAL INFORMATIONAL SVC, INC ..... MIAMI, FL	03/20/2003
SASB, INC ..... RESEDA, CA	03/20/2003
T & T MEDICAL, INC ..... MIAMI, FL	03/20/2003
DEFAULT ON HEAL LOAN	
ENGLISH, THOMAS W ..... DAVENPORT, IA	01/23/2003

Dated: February 28, 2003.

Katherine B. Petrowski,

Director, Exclusions Staff, Office of Inspector General.

[FR Doc. 03–6173 Filed 3–13–03; 8:45 am]

BILLING CODE 4150–04–P

DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

[Docket No. FR–4809–N–11]

Federal Property Suitable as Facilities To Assist the Homeless

AGENCY: Office of the Assistant Secretary for Community Planning and Development, HUD.

ACTION: Notice.

SUMMARY: This Notice identifies unutilized, underutilized, excess, and surplus Federal property reviewed by HUD for suitability for possible use to assist the homeless.

EFFECTIVE DATE: March 14, 2003.

FOR FURTHER INFORMATION CONTACT: Mark Johnston, Department of Housing and Urban Development, Room 7262, 451 Seventh Street SW., Washington DC 20410; telephone (202) 708–1234; TTY number for the hearing- and speech-impaired (202) 708–2565, (these telephone numbers are not toll-free), or call the toll-free Title V information line at 1–800–927–7588.

SUPPLEMENTARY INFORMATION: In accordance with the December 12, 1998 court order in *National Coalition for the Homeless* v. *Veterans Administration,* No. 88–2503–OG (D.D.C.), HUD publishes a Notice, on a weekly basis, identifying unutilized, underutilized, excess and surplus Federal buildings and real property that HUD has reviewed for suitability for use to assist the homeless. Today's Notice is for the purpose of announcing that no additional properties have been determined suitable or unsuitable this week.

Dated: March 6, 2003.

John D. Garrity,

Director, Office of Special Needs Assistant Programs.

[FR Doc. 03–5786 Filed 3–13–03; 8:45 am]

BILLING CODE 4210–29–M

DEPARTMENT OF THE INTERIOR

Fish and Wildlife Service

Hanford Reach National Monument Federal Advisory Committee Meetings Notice

AGENCY: Fish and Wildlife Service.

ACTION: Hanford Reach National Monument Federal Advisory Committee meetings notice.

SUMMARY: The U.S. Fish and Wildlife Service (Service) is announcing two meetings of the Hanford Reach National Monument Federal Planning Advisory Committee (Committee). Meeting details are under **DATES.**

DATES: The Committee has scheduled the following two meetings:

1. Wednesday, April 16, 2003 from 1 p.m. to 7 p.m., Columbia Basin College, CH2M Hill Technology Education Center Rooms 180 B and E, 2600 N. 20th Avenue, Pasco, Washington.

2. Thursday, May 29, 2003 from 9 a.m. to 4 p.m., Washington State University Tri-Cities, Consolidate Information Center Rooms 120 and 120A, 2770 University Drive, Richland, Washington.

Verbal comments will be considered during the course of the meeting and written comments will be accepted at the close of the meeting. Comments may also be submitted via email or mail to the Monument office addresses below. The meetings are open to the public.

ADDRESSES: Any member of the public wishing to submit written comments should send those to Mr. Greg Hughes, Designated Federal Official for the Hanford Reach National Monument (HRNM) Federal Planning Advisory Committee, Hanford Reach National Monument/Saddle Mountain National Wildlife Refuge, 3250 Port of Benton Blvd., Richland, WA 99352; fax (509) 375–0196. Copies of the draft meeting agenda can be obtained from the Designated Federal Official. Comments may be submitted via email to *hanfordreach@fws.gov.*

FOR FURTHER INFORMATION CONTACT: Any member of the public wishing further information concerning the meeting should contact Mr. Greg Hughes, Designated Federal Official for the HRNM Federal Planning Advisory Committee; phone (509) 371–1801, fax (509) 375–0196.

SUPPLEMENTARY INFORMATION: Over the next several months, the Committee will receive information from Planning Workshops and present advice to the Service and Department of Energy on draft products from the Workshops to be considered in the Comprehensive Conservation Plan and Environmental Impact Statement. The Committee will also nominate and elect a chair and vice-chair.

Dated: February 14, 2003.

Rowan Gould,

Deputy Regional Director, Region 1, Portland, Oregon.

[FR Doc. 03–6135 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–55–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA–610–03–1220–AA]

Notice of Cancellation of Public Meeting, California Desert District Advisory Council

AGENCY: Bureau of Land Management, Interior.

ACTION: Cancellation Notice of California Desert District Advisory Council Public Meeting.

SUMMARY: Publication of this notice serves to notify the public that the U.S. Department of the Interior, Bureau of Land Management (BLM) California Desert District Advisory Council (DAC) field tour scheduled on Thursday, March 27, 2003, and the public meeting scheduled on Friday, March 28 and Saturday, March 29, 2003, in Barstow, California have been canceled.

FOR MORE INFORMATION CONTACT: Doran Sanchez, BLM California Desert District External Affairs, at (909) 697–5220.

Dated: March 10, 2003.

Linda Hansen,

District Manager.

[FR Doc. 03–6138 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–40–P

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CO–154–1610–DP–GGCA]

Notice of Availability of a Draft Resource Management Plan and Environmental Impact Statement for the Gunnison Gorge National Conservation Area

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice of availability of Draft Resource Management Plan and Environmental Impact Statement (DRMP/EIS) for the Gunnison Gorge National Conservation Area (NCA).

SUMMARY: In accordance with section 202 of the National Environmental Policy Act (NEPA) of 1969, and under authority of the Federal Land Policy and Management Act of 1976 (FLPMA), a Draft RMP/EIS has been prepared for the

Gunnison Gorge National Conservation Area. The planning area lies in Montrose and Delta Counties, Colorado. The DRMP/EIS provides direction and guidance for the management of public lands and resources of the NCA, as well as monitoring and evaluation requirements. The RMP will also amend the Uncompahgre RMP (1989) for the affected lands in the planning area. Some decisions in the existing planning and management documents may be carried forward into the new NCA RMP. Once approved in a Record of Decision (ROD), the RMP for the NCA will supercede all existing management plans for the public lands within the NCA. The DRMP/EIS evaluates the Current Management Alternative, the Agency Preferred Alternative, and two other alternative management approaches. Tetra Tech, Inc., an environmental consulting firm in Boulder, Colorado, is assisting the BLM in the preparation of these documents and in the planning process for the NCA.

DATES: Written comments on the DRMP/EIS will be accepted for 90 days following the date the Environmental Protection Agency (EPA) publishes this Notice of Availability in the **Federal Register**. Future public meetings and any other public involvement activities will be announced at least 15 days in advance through public notices, media news releases, the project Web site at *http://www.gunnison-gorge-eis.com,* and/or mailings.

ADDRESSES: Written comments should be sent to Angie Nelson, Tetra Tech, Inc., 3775 Iris Avenue, Suite #4, Boulder, Colorado, 80301. Comments also may be sent by e-mail to Angie Nelson at *angie.nelson@tetratech.com.* Written comments, including names and addresses of respondents, will be available for public review at either the office of Tetra Tech in Boulder (address above) or at the offices of the Gunnison Gorge National Conservation Area, 2465 South Townsend Avenue, Montrose, Colorado, 81401 during normal working hours (7:45 a.m. to 4:30 p.m., except holidays). Responses to the comments will be published as part of the Proposed Resource Management Plan/Final Environmental Impact Statement. Individuals may request confidentiality. If you wish to withhold your name or address from public review or from disclosure under the Freedom of Information Act, you must state this prominently at the beginning of your comment. Such requests will be honored to the extent allowed by law. All submissions from organizations or businesses will be made available for public inspection in their entirety.

Copies of the DRMP/EIS are available at the Gunnison Gorge National Conservation Area office and at the office of Tetra Tech, Inc. in Boulder at the addresses above. Copies are also available at the following libraries:

Montrose Public Library, 320 South 2nd Street, Montrose, CO 81401.

Delta Public Library, 211 West 6th Street, Delta, CO 81416.

Crawford Public Library, 425 Highway 92, Crawford, CO 81415.

Hotchkiss Public Library, 1st and Main Street, Hotchkiss, CO 81419.

The planning documents and direct supporting record for the analysis for the DRMP/EIS will be available for inspection at the offices of Tetra Tech, Inc. in Boulder or at the NCA offices during normal working hours. The DRMP/EIS and other associated documents or background information may be viewed and downloaded in PDF format at the project Web site at *http://www.gunnison-gorge-eis.com.*

FOR FURTHER INFORMATION CONTACT: For further information and/or to have your name added to our mailing list, contact Bill Bottomly (970) 240–5337, Planning and Environmental Coordinator (*bill_bottomly@co.blm.gov*), or Karen Tucker at (970) 240–5309 (*karen_tucker@co.blm.gov*), Gunnison Gorge NCA Manager, Bureau of Land Management, Gunnison Gorge National Conservation Area, 2465 South Townsend Avenue, Montrose, CO 81401.

SUPPLEMENTARY INFORMATION: The Black Canyon of the Gunnison National Park and Gunnison Gorge National Conservation Act of 1999 designated the Gunnison Gorge NCA and Wilderness within the NCA. The BLM Uncompahgre Field Office (UFO) in Montrose, Colorado, manages these lands. The 1999 Act directs the BLM to develop ''a comprehensive plan for the long-range protection and management of the Conservation Area''.

The planning area addressed in the RMP contains 55,745 acres of public surface estate within the NCA and Wilderness, 39,888 acres of other BLM managed lands, 666 acres at Sweitzer Lake State Park, and 99,890 acres of private lands. The Gunnison Gorge Wilderness within the NCA contains 17,700 acres. While the RMP only applies to federal lands, state and private lands are included because these lands are interspersed with the BLM managed lands and could be impacted by BLM management actions. Lands managed by BLM immediately adjacent to the NCA and Wilderness are included within the planning area boundary.

The DRMP/EIS contains four alternatives: Alternative A (Continuation of Current Management); Alternative B (Conservation), Alternative C (Mixed use), and Alternative D (Agency Preferred Alternative). The Planning Themes and associated issues addressed in the process of formulating alternatives include the following: 1. Preservation of natural and wilderness resources of the NCA and Wilderness, promoting conservation of fish and wildlife, including special status species; 2. Management of human activities and uses; 3. Integration of NCA management with other agency and community plans; 4. Determination of facilities and infrastructure needed to provide visitor services and administration of the NCA; 5. Management of transportation and access; and 6. Consideration of private property in the planning area. Some of the issues that have been identified in the scoping process phase of the NCA planning process include: motorized and non-motorized vehicle use, livestock grazing management, allocation of commercial and private river and upland recreation use, river-related resource management, water quantity and quality, land health, riparian and aquatic habitat protection, threatened and endangered and special status species and critical habitat protection, wildlife habitat quality and fragmentation, declining biodiversity, reintroduction of native species, and noxious weed control. Other factors considered include recreation and resource use, protection of wilderness, riparian, and scenic values, the level and intensity of dispersed and developed recreation management, cultural resource protection and interpretation, management of the mineral estate on adjacent areas not withdrawn from mineral entry and location, public access, transportation and utility corridors, and woodland product harvest.

The public collaboration program implemented for this effort included the distribution of a newsletter, three public open houses, and a public collaboration focus group. During this process, sixteen Planning Criteria were developed and reviewed by the public. The Planning Criteria provide the planning team guidance, help set the parameters and sideboards for analysis during the planning process, and help ensure important considerations of concern to the public are addressed. The Planning Criteria include laws, regulations, policy, and other guidance. The complete list of the Planning Criteria

can be found on the project Web site at *http://www.gunnison-gorge-eis.com.* In addition to the 16 Planning Criteria, The Black Canyon of the Gunnison National Park and Gunnison Gorge National Conservation Area Act of 1999 (Pub. L. 106–76, October 21, 1999), the Wilderness Act, public land health standards, as well as other requirements to maintain scenic values, recreational values and meet public recreation demands are additional criteria applied during the process.

The DRMP/EIS recommends the retention of an existing Area of Critical Environmental Concern (ACEC) and the designation of new ACECs in the various alternatives. Under all alternatives, the effects of retaining and/or recommending designations of ACECs regarding restrictions in surface disturbing activities will occur only to the degree necessary to prevent damage and disturbance to the features and resources for which the area was designated. ACEC recommendations are as follows:

In Alternative A (Continuation of Current Management): The existing designation of the 161-acre Fairview Research Natural Area/Area of Critical Environmental Concern (RNA/ACEC) is retained.

In Alternative B (Conservation): (1) The existing designation of the 161-acres Fairview Research Natural Area/Area of Critical Environmental Concern (RNA/ACEC) is retained; (2) The Gunnison Sage Grouse Important Bird Area/ACEC (IBA/ACEC–16,531 acres outside the NCA boundary) is recommended for designation. The nomination was made by the public collaboration group. The lands are currently being managed according to the existing *Gunnison Sage Grouse Conservation Plan, Crawford Area, Colorado;* (3) Mancos Shale ACEC/Research Natural Area (19,797 acres inside NCA) is recommended for designation by USGS and BLM; (4) Relic Tree ACEC/Outstanding Natural Area (387 acres inside the NCA) is nominated for designation by a public collaboration group and former Management Framework Plan; (5) Native Plant Community ACEC/Outstanding Natural Area (4,577 acres inside NCA) is nominated for designation by The Nature Conservancy, and (6) Gunnison and North Fork Rivers ACEC, 2,702 acres outside the NCA, nominated by the focus group and BLM.

In Alternative C (Mixed Use): The existing designation of the 161-acre Fairview Research Natural Area/Area of Critical Environmental Concern (RNA/ACEC) is retained.

In Alternative D (Agency Preferred Alternative): (1) The existing designation of the 161-acre Fairview Research Natural Area/Area of Critical Environmental Concern (RNA/ACEC) is retained; (2) The Gunnison Sage Grouse Important Bird Area/ACEC (IBA/ACEC—16,531 acres outside the NCA boundary and 5,669 acres inside the NCA boundary for 22,200 acres total) would be recommended for designation. The same values and features as described in Alternative B are contained in the area; and, (3) Native Plant Community ACEC/ACEC/Outstanding Natural Area (3,785 acres inside NCA) is nominated for designation by The Nature Conservancy.

Dated: December 19, 2002.

Allan J. Belt,

Manager, Uncompahgre Field Office.

[FR Doc. 03–5889 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–JB–P

DEPARTMENT OF THE INTERIOR

National Park Service

General Management Plan/Environmental Impact Statement, Canyon De Chelly National Monument, Arizona

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of Intent to prepare an environmental impact statement for the general management plan, Canyon De Chelly National Monument.

SUMMARY: Under the provisions of the National Environmental Policy Act, the National Park Service is preparing an environmental impact statement for the general management plan for Canyon De Chelly National Monument. The environmental impact statement will be approved by the Director, Intermountain Region.

Canyon de Chelly National Monument is in Apache County, Arizona, on the Navajo Reservation. The monument was authorized by Congress on February 14, 1931, following approval of the monument by the Navajo Tribal Council. Congress charged the National Park Service with the ''* * * care, maintenance, preservation, and restoration of the prehistoric ruins, or other features of scientific or historical interest.'' The National Park Service was also given the right to provide improvements for the ''* * *. administration and protection of the monument * * *,'' and for the ''* * *. care and accommodation of visitors.''

The general management plan will prescribe the resource conditions, visitor experiences, and the nature of the relationship with the Navajo Nation and canyon community that are to be achieved and maintained in the monument over the next 15 to 20 years. The clarification of what must be achieved according to law and policy will be based on review of the monument's purpose, significance, special mandates, and the body of laws and policies directing monument management. Management decisions to be made where law, policy, or regulations do not provide clear guidance or limits will be based on the purposes of the monument, the range of public expectations and concerns, resource analysis, an evaluation of the natural, cultural, and social impacts of alternative courses of action, and consideration of long-term economic costs. Based on determinations of desired conditions, the general management plan will outline the kinds of resource management activities, visitor activities, and development that would be appropriate in the monument in the future. Alternatives will be developed through this planning process and will include, at a minimum, no-action and the preferred alternative.

Major issues include protection of natural and cultural resources; the adequacy of interpretive programs; and potential partnerships with the Navajo Nation and associated American Indian communities, as well as other agencies, organizations, and local interests.

DATES: The National Park Service will conduct public scoping for 60 days from the date of publication of this notice in the **Federal Register**. Open house meetings regarding the general management plan will be held during the public scoping period. Specific dates, times, and locations will be announced in the local media and will also be available by contacting the Superintendent of Canyon De Chelly National Monument.

ADDRESSES: Throughout the scoping and planning process information will be available for public review and comment in the office of the superintendent (Scott Travis, Canyon De Chelly National Monument, PO Box 588, Chinle, AZ 86503).

FOR FURTHER INFORMATION CONTACT: Superintendent Scott Travis, Canyon De Chelly National Monument, PO Box 588, Chinle, AZ 86503; Tel: (928) 674–5500; FAX: (928) 674–5507; e-mail: *scott_travis@nps.gov.*

SUPPLEMENTARY INFORMATION: If you wish to comment on the general management planning process for Canyon de Chelly National Monument, or on any issues associated with the

plan, you may submit your comments by any one of several methods. You may mail comments to Superintendent Scott Travis, Canyon de Chelly National Monument, PO Box 588, Chinle, AZ 86503. You may also e-mail comments to *scott_travis@nps.gov.* Finally, you may hand-deliver comments to the Canyon de Chelly National Monument visitor center (3 miles east of Chinle, Arizona on Highway 7). Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

Dated: January 22, 2003.

Karen P. Wade,

Director, Intermountain Region.

[FR Doc. 03–6207 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Draft Environmental Impact Statement on Vessel Quotas and Operating Requirements for Glacier Bay National Park and Preserve, Alaska

AGENCY: National Park Service, Interior.

ACTION: Notice of availability of the Draft Environmental Impact Statement on Vessel Quotas and Operating Requirements.

SUMMARY: The National Park Service (NPS) announces the availability of the Draft Environmental Impact Statement (EIS) on Vessel Quotas and Operating Requirements for Glacier Bay National Park and Preserve. The document describes and analyzes the environmental impacts of four action alternatives, including a preferred alternative, for managing vessels in Glacier Bay and Dundas Bay. A no action alternative also is evaluated. This notice announces the public comment period, the locations of public hearings, and solicits comments on the EIS.

DATES: Comments on the draft plan and EIS must be received no later than May 13, 2003.

ADDRESSES: Written comments on the EIS should be submitted to Nancy Swanton, EIS Project Manager, 2525 Gambell Street, Anchorage, Alaska 99503. Submit written comments electronically through the park's Web site at *http://www.nps.gov/glba.* The draft EIS may be viewed at this Web site as well. Hard copies and CDs of the Draft EIS are available by request from the aforementioned address. See **SUPPLEMENTARY INFORMATION** for the locations of public hearings.

FOR FURTHER INFORMATION CONTACT: Nancy Swanton, EIS Project Manager, Glacier Bay National Park and Preserve. Telephone: (907) 257–2651.

SUPPLEMENTARY INFORMATION: The National Park Service (NPS) proposes to establish new or keep existing quotas (limits) and operating requirements for four types of waterborne motorized vessels—cruise ships and tour, charter, and private vessels—within Glacier Bay and Dundas Bay in Glacier Bay National Park and Preserve. The purpose for the action is to address the continuing demand for vessel access into Glacier Bay National Park and Preserve in a manner that assures continuing protection of park resources and values while providing for a range of high-quality recreational opportunities for visitors. The need for action stems from legislation enacted in 2001, wherein the U.S. Congress directed the NPS to set the maximum level of vessel entries based on the analysis in this EIS.

The EIS considers a reasonable range of alternatives that include:

- Alternative 1 (no action) would maintain the current vessel quotas, quota season, and operating requirements for Glacier Bay.
- Alternative 2 would set vessel quotas in accordance with the 1985-authorized levels and maintain the current quota season and operating requirements for Glacier Bay.
- Alternative 3 (NPS preferred alternative) would maintain the current vessel quotas for Glacier Bay, with a provision to increase the number of cruise ships. It would maintain the current quota season and operating requirements for Glacier Bay.
- Alternative 4 (environmentally preferred alternative) would maintain the daily quotas for cruise ships and reduce slightly the daily quotas for the other three vessel classes. It would reduce seasonal use days for cruise ships, tour vessels and charter vessels, and would increase slightly the number of seasonal use days for private vessels for Glacier Bay. The quota season would be lengthened to include May and September for all vessel classes. Seasonal entry quotas would be eliminated. Vessel quotas would be initiated for Dundas Bay. Operating requirements would be modified, including limited closure of certain waters to cruise ships and tour vessels.
- Alternative 5 would maintain the current daily vessel quotas and lengthen the quota season to include May and September for cruise ships. It would maintain the number of seasonal use days for cruise ships, tour vessels, and charter vessels during the current quota season but decrease the number of seasonal use days for cruise ships during May and September. It would increase the number of seasonal use days for private vessels. Seasonal entry quotas would be eliminated. Vessel quotas would be initiated for tour and charter vessels in Dundas Bay. Operating requirements would be modified, including limited closures of certain waters to cruise ships and tour vessels.

Public hearings will take place in April 2003 at the following locations: Anchorage, Juneau, Gustavus, Hoonah, Elfin Cove, and Pelican, Alaska, and Seattle, Washington. The specific dates and times of the public hearings will be announced in local media.

Dated: February 12, 2003.

Marcia Blaszak,

Acting Regional Director, Alaska.

[FR Doc. 03–6206 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

General Management Plan Revision, Draft Environmental Impact Statement, Petrified Forest National Park, Arizona

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of availability of the draft Environmental Impact Statement for the General Management Plan Revision for Petrified Forest National Park.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(C), the National Park Service announces the availability of a draft Environmental Impact Statement and General Management Plan Revision for Petrified Forest National Park, Arizona.

DATES: The draft Environmental Impact Statement and General Management Plan Revision will remain available for public review through May 13, 2003. No

public meetings are scheduled at this time.

If you wish to comment, you may submit your comments by any one of several methods. You may mail comments to Superintendent, Petrified Forest National Park, P.O. Box 2217, Petrified Forest National Park, Arizona 86028. You may also comment via the Internet to *Suzy_Stutzman@nps.gov.* Please submit Internet comments either as an ASCII file avoiding the use of special characters and any form of encryption, as a Microsoft Word file, or as a Word Perfect file. Please also include your name and return address in your Internet message. If you do not receive a confirmation from the system that we have received your Internet message, contact us directly by calling Suzy Stutzman at 303–987–6671. Finally, you may hand-deliver comments to the Petrified Forest National Park visitor center or the Intermountain Support Office-Denver, 12795 W. Alameda Parkway, Lakewood, CO (room 186) 80228.

Our practice is to make comments, including names and home addresses of respondents, available for public review during regular business hours. Individual respondents may request that we withhold their home address from the record, which we will honor to the extent allowable by law. There also may be circumstances in which we would withhold from the record a respondent's identity, as allowable by law. If you wish us to withhold your name and/or address, you must state this prominently at the beginning of your comment. We will make all submissions from organizations or businesses, and from individuals identifying themselves as representatives or officials of organizations or businesses, available for public inspection in their entirety.

ADDRESSES: Copies of the draft Environmental Impact Statement and General Management Plan Revision are available from the Superintendent, Petrified Forest National Park, P.O. Box 2217, Petrified Forest National Park, Arizona 86028. The plan is also available on the Internet at: *http://planning.nps.gov/plans.cfm.*

Public reading copies of the document will be available for review at the following locations:

Petrified Forest National Park,
P.O. Box 2217,
Petrified Forest National Park, Arizona 86028,
Telephone: 928–672–2700.

Planning and Environmental Quality,
Intermountain Support Office—Denver,
National Park Service,
12795 W. Alameda Parkway,
Lakewood, CO 80228,
Telephone: (303) 987–6671.

Office of Public Affairs, National Park Service,
Department of Interior,
18th and C Streets NW.,
Washington, DC 20240,
Telephone: (202) 208–6843.

FOR FURTHER INFORMATION CONTACT: Superintendent, Petrified Forest National Park, at the above address and telephone number.

SUPPLEMENTARY INFORMATION: This General Management Plan Revision / Environmental Impact Statement describes and analyzes four alternatives for managing Petrified Forest National Park. The approved plan revision will help managers make decisions about managing resources, visitation, and development for the next 15 to 20 years. Issues addressed by the plan revision relate to use of Painted Desert Inn National Historic Landmark, staff housing needs, cultural landscape values, use and treatment of Painted Desert headquarters complex, museum collections, accommodating researchers, concessions, and providing for resource protection and visitor experience/ understanding in different areas of the park.

Alternative 1, the no-action alternative, would continue present management. It provides a baseline for understanding changes and impacts of the other alternatives. There would be no new construction or major changes, and the park would be operated and maintained as before. Resources would be protected as funding allows. Visitor and operational facilities would remain concentrated in the Painted Desert and Rainbow Forest areas. Some areas would be closed or access modified to address harmful resource impacts. Visitor uses would be reassessed and revised as new information about natural and cultural resource impacts becomes available. Museum collections would be stored offsite and in the park, some in substandard facilities. In *alternative 2,* the preferred alternative, reusing and maintaining the historic integrity of Painted Desert headquarters complex would be a priority. Visitor services at Painted Desert Inn (rehabilitated) would be expanded. Facility improvements would be made at Rainbow Forest. Park lands would be managed similar to now, but with greater protection for natural and cultural resources from increased monitoring and adapting to new information. Some trails and turnouts would be added, and visitor hours would be expanded in the north. Most park collections would be housed in a new facility at headquarters. In *alternative 3,* the park would be managed as a fossil resource preserve. Painted Desert Inn and the headquarters complex would be rehabilitated and adaptively reused. Improvements would be made at Rainbow Forest developed area. This alternative would provide the most protection for natural and cultural resources. Visitors would be encouraged to explore the park primarily in selected frontcountry areas. Some sensitive areas would be closed to visitor use. Backcountry access would be managed with permits and/or other methods (*e.g.*, guided access only). Interpretive services would be expanded to increase understanding of park resources. Park collections would be reunited at the park in a new facility. In *alternative 4,* resources would be protected while more opportunities to experience park resources would be provided. Visitor services at Painted Desert Inn (rehabilitated) would be expanded. Painted Desert headquarters complex would be demolished and rebuilt in phases in the same location. Improvements would be made at Rainbow Forest developed area. New trails, turnouts, and other options would expand opportunities to experience and understand park resources. Visitor hours would be expanded in the north. Park collections would be moved to institutions and/or agency facilities outside the park that meet National Park Service standards.

This document includes discussion of the potential environmental consequences of each alternative. Notable impacts of alternative 1 include adverse impacts to the Painted Desert headquarters complex and historic residences near the Painted Desert Inn from continued deterioration; adverse impacts on museum collections from inadequate facilities, limited work space, and inaccuracies in recordkeeping; adverse impacts on archeological resources and petrified wood and other fossils, primarily from visitor use; adverse impacts on visitor experience and appreciation from dated interpretive materials and lack of opportunities and accessibility. Notable impacts of alternative 2 include potential adverse impacts to archeological sites and petrified wood from new trails; adverse impacts to Rainbow Forest cultural landscape from parking and walkway realignment; beneficial impacts to park collections from construction of a new collections facility; beneficial impacts on visitor experience and appreciation from new turnouts, trails, and facility improvements; beneficial impacts to

park operations from improved work conditions and facilities. Impacts of alternative 3 include adverse impacts to Rainbow Forest cultural landscape from parking and walkway realignment; beneficial impacts on archeological sites and petrified wood from reducing trails and controlling backcountry use; adverse impacts to operations from new visitor programs; beneficial impacts on park operations from improved work conditions and facilities. Impacts of alternative 4 include adverse impacts to Rainbow Forest cultural landscape from parking and walkway realignment; adverse impacts to archeological sites and petrified wood from new trails and turnouts; beneficial impacts on visitor experience and appreciation from new facilities, turnouts, trails, and expanded services; beneficial impacts to park operations from new facilities and removal of deteriorating structures.

Dated: January 24, 2003.

Karen P. Wade,

Director, Intermountain Region, National Park Service.

[FR Doc. 03–6208 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

Notice of Availability of a General Management Plan

AGENCY: National Park Service, Interior.

ACTION: Notice of Availability of a General Management Plan, Draft Environmental Impact Statement for Rock Creek Park, Washington, DC

SUMMARY: Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the National Park Service announces the availability of a draft Environmental Impact Statement and General Management Plan (DEIS/GMP) for Rock Creek Park, Washington, D.C. The DEIS/GMP evaluates four alternatives for the park. The document describes and analyzes the environmental impacts of three action alternatives and a no-action alternative. When approved, the plan will guide management actions during the next 15–20 years.

Alternatives: Alternative A would improve visitor safety, better control traffic volumes and speeds through the park, enhance interpretation and educational opportunities, and improve the use of park resources, especially cultural resources. It generally would retain the current scope of visitor uses. In Alternative B, the no action alternative, Rock Creek Park and the Rock Creek and Potomac Parkway would be maintained as they have evolved thus far. There would not be any major changes in resources management, visitor programs, or facilities beyond regular maintenance. The current park road system would be retained and existing traffic management would continue. Developed in response to comments by members of the public who want to promote non-motorized recreation, Alternative C would eliminate traffic in much of the northern part of the park by closing three sections of Beach Drive to automobiles at all times. These would be the same three segments that currently are closed on weekends. It also would implement traffic-reducing and traffic-calming measures on roads in the southern portion of the park and on the Rock Creek and Potomac Parkway. Under Alternative C management of resources other than traffic would be the same as those listed above for Alternative A. Alternative D was developed in response to a letter sent to the National Park Service by the Mayor of Washington, DC. Alternative D, the National Park Service's preferred alternative, would close three segments of Beach Drive in the northern portion of the park to motorized vehicles for a 6-hour period, from 9:30 a.m. to 3:30 p.m. on weekdays. These would be the same segments that currently are closed on weekends. For the other 18 hours of each weekday, including both rush-hour periods, traffic management would be similar to Alternative B, although traffic-calming measures like those in Alternative A would be used to reduce speeds. Under Alternative D management of resources other than traffic would be in the same manner as presented above for Alternative A.

Public Review: A 90-day public review period for comment on the draft document will begin after publication of this notice. In order to facilitate the review process, public reading copies of the DEIS/GMP will be available for review at the following locations:

Rock Creek Park, 3545 Williamsburg Lane,Washington, DC 20008.

National Capital Region, National Park Service, Lobby,1100 Ohio Drive, NW., Washington, DC 20242.

In addition, the document will be posted on the National Park Service Planning site under: *http://www.nps.gov/rocr/.* Comments on the draft DEIS/GMP should be received (or transmitted by e-mail) no later than 60 days after publication of this **Federal Register** notice. Written comments may be submitted to: Craig Cellar, National Park Service, P.O. Box 25287, Denver, CO 80225–0287 or e-mailed to: *rocr_gmp@nps.gov.*

All comments received will be available for public review at Rock Creek Park headquarters. If individuals submitting comments request that their name and/or address be withheld from public disclosure, it will be honored to the extent allowable by law. Such requests must be stated prominently in the beginning of the comments. There also may be circumstances wherein the National Park Service will withhold a respondent's identity as allowable by law. As always, the National Park Service will make available for public inspection all submissions from organizations or businesses and from persons identifying themselves as representatives or officials of organizations and businesses. Anonymous comments may not be considered.

There will also be a public meeting with a date and location to be determined. The meeting will take place no later than two weeks prior to the closing of the public comment period. The date, time and location of the meeting will be identified in local newspapers as well as on the Internet at *http://www.nps.gov/rocr.*

Decision Process: Notice of the availability of the final document will be published in the **Federal Register**. Subsequently, notice of an approved Record of Decision will be published in the **Federal Register** not sooner than 30 days after the final document is distributed. The official responsible for the decision is the Regional Director, National Capital Region, National Park Service; the official responsible for implementation is the Superintendent of Rock Creek Park.

FOR FURTHER INFORMATION CONTACT: Superintendent Adrienne Applewhaite-Coleman, Rock Creek Park, 3545 Williamsburg Lane, Washington, DC 20008, phone 202–895–6000, fax 202–895–6015, e-mail: *rocr_superintendent@nps.gov.*

Terry R. Carlstrom,

Regional Director, National Capital Region.

[FR Doc. 03–6200 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–M

DEPARTMENT OF THE INTERIOR

National Park Service

General Management Plan, Final Environmental Impact Statement, Tonto National Monument, AR.

AGENCY: National Park Service, Department of the Interior.

ACTION: Notice of availability of the Final Environmental Impact Statement

for the General Management Plan, Tonto National Monument.

SUMMARY: Pursuant to the National Environmental Policy Act of 1969, 42 U.S.C. 4332(c), the National Park Service announces the availability of the Final Environmental Impact Statement for a General Management Plan for Tonto National Monument, Arizona.

DATES: The National Park Service will execute a Record of Decision (ROD) no sooner than 30 days following publication by the Environmental Protection Agency of the notice of availability of the Final Environmental Impact Statement.

ADDRESSES: Information will be available for the public at the following locations: (1) Tonto National Monument, HC02, Box 4602, Roosevelt, AZ 85545. (2) On the NPS Planning Web site at: *http://planning.nps.gov/plans.cfm.*

FOR FURTHER INFORMATION CONTACT: Superintendent, Tonto National Monument, HC02, Box 4602, Roosevelt, AZ 85545 928–467–2241(P).

Dated: January 15, 2003.

Karen P. Wade,

Director, Intermountain Region, National Park Service.

[FR Doc. 03–6204 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Cape Cod National Seashore, South Wellfleet, Massachusetts; Cape Cod National Seashore Advisory Commission, Two Hundred Forty-First Meeting; Notice of Meeting

Notice is hereby given in accordance with the Federal Advisory Committee Act (Pub. L. 92–463, 86 Stat. 770, 5 U.S.C. App 1, section 10), that a meeting of the Cape Cod National Seashore Advisory Commission will be held on April 4, 2003.

The Commission was reestablished pursuant to Public Law 87–126 as amended by Public Law 105–280. The purpose of the Commission is to consult with the Secretary of the Interior, or his designee, with respect to matters relating to the development of Cape Cod National Seashore, and with respect to carrying out the provisions of sections 4 and 5 of the Act establishing the Seashore.

The Commission members will meet at 1 p.m. at Headquarters, Marconi Station, Wellfleet, Massachusetts for the regular business meeting to discuss the following:

1. Adoption of Agenda
2. Approval of minutes of previous meeting (January 24, 2003)
3. Reports of Officers
4. Reports of Subcommittees, Nickerson Fellowship Subcommittee
5. Superintendent's Report, Renewable Energy Initiatives, Salt Pond Visitor Center Update, Prescribed Burns Program, UMass/Olmsted Center work on ''Character'', News from Washington
6. Old Business, Invasive Species, Dune Shack Subcommittee Report
7. New Business
8. Date and agenda for next meeting
9. Public comment and
10. Adjournment

The meeting is open to the public. It is expected that 15 persons will be able to attend the meeting in addition to Commission members.

Interested persons may make oral/written presentations to the Commission during the business meeting or file written statements. Such requests should be made to the park superintendent at least seven days prior to the meeting. Further information concerning the meeting may be obtained from the Superintendent, Cape Cod National Seashore, 99 Marconi Site Road, Wellfleet, MA 02667.

Dated: February 12, 2003.

Ted C. Nicholson,

Acting Superintendent.

[FR Doc. 03–6205 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Chalmette Battlefield Task Force Committee Act

AGENCY: National Park Service, Jean Lafitte National Historical Park and Preserve.

ACTION: Notice of Task Force meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act, 5 U.S.C. App.1, Section 10(a)(2), that a meeting of the Chalmette Battlefield Task Force Committee will be held at 4:00 p.m. at the following location and date:

DATES: Wednesday, March 26, 2003.

ADDRESSES: The Council Chambers Meeting Room at the St. Bernard Parish Government Complex, 8245 W. Judge Perez Drive in Chalmette, LA 70042.

FOR FURTHER INFORMATION CONTACT: Ms. Geraldine Smith, Superintendent, Jean Lafitte National Historical Park and Preserve, 419 Decatur Street, New Orleans, LA 70130, (504) 589–3882, extension 137 or 108.

SUPPLEMENTARY INFORMATION: The purpose of the Chalmette Battlefield Task Force Committee is to advise the Secretary of the Interior on suggested improvements at the Chalmette Battlefield site within Jean Lafitte National Historical Park and Preserve. The members of the Task Force are as follows: Ms. Elizabeth McDougall, chairperson, Ms. Faith Moran, Mr. Anthony A. Fernandez, Jr., Mr. Drew Heaphy, Mr. Alvin W. Guillot, Mrs. George W. Davis, Mr. Eric Cager, Mr. Paul V. Perez, Captain Bonnie Pepper Cook, vice-chairperson, Mr. Michael L. Fraering, Colonel John F. Pugh, Jr., and Geraldine Smith.

The matters to be discussed at this meeting include the purpose of the committee, background and history of the area, current citizens concerns and issues, and scheduling of future meetings. This meeting will be open to the public. However, facilities and space for accommodating members of the public are limited. Any member of the public may file with the committee a written statement concerning the matters to be discussed. Written statements may also be submitted to the superintendent at the address above. Minutes of the meeting will be available at park headquarters for public inspection at 419 Decatur Street, New Orleans, Louisiana for public inspection approximately 4 weeks after the meeting and on the park Web site at *http://www.nps.gov/jela.htm.*

Dated: February 7, 2003.

William W. Schenk,

Regional Director, Southeast Region.

[FR Doc. 03–6203 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Announcement of Gates of the Arctic National Park Subsistence Resource Commission Meeting

AGENCY: National Park Service, Interior.

ACTION: Announcement of Gates of the Arctic National Park Subsistence Resource Commission (SRC) meeting.

SUMMARY: Notice is hereby given in accordance with the Federal Advisory Committee Act that a meeting of the Gates of the Arctic National Park Subsistence Resource Commissions will be held at Shungnak, Alaska. The purpose of the meeting will be to continue work on currently authorized and proposed National Park Service

subsistence hunting program recommendations including other related subsistence management issues. The meeting will be open to the public. Any person may file with the Commission a written statement concerning the matters to be discussed.

The Subsistence Resource Commission is authorized under Title VIII, Section 808, of the Alaska National Interest Lands Conservation Act, Pub. L. 96–487, and operates in accordance with the provisions of the Federal Advisory Committee Act.

DATES: The meeting will begin on Tuesday, May 20, 2003, at 9 a.m. and conclude at approximately 5 p.m. The meeting will reconvene at 9 a.m. on Wednesday, May 21, 2003, and adjourn at approximately 5 p.m. If weather or local circumstances prevent the Commission from meeting on the proposed dates, the Commission will meet on May 28, 2003 and May 29, 2003.

Location: The Commission plans to conduct the public meeting at the National Guard Armory in Shungnak, Alaska.

SUPPLEMENTARY INFORMATION: Notice of this meeting will be published in local newspapers and announced on local radio stations prior to the meeting dates. The agenda for the meeting is as follows:

1. Call to order (SRC Chair).
2. SRC Roll Call and Confirmation of Quorum.
3. SRC Chair and Superintendent's Welcome and Introductions.
4. Review and Approve Agenda.
5. Review and adopt minutes from November 7–8, 2002 meeting.
6. Review Commission Purpose and Status of Membership.
7. Superintendent's Report.
8. Public and Agency Comments.
9. Durational Residency.
10. John River Water Quality Study.
11. Customary Trade Federal Subsistence Regulations.
12. Review New Federal Subsistence Board Wildlife Proposals.
13. Alatna River Archeological Study.
14. Cultural Resources Research Update.
15. Backcountry/Wilderness Planning Update.
16. Federal Subsistence Board Update.
17. Western Arctic Caribou Heard Working Group Update.
18. State Board of Game Update.
19. Set time and place of next SRC meeting.
20. Adjournment

Draft minutes of the meeting will be available for public inspection approximately six weeks after the meeting from the Superintendent, Gates of the Arctic National Park and Preserve, 201 First Ave., Fairbanks, Alaska, 99701.

FOR FURTHER INFORMATION CONTACT: Dave Mills, Superintendent or Fred Andersen, Subsistence Manager at park headquarters, telephone (907) 457–5752.

Robert L. Arnberger,

Regional Director, Alaska.

[FR Doc. 03–6209 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before March 1, 2003. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St., NW., 8th floor, Washington DC 20005; or by fax, 202–343–1836. Written or faxed comments should be submitted by March 31, 2003.

Carol D. Shull,

Keeper of the National Register of Historic Places.

Alaska

Lake and Peninsula Borough-Census Area

Kukak Cannery Archeological Historic District, Katmai National Park and Preserve, Kukak Bay, 03000192.

Arkansas

Cross County

Memphis to Little Rock Road—Village Creek Segment, (Cherokee Trail of Tears MPS), E of Lake Austell within Village Creek State Park, Newcastle, 03000193.

St. Francis County

Blackfish Lake Ferry Site, (Cherokee Trail of Tears MPS), Address Restricted, New Shady Grove, 03000195.

Colorado

Montrose County

Sherman and Ross Block Building, 232–236 Main St., Montrose, 03000196.

Connecticut

Tolland County

Mansfield Hollow Dam, 141 Mansfield Hollow Rd., Mansfield Hollow Dam, Mansfield Center, 03000194.

Georgia

Forsyth County

Fowler Family Farm, 3813 Atlanta Highway, Cumming, 03000200.

Fulton County

Oakland City Historic District, Bounded by Donnelly St., Lee St., Campbellton Rd., and Ingram Rd., Cascade Ave., Westmont Rd., and Epworth Rd., Atlanta, 03000198.

Tattnall County

Glennwanis Hotel, 209–215 E. Barnard St., Glennville, 03000199.

Ware County

First African Baptist Church and Parsonage, 615 Knight St. and 407 Satilla Blvd., Waycross, 03000197.

Iowa

Mahaska County

Rose Hill Methodist Episcopal Church, 304 Main St., Rose Hill, 03000201.

Louisiana

Orleans Parish

Dillard University, 2601 Gentilly Blvd., New Orleans, 03000202.

Maine

Knox County

Rockland Breakwater, S of Jameson Point, Rockland, 03000203.

Missouri

Franklin County

St. Albans General Store, 3516 St. Albans Rd., St. Albans, 03000204.

North Carolina

Vance County

Glebe House, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Harris Crossroads, 03000226.

South Carolina

Greenville County

Aiken, Hugh, House, 1 Parkside Dr., Greenville, 03000207.

Spartanburg County

Alexander House, 319 E. Main St., Spartanburg, 03000205.

Union County

Union Downtown Historic District (Boundary Increase), 125–129 W. Main St., Union, 03000206.

Virginia

Accomack County

Bunting Place, 31181 Drummondtown Rd., Wachapreague, 03000210.

Arlington County

Arlington Village Historic District, S 13th St., S 13 Rd., S 16th St., S Barton S., S. Cleveland St. and Edgewood St., Arlington, 03000215.

Dinwiddie County

Butterwood Methodist Church and Butterwood Cemetery, VA 40, Blackstone, 03000213.

Stony Creek Plantation, VA 624, De Witt, 03000212.

Gloucester County

Cappahosic House, 3198 Cappahosic Rd., Gloucester, 03000211.

Lynchburg Independent City Rivermont Historic District, Rivermont Ave, Lynchburg (Independent City), 03000224.

Mecklenburg County

Cedar Grove, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Clarksville, 03000217.

Garrett Woods—Complex #1, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Clarksville, 03000218.

Garrett Woods—Complex #2, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Clarksville, 03000219.

Garrett Woods—Complex #3, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Clarksville, 03000220.

Ivy Hill Plantation—Samuel Tarry Plantation, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Clarksville, 03000222.

Newman Point, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Boydton, 03000221.

Occoneechee Plantation, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Clarkesville, 03000223.

Rudd Branch Ridge—Complexes #3 and #4, (Archeological Sites within the John H. Kerr Reservoir Area), Address Restricted, Boydton, 03000216.

Powhatan County

Mosby Tavern, 2625 Old Tavern Rd., Powhatan, 03000214.

Prince George County

Chester Plantation, 8401 Golf Course Dr., Disputanta, 03000208.

Warren County

Front Royal Historic District, Irregular district around E and W Main St., and S Royal Ave., Front Royal, 03000209.

Wisconsin

Waukesha County

Saylesville Historic District, Saylesville Rd. From Genesee Creek to Point Dr., Genesee, 03000225.

[FR Doc. 03–6201 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properties being considered for listing in the National Register were received by the National Park Service before February 8, 2003. Pursuant to section 60.13 of 36 CFR part 60 written comments concerning the significance of these properties under the National Register criteria for evaluation may be forwarded by United States Postal Service, to the National Register Historic Places, National Park Service, 1849 C St., NW., 2280, Washington, DC 20240; by all other carriers, National Register of Historic Places, National Park Service, 1201 Eye St., NW., 8th floor, Washington DC 20005; or by fax, 202–343–1836. Written or faxed comments should be submitted by March 31, 2003.

Carol D. Shull,

Keeper of the National Register of Historic Places.

Alaska

Lake and Peninsula Borough-Census Area

Savonoski River Archeological District (Boundary Increase), Address Restricted, Brooks Camp, 03000112.

California

Fresno County

Birdwell Rock Petroglyph Site, Address Restricted, Coalinga, 03000117.

Imperial County

Spoke Wheel Rock Alignment, Address Restricted, Ocotillo, 03000120.

Inyo County

Archeological site CA-INY–134, Address Restricted, Olancha, 03000116.

Kern County

Burro Schmidt's Tunnel, Address Restricted, Ridgecrest, 03000113.

Riverside County

Archeological Sites CA-RIV–504 and CA-RIV–773, Address Restricted, Blythe, 03000121.

Lederer, Gus, Site, Address Restricted, Desert Center, 03000118.

San Bernardino County

Archeological Site CA-SBR–140, Address Restricted, Baker, 03000119.

Iron Mountain Divisional Camp, (Desert Training Center/California-Arizona Maneuver Area (DTC/C-AMA) MPS), CA 62, Iron Mountain Pumping Plant, 03000114.

Shasta County

Swasey Discontiguous Archeological District, Address Restricted, Redding, 03000115.

Idaho

Ada County

Mittleider Farmstead Historic District, (Ada County, Idaho MPS) 575 Rumpel Ln., Meridian, 03000122.

Kootenai County

Spokane Valley Land and Water Company Canal, Diverts in Falls Park, Fourth St., Post Falls, 03000124.

Twin Falls County

Union School, (Public School Buildings in Idaho MPS), 21337 U.S. 30, Filer, 03000123.

Iowa

Davis County

Trimble—Parker Historic Farmstead District, 23981 240th St., Bloomfield, 03000125.

Missouri

St. Louis Independent City Arcade Building, 810 Olive St., St. Louis (Independent City), 03000126.

Montana

Powell County

Grant—Kohrs Ranch/Warren Ranch, Cattle Drive, Grant—Kohrs Ranch National Historic Site, Deer Lodge, 03000127.

New Jersey

Cape May County

Ocean City Residential Historic District, Roughly bounded by 3rd and 8th Sts. and Central and Ocean Aves., Ocean City, 03000129.

Warren County

Delaware Historic District, Ann, Clinton, Charles, and Valley Sts., Delaware Rd., NJ 46 and Ferry Ln., Knowlton Township, 03000128.

New York

Ontario County

Wilder Cemetery, NY 64, S. Bristol, 03000130.

Pennsylvania

Franklin County

Corker Hill, 1237 Garver Ln. Scotland, Greene Township, 03000131.

Tennessee

McMinn County

Etowah Carnegie Library, 723–725 Ohio Ave., Etowah, 03000132.

Wisconsin

Polk County

Frederic Depot, 210 Oak St. W, Frederic, 03000133.

A request for removal for the following resource:

Pennsylvania

Lehigh County

Bridge in Lynn Township, (Highway Bridges Owned by the Commonwealth of Pennsylvania, Department of

Transportation TR), LR39112 over Ontelaunee Creek, Steinsville vicinity, 88000822.

[FR Doc. 03–6202 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–P

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: Denver Art Museum, Denver, CO

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, Sec. 7, of the intent to repatriate cultural items in the possession of the Denver Art Museum, Denver, CO, that meet the definition of ''sacred objects'' under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these cultural items. The National Park Service is not responsible for the determinations within this notice.

The seven cultural items are one medicine cord, one painted wood figurine, two painted skin caps, and three Gaan masks.

In 1936, the Denver Art Museum purchased a medicine cord (1936.216.1) from The Field Museum of Natural History, Chicago, IL. The medicine cord consists of a cord with stone, shell, and bone objects, feathers, and a painted buckskin pouch attached. Accession records indicate that the medicine cord was originally purchased in 1903 by C.L. Owen at ''Cibicu'' on the White Mountain Apache Reservation.

In 1936, the Denver Art Museum purchased a wooden doll figurine (1936.216.2) from The Field Museum of Natural History, Chicago, IL. The painted wood figurine is about 5 inches long with a pony bead choker and feather attached to the neck. The wooden doll figurine originally accompanied a medicine cord that is still at The Field Museum of Natural History. Accession records indicate that the wooden doll figurine and accompanying medicine cord were originally purchased for The Field Museum of Natural History by C.L. Owen from ''Hacka Nelgda,'' also known as ''Angry in Battle'' or ''Old Brigham Young.'' Mr. Owen indicated that he had purchased the wooden doll figurine and accompanying medicine cord at the ''North Fork, W.R.,'' which is assumed to refer to the area of Cibicue, AZ, along the north fork of the White River. The United States census of 1900 (volume 6, 77, sheet 40, line 13) lists Brigham Young as a White Mountain Apache born in 1809 and living in the Cibicue area. Brigham Young's wife is identified in the census records as ''In a Son.''

In 1941, the Denver Art Museum purchased a painted skin cap (1946.179) from M. J. Kolhberg & Company, a Denver antique dealer. The painted skin cap has several feathers attached to the top. It is not known how M.J. Kolhberg & Company acquired the painted skin cap.

In 1946, the Denver Art Museum purchased a painted buckskin cap (1946.215) from Clay Lockett's Yucca House in Tucson, AZ. The painted buckskin cap has a large group of feathers attached to the top. The bill of sale from Clay Lockett's Yucca House lists the hat among ''Apache material'' and describes it as ''M M's Hat.'' This could mean ''medicine man's hat.'' Accession records indicate that the painted buckskin cap was originally collected by Maynard Dixon at Rice, AZ, in 1915. Rice, AZ, is located on the San Carlos Apache Reservation. Accession records identify the painted buckskin cap as ''Western Apache.''

In 1947, the Denver Art Museum purchased the three Gaan masks from Altman Antiques, a Los Angeles, CA, antique dealer. One Gaan mask (1947.256) consists of a fabric hood mask and attached three-pronged wood rack with painted designs. A handwritten note on the catalog card identifies the mask as ''W. Apache.'' The second Gaan clown mask (1947.257) consists of a fabric hood mask and attached triangular wood rack with painted designs. Printing on the fabric on the inside of this mask reads ''Gila Valley Flour Mills.'' Gila Valley Flour Mills is located in the vicinity of the San Carlos Apache Reservation and White Mountain Apache Reservation. The third Gaan mask (1947.258) consists of a fabric hood mask and attached fan-shaped wood rack with painted designs and feathers. The catalog card identifies the mask as ''Apache.'' It is not known how Altman Antiques acquired the three Gaan masks.

Officials of the Denver Art Museum consulted with the Western Apache NAGPRA Working Group regarding the identity and cultural affiliation of the seven cultural items. The Western Apache NAGPRA Working Group represents the interests of the Fort McDowell Yavapai Nation, Arizona; San Carlos Apache Tribe of the San Carlos Apache Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona. The Western Apache NAGPRA Working Group identified Ramon Riley (White Mountain Apache Tribe) and Carlyle Russell (San Carlos Apache Tribe) as traditional religious leaders pursuant to 43 CFR 10.2 (d)(3).

Mr. Riley and Mr. Russell indicated that the seven cultural items must be ritually retired according to traditional Apache religious practice. Research prepared by the Denver Art Museum at the recommendation of the Native American Graves Protection and Repatriation Review Committee confirms that ritual retirement is a traditional ceremonial use of these types of cultural items. Research conducted by the Denver Art Museum identified the design painted on the skin cap (1941.179) as similar to designs painted on caps associated with the 1903-1907 daagodighá religious movement among the White Mountain Apache. Mr. Riley identified the Gaan mask (1947.256) as having been made and used by the White Mountain Apache. Consultation with representatives of the Mescalero Apache Tribe of the Mescalero Reservation, New Mexico, and the Fort Sill Apache Tribe of Oklahoma confirms Mr. Riley's identification. Mr. Riley identified the Gaan mask (1947.258) as having been made and used by the White Mountain Apache based on the materials used, design of the mask, and choice of paint.

Officials of the Denver Art Museum have informed the Western Apache NAGPRA Working Group that the wooden figurine (1936.216.2) was originally collected from a named individual and that a claim from a lineal descendant may be possible, pursuant to 25 U.S.C. 3005, Sec. 7 (a)(5)(C).

Accession records for the medicine cord (1936.216.1) and wooden figure (1936.216.2) are sufficiently detailed to demonstrate a cultural affiliation between these cultural items and the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona. Accession records and consultation with the traditional religious leaders regarding the medicine cap (1941.179), Gaan mask (1947.256), and Gaan mask (1947.258) are sufficient to demonstrate a cultural affiliation between these cultural items and the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona. Accession records for the medicine cap (1946.215) and

Gaan mask (1947.257) are sufficiently detailed to demonstrate a cultural affiliation between these cultural items and the San Carlos Apache Tribe of the San Carlos Apache Reservation, Arizona.

Officials of the Denver Art Museum have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (3)(C), these seven cultural items are specific ceremonial objects needed by traditional Native American religious leaders for the practice of traditional Native American religions by their present-day adherents. Officials of the Denver Art Museum also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (2), there is a relationship of shared group identity that can be reasonably traced between the medicine cord (1936.216.1), wooden figure (1936.216.2), medicine cap (1941.179), Gaan mask (1947.256), and Gaan mask (1947.258) and the White Mountain Apache Tribe of the Fort Apache Reservation, Arizona. Officials of the Denver Art Museum also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (2), there is a relationship of shared group identity that can be reasonably traced between the medicine cap (1946.215) and Gaan mask (1947.257) and the San Carlos Apache Tribe of the San Carlos Apache Reservation, Arizona. Officials of the Denver Art Museum have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (13), the museum holds right of possession to the seven sacred objects. However, the Denver Art Museum has deaccessioned the seven cultural items for purposes of transferring right of possession and control of the items to the Western Apache NAGPRA Working Group pursuant to 25 U.S.C. 3009, Sec. 11 (1).

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these sacred objects should contact Nancy J. Blomberg, Curator of Native Arts, Denver Art Museum, 100 West 14th Avenue Parkway, Denver, CO 80204, telephone (720) 913-0161, before April 14, 2003. Repatriation of the seven sacred objects to the Western Apache NAGPRA Working Group, representing the interests of the Fort McDowell Yavapai Nation, Arizona; San Carlos Apache Tribe of the San Carlos Apache Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; and Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona, may proceed after that date if no additional claimants come forward.

The Denver Art Museum is responsible for notifying the Fort McDowell Yavapai Nation, Arizona; Fort Sill Apache Tribe of Oklahoma; Mescalaro Apache Tribe of the Mescalaro Reservation, New Mexico; San Carlos Apache Tribe of the San Carlos Apache Reservation, Arizona; Tonto Apache Tribe of Arizona; White Mountain Apache Tribe of the Fort Apache Reservation, Arizona; Yavapai-Apache Nation of the Camp Verde Indian Reservation, Arizona; and Western Apache NAGPRA Working Group that this notice has been published.

Dated: January 31, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6215 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: U.S. Department of Justice, United States Marshals Service, Western District of Oklahoma, Oklahoma City, OK

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, Sec. 5, of the completion of an inventory of human remains and associated funerary objects in the possession of the U.S. Department of Justice, United States Marshals Service, Western District of Oklahoma, Oklahoma City, OK. These human remains and associated funerary objects were removed from Greer County, OK.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by United States Marshals Service professional staff in consultation with representatives of the Apache Tribe of Oklahoma; Caddo Indian Tribe of Oklahoma; Cheyenne-Arapaho Tribes of Oklahoma; Chickasaw Nation, Oklahoma; Choctaw Nation of Oklahoma; Comanche Nation, Oklahoma; Quapaw Tribe of Indians, Oklahoma; and Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma. Representatives of the Oklahoma Archeological Survey; Sam Noble Oklahoma Museum of Natural History; and U.S. Department of Interior, Bureau of Indian Affairs were also consulted.

At an unspecified date, human remains representing a minimum of one individual were collected from a specific site in or around Greer County, OK. On June 30, 2001, the human remains were seized by the United States Marshals Service as part of an asset forfeiture from a private residence in Greer County, OK. No known individual was identified. The one associated funerary object is an olivella shell bead.

Based on the general condition of the human remains and the lack of historic period artifacts in the collection that was seized, it is believed that these human remains and associated funerary object were originally interred between 3000 B.C. and A.D. 1500. Archeological evidence indicates that during the period from 3000 B.C. to A.D. 1500, the area including present-day Greer County, OK, was occupied by semisedentary horticulturalists believed to be the ancestors of members of the present-day Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma.

Other items seized as part of the asset forfeiture, including beads, grinding stones, flake tools, scrapers, and arrowheads, do not appear to meet the statutory definition of ''associated funerary objects.'' Officials of the United States Marshals Service have determined, pursuant to standard practice regarding personal property, as set forth in 28 CFR 0.111 (i) and the Attorney General's Guidelines on Seized and Forfeited Property (July 1990), that these items are subject to transfer to the U.S. Department of the Interior, Bureau of Indian Affairs.

Officials of the United States Marshals Service have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (9-10), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the United States Marshals Service also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (3)(A), the one object listed above is reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the United States Marshals Service have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (2), there is a relationship of shared group identity that can be

reasonably traced between these Native American human remains and associated funerary object and the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains and associated funerary object should contact Mr. John Laster, Deputy U.S. Marshal, United States Marshals Service, 200 NW 4th Street, 2nd Floor, Oklahoma City, OK, 73102, telephone (405) 231-4206, before April 14, 2003. Repatriation of these human remains and associated funerary object to the Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma may proceed after that date if no additional claimants come forward.

The United States Marshals Service is responsible for notifying the Apache Tribe of Oklahoma; Caddo Indian Tribe of Oklahoma; Cheyenne-Arapaho Tribes of Oklahoma; Chickasaw Nation, Oklahoma; Choctaw Nation of Oklahama; Comanche Nation, Oklahoma; Quapaw Tribe of Indians, Oklahoma; and Wichita and Affiliated Tribes (Wichita, Keechi, Waco & Tawakonie), Oklahoma that this notice has been published.

Dated: January 28, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6214 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: U.S. Department of Justice, Federal Bureau of Investigation, Resident Agency, Rapid City, SD

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, Sec. 5, of the completion of an inventory of human remains in the possession of the U.S. Department of Justice, Federal Bureau of Investigation, Resident Agency, Rapid City, SD. These human remains were removed from Crystal Cave Park, Pennington County, SD.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Federal Bureau of Investigation, Resident Agency, Rapid City and Smithsonian Institution professional staff in consultation with a representative of the Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota, representing the interests of the Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Flandreau Santee Sioux Tribe of South Dakota; Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Santee Sioux Tribe of the Santee Reservation of Nebraska; and Yankton Sioux Tribe of South Dakota.

According to the owners of Crystal Cave Park, a tourist attraction near Rapid City, SD, at an unknown date human remains representing a minimum of two individuals were removed from Crystal Cave, on the premises of Crystal Cave Park, Pennington County, SD, by prior owners of the facility. In 1997, these human remains were seized from a display case at Crystal Cave Park in connection with an investigation by the Federal Bureau of Investigation, Resident Agency, Rapid City. The human remains consist of the the nearly complete cranium of an adult and the left parietal of a child. No known individuals were identified. No funerary objects were present at the time of seizure.

Following seizure, the two sets of human remains were forwarded to the Smithsonian Institution, National Museum of Natural History, for analysis. Analysis indicated that the adult human remains are Native American. Preservation and appearance of the cranium are consistent with a Historic period burial. These human remains probably came from an exposed context, such as a 19th-century above-ground burial. The presence of copper artifact staining further supports this conclusion in that such staining is a common occurrence in Historic period burials. At some time, it appears likely that the human remains were removed from a burial site and placed inside Crystal Cave. The adult human remains show features specifically characteristic of the Sioux. Based upon cranial measurements and morphological comparisons and consultation with the representative of the Cheyenne River Sioux Tribe of the Cheyenne River Reservation, the tribal affiliation of the adult individual is most likely Sioux, with the closest affinity being the Teton division. Teton is the Lakota group of the Sioux found throughout South Dakota.

Analysis indicated that the child human remains, recovered with the skull from Crystal Cave Park, was the left parietal of a child aged approximately 6 months to 1 year. The condition of the parietal suggested a Historic period context. The sex of the child was indeterminate and the Smithsonian Institution could not make a statement on tribal affiliation. Based on the association of the two sets of human remains, the Federal Bureau of Investigation, Resident Agency, Rapid City considers the human remains of the child to belong to the Teton division of the Sioux.

Officials of the Federal Bureau of Investigation, Resident Agency, Rapid City have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (9-10), the human remains listed above represent the physical remains of two individuals of Native American ancestry. Officials of the Federal Bureau of Investigation, Resident Agency, Rapid City also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (2), there is a relationship of shared group identity that can reasonably be traced between these Native American human remains and the Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Flandreau Santee Sioux Tribe of South Dakota; Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Santee Sioux Tribe of the Santee Reservation of Nebraska; and Yankton Sioux Tribe of South Dakota.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Assistant United States Attorney Gregg S. Peterman, U.S. Department of Justice, 515 Ninth Street, Room 201, Rapid City, SD 57701, telephone (605) 342-7822, before April 14, 2003. Repatriation of the human remains to the Cheyenne River Sioux Tribe of the Cheyenne River Reservation may proceed after that date if no additional claimants come forward.

The Federal Bureau of Investigation, Resident Agency, Rapid City is responsible for notifying the Cheyenne River Sioux Tribe of the Cheyenne River Reservation, South Dakota; Flandreau Santee Sioux Tribe of South Dakota; Oglala Sioux Tribe of the Pine Ridge Reservation, South Dakota; Rosebud Sioux Tribe of the Rosebud Indian Reservation, South Dakota; Santee Sioux Tribe of the Santee Reservation of

Nebraska; and Yankton Sioux Tribe of South Dakota that this notice has been published.

Dated: January 29, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6216 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: Nevada State Museum, Reno, NV, and U.S. Department of Interior, Bureau of Land Management, Nevada State Office, Reno, NV

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, Sec. 5, of the completion of an inventory of human remains and associated funerary objects in the possession of the Nevada State Museum, Reno, NV, and in the control of the U.S. Department of Interior, Bureau of Land Management, Nevada State Office, Reno, NV. These human remains and associated funerary objects were removed from the vicinity of Winnemucca Lake, Washoe County, NV.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by Bureau of Land Management, Nevada State Office professional staff and Nevada State Museum professional staff in consultation with representatives of the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada.

In 1952, human remains representing a minimum of two individuals were removed by the Nevada State Museum during legally authorized excavations at Chimney Cave (site 26Pe3b) near Winnemucca Lake, Washoe County, NV. One of the individuals may have been cremated. No known individuals were identified. No funerary objects are present.

In 1953, human remains representing a minimum of two individuals were removed by the Nevada State Museum during legally authorized excavations at Horse Cave (site 26Pe2) near Winnemucca Lake, Washoe County, NV. One of the individuals may have been cremated. No known individuals were identified. No funerary objects are present.

Between 1952 and 1954, human remains representing a minimum of seven individuals were removed by the Nevada State Museum during legally authorized excavations at Crypt Cave (site 26Pe3a) near Winnemucca Lake, Washoe County, NV. Some of the individuals may have been cremated. No known individuals were identified. The 13 associated funerary objects, found with one individual, are 1 bunch of moss, 2 grass bundles, 8 animal bones, 1 obsidian flake, and 1 piece of worked wood.

In 1960 and 1961, human remains representing a minimum of 14 individuals were removed by the Nevada State Museum during legally authorized excavations at Kramer Cave (site 26Wa196) near Winnemucca Lake, Washoe County, NV. Some of the individuals may have been cremated. No known individuals were identified. No funerary objects are present.

In 1983, human remains representing a minimum of one individual were removed by an unnamed person from the eastern shore of Lake Winnemucca, Washoe County, NV, and were donated anonymously to the Nevada State Museum. No known individuals were identified. No funerary objects are present.

In 1987, human remains representing a minimum of two individuals were removed by Nevada State Museum staff from the backdirt of a looted cave site, Loran's Shelter (26Pe3nl), near Winnemucca Lake, Washoe County, NV. No known individuals were identified. No funerary objects are present.

Some time prior to 1997, human remains representing a minimum of three individuals were removed from an unidentified site, possibly Rollins or Cowbone Cave (site 26Pe3c), near Winnemucca Lake, Washoe County, NV, and were donated anonymously to the Nevada State Museum. No known individuals were identified. No funerary objects are present.

Between 1950 and 1960, human remains representing a minimum of four individuals were donated anonymously to the Nevada State Museum. Museum records suggest that these human remains had been removed from a sand pit on the eastern shore of Lake Winnemucca, Washoe County, NV, but do not indicate when these human remains were removed. No known individuals were identified. No funerary objects are present.

Based on geographic location, stratigraphy, and oral traditions presented by representatives of the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada, the human remains and associated funerary objects are considered to be Native American and culturally affiliated with the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada.

Officials of the Bureau of Land Management, Nevada State Office have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (9-10), the human remains listed above represent the physical remains of a minimum of 35 individuals of Native American ancestry. Officials of the Bureau of Land Management, Nevada State Office also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (3)(A), the 13 objects listed above are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony. Lastly, officials of the Bureau of Land Management, Nevada State Office have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (2), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada.

Representatives of any other Indian tribe, that believes itself to be culturally affiliated with these human remains and associated funerary objects should contact Pat Barker, Bureau of Land Management, Nevada State Office, P.O. Box 12000 Reno, NV 89520, telephone (775) 861-6482, before April 14, 2003. Repatriation of the human remains and associated funerary objects to the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada may proceed after that date if no additional claimants come forward.

The Bureau of Land Management, Nevada State Office is responsible for notifying the Pyramid Lake Paiute Tribe of the Pyramid Lake Reservation, Nevada that this notice has been published.

Dated: February 19, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6212 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: Oregon State Museum of Anthropology, Eugene, OR

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, Sec. 5, of the completion of an inventory of human remains in the possession of the Oregon State Museum of Anthropology, Eugene, OR. These human remains were removed from the vicinity of Dufur, Wasco County, OR.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Oregon State Museum of Anthropology professional staff in consultation with representatives of the Confederated Tribes of the Warm Springs Reservation of Oregon.

In 1963, human remains representing a minimum of one individual were removed by the Oregon State Highway Department from the vicinity of Dufur, south of The Dalles, Wasco County, OR. The human remains were eroding from the edge of Highway 197, approximately 3 miles south of Dufur. The human remains were transferred to the Oregon State Museum of Anthropology during the museum curator's visit to the site in September 1963. No known individual was identified. No associated funerary objects are present.

Historical documents, ethnographic sources, and oral history indicate that the Tenino people have occupied this area of north-central Oregon since precontact times. Based on archeological context, the individual listed above was determined to be Native American and of possible Tenino cultural affiliation. The Tenino is one of the Confederated Tribes of the Warm Springs Reservation of Oregon.

Officials of the Oregon State Museum of Anthropology have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (9-10), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the Oregon State Museum of Anthropology also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (2), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and the Confederated Tribes of the Warm Springs Reservation of Oregon.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact C. Melvin Aikens, Oregon State Museum of Anthropology, 1224 University of Oregon, Eugene, OR 97403-1224, telephone (541) 346-5115, before April 14, 2003. Repatriation of these human remains to the Confederated Tribes of the Warm Springs Reservation of Oregon may proceed after that date if no additional claimants come forward.

The Oregon State Museum of Anthropology is responsible for notifying the Confederated Tribes of the Warm Springs Reservation of Oregon that this notice has been published.

Dated: February 7, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6213 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects in the Possession of the Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, Sec. 5, of the completion of an inventory of human remains and associated funerary objects in the possession of the Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA. These human remains and cultural items were removed from three localities in Jefferson County, NY.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains and associated funerary objects. The National Park Service is not responsible for the determinations within this notice.

This notice corrects the list of culturally affiliated tribes cited in a Notice of Inventory Completion for Native American Human Remains and Associated Funerary Objects published on October 5, 2001. During consultation following the publication of this notice, the museum determined that the human remains of 58 individuals and 6 associated funerary objects are culturally affiliated with the Onondaga Nation of New York, as well as the Oneida Nation of New York and the Oneida Tribe of Wisconsin.

In the **Federal Register** of October 5, 2001, FR doc. 01-24964, pages 51062-51064, paragraphs 11 and 12 are corrected by substituting the following three paragraphs:

Based on the above-mentioned information, officials of the Peabody Museum of Archaeology and Ethnology have determined that, pursuant to 43 CFR 10.2 (d)(1), the human remains listed above represent the physical remains of 58 individuals of Native American ancestry. Officials of the Peabody Museum of Archaeology and Ethnology also have determined that, pursuant to 43 CFR 10.2 (d)(2), the six associated funerary objects described above are reasonably believed to have been placed with or near individual human remains at the times of death or later as part of the death rite or ceremony. Lastly, officials at the Peabody Museum of Archaeology and Ethnology have determined that, pursuant to 43 CFR 10.2 (e), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and associated funerary objects and the Oneida Nation of New York, Oneida Tribe of Wisconsin, and Onondaga Nation of New York.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these objects should contact Patricia Capone, Repatriation Coordinator, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496-3702, before April 14, 2003. Repatriation of these human remains and associated funerary objects to the Oneida Nation of New York, Oneida Tribe of Wisconsin, and Onondaga Nation of New York may proceed after that date if no additional claimants come forward.

The Peabody Museum of Archaeology and Ethnology is responsible for

notifying the Cayuga Nation of New York; Delaware Nation, Oklahoma; Delaware Tribe of Indians, Oklahoma; Oneida Nation of New York; Oneida Tribe of Wisconsin; Onondaga Nation of New York; St. Regis Band of Mohawk Indians of New York; Seneca Nation of New York; Seneca-Cayuga Tribe of Oklahoma; Stockbridge-Munsee Community of Mohican Indians of Wisconsin; Tonawanda Band of Seneca Indians of New York; Tuscarora Nation of New York; and the nonfederally recognized Mohawk Nation Council of Chiefs that this notice has been published.

Dated: January 31, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6210 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items in the Possession of the Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA; Correction

AGENCY: National Park Service, Interior.

ACTION: Notice; correction.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, Sec. 7, of the intent to repatriate cultural items in the possession of the Peabody Museum of Archaeology and Ethnology, Harvard University, Cambridge, MA, that meet the definition of ''unassociated funerary objects'' under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these cultural items. The National Park Service is not responsible for the determinations within this notice.

This notice corrects the list of culturally affiliated tribes cited in the Notice of Intent to Repatriate Cultural Items published on October 5, 2001. During consultation following the publication of the original notice, the museum determined that the 10 unassociated funerary objects described in the notice are culturally affiliated with the Onondaga Nation of New York, as well as the Oneida Nation of New York and the Oneida Tribe of Wisconsin.

In the **Federal Register** of October 5, 2001, FR Doc. 01-24966, pages 51065-51066, paragraphs 5, 6, and 7 are corrected by substituting the following four paragraphs.

Museum records clearly indicate that these cultural items were removed from specific burials of Native American individuals. Based on the archeological materials from the sites, museum documentation, oral histories presented by the Cayuga Nation of New York, Oneida Nation of New York, Oneida Tribe of Wisconsin, Onondaga Nation of New York, St. Regis Band of Mohawk Indians of New York, Seneca Nation of New York, Seneca-Cayuga Tribe of Oklahoma, Tonawanda Band of Seneca Indians of New York, and Tuscarora Nation of New York, the date of the cultural items, and the provenience of these cultural items from areas considered to be aboriginal homelands and traditional burial areas of the Oneida and the Onondaga, a reasonable link of shared group identity may be made between these cultural items and the Oneida Nation of New York, Oneida Tribe of Wisconsin, and Onondaga Nation of New York.

Based upon the above-mentioned information, officials of the Peabody Museum of Archaeology and Ethnology have determined that, pursuant to 43 CFR 10.2(d)(2)(ii), these 10 cultural items are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from specific burial sites of Native American individuals. Officials of the Peabody Museum of Archaeology and Ethnology also have determined that, pursuant to 43 CFR 10.2(e), there is a relationship of shared group identity that can be reasonably traced between these unassociated funerary objects and the Oneida Nation of New York, Oneida Tribe of Wisconsin, and Onondaga Nation of New York.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these unassociated funerary objects should contact Patricia Capone, Repatriation Coordinator, Peabody Museum of Archaeology and Ethnology, Harvard University, 11 Divinity Avenue, Cambridge, MA 02138, telephone (617) 496-3702, before April 14, 2003. Repatriation of these unassociated funerary objects to the Oneida Nation of New York, Oneida Tribe of Wisconsin, and Onondaga Nation of New York may proceed after that date if no additional claimants come forward.

The Peabody Museum of Archaeology and Ethnology is responsible for notifying the Cayuga Nation of New York; Delaware Nation, Oklahoma; Delaware Tribe of Indians, Oklahoma; Oneida Nation of New York; Oneida Tribe of Wisconsin; Onondaga Nation of New York; St. Regis Band of Mohawk Indians of New York; Seneca Nation of New York; Seneca-Cayuga Tribe of Oklahoma; Stockbridge-Munsee Community of Mohican Indians of Wisconsin; Tonawanda Band of Seneca Indians of New York; Tuscarora Nation of New York; and the nonfederally recognized Mohawk Nation Council of Chiefs.

Dated: January 31, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6211 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Intent to Repatriate Cultural Items: Springfield Science Museum, Springfield, MA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3005, Sec. 7, of the intent to repatriate cultural items in the possession of the Springfield Science Museum, Springfield, MA, that meet the definition of ''unassociated funerary objects'' under 25 U.S.C. 3001.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these cultural items. The National Park Service is not responsible for the determinations within this notice.

In 1912, 18 shell beads were removed from the Shield's Mound Complex (Florida site #8DU12), Duval County, FL, by C.B. Moore. These beads were donated the same year to the Springfield Science Museum by Mr. Moore. Accession records indicate that these shell beads were removed from a human burial that also contained a projectile point. Neither the human remains nor

the projectile point were donated to the museum.

Consultation with the Florida State archaeologist revealed that pottery dating to the St. Johns I and II periods was recovered from the Shield's Mound Complex site indicating that the site likely dates from 500 B.C. to A.D. 1562. An assessment of these cultural items has been made by the staff of the Springfield Science Museum in consultation with representatives of the Miccosukee Tribe of Indians of Florida and the Seminole Tribe of Florida, Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations. The Shield's Mound Complex is located within the territory historically occupied by the Miccosukee and has been identified as an earlier occupation area by representatives of the Miccosukee Tribe of Indians of Florida.

Officials of the Springfield Science Museum have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (3)(B), these cultural items are reasonably believed to have been placed with or near individual human remains at the time of death or later as part of the death rite or ceremony and are believed, by a preponderance of the evidence, to have been removed from a specific burial site of an Native American individual. Officials of the Springfield Science Museum also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (2), there is a relationship of shared group identity that can be reasonably traced between these unassociated funerary objects and the Miccosukee Tribe of Indians of Florida.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these unassociated funerary objects should contact David Stier, Director, Springfield Science Museum, 220 State Street, Springfield, MA 01103, telephone (413) 263-6800, extension 321, before April 14, 2003. Repatriation of these unassociated funerary objects to the Miccosukee Tribe of Indians of Florida may proceed after that date if no additional claimants come forward.

The Springfield Science Museum is responsible for notifying the Miccosukee Tribe of Indians of Florida and the Seminole Tribe of Florida, Dania, Big Cypress, Brighton, Hollywood & Tampa Reservations that this notice has been published.

Dated: December 12, 2002.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6218 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF THE INTERIOR

National Park Service

Notice of Inventory Completion: UCLA Fowler Museum of Cultural History, University of California, Los Angeles, Los Angeles, CA, and Department of Anthropology, San Francisco State University, San Francisco, CA

AGENCY: National Park Service, Interior.

ACTION: Notice.

Notice is here given in accordance with the Native American Graves Protection and Repatriation Act (NAGPRA), 25 U.S.C. 3003, Sec. 5, of the completion of an inventory of human remains in the possession of the UCLA Fowler Museum of Cultural History, University of California, Los Angeles, Los Angeles, CA, and in the control of the Department of Anthropology, San Francisco State University, San Francisco, CA. These human remains were removed from a site in Stanislaus County, CA.

This notice is published as part of the National Park Service's administrative responsibilities under NAGPRA, 25 U.S.C. 3003, Sec. 5 (d)(3). The determinations within this notice are the sole responsibility of the museum, institution, or Federal agency that has control of these Native American human remains. The National Park Service is not responsible for the determinations within this notice.

A detailed assessment of the human remains was made by the Department of Anthropology, San Francisco State University professional staff in consultation with representatives of the Central Valley and Mountain Reinterment Association on behalf of the Santa Rosa Indian Community of the Santa Rosa Rancheria, California, and by UCLA Fowler Museum of Cultural History professional staff.

Around 1962, human remains representing a minimum of three individuals were removed from CA-STA-133, a site near Patterson, CA. Collections documentation indicates that the site was recorded in 1962 by Leonard Foote and that the remains were removed during archeological survey and excavations conducted by San Francisco State University students. No known individuals were identified. No funerary objects are present.

Human remains representing two of the three individuals from CA-STA-133 were included in a Notice of Inventory Completion published in the **Federal Register** on December 22, 2000 (FR Doc. 00-32662, pages 80959-8096), by the Department of Anthropology, San Francisco State University and were subsequently repatriated to the Central Valley and Mountain Reinterment Association on behalf of the Santa Rosa Indian Community of the Santa Rosa Rancheria, California. In August 2002, the UCLA Fowler Museum of Cultural History informed the Department of Anthropology at San Francisco State University that among their collections were Native American human remains representing a minimum of one individual from site CA-STA-133. These human remains were never accessioned and are assumed to have been left there by Leonard Foote who was associated with the University of California, Los Angeles, Department of Anthropology for a period some time after 1962.

This individual is identified as Native American based on geographic and oral history evidence. The site is located in the historic territory of the Northern Valley Yokuts Indians. Oral history evidence presented during consultation indicates that there is an association between the Yokuts and the present-day Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

Officials of the Department of Anthropology, San Francisco State University have determined that, pursuant to 25 U.S.C. 3001, Sec. 2 (9-10), the human remains listed above represent the physical remains of one individual of Native American ancestry. Officials of the Department of Anthropology, San Francisco State University also have determined that, pursuant to 25 U.S.C. 3001, Sec. 2(2), there is a relationship of shared group identity that can be reasonably traced between these Native American human remains and the Santa Rosa Indian Community of the Santa Rosa Rancheria, California.

Representatives of any other Indian tribe that believes itself to be culturally affiliated with these human remains should contact Jeff Fentress, NAGPRA Coordinator, Department of Anthropology, San Francisco State University, 1600 Holloway Avenue, San Francisco, CA 94132, telephone (415) 338-2046, before April 14, 2003. Repatriation of the human remains to the Central Valley and Mountain Reinterment Association on behalf of the Santa Rosa Indian Community of the Santa Rosa Rancheria, California may proceed after that date if no additional claimants come forward.

The Department of Anthropology, San Francisco State University is responsible for notifying the Central Valley and Mountain Reinterment Association and the Santa Rosa Indian Community of the Santa Rosa

Rancheria, California that this notice has been published.

Dated: February 19, 2003.

John Robbins,

Assistant Director, Cultural Resources Stewardship and Partnerships.

[FR Doc. 03–6217 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–70–S

DEPARTMENT OF INTERIOR

Office of Surface Mining Reclamation and Enforcement

Notice of Proposed Information Collection for 1029–0025, 1029–0040 and 1029–0104

AGENCY: Office of Surface Mining Reclamation and Enforcement.

ACTION: Notice and request for comments.

SUMMARY: In compliance with the Paperwork Reduction Act of 1995, the Office of Surface Mining Reclamation and Enforcement (OSM) is announcing its intention to request renewed approval for the collections of information for 30 CFR 733, Maintenance of state programs and procedures for substituting federal enforcement of state programs and withdrawing approval of state programs; 785, Requirements for permits for special categories of mining; and 876, Acid mine drainage treatment and abatement program.

DATES: Comments on the proposed information collection activities must be received by May 13, 2003, to be assured of consideration.

ADDRESSES: Comments may be mailed to John A. Trelease, Office of Surface Mining Reclamation and Enforcement, 1951 Constitution Ave, NW., Room 210—SIB, Washington, DC 20240. Comments may also be submitted electronically to *jtreleas@osmre.gov*.

FOR FURTHER INFORMATION CONTACT: To request a copy of the information collection request, explanatory information and related forms, contact John A. Trelease, at (202) 208–2783 or via e-mail at the address listed above.

SUPPLEMENTARY INFORMATION: The Office of Management and Budget (OMB) regulations at 5 CFR 1320, which implement provisions of the Paperwork Reduction Act of 1995 (Pub. L. 104–13), require that interested members of the public and affected agencies have an opportunity to comment on information collection and recordkeeping activities [*see* 5 CFR 1320.8(d)]. This notice identifies information collections that OSM will be submitting to OMB for approval. These collections are contained in (1) 30 CFR 733, Maintenance of state programs and procedures for substituting federal enforcement of state programs and withdrawing approval of state programs; (2) 30 CFR 785, Requirements for permits for special categories of mining; and (3) 30 CFR 876, Acid mine drainage treatment and abatement program. OSM will request a 3-year term of approval for each information collection activity.

Comments are invited on: (1) The need for the collection of information for the performance of the functions of the agency; (2) the accuracy of the agency's burden estimates; (3) ways to enhance the quality, utility and clarity of the information collection; and (4) ways to minimize the information collection burden on respondents, such as use of automated means of collection of the information. A summary of the public comments will accompany OSM's submission of the information collection request to OMB.

The following information is provided for the information collection: (1) Title of the information collection; (2) OMB control number; (3) summary of the information collection activity; and (4) frequency of collection, description of the respondents, estimated total annual responses, and the total annual reporting and recordkeeping burden for the collection of information.

Title: Maintenance of State programs and procedures for substituting Federal enforcement of State programs and withdrawing approval of State programs, 30 CFR 733.

OMB Control Number: 1029–0025.

Summary: This part provides that any interested person may request the Director of OSM to evaluate a State program by setting forth in the request a concise statement of facts that the person believes establishes the need for the evaluation.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Any interested person (individuals, businesses, institutions, organizations).

Total Annual Responses: 2.

Total Annual Burden Hours: 200.

Title: Requirements for permits for special categories of mining, 30 CFR 785.

OMB Control Number: 1029–0040.

Summary: The information is being collected to meet the requirements of sections 507, 508, 510, 515, 701 and 711 of Pub. L. 95–87, which requires applicants for special types of mining activities to provide descriptions, maps, plans and data of the proposed activity. This information will be used by the regulatory authority in determining if the applicant can meet the applicable performance standards for the special type of mining activity.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: Applicants for coalmine permits.

Total Annual Responses: 432.

Total Annual Burden Hours: 47,850.

Title: Acid mine drainage treatment and abatement program, 30 CFR 876.

OMB Control Number: 1029–0104.

Summary: This part establishes the requirements and procedures allowing states and Indian tribes to establish acid mine drainage abatement and treatment programs under the Abandoned Mine Land fund as directed through Pub. L. 101–508.

Bureau Form Number: None.

Frequency of Collection: Once.

Description of Respondents: State governments and Indian tribes.

Total Annual Responses: 1.

Total Annual Burden Hours: 350.

Dated: March 4, 2003.

Sarah E. Donnelly,

Acting Chief, Division of Regulatory Support.

[FR Doc. 03–6189 Filed 3–13–03; 8:45 am]

BILLING CODE 4310–05–M

INTERNATIONAL TRADE COMMISSION

[Investigation No. 332–451]

Advice Concerning Possible Modifications to the U.S. Generalized System of Preferences, 2002 Review

AGENCY: International Trade Commission.

ACTION: Correction of notice of investigation.

SUMMARY: The Commission's notice published in the **Federal Register** on March 7, 2003 (68 FR 11143) contained a typographical error that incorrectly identified one of the HTS subheadings upon which the Commission will provide advice as to the probable economic effect on U.S. industries producing like or directly competitive articles and on consumers of the elimination of U.S. import duties for all beneficiary countries under the GSP. The Commission will provide advice for HTS subheading 7202.93.00; it will not provide advice for HTS subheading 7202.93.00 (pt.).

By order of the Commission.

Issued: March 10, 2003.

Marilyn R. Abbott,

Secretary.

[FR Doc. 03–6124 Filed 3–13–03; 8:45 am]

BILLING CODE 7020–02–P

INTERNATIONAL TRADE COMMISSION

[Investigation No. TA–204–9]

Steel: Monitoring Developments in the Domestic Industry

AGENCY: United States International Trade Commission.

ACTION: Institution and scheduling of an investigation under section 204(a) of the Trade Act of 1974 (19 U.S.C. 2254(a)) (the Act).

SUMMARY: The Commission instituted the investigation for the purpose of preparing the report to the President and the Congress required by section 204(a)(2) of the Trade Act of 1974 on the results of its monitoring of developments with respect to the domestic steel industry since the President imposed tariffs and tariff-rate quotas on imports of certain steel products,[1] effective March 20, 2002.

For further information concerning the conduct of this investigation, hearing procedures, and rules of general application, consult the Commission's Rules of Practice and Procedure, part 201, subparts A through E (19 CFR part 201), and part 206, subparts A and F (19 CFR part 206).

EFFECTIVE DATE: March 5, 2003.

FOR FURTHER INFORMATION CONTACT: Elizabeth Haines (202–205–3200), Office of Investigations, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436. Hearing-impaired persons can obtain information on this matter by contacting the Commission's TDD terminal on 202–205–1810. Persons with mobility impairments who will need special assistance in gaining access to the Commission should contact the Office of the Secretary at 202–205–2000. General information concerning the Commission may also be obtained by accessing its internet server (*http://www.usitc.gov*). The public record for this investigation may be viewed on the Commission's electronic docket (EDIS) at *http://edis.usitc.gov.*

SUPPLEMENTARY INFORMATION:

Background.—Following receipt of a report from the Commission in December 2001 under section 202 of the Trade Act of 1974 (19 U.S.C. 2252) containing affirmative determinations and remedy recommendations, the President, on March 5, 2002, pursuant to section 203 of the Trade Act of 1974 (19 U.S.C. 2253), issued Proclamation 7529, imposing import relief in the form of tariffs and tariff-rate quotas on imports of certain steel products for a period of 3 years and 1 day, effective March 20, 2002. Section 204(a)(1) of the Trade Act of 1974 (19 U.S.C. 2254(a)(1)) requires that the Commission, so long as any action under section 203 of the Trade Act remains in effect, monitor developments with respect to the domestic industry, including the progress and specific efforts made by workers and firms in the domestic industry to make a positive adjustment to import competition. Section 204(a)(2) requires, whenever the initial period of an action under section 203 of the Trade Act exceeds 3 years, that the Commission submit a report on the results of the monitoring under section 204(a)(1) to the President and the Congress not later than the mid-point of the initial period of the relief, or by September 19, 2003, in this case. Section 204(a)(3) requires that the Commission hold a hearing in the course of preparing each such report.

Participation in the investigation and service list.—Persons wishing to participate in the investigation as parties must file an entry of appearance with the Secretary to the Commission, as provided in section 201.11 of the Commission's rules, not later than 21 days after publication of this notice in the **Federal Register**. The Secretary will prepare a service list containing the names and addresses of all persons, or their representatives, who are parties to this investigation upon the expiration of the period for filing entries of appearance.

Limited disclosure of confidential business information (CBI).—Pursuant to section 206.17 of the Commission's rules, the Secretary will make CBI gathered in this investigation available to authorized applicants under an administrative protective order (APO) issued in the investigation, provided that the application is made not later than 21 days after the publication of this notice in the **Federal Register**. A separate service list will be maintained by the Secretary for those parties authorized to receive CBI under the APO.

Public hearings.—As required by statute, the Commission has scheduled hearings in connection with this investigation. The hearings will be held beginning at 9:30 a.m. on July 10, 2003 (stainless steel products), July 15, 2003 (carbon and alloy flat products), July 17, 2003 (carbon and alloy long products), and July 22, 2003 (carbon and alloy tubular products), at the U.S. International Trade Commission Building, 500 E Street SW., Washington, DC. Requests to appear at the hearings should be filed in writing with the Secretary to the Commission on or before June 20, 2003. Requests should identify the products to be addressed and the amount of time requested. All persons desiring to appear at the hearings and make oral presentations should attend a prehearing conference to be held at 9:30 a.m. on July 7, 2003, at the U.S. International Trade Commission Building. Oral testimony and written materials to be submitted at the hearings are governed by sections 201.6(b)(2) and 201.13(f) of the Commission's rules. Parties must submit any request to present a portion of their hearing testimony in camera no later than 7 days prior to the date of the hearing.

Written submissions.—Each party is encouraged to submit a prehearing brief to the Commission. The deadline for filing prehearing briefs is July 2, 2003. Parties may also file posthearing briefs. The deadlines for filing posthearing briefs are July 18, 2003 (for material covered at the hearing on July 10, 2003), July 25, 2003 (for material covered at the hearings on July 15 and 17, 2003) and August 1, 2003 (for material covered at the hearing on July 22, 2003). In addition, any person who has not entered an appearance as a party to the investigation may submit, on or before August 1, 2003, a written statement concerning the matters to be addressed in the Commission's report to the President. All written submissions must conform with the provisions of section 201.8 of the Commission's rules; any submissions that contain confidential business information must also conform with the requirements of section 201.6 of the Commission's rules. Any CBI that is provided will be subject to limited disclosure under the APO (see above) and may be included in the report that the Commission sends to the President. The Commission's rules do not authorize filing of submissions with the Secretary by facsimile or electronic

[1] Subheadings 9903.72.30 through 9903.74.24 of the Harmonized Tariff Schedule of the United States cover the steel products included in these safeguard measures as well as specifying products and sources excluded from the safeguard measures. In the 2003 HTS, subheadings 9903.72.30 through 9903.72.48 cover carbon and alloy steel slabs; subheadings 9903.72.50 through 9903.73.39 cover carbon and alloy steel flat-rolled products (including plates and other hot-rolled steel, cold-rolled steel other than grain-oriented steel, and clad, coated, and plated steel); subheadings 9903.73.42 through 9903.73.62 cover certain carbon and alloy steel bars, rods, and light shapes; subheadings 9903.73.65 through 9903.73.71 cover carbon steel concrete reinforcing bars (rebars); subheadings 9903.73.74 through 9903.73.86 cover certain carbon and alloy steel non-seamless pipes and tubes; subheadings 9903.73.88 through 9903.73.95 cover certain tube and pipe fittings; subheadings 9903.73.97 through 9903.74.16 cover stainless steel bars, rods, angles, shapes, and sections; and subheadings 9903.74.18 through 9903.74.24 cover stainless steel wire.

means, except to the extent permitted by section 201.8 of the Commission's rules, as amended, 67 Fed. Reg. 68036 (November 8, 2002).

In accordance with section 201.16(c) of the Commission's rules, each document filed by a party to the investigation must be served on all other parties to the investigation (as identified by the service list), and a certificate of service must be timely filed. The Secretary will not accept a document for filing without a certificate of service.

Authority: This investigation is being conducted under the authority of section 204(a) of the Trade Act of 1974; this notice is published pursuant to section 206.3 of the Commission's rules.

Dated: March 10, 2003.

By order of the Commission.

Marilyn R. Abbott,

Secretary to the Commission.

[FR Doc. 03–6123 Filed 3–13–03; 8:45 am]

BILLING CODE 7020–02–P

DEPARTMENT OF LABOR

Employment Standards Administration

Wage and Hour Division

Minimum Wages for Federal and Federally Assisted Construction; General Wage Determination Decisions

General wage determination decisions of the Secretary of Labor are issued in accordance with applicable law and are based on the information obtained by the Department of Labor from its study of local wage conditions and data made available from other sources. They specify the basic hourly wage rates and fringe benefits which are determined to be prevailing for the described classes of laborers and mechanics employed on construction projects of a similar character and in the localities specified therein.

The determinations in these decisions of prevailing rates and fringe benefits have been made in accordance with 29 CFR part 1, by authority of the Secretary of Labor pursuant to the provisions of the Davis-Bacon Act of March 3, 1931, as amended (46 Stat. 1494, as amended, 40 U.S.C. 276a) and of other Federal statutes referred to in 29 CFR part 1, Appendix, as well as such additional statutes as may from time to time be enacted containing provisions for the payment of wages determined to be prevailing by the Secretary of Labor in accordance with the Davis-Bacon Act. The prevailing rates and fringe benefits determined in these decisions shall, in accordance with the provisions of the foregoing statutes, constitute the minimum wages payable on Federal and federally assisted construction projects to laborers and mechanics of the specified classes engaged on contract work of the character and in the localities described therein.

Good cause is hereby found for not utilizing notice and public comment procedure thereon prior to the issuance of these determinations as prescribed in 5 U.S.C. 553 and not providing for delay in the effective date as prescribed in that section, because the necessity to issue current construction industry wage determinations frequently and in large volume causes procedures to be impractical and contrary to the public interest.

General wage determination decisions, and modifications and supersedeas decisions thereto, contain no expiration dates and are effective from their date of notice in the **Federal Register**, or on the date written notice is received by the agency, whichever is earlier. These decisions are to be used in accordance with the provisions of 29 CFR parts 1 and 5. Accordingly, the applicable decision, together with any modifications issued, must be made a part of every contract for performance of the described work within the geographic area indicated as required by an applicable Federal prevailing wage law and 29 CFR part 5. The wage rates and fringe benefits, notice of which is published herein, and which are contained in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts,'' shall be the minimum paid by contractors and subcontractors to laborers and mechanics.

Any person, organization, or governmental agency having an interest in the rates determined as prevailing is encouraged to submit wage rate and fringe benefit information for consideration by the Department.

Further information and self-explanatory forms for the purpose of submitting this data may be obtained by writing to the U.S. Department of Labor, Employment Standards Administration, Wage and Hour Division, Division of Wage Determinations, 200 Constitution Avenue, NW., Room S–3014, Washington, DC 20210.

Modification to General Wage Determination Decisions

The number of the decisions listed to the Government Printing Office document entitled ''General Wage Determinations Issued Under the Davis-Bacon and Related Acts'' being modified are listed by Volume and State. Dates of publication in the **Federal Register** are in parentheses following the decisions being modified.

Volume I

None

Volume II

District of Columbia
- DC020001 (Mar. 1, 2002)
- DC020003 (Mar. 1, 2002)

Maryland
- MD020001 (Mar. 1, 2002)
- MD020002 (Mar. 1, 2002)
- MD020009 (Mar. 1, 2002)
- MD020021 (Mar. 1, 2002)
- MD020034 (Mar. 1, 2002)
- MD020036 (Mar. 1, 2002)
- MD020037 (Mar. 1, 2002)
- MD020042 (Mar. 1, 2002)
- MD020043 (Mar. 1, 2002)
- MD020048 (Mar. 1, 2002)
- MD020056 (Mar. 1, 2002)
- MD020057 (Mar. 1, 2002)
- MD020058 (Mar. 1, 2002)

Virginia
- VA020009 (Mar. 1, 2002)
- VA020015 (Mar. 1, 2002)
- VA020017 (Mar. 1, 2002)
- VA020019 (Mar. 1, 2002)
- VA020052 (Mar. 1, 2002)
- VA020078 (Mar. 1, 2002)
- VA020079 (Mar. 1, 2002)
- VA020080 (Mar. 1, 2002)
- VA020085 (Mar. 1, 2002)
- VA020092 (Mar. 1, 2002)
- VA020099 (Mar. 1, 2002)

Volume III

None

Volume IV

Illinois
- IL020001 (Mar. 1, 2002)
- IL020007 (Mar. 1, 2002)
- IL020013 (Mar. 1, 2002)
- IL020016 (Mar. 1, 2002)
- IL020023 (Mar. 1, 2002)
- IL020030 (Mar. 1, 2002)
- IL020042 (Mar. 1, 2002)

Wisconsin
- WI020011 (Mar. 1, 2002)
- WI020019 (Mar. 1, 2002)

Volume V

None

Volume VI

Alaska
- AK020001 (Mar. 1, 2002)

Idaho
- ID020002 (Mar. 1, 2002)
- ID020003 (Mar. 1, 2002)

North Dakota
- ND020008 (Mar. 1, 2002)

Oregon
- OR020001 (Mar. 1, 2002)
- OR020002 (Mar. 1, 2002)

Utah
- UT020015 (Mar. 1, 2002)
- UT020023 (Mar. 1, 2002)
- UT020024 (Mar. 1, 2002)
- UT020027 (Mar. 1, 2002)
- UT020029 (Mar. 1, 2002)
- UT020031 (Mar. 1, 2002)

Volume VII

Nevada

NV020002 (Mar. 1, 2002)

General Wage Determination Publication

General wage determinations issued under the Davis-Bacon and related acts, including those noted above, may be found in the Government Printing Office (GPO) document entitled ''General Wage Determinations Issued Under the Davis-Bacon And Related Act''. This publication is available at each of the 50 Regional Government Depository Libraries and many of the 1,400 Government Depository Libraries across the country.

General wage determinations issued under the Davis-Bacon and related Acts are available electronically at no cost on the Government Printing Office site at *http://www.access.gpo.gov/davisbacon.* They are also available electronically by subscription to the Davis-Bacon Online Service (*http://www.davisbacon.fedworld.gov*) of the National Technical Information Service (NTIS) of the U.S. Department of Commerce at 1–800–363–2068. This subscription offers value-added features such as electronic delivery of modified wage decisions directly to the user's desktop, the ability to access prior wage decisions issued during the year, extensive Help Desk Support, etc.

Hard-copy subscriptions may be purchased from: Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402, (202) 512–1800.

When ordering hard-copy subscription(s), be sure to specify the State(s) of interest, since subscriptions may be ordered for any or all of the six separate Volumes, arranged by State. Subscriptions include an annual edition (issued in January or February) which includes all current general wage determinations for the States covered by each volume. Throughout the remainder of the year, regular weekly updates will be distributed to subscribers.

Signed at Washington, DC this 6th day of March 2003.

Carl J. Poleskey,

Chief, Branch of Construction Wage Determinations.

[FR Doc. 03–5905 Filed 3–13–03; 8:45 am]

BILLING CODE 4510–27–M

DEPARTMENT OF LABOR

Veterans' Employment and Training Service

Secretary of Labor's Advisory Committee for Veterans' Employment and Training; Notice of Open Meeting

The Secretary's Advisory Committee for Veterans' Employment and Training was established under section 4110 of title 38, United States Code, to bring to the attention of the Secretary, problems and issues relating to veterans' employment and training.

Notice is hereby given that the Secretary of Labor's Advisory Committee for Veterans' Employment and Training will meet on Thursday, March 27, 2003, beginning at 9 a.m. at the U.S. Department of Labor, 200 Constitution Avenue, NW., Room, S–2508, Washington, DC, 20210.

Written comments may be submitted by addressing them to: Mr. John Muckelbauer, Designated Federal Official, Office of the Assistant Secretary for Veterans' Employment and Training, U.S. Department of Labor, 200 Constitution Avenue, NW., Room S–1325, Washington, DC, 20210.

The Committee will discuss the implementation of Public Law 107–288, the ''Jobs for Veterans Act,'' continue its review and discussion of its draft recommendations to the Secretary, and discuss other programs and activities of interest to the Committee. The meeting will be open to the public.

Persons with disabilities needing special accommodations should contact Mr. John Muckelbauer at telephone number (202) 693–4700 no later than March 25, 2003.

Signed at Washington, DC March 10, 2003.

Frederico Juarbe, Jr.,

Assistant Secretary of Labor for Veterans' Employment and Training.

[FR Doc. 03–6146 Filed 3–13–03; 8:45 am]

BILLING CODE 4510–79–P

NATIONAL LABOR RELATIONS BOARD

Appointments of Individuals To Serve as Members of Performance Review Boards

5 U.S.C. 4314(c)(4) requires that the appointments of individuals to serve as members of performance review boards be published in the **Federal Register.** Therefore, in compliance with this requirement, notice is hereby given that the individuals whose names and position titles appear below have been appointed to serve as members of performance review boards in the National Labor Relations Board for the rating year beginning October 1, 2001 and ending September 30, 2002.

Name and Title

Richard L. Ahearn—Regional Director, Region 9
Frank V. Battle—Deputy Director of Administration
John F. Colwell—Chief Counsel to Board Member
Harold J. Datz—Chief Counsel to the Chairman
Yvonne T. Dixon—Director, Office of Appeals
John H. Ferguson—Associated General Counsel, Enforcement Litigation
Robert A. Giannasi—Chief Administration Law Judge
Lester A. Heltzer—Deputy Executive Secretary
John E. Higgins—Deputy General Counsel
Peter B. Hoffman—Regional Director, Region 34
Gloria Joseph—Director of Administration
Barry J. Kearney—Associated General Counsel, Advice
James R. Murphy—Chief Counsel to Board Member
Gary W. Shinners—Chief Counsel to Board Member
Richard A. Siegel—Associate General Counsel, Operations-Management
Lafe E. Solomon—Director, Office of Representation Appeals
Jeffrey D. Wedekind—Solicitor
Peter D. Winkler—Chief Counsel to Board Member

Dated: Washington, DC, March 10, 2003, by direction of the Board.

Lester A. Heltzer,

Deputy Executive Secretary.

[FR Doc. 03–6116 Filed 3–13–03; 8:45 am]

BILLING CODE 7545–01–M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–327]

Tennessee Valley Authority; Notice of Consideration of Issuance of Amendment to Facility Operating License, Proposed No Significant Hazards Consideration Determination, and Opportunity for a Hearing

The U.S. Nuclear Regulatory Commission (NRC or the Commission) is considering issuance of an amendment to Facility Operating License DPR–77 issued to the Sequoyah Nuclear Plant (SQN) for operation of Unit 1 located in Hamilton County, Tennessee.

The proposed amendment would revise the SQN, Unit 1, Updated Final Safety Analysis Report (UFSAR). The revision provides a change in methodology using a through-bolted connection frame methodology that is different than the original design and construction of the Unit 1 steam generator (SG) roof compartment. This proposed frame methodology is described in Topical Report No. 24370–TR–C–003, Revision 1, and is requested for implementation upon the restoration of the roof compartment as part of the upcoming SG replacement project for SQN, Unit 1.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act), and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in Title 10 of the Code of Federal Regulations (10 CFR), section 50.92, this means that operation of the facility in accordance with the proposed amendment would not (1) involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety. As required by 10 CFR 50.91(a), the licensee has provided its analysis of the issue of no significant hazards consideration, which is presented below:

1. Does the proposed change involve a significant increase in the probability or consequences of an accident previously evaluated?

No. The probability of occurrence or the consequences of an accident are not increased as presently analyzed in the safety analyses since the objective of the event mitigation is not changed. No changes in event classification as discussed in UFSAR Chapter 15 will occur due to the modification of the Unit 1 steam generator (SG) compartment roof design.

The grout used to fill the gap between the replaced concrete and the surrounding concrete, like the surrounding concrete, could ''theoretically'' experience the formation of micro-cracks when subjected to the design pressure load. Conservative estimates of the flow path through these micro-cracks yield values that are numerically insignificant when compared to the allowable divider barrier bypass leakage. Micro-cracks resulting from the design pressure load will have a negligible effect on the function of the divider barrier and the analyses that depend on the divider barrier. Therefore, the containment design pressure is not challenged, thereby ensuring that the potential for increasing offsite dose limits above those presently analyzed at the containment design pressure of 12.0 pounds per square inch (psi) is not a concern.

Therefore, the proposed modification to the Unit 1 SG compartment roof design will not significantly increase the probability or consequences of an accident previously evaluated.

2. Does the proposed change create the possibility of a new or different kind of accident from any accident previously evaluated?

No. The possibility of a new or different accident situation occurring as a result of this condition is not created. The SG compartment roof forms part of the divider barrier. This barrier is not an initiator of any accident and only serves to force steam that is released from a loss-of-coolant accident/design basis accident (LOCA/DBA) to pass through the ice condenser. The failure of any part of the divider barrier is considered critical since it would allow LOCA/DBA steam to bypass the ice condenser, thereby increasing the pressure within the primary containment.

As discussed in the UFSAR, there is a maximum calculated leakage of 250 cubic feet per minute (cfm) between the upper and lower containment through the divider barrier. The amount of leakage between the two sections of the containment will not be significantly affected by the restoration of the SG compartment roofs. The use of non-shrink grout to seal the joint created between the concrete sections and the remaining structure will maintain the boundaries between upper and lower containment. It is noted that any leakage due to possible cracks in the grout, particularly under DBA loading, will be extremely small and therefore insignificant.

Therefore, the potential for creating a new or unanalyzed condition is not created.

3. Does the proposed change involve a significant reduction in a margin of safety?

No. A design DBA differential pressure assumed in the original design of the SG compartment roof is 23 percent higher than the maximum calculated differential pressure of 19.52 psi. Since the same design differential pressure was also used in the modified SG compartment roof stress evaluation, the margin of safety was not reduced.

As discussed previously, the amount of leakage that bypasses the divider barrier will not be affected by the restoration of the SG compartment roofs. The use of non-shrink grout to seal the joint created between the concrete sections and the remaining structure will maintain the boundaries between upper and lower containment. Hence, the worse-case accident conditions for the containment will not be affected by the proposed modifications.

Therefore, a significant reduction in the margin to safety is not created by this modification.

The NRC staff has reviewed the licensee's analysis and, based on this review, it appears that the three standards of 10 CFR 50.92(c) are satisfied. Therefore, the NRC staff proposes to determine that the amendment request involves no significant hazards consideration.

The Commission is seeking public comments on this proposed determination. Any comments received within 30 days after the date of publication of this notice will be considered in making any final determination.

Normally, the Commission will not issue the amendment until the expiration of the 30-day notice period. However, should circumstances change during the notice period such that failure to act in a timely way would result, for example, in derating or shutdown of the facility, the Commission may issue the license amendment before the expiration of the 30-day notice period, provided that its final determination is that the amendment involves no significant hazards consideration. The final determination will consider all public and State comments received. Should the Commission take this action, it will publish in the **Federal Register** a notice of issuance and provide for opportunity for a hearing after issuance. The Commission expects that the need to take this action will occur very infrequently.

Written comments may be submitted by mail to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Written comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. Federal workdays. Documents may be examined, and/or copied for a fee, at the NRC's Public Document Room, located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland.

The filing of requests for hearing and petitions for leave to intervene is discussed below.

By April 14, 2003, the licensee may file a request for a hearing with respect to issuance of the amendment to the subject facility operating license and any person whose interest may be affected by this proceeding and who wishes to participate as a party in the proceeding must file a written request for a hearing and a petition for leave to intervene. Requests for a hearing and a petition for leave to intervene shall be filed in accordance with the Commission's ''Rules of Practice for Domestic Licensing Proceedings'' in 10

CFR part 2. Interested persons should consult a current copy of 10 CFR 2.714,[1] which is available at the Commission's Public Document Room, located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, or electronically on the Internet at the NRC Web site *http://www.nrc.gov/reading-rm/doc-collections/cfr/*. If there are problems in accessing the document, contact the Public Document Room Reference staff at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.* If a request for a hearing or petition for leave to intervene is filed by the above date, the Commission or an Atomic Safety and Licensing Board, designated by the Commission or by the Chairman of the Atomic Safety and Licensing Board Panel, will rule on the request and/or petition; and the Secretary or the designated Atomic Safety and Licensing Board will issue a notice of hearing or an appropriate order.

As required by 10 CFR 2.714, a petition for leave to intervene shall set forth with particularity the interest of the petitioner in the proceeding, and how that interest may be affected by the results of the proceeding. The petition should specifically explain the reasons why intervention should be permitted with particular reference to the following factors: (1) The nature of the petitioner's right under the Act to be made party to the proceeding; (2) the nature and extent of the petitioner's property, financial, or other interest in the proceeding; and (3) the possible effect of any order which may be entered in the proceeding on the petitioner's interest. The petition should also identify the specific aspect(s) of the subject matter of the proceeding as to which petitioner wishes to intervene. Any person who has filed a petition for leave to intervene or who has been admitted as a party may amend the petition without requesting leave of the Board up to 15 days prior to the first prehearing conference scheduled in the proceeding, but such an amended petition must satisfy the specificity requirements described above.

Not later than 15 days prior to the first prehearing conference scheduled in the proceeding, a petitioner shall file a supplement to the petition to intervene which must include a list of the contentions which are sought to be litigated in the matter. Each contention must consist of a specific statement of the issue of law or fact to be raised or controverted. In addition, the petitioner shall provide a brief explanation of the bases of the contention and a concise statement of the alleged facts or expert opinion which support the contention and on which the petitioner intends to rely in proving the contention at the hearing. The petitioner must also provide references to those specific sources and documents of which the petitioner is aware and on which the petitioner intends to rely to establish those facts or expert opinion. Petitioner must provide sufficient information to show that a genuine dispute exists with the applicant on a material issue of law or fact. Contentions shall be limited to matters within the scope of the amendment under consideration. The contention must be one which, if proven, would entitle the petitioner to relief. A petitioner who fails to file such a supplement which satisfies these requirements with respect to at least one contention will not be permitted to participate as a party.

Those permitted to intervene become parties to the proceeding, subject to any limitations in the order granting leave to intervene, and have the opportunity to participate fully in the conduct of the hearing, including the opportunity to present evidence and cross-examine witnesses.

If a hearing is requested, the Commission will make a final determination on the issue of no significant hazards consideration. The final determination will serve to decide when the hearing is held.

If the final determination is that the amendment request involves no significant hazards consideration, the Commission may issue the amendment and make it immediately effective, notwithstanding the request for a hearing. Any hearing held would take place after issuance of the amendment.

If the final determination is that the amendment request involves a significant hazards consideration, any hearing held would take place before the issuance of any amendment.

A request for a hearing or a petition for leave to intervene must be filed with the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, Attention: Rulemakings and Adjudications Staff, or may be delivered to the Commission's Public Document Room (PDR), located at One White Flint North, Public File Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland, by the above date. Because of the continuing disruptions in delivery of mail to United States Government offices, it is requested that petitions for leave to intervene and requests for hearing be transmitted to the Secretary of the Commission either by means of facsimile transmission to 301–415–1101 or by e-mail to *hearingdocket@nrc.gov.* A copy of the petition for leave to intervene and request for hearing should also be sent to the Office of the General Counsel, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and because of continuing disruptions in delivery of mail to United States Government offices, it is requested that copies be transmitted either by means of facsimile transmission to 301–415–3725 or by e-mail to *OGCMailCenter@nrc.gov.* A copy of the request for hearing and petition for leave to intervene should also be sent to General Counsel, Tennessee Valley Authority, 400 West Summit Hill Drive, ET 10H, Knoxville, Tennessee 37902, attorney for the licensee.

Nontimely filings of petitions for leave to intervene, amended petitions, supplemental petitions and/or requests for hearing will not be entertained absent a determination by the Commission, the presiding officer or the presiding Atomic Safety and Licensing Board that the petition and/or request should be granted based upon a balancing of the factors specified in 10 CFR 2.714(a)(1)(i)–(v) and 2.714(d).

For further details with respect to this action, see the application for amendment dated February 14, 2003, which is available for public inspection at the Commission's PDR, located at One White Flint North, File Public Area O1 F21, 11555 Rockville Pike (first floor), Rockville, Maryland. Publicly available records will be accessible from the Agencywide Documents Access and Management System's (ADAMS) Public Electronic Reading Room on the Internet at the NRC Web site, *http://www.nrc.gov/reading-rm/adams.html.* Persons who do not have access to ADAMS or who encounter problems in accessing the documents located in ADAMS, should contact the NRC PDR Reference staff by telephone at 1–800–397–4209, 301–415–4737, or by e-mail to *pdr@nrc.gov.*

Dated at Rockville, Maryland, this 10th day of March, 2003.

For the Nuclear Regulatory Commission.

Raj K. Anand,

Senior Project Manager, Section 2, Project Directorate II, Division of Licensing Project Management, Office of Nuclear Reactor Regulation.

[FR Doc. 03–6159 Filed 3–13–03; 8:45 am]

BILLING CODE 7590–01–P

[1] The most recent version of Title 10 of the Code of Federal Regulations, published January 1, 2002, inadvertently omitted the last sentence of 10 CFR 2.714(d) and subparagraphs (d)(1) and (2), regarding petitions to intervene and contentions. For the complete, corrected text of 10 CFR 2.714(d), please *see* 67 FR 20884; April 29, 2002.''

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–254 AND 50–265]

Exelon Generation Company, LLC, Quad Cities Nuclear Power Station, Units 1 and 2; Notice of Intent To Prepare an Environmental Impact Statement and Conduct Scoping Process

Exelon Generation Company, LLC (Exelon) has submitted an application for renewal of Facility Operating License DPR–29 and DPR–30 for an additional 20 years of operation at the Quad Cities Nuclear Power Station (QCNPS). QCNPS is located in Rock Island County, Illinois, approximately 4 miles north of Cordova, Illinois. The application for renewal was submitted by letter dated January 3, 2003, pursuant to 10 CFR part 54. A notice of receipt of the application, which included the environmental report (ER), was published in the **Federal Register** on January 30, 2003 (68 FR 4800). A notice of acceptance for docketing of the application for renewal of the facility operating license was published in the **Federal Register** on March 4, 2003 (68 FR 10273). The purpose of this notice is to inform the public that the U.S. Nuclear Regulatory Commission (NRC) will be preparing an environmental impact statement (EIS) in support of the review of the license renewal application and to provide the public an opportunity to participate in the environmental scoping process, as defined in 10 CFR 51.29.

In accordance with 10 CFR 54.23 and 10 CFR 51.53(c), Exelon submitted the ER as part of the application. The ER was prepared pursuant to 10 CFR part 51 and is available for public inspection at the NRC Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS).

ADAMS is accessible at *http://www.nrc.gov/reading-rm/adams.html,* which provides access through the NRC's Public Electronic Reading Room (PERR) link. Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR Reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail to *pdr@nrc.gov.* The application may also be viewed on the Internet at *http://www.nrc.gov/reactors/operating/licensing/renewal/applications/dresden-quad.html.* In addition, the Cordova District Library, 402 Main Avenue, Cordova, Illinois; the River Valley Library, 214 South Main Street, Port Byron, Illinois; and the Davenport Public Library, 321 Main Street, Davenport, Iowa, have agreed to make the ER available for public inspection.

This notice advises the public that the NRC intends to gather the information necessary to prepare a plant-specific supplement to the Commission's ''Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants,'' (NUREG–1437) in support of the review of the application for renewal of the QCNPS operating licenses for an additional 20 years. Possible alternatives to the proposed action (license renewal) include no action and reasonable alternative energy sources. The NRC is required by 10 CFR 51.95 to prepare a supplement to the GEIS in connection with the renewal of an operating license. This notice is being published in accordance with the National Environmental Policy Act (NEPA) and the NRC's regulations found in 10 CFR part 51.

The NRC will first conduct a scoping process for the supplement to the GEIS and, as soon as practicable thereafter, will prepare a draft supplement to the GEIS for public comment. Participation in the scoping process by members of the public and local, State, tribal, and Federal government agencies is encouraged. The scoping process for the supplement to the GEIS will be used to accomplish the following:

a. Define the proposed action which is to be the subject of the supplement to the GEIS.

b. Determine the scope of the supplement to the GEIS and identify the significant issues to be analyzed in depth.

c. Identify and eliminate from detailed study those issues that are peripheral or that are not significant.

d. Identify any environmental assessments and other EISs that are being or will be prepared that are related to, but are not part of the scope of the supplement to the GEIS being considered.

e. Identify other environmental review and consultation requirements related to the proposed action.

f. Indicate the relationship between the timing of the preparation of the environmental analyses and the Commission's tentative planning and decision-making schedule.

g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the supplement to the GEIS to the NRC and any cooperating agencies.

h. Describe how the supplement to the GEIS will be prepared, and include any contractor assistance to be used.

The NRC invites the following entities to participate in the scoping process:

a. The applicant, Exelon Generation Company, LLC.

b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved, or that is authorized to develop and enforce relevant environmental standards.

c. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards.

d. Any affected Indian tribe.

e. Any person who requests or has requested an opportunity to participate in the scoping process.

f. Any person who intends to petition for leave to intervene.

In accordance with 10 CFR 51.26, the scoping process for an EIS may include a public scoping meeting to help identify significant issues related to a proposed activity and to determine the scope of issues to be addressed in an EIS. The NRC has decided to hold public meetings for the QCNPS license renewal supplement to the GEIS. The scoping meetings will be held at the The Mark of the Quad Cities, 1201 River Drive, Moline, Illinois, on Tuesday, April 8, 2003. There will be two sessions to accommodate interested parties. The first session will convene at 1:30 p.m. and will continue until 4:30 p.m., as necessary. The second session will convene at 7 p.m. with a repeat of the overview portions of the meeting and will continue until 10 p.m., as necessary. Both meetings will be transcribed and will include (1) an overview by the NRC staff of the NEPA environmental review process, the proposed scope of the supplement to the GEIS, and the proposed review schedule; and (2) the opportunity for interested government agencies, organizations, and individuals to submit comments or suggestions on the environmental issues or the proposed scope of the supplement to the GEIS. Additionally, the NRC staff will host informal discussions one hour before the start of each session at The Mark of the Quad Cities. No formal comments on the proposed scope of the supplement to the GEIS will be accepted during the informal discussions. To be considered, comments must be provided either at the transcribed public meetings or in writing, as discussed below. Persons may register to attend or present oral comments at the meetings on the scope of the NEPA review by contacting Mr. Louis L. Wheeler, by telephone at

1–800–368–5642, extension 1444, or by Internet to the NRC at *QuadCitiesEIS@nrc.gov* no later than April 2, 2003. Members of the public may also register to speak at the meeting within 15 minutes of the start of each session. Individual oral comments may be limited by the time available, depending on the number of persons who register. Members of the public who have not registered may also have an opportunity to speak, if time permits. Public comments will be considered in the scoping process for the supplement to the GEIS. Mr. Wheeler will need to be contacted no later than March 25, 2003, if special equipment or accommodations are needed to attend or present information at the public meeting, so that the NRC staff can determine whether the request can be accommodated.

Members of the public may send written comments on the environmental scope of the QCNPS license renewal review to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mailstop T–6 D 59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Comments may also be delivered to Room T–6 D 59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. during Federal workdays. To be considered in the scoping process, written comments should be postmarked by May 12, 2003. Electronic comments may be sent by the Internet to the NRC at *QuadCitiesEIS@nrc.gov.* Electronic submissions should be sent no later than May 12, 2003, to be considered in the scoping process. Comments will be available electronically and accessible through the NRC's PERR link at *http://www.nrc.gov/reading-rm/adams.html.*

Participation in the scoping process for the supplement to the GEIS does not entitle participants to become parties to the proceeding to which the supplement to the GEIS relates. Notice of opportunity for a hearing regarding the renewal application was the subject of the aforementioned **Federal Register** notice of acceptance for docketing. Matters related to participation in any hearing are outside the scope of matters to be discussed at this public meeting.

At the conclusion of the scoping process, the NRC will prepare a concise summary of the determination and conclusions reached, including the significant issues identified, and will send a copy of the summary to each participant in the scoping process. The summary will also be available for inspection through the PERR link. The staff will then prepare and issue for comment the draft supplement to the GEIS, which will be the subject of separate notices and separate public meetings. Copies will be available for public inspection at the above-mentioned addresses, and one copy per request will be provided free of charge. After receipt and consideration of the comments, the NRC will prepare a final supplement to the GEIS, which will also be available for public inspection.

Information about the proposed action, the supplement to the GEIS, and the scoping process may be obtained from Mr. Wheeler at the aforementioned telephone number or e-mail address.

Dated in Rockville, Maryland, this 6th day of March, 2003.

For the Nuclear Regulatory Commission.

Pao-Tsin Kuo,

Program Director, License Renewal and Environmental Impacts Program, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.

[FR Doc. 03–6157 Filed 3–13–03; 8:45 am]

BILLING CODE 7590–01–P

NUCLEAR REGULATORY COMMISSION

[Docket No. 50–237, 50–249]

Exelon Generation Company, LLC, Dresden Nuclear Power Station, Units 2 and 3; Notice of Intent To Prepare an Environmental Impact Statement and Conduct Scoping Process

Exelon Generation Company, LLC (Exelon) has submitted an application for renewal of Facility Operating License DPR–19 and DPR–25 for an additional 20 years of operation at the Dresden Nuclear Power Station, Units 2 and 3 (DNPS). DNPS is located in Goose Lake Township, Grundy County, Illinois, on the shoreline of the Illinois River at the confluence of the Des Plaines and Kankakee Rivers. The application for renewal was submitted by letter dated January 3, 2003, pursuant to 10 CFR part 54. A notice of receipt of the application, which included the environmental report (ER), was published in the **Federal Register** on January 30, 2003 (68 FR 4800). A notice of acceptance for docketing of the application for renewal of the facility operating license was published in the **Federal Register** on March 4, 2003 (67 FR 68 FR 10273). The purpose of this notice is to inform the public that the U.S. Nuclear Regulatory Commission (NRC) will be preparing an environmental impact statement (EIS) in support of the review of the license renewal application and to provide the public an opportunity to participate in the environmental scoping process, as defined in 10 CFR 51.29.

In accordance with 10 CFR 54.23 and 10 CFR 51.53(c), Exelon submitted the ER as part of the application. The ER was prepared pursuant to 10 CFR part 51 and is available for public inspection at the NRC Public Document Room (PDR), located at One White Flint North, 11555 Rockville Pike (first floor), Rockville, Maryland, or from the Publicly Available Records component of NRC's Agencywide Documents Access and Management System (ADAMS). ADAMS is accessible at *http://www.nrc.gov/reading-rm/adams.html,* which provides access through the NRC's Public Electronic Reading Room (PERR) link. Persons who do not have access to ADAMS, or who encounter problems in accessing the documents located in ADAMS, should contact the NRC's PDR Reference staff at 1–800–397–4209, or 301–415–4737, or by e-mail to *pdr@nrc.gov.* The application may also be viewed on the Internet at *http://www.nrc.gov/reactors/operating/licensing/renewal/applications/dresden-quad.html.* In addition, the Morris Area Public Library, located at 604 West Liberty Street, Morris, Illinois; and the Coal City Public Library District, located at 85 North Garfield Street, Coal City, Illinois, have agreed to make the ER available for public inspection.

This notice advises the public that the NRC intends to gather the information necessary to prepare a plant-specific supplement to the Commission's ''Generic Environmental Impact Statement (GEIS) for License Renewal of Nuclear Plants,'' (NUREG–1437) in support of the review of the application for renewal of the DNPS operating licenses for an additional 20 years. Possible alternatives to the proposed action (license renewal) include no action and reasonable alternative energy sources. The NRC is required by 10 CFR 51.95 to prepare a supplement to the GEIS in connection with the renewal of an operating license. This notice is being published in accordance with the National Environmental Policy Act (NEPA) and the NRC's regulations found in 10 CFR part 51.

The NRC will first conduct a scoping process for the supplement to the GEIS and, as soon as practicable thereafter, will prepare a draft supplement to the GEIS for public comment. Participation in the scoping process by members of the public and local, State, tribal, and Federal government agencies is encouraged. The scoping process for the

supplement to the GEIS will be used to accomplish the following:

a. Define the proposed action which is to be the subject of the supplement to the GEIS.

b. Determine the scope of the supplement to the GEIS and identify the significant issues to be analyzed in depth.

c. Identify and eliminate from detailed study those issues that are peripheral or that are not significant.

d. Identify any environmental assessments and other EISs that are being or will be prepared that are related to, but are not part of the scope of the supplement to the GEIS being considered.

e. Identify other environmental review and consultation requirements related to the proposed action.

f. Indicate the relationship between the timing of the preparation of the environmental analyses and the Commission's tentative planning and decision-making schedule.

g. Identify any cooperating agencies and, as appropriate, allocate assignments for preparation and schedules for completing the supplement to the GEIS to the NRC and any cooperating agencies.

h. Describe how the supplement to the GEIS will be prepared, and include any contractor assistance to be used.

The NRC invites the following entities to participate in the scoping process:

a. The applicant, Exelon Generation Company, LLC.

b. Any Federal agency that has jurisdiction by law or special expertise with respect to any environmental impact involved, or that is authorized to develop and enforce relevant environmental standards.

c. Affected State and local government agencies, including those authorized to develop and enforce relevant environmental standards.

d. Any affected Indian tribe.

e. Any person who requests or has requested an opportunity to participate in the scoping process.

f. Any person who intends to petition for leave to intervene.

In accordance with 10 CFR 51.26, the scoping process for an EIS may include a public scoping meeting to help identify significant issues related to a proposed activity and to determine the scope of issues to be addressed in an EIS. The NRC has decided to hold public meetings for the DNPS license renewal supplement to the GEIS. The scoping meetings will be held at Jennifer's Garden Banquet and Convention Center located at 555 West Gore Road, Morris, Illinois on Thursday, April 10, 2003. There will be two sessions to accommodate interested parties. The first session will convene at 1:30 p.m. and will continue until 4:30 p.m., as necessary. The second session will convene at 7 p.m. with a repeat of the overview portions of the meeting and will continue until 10 p.m., as necessary. Both meetings will be transcribed and will include (1) an overview by the NRC staff of the NEPA environmental review process, the proposed scope of the supplement to the GEIS, and the proposed review schedule; and (2) the opportunity for interested government agencies, organizations, and individuals to submit comments or suggestions on the environmental issues or the proposed scope of the supplement to the GEIS. Additionally, the NRC staff will host informal discussions one hour before the start of each session at Jennifer's Garden Banquet and Convention Center. No formal comments on the proposed scope of the supplement to the GEIS will be accepted during the informal discussions. To be considered, comments must be provided either at the transcribed public meetings or in writing, as discussed below. Persons may register to attend or present oral comments at the meetings on the scope of the NEPA review by contacting Mr. Louis L. Wheeler, by telephone at 1–800–368–5642, extension 1444, or by Internet to the NRC at *DresdenEIS@nrc.gov* no later than April 2, 2003. Members of the public may also register to speak at the meeting within 15 minutes of the start of each session. Individual oral comments may be limited by the time available, depending on the number of persons who register. Members of the public who have not registered may also have an opportunity to speak, if time permits. Public comments will be considered in the scoping process for the supplement to the GEIS. Mr. Wheeler will need to be contacted no later than March 25, 2003, if special equipment or accommodations are needed to attend or present information at the public meeting, so that the NRC staff can determine whether the request can be accommodated.

Members of the public may send written comments on the environmental scope of the DNPS license renewal review to the Chief, Rules and Directives Branch, Division of Administrative Services, Office of Administration, Mailstop T–6 D 59, U.S. Nuclear Regulatory Commission, Washington, DC 20555–0001, and should cite the publication date and page number of this **Federal Register** notice. Comments may also be delivered to Room 6D59, Two White Flint North, 11545 Rockville Pike, Rockville, Maryland, from 7:30 a.m. to 4:15 p.m. during Federal workdays. To be considered in the scoping process, written comments should be postmarked by May 12, 2003. Electronic comments may be sent by the Internet to the NRC at *DresdenEIS@nrc.gov.* Electronic submissions should be sent no later than May 12, 2003, to be considered in the scoping process. Comments will be available electronically and accessible through the NRC's PERR link at *http://www.nrc.gov/reading-rm/adams.html.*

Participation in the scoping process for the supplement to the GEIS does not entitle participants to become parties to the proceeding to which the supplement to the GEIS relates. Notice of opportunity for a hearing regarding the renewal application was the subject of the aforementioned **Federal Register** notice of acceptance for docketing. Matters related to participation in any hearing are outside the scope of matters to be discussed at this public meeting.

At the conclusion of the scoping process, the NRC will prepare a concise summary of the determination and conclusions reached, including the significant issues identified, and will send a copy of the summary to each participant in the scoping process. The summary will also be available for inspection through the PERR link. The staff will then prepare and issue for comment the draft supplement to the GEIS, which will be the subject of separate notices and separate public meetings. Copies will be available for public inspection at the above-mentioned addresses, and one copy per request will be provided free of charge. After receipt and consideration of the comments, the NRC will prepare a final supplement to the GEIS, which will also be available for public inspection.

Information about the proposed action, the supplement to the GEIS, and the scoping process may be obtained from Mr. Wheeler at the aforementioned telephone number or e-mail address.

Dated in Rockville, Maryland, this 6th day of March, 2003.

For the Nuclear Regulatory Commission.

Pao-Tsin Kuo,

Program Director, License Renewal and Environmental Impacts Program, Division of Regulatory Improvement Programs, Office of Nuclear Reactor Regulation.

[FR Doc. 03–6158 Filed 3–13–03; 8:45 am]

BILLING CODE 7590–01–P

OFFICE OF MANAGEMENT AND BUDGET

OMB Circular No. A–76, Performance of Commercial Activities

AGENCY: Office of Management and Budget, Executive Office of the President.

ACTION: Issuance of Transmittal Memorandum No. 25, amending OMB Circular No. A–76, ''Performance of Commercial Activities.''

SUMMARY: This Transmittal Memorandum updates the annual federal pay raise assumptions and inflation factors used for computing the government's in-house personnel and non-pay costs, as generally provided in the President's Budget for Fiscal Year 2004.

DATES: All changes in the Transmittal Memorandum are effective immediately and shall apply to all OMB Circular A–76 cost comparisons in process where the government's in-house cost estimate has not been publicly revealed before this date.

FOR FURTHER INFORMATION CONTACT: Mr. David C. Childs, Office of Federal Procurement Policy, NEOB, Room 9013, Office of Management and Budget, 725 17th Street, NW., Washington, DC 20503, Tel. No. (202) 395–6104.

Availability: Copies of the OMB Circular A–76, its Revised Supplemental Handbook and currently applicable Transmittal Memoranda changes may be obtained at the online OMB Homepage address (URL): *http://www.whitehouse.gov/omb/.*

Mitchell E. Daniels, Jr.,

Director.

Circular No. A–76 (Revised), Transmittal Memorandum No. 25

To the Heads of Executive Departments and Agencies

Subject: Performance of Commercial Activities.

This Transmittal Memorandum updates the annual federal pay raise assumptions and inflation factors used for computing the government's in-house personnel and non-pay costs, as generally provided in the President's Budget for Fiscal Year 2004.

The non-pay inflation factors are for purposes of A–76 cost comparison determinations only. They reflect the generic non-pay inflation assumptions used to develop the fiscal year 2004 budget baseline estimates required by law. The law requires that a specific inflation factor (GDP FY/FY chained price index) be used for this purpose. These inflation factors should not be viewed as estimates of expected inflation rates for major long-term procurement items or as an estimate of inflation for any particular agency's non-pay purchases mix.

FEDERAL PAY RAISE ASSUMPTIONS

[In percent]

Effective date	Civilian	Military
January 2002	4.6	[1] 6.9
January 2003	4.1	4.7
January 2004	2.0	4.1
January 2005	3.4	3.4
January 2006	3.4	3.4
January 2007	3.4	3.4
January 2008 [2] ..	3.4	3.4

[1] Average of various longevity- and rank-specific increases.

[2] Any subsequent years included in the period of performance and cost comparison shall continue to use the 3.4% figures, until otherwise revised by OMB.

NON-PAY CATEGORIES (SUPPLIES AND EQUIPMENT, ETC.)

	Percent
FY 2002	1.3
FY 2003	1.3
FY 2004	1.5
FY 2005	1.5
FY 2006	1.6
FY 2007	1.7
FY 2008	[1] 1.8

[1] Any subsequent years included in the period of performance and cost comparison shall continue to use the 1.8% figure, until otherwise revised by OMB.

The pay rate (including geographic pay differentials) that are in effect for 2003 shall be included for the development of in-house personnel costs. The pay raise factors provided for 2004 and beyond shall be applied to all employees, with no assumption being made as to how they will be distributed between possible locality and ECI-based increases.

Agencies are reminded that OMB Circular No. A–76, Transmittal Memoranda 1 through Transmittal Memorandum 14 are canceled. Transmittal Memorandum No. 15 provides the Revised Supplemental Handbook, and is dated March 27, 1996 (**Federal Register**, April 1, 1996, pages 14338–14346). Transmittal Memoranda No. 16, 17, 18 and 19 (to the extent they provided Circular A–76 federal pay raise and inflation factors) are canceled. Transmittal Memorandum No. 20 provided changes to the Revised Supplemental Handbook to implement the Federal Activities Inventory Reform Act of 1998 (Pub. L. 105.270). Transmittal Memorandum No. 21, provided A–76 federal pay raise and inflation factor assumptions and is canceled. Transmittal Memorandum No. 22 made technical changes to the Revised Supplemental Handbook regarding the implementation of the FAIR Act, A–76 administrative appeals and, the participation of directly affected employees on A–76 Source Selection Boards and their evaluation teams. Transmittal Memorandum No. 23 and Transmittal Memorandum No. 24, which provided last year's Circular A–76 federal pay raise and inflation factor assumptions are canceled.

Mitchell E. Daniels, Jr.,

Director.

[FR Doc. 03–6127 Filed 3–13–03; 8:45 am]

BILLING CODE 3110–01–P

PENSION BENEFIT GUARANTY CORPORATION

Required Interest Rate Assumption for Determining Variable-Rate Premium; Interest Assumptions for Multiemployer Plan Valuations Following Mass Withdrawal

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of interest rates and assumptions.

SUMMARY: This notice informs the public of the interest rates and assumptions to be used under certain Pension Benefit Guaranty Corporation regulations. These rates and assumptions are published elsewhere (or can be derived from rates published elsewhere), but are collected and published in this notice for the convenience of the public. Interest rates are also published on the PBGC's Web site (*http://www.pbgc.gov*).

DATES: The required interest rate for determining the variable-rate premium under part 4006 applies to premium payment years beginning in March 2003. The interest assumptions for performing multiemployer plan valuations following mass withdrawal under part 4281 apply to valuation dates occurring in April 2003.

FOR FURTHER INFORMATION CONTACT: Harold J. Ashner, Assistant General Counsel, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005, 202–326–4024. (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION:

Variable-Rate Premiums

Section 4006(a)(3)(E)(iii)(II) of the Employee Retirement Income Security Act of 1974 (ERISA) and § 4006.4(b)(1) of the PBGC's regulation on Premium Rates (29 CFR part 4006) prescribe use of an assumed interest rate (the ''required interest rate'') in determining a single-employer plan's variable-rate premium. The required interest rate is the ''applicable percentage'' (currently 100 percent) of the annual yield on 30-year Treasury securities for the month preceding the beginning of the plan year for which premiums are being paid (the ''premium payment year''). (Although the Treasury Department has ceased issuing 30-year securities, the Internal

Revenue Service announces a surrogate yield figure each month—based on the 30-year Treasury bond maturing in February 2031—which the PBGC uses to determine the required interest rate.)

The required interest rate to be used in determining variable-rate premiums for premium payment years beginning in March 2003 is 4.81 percent.

The following table lists the required interest rates to be used in determining variable-rate premiums for premium payment years beginning between April 2002 and March 2003.

For premium payment years beginning in:	The required interest rate is:
April 2002	5.71
May 2002	5.68
June 2002	5.65
July 2002	5.52
August 2002	5.39
September 2002	5.08
October 2002	4.76
November 2002	4.93
December 2002	4.96
January 2003	4.92
February 2003	4.94
March 2003	4.81

Multiemployer Plan Valuations Following Mass Withdrawal

The PBGC's regulation on Duties of Plan Sponsor Following Mass Withdrawal (29 CFR part 4281) prescribes the use of interest assumptions under the PBGC's regulation on Allocation of Assets in Single-Employer Plans (29 CFR part 4044). The interest assumptions applicable to valuation dates in April 2003 under part 4044 are contained in an amendment to part 4044 published elsewhere in today's **Federal Register**. Tables showing the assumptions applicable to prior periods are codified in appendix B to 29 CFR part 4044.

Issued in Washington, DC, on this 10th day of March, 2003.

Joseph H. Grant,

Deputy Executive Director and Chief Operating Officer, Pension Benefit Guaranty Corporation.

[FR Doc. 03–6141 Filed 3–13–03; 8:45 am]

BILLING CODE 7708–01–P

PENSION BENEFIT GUARANTY CORPORATION

Privacy Act of 1974; System of Records

AGENCY: Pension Benefit Guaranty Corporation.

ACTION: Notice of a new routine use of records for PBGC–6, Plan Participant and Beneficiary Data—PBGC.

SUMMARY: The Pension Benefit Guaranty Corporation is proposing to add a routine use of records for a system of records maintained pursuant to the Privacy Act of 1974, as amended, entitled PBGC–6, Plan Participant and Beneficiary Data—PBGC. The new routine use permits PBGC to disclose to a state workforce agency the names of and certain identifying information about PBGC pension recipients residing in the state who may be eligible for health insurance coverage assistance from the state workforce agency under the Trade Act of 2002. Participating state workforce agencies are authorized to provide health insurance coverage assistance to eligible PBGC pension recipients until a Federal income tax credit advance payment program becomes effective in August 2003.

DATES: Comments on the new routine use must be received by April 14, 2003. The new routine use will become effective April 15, 2003, without further notice, unless comments result in a contrary determination and a notice is published to that effect.

ADDRESSES: Comments may be mailed to the Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026, or delivered to Suite 340 at the above address. Comments also may be sent by Internet e-mail to *regcomments@pbgc.gov.* Copies of comments may be obtained by writing to the PBGC's Communications and Public Affairs Department at Suite 240 at the above address or by visiting that office or calling 202–326–4040 during normal business hours.

FOR FURTHER INFORMATION CONTACT: D. Bruce Campbell, Attorney, Office of the General Counsel, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4016, 202–326–4020 (extension 3672). (TTY/TDD users may call the Federal relay service toll-free at 1–800–877–8339 and ask to be connected to 202–326–4024.)

SUPPLEMENTARY INFORMATION: The Trade Act of 2002 amended the Internal Revenue Code to create an income tax credit for health insurance costs of eligible individuals. Public Law 107–210, sec. 201, 116 Stat. 933, 954 (Aug. 6, 2002) (to be codified at 26 U.S.C. 35). The legislation requires the Department of Treasury to establish a program for making advance payments to eligible individuals of the income tax credit. Public Law 107–210, sec. 202, 116 Stat. at 960 (to be codified at 26 U.S.C. 7527). The tax credit is to be made available on an advance payment basis by August 1, 2003.

The income tax credit and advance payment program are open to, among others, any individual who is an ''eligible PBGC pension recipient.'' 26 U.S.C. 35(c) and 26 U.S.C. 7527(d)(2). An eligible PBGC pension recipient is defined to mean, with respect to any month, an individual ''who has attained age 55 as the first day of such month, and * * * is receiving a benefit for such month any portion of which is paid by the (PBGC).'' 26 U.S.C. 35(c)(4).

The income tax credit and advance payment program are also open to any individual who is an ''eligible TAA recipient'' 26 U.S.C. 35(c) and 26 U.S.C. 7527(d)(2). The term eligible TAA recipient is defined to include, for any month, an individual who is receiving ''a trade readjustment allowance under * * * the Trade Act of 1974.'' The Department of Labor, with the states, is responsible for implementing the trade readjustment assistance program for eligible workers. 19 U.S.C. 2271–2296.

The Trade Act of 2002 also amended the Workforce Investment Act of 1988 to permit states to use National Emergency Grant funds from the Department of Labor to pay the cost of qualified health insurance coverage for eligible individuals during the initial start up period from September 1, 2002, (the first full month beginning after the date of enactment) until such time as the advance payment program is implemented. Public Law 107–210, sec. 203, 116 Stat. 933, 963 (to be codified at 29 U.S.C. 2918(a) and (f)). The new routine use permits the PBGC to disclose the names, addresses, social security numbers, and dates of birth of eligible PBGC pension recipients residing in a state to the state's workforce agency if the agency received a grant to provide health insurance coverage assistance and support services for state residents under section 203 of the Trade Act of 2002.

For the convenience of the public, PBGC–6, as amended, is published in full below with new routine use 15 italicized.

Issued in Washington, DC, this 11th day of March, 2003.

Steven A. Kandarian,

Executive Director, Pension Benefit Guaranty Corporation.

PBGC–6

SYSTEM NAME:

Plan Participant and Beneficiary Data—PBGC.

SECURITY CLASSIFICATION:

Not applicable.

SYSTEM LOCATION:

Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026 and/or field benefit administrator, plan administrator, and paying agent worksites.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Participants and beneficiaries in terminating and terminated pension plans covered by Title IV of the Employee Retirement Income Security Act of 1974, as amended (''ERISA'').

CATEGORIES OF RECORDS IN THE SYSTEM:

Names, addresses, telephone numbers, sex, social security numbers and other Social Security Administration information, dates of birth, dates of hire, salary, marital status, domestic relations orders, time of plan participation, eligibility status, pay status, benefit data, health-related information, insurance information where plan benefits are provided by private insurers, initial and final PBGC determinations (29 CFR 4003.21 and 4003.59). The records listed herein are included only as pertinent or applicable to the individual plan participant or beneficiary.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

29 U.S.C. 1055, 1056(d)(3), 1302, 1321, 1322, 1322a, 1341, 1342 and 1350.

PURPOSE(S):

This system of records is maintained for use in determining whether participants and beneficiaries are eligible for benefits under plans covered by Title IV of ERISA, the amounts of benefits to be paid, making benefit payments, and collecting benefit overpayments. Names, addresses, and telephone numbers are used to survey customers to measure their satisfaction with the PBGC's benefit payment services and to track (for follow up) those who do not respond to surveys.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

1. A record from this system of records may be disclosed to third parties, such as banks, insurance companies, or trustees, to make benefit payments to plan participants and beneficiaries.

2. A record from this system of records may be disclosed, in furtherance of proceedings under Title IV of ERISA, to a contributing sponsor (or other employer who maintained the plan), including any predecessor or successor, and any member of the same controlled group.

3. A record from this system of records may be disclosed, upon request for a purpose authorized under Title IV of ERISA, to an official of a labor organization recognized as the collective bargaining representative of the individual about whom a request is made.

4. Names, addresses, and telephone numbers of participants and beneficiaries and information pertaining to debts owed by such participants and beneficiaries to the PBGC may be disclosed to a debt collection agency or firm to collect a claim. Disclosure shall be made only under a contract that binds any such contractor or employee of such contractor to the criminal penalties of the Privacy Act. The information so disclosed shall be used exclusively pursuant to the terms and conditions of such contract and shall be used solely for the purposes prescribed therein. The contract shall provide that the information so disclosed shall be returned at the conclusion of the debt collection effort.

5. The name and social security number of a participant employed or formerly employed as a pilot by a commercial airline may be disclosed to the Federal Aviation Administration (''FAA'') to obtain information relevant to the participant's eligibility or continued eligibility for disability benefits.

6. Names and social security numbers of plan participants and beneficiaries may be disclosed to the Internal Revenue Service (''IRS'') to obtain current addresses from tax return information and to the Social Security Administration (''SSA'') to obtain current addresses. Such information will be disclosed only if the PBGC has no address for an individual or if mail sent to the individual at the last known address is returned as undeliverable.

7. Names and last known addresses may be disclosed to an official of a labor organization recognized as the collective bargaining representative of participants for posting in union halls or for other means of publication to obtain current addresses of participants and beneficiaries. Such information will be disclosed only if the PBGC has no address for an individual or if mail sent to the individual at the last known address is returned as undeliverable.

8. Names, social security numbers, last known addresses, and dates of birth and death may be disclosed to private firms and agencies that provide locator services, including credit reporting agencies and debt collection firms or agencies, to locate participants and beneficiaries. Such information will be disclosed only if the PBGC has no address for an individual or if mail sent to the individual at the last known address is returned as undeliverable. Disclosure shall be made only under a contract that binds the firm or agency providing the service and its employees to the criminal penalties of the Privacy Act. The information so disclosed shall be used exclusively pursuant to the terms and conditions of such contract and shall be used solely for the purposes prescribed therein. The contract shall provide that the information so disclosed shall be returned at the conclusion of the locating effort.

9. Names and last known addresses may be disclosed to licensees of the United States Postal Service (''USPS'') to obtain current addresses under the USPS's National Change of Address Program. Such information will be disclosed only if the PBGC has no address for an individual or if mail sent to the individual at the last known address is returned as undeliverable. Disclosure shall be made only under a contract that binds the licensee of the Postal Service and its employees to the criminal penalties of the Privacy Act. The information so disclosed shall be used exclusively pursuant to the terms and conditions of such contract and shall be used solely for the purposes prescribed therein. The contract shall provide that the information so disclosed shall be returned at the conclusion of the locating effort.

10. Names and last known addresses may be disclosed to other participants in, and beneficiaries under, a pension plan to obtain the current addresses of individuals. Such information will be disclosed only if the PBGC has no address for an individual or if mail sent to the individual at the last known address is returned as undeliverable.

11. Names and last known addresses of participants and beneficiaries, and the names and addresses of participants' former employers, may be disclosed to the public to obtain current addresses of the individuals. Such information will be disclosed to the public only if the PBGC is unable to make benefit payments to the participants and beneficiaries because the address it has does not appear to be current or correct.

12. The name of a participant's pension plan, the actual or estimated amount of a participant's benefit under Title IV of ERISA, the form(s) in which the benefit is payable, and whether the participant is currently receiving benefit payments under the plan or (if not) the earliest date(s) such payments could commence may be disclosed to the participant's spouse, former spouse, child, or other dependent solely to

obtain a qualified domestic relations order under 29 U.S.C. 1056(d) and 26 U.S.C. 414(p). The PBGC will disclose the information only upon the receipt of a notarized, written request by a prospective alternate payee that describes the requester's relationship to the participant and states that the information will be used solely to obtain a qualified domestic relations order under state domestic relations law. The PBGC will notify the participant of any information disclosed to a prospective alternate payee under this routine use. Any person who knowingly and willfully requests or obtains any record concerning an individual under false pretenses is subject to a criminal penalty under 5 U.S.C. 552a(i)(3).

13. Information from a participant's initial determination under 29 CFR 4003.1(b) (excluding the participant's address, telephone number, social security number, and any sensitive medical information) may be disclosed to a participant's spouse, former spouse, child, or other dependent who is an alternate payee under a qualified domestic relations order issued pursuant to 29 U.S.C. 1056(d) and 26 U.S.C. 414(p) to explain how the PBGC determined the benefit due the alternate payee so that the alternate payee can pursue an administrative appeal of the benefit determination under 29 CFR 4003.51. The PBGC will notify the participant of the information disclosed to an alternate payee under this routine use.

14. The names, addresses, social security numbers, and dates of birth of eligible PBGC pension recipients may be disclosed to the Department of Treasury and the Department of Labor to implement the income tax credit for health insurance costs under 26 U.S.C. 35 and the program for advance payment of the tax credit under 26 U.S.C. 7527.

15. *The names, addresses, social security numbers, and dates of birth of eligible PBGC pension recipients residing in a particular state may be disclosed to the state's workforce agency if the agency received a National Emergency Grant from the Department of Labor under the Workforce Investment Act of 1988 to provide health insurance coverage assistance and support services for state residents under 29 U.S.C. 2918(a) and (f).*

General Routine Uses G1 and G4 through G7 (see Prefatory Statement of General Routine Uses) apply to this system of records.

DISCLOSURE TO CONSUMER REPORTING AGENCIES:

Information may be disclosed to a consumer reporting agency in accordance with 31 U.S.C. 3711(f) (5 U.S.C. 552a(b)(12)).

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

Records are maintained in paper and electronic form.

RETRIEVABILITY:

Records are indexed by plan and participant and/or beneficiary name. Customer satisfaction survey responses are aggregated for statistical purposes after they have been received by the PBGC and are not retrievable by a participant or beneficiary's name or other assigned identifier.

SAFEGUARDS:

Paper records are kept in file folders in areas of restricted access that are locked after office hours. Electronic records are stored on computer networks and protected by assigning user identification numbers to individuals needing access to the records and by passwords set by authorized users that must be changed periodically.

RETENTION AND DISPOSAL:

Records for plan participants are transferred to the Washington National Federal Records Center 6 months after either the final payment to a participant and/or beneficiary or the PBGC's final determination that a participant or beneficiary is not entitled to any benefits and are destroyed 7 years after such payment or determination.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Insurance Operations Department, Pension Benefit Guaranty Corporation, 1200 K Street, NW., Washington, DC 20005–4026.

NOTIFICATION PROCEDURE:

Procedures are detailed in the PBGC's regulations: 29 CFR part 4902.

RECORD ACCESS PROCEDURES:

Same as notification procedure.

CONTESTING RECORDS PROCEDURE:

Same as notification procedure.

RECORD SOURCE CATEGORIES:

Plan administrators, participants and beneficiaries, the FAA, the SSA, labor organization officials, firms or agencies providing locator services, and USPS licensees.

EXEMPTIONS CLAIMED FOR THE SYSTEM:

None.

[FR Doc. 03–6271 Filed 3–13–03; 8:45 am]

BILLING CODE 7708–01–P

SECURITIES AND EXCHANGE COMMISSION

Existing Collection; Comment Request

Upon Written Request, Copies Available From:

Securities and Exchange Commission, Office of Filings and Information Services, 450 Fifth Street, NW., Washington, DC 20549.

Extension

Form 24F–2, SEC File No. 270–399, OMB Control No. 3235–0456

Notice is hereby given that pursuant to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520), the Securities and Exchange Commission (''Commission'') is publishing for public comment the following summary of previously approved information collection requirements. The Commission plans to submit this existing collection of information to the Office of Management and Budget for extension and approval.

Under 17 CFR 270.24f–2, any open-end management companies (''mutual funds''), unit investment trusts (''UITs'') or face-amount certificate companies (collectively, ''funds'') that are deemed to have registered an indefinite amount of securities must, not later than 90 days after the end of any fiscal year in which it has publicly offered such securities, file Form 24F–2 with the Commission. Form 24F–2 is the annual notice of securities sold by funds that accompanies the payment of registration fees with respect to the securities sold during the fiscal year.

The Commission estimates that 7,428 funds file Form 24F–2 on the required annual basis. The average annual burden per respondent for Form 24F–2 is estimated to be two hours. The total annual burden for all respondents to Form 24F–2 is estimated to be 14,856 hours.

The estimate of average burden hours is made solely for the purposes of the Paperwork Reduction Act, and is not derived from a comprehensive or even a representative survey or study of the costs of Commission rules.

Compliance with the collection of information required by Form 24F–2 is mandatory. The Form 24F–2 filing that must be made to the Commission is available to the public. An agency may not conduct or sponsor, and a person is not required to respond to, a collection

of information unless it displays a currently valid control number.

The Commission requests written comments on: (a) Whether the collection of information is necessary for the proper performance of the functions of the Commission, including whether the information has practical utility; (b) the accuracy of the Commission's estimate of the burdens of the collection of information; (c) ways to enhance the quality, utility, and clarity of the information collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted in writing within 60 days of this publication.

Please direct your written comments to 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 7, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–6190 Filed 3–13–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Proposed Collection; Comment Request

Upon Written Request, Copies Available From:

Securities and Exchange Commission, Office of Filings and Information Services, Washington, DC 20549.

Extension

Rule 6e–2, SEC File No. 270–177, OMB Control No. 3235–0177.

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 to the Office of Management and Budget for extension and approval.

Rule 6e–2 [17 CFR 270.6e–2] under the Investment Company Act of 1940 (''Act''), is an exemptive rule that permits separate accounts, formed by life insurance companies, to fund certain variable life insurance products. The rule exempts such separate accounts from the registration requirements under the Act, among others, on condition that they comply with all but certain designated provisions of the Act and meet the other requirements of the rule. The rule sets forth several information collection requirements.

Rule 6e–2 provides a separate account with an exemption from the registration provisions of section 8(a) of the Act if the account files with the Commission Form N–6EI–1, a notification of claim of exemption.

The rule also exempts a separate account from a number of other sections of the Act, provided that the separate account makes certain disclosure in its registration statements, reports to contractholders, proxy solicitations, and submissions to state regulatory authorities, as prescribed by the rule.

Paragraph (b)(9) of rule 6e–2 provides an exemption from the requirements of section 17(f) of the Act and imposes a reporting burden and certain other conditions. Section 17(f) requires that every registered management company meet various custody requirements for its securities and similar investments. Paragraph (b)(9) applies only to management accounts that offer life insurance contracts subject to rule 6e–2.

Since 2000, there have been no filings under paragraph (b)(9) of rule 6e–2 by management accounts. Further, all variable life separate accounts that have filed post-effective amendments to their registration statements during this period have been structured as unit investment trusts and thus have not been subject to the requirements of paragraph (b)(9) of the rule. Therefore, since 2000, there has been no cost or burden to the industry regarding the information collection requirements of paragraph (b)(9) of rule 6e–2. In addition, there have been no filings of Form N–6EI–1 by separate accounts since 2000. Therefore there has been no cost or burden to the industry since that time.

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 estimate 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.

Direct your written comments to Kenneth A. Fogash, Acting Associate Executive Director/CIO, Office of Information Technology, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549.

Dated: March 7, 2003.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–6191 Filed 3–13–03; 8:45 am]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

Sunshine Act Meeting

FEDERAL REGISTER CITATION OF PREVIOUS ANNOUNCEMENT: (68 FR 11418, March 10, 2003).

STATUS: Closed meeting.

PLACE: 450 Fifth Street, NW., Washington, DC.

DATE AND TIME OF PREVIOUSLY ANNOUNCED MEETING: Wednesday, March 12, 2003, at 2:30 p.m.

CHANGE IN THE MEETING: Additional item.

The following item has been added to the closed meeting scheduled for Wednesday, March 12, 2003: Litigation matter.

Commissioner Atkins, as duty officer, determined that Commission business required the above change and that no earlier notice thereof was possible.

At times, changes in Commission priorities require alterations in the scheduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: the Office of the Secretary at (202) 942–7070.

Dated: March 10, 2003.

Jonathan G. Katz,

Secretary.

[FR Doc. 03–6326 Filed 3–12–03; 2:41 pm]

BILLING CODE 8010–01–P

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47469; File No. SR–Amex–2002–104]

Self-Regulatory Organizations; Notice of Filing of Proposed Rule Change by the American Stock Exchange LLC Relating to Amex Rules 26, 29, 171, and 950 To Revise Specialist Capital Requirements and the Method for Computing Specialist Capital Requirements and To Create an Early Warning Level With Respect to Specialist Capital

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 December 10, 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 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 Amex proposes to amend Amex rules 26, 29, 171, and 950 to (1) revise specialist capital requirements and the method for computing specialist capital requirements, and (2) to create an early warning level with respect to specialist capital. 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.

* * * * *

Performance Committee

Rule 26. (a) No change.

(b) The Performance Committee shall review, and approve, disapprove or conditionally approve, mergers and acquisitions of specialist units, transfers of one or more specialist registrations, specialist joint accounts, and changes in control or composition of specialist units. The Performance Committee shall approve a proposed transaction involving a specialist unit unless it determines that a countervailing institutional interest indicates that the transaction should be disapproved or conditionally approved. In determining whether there is a countervailing institutional interest, the Performance Committee shall consider the maintenance or enhancement of the quality of the Exchange's market, taking into account the criteria that the Allocations Committee may consider in making an initial allocation determination (Rule 27(b)) and other considerations as may be relevant in the particular circumstances.

The Performance Committee shall evaluate specialists, individually and/or collectively as units, to determine whether they have fulfilled performance standards relating to, among other things: (1) Quality of markets, (2) competition with other markets, (3) observance of ethical standards, and (4) administrative factors. The Performance Committee may consider any relevant information, including but not limited to the results of the Specialist Floor Broker Questionnaire, trading data, a member's regulatory history, order flow statistics, and such other factors and data as may be pertinent in the circumstances. *The Performance Committee also may review specialists, individually and/or collectively as units, with respect to capital requirements and the ''early warning level'' set forth in Commentary .06 to rule 171.* The Performance Committee may take one or more of the following actions if it finds that a specialist or unit has failed to properly perform as a specialist: (1) Send admonitory letters, (2) refer matters to the Minor Floor Violation Disciplinary Committee for possible action pursuant to Exchange rule 590, (3) refer matters to the Exchange's Enforcement Department for investigation and possible disciplinary proceedings, (4) counsel specialists on how to improve their performance, (5) require specialists to adopt a performance improvement plan, (6) reorganize specialist units, (7) require the reallocation of securities, (8) suspend a specialist's or unit's registration as a specialist for a specific period of time, or (9) prohibit a specialist or unit from receiving allocations in a particular situation or for a specified period of time. In appropriate circumstances, the Performance Committee may confine a prohibition on new allocations to one of the three classes of securities traded on the Exchange (*i.e.*, equities, Exchange Traded Funds or options), or otherwise target a remedial action to a particular class of security traded by a specialist or unit.

(c) and (d) No change.

(e) The Performance Committee may meet with one or more specialists, specialist units, registered traders or brokers that may have failed to meet minimum performance standards, *capital requirements, or the ''early warning level'' set forth in Commentary .06 to rule 171.* In such an event, the member or members shall be notified in writing of the grounds to be considered by the Performance Committee and afforded an opportunity to make a presentation of relevant information in rebuttal. Such member or members shall be given access to all written material to be reviewed by the Performance Committee, and all persons appearing before the Performance Committee may be represented by counsel. However, formal rules of evidence shall not apply in Performance Committee meetings. A failure to meet minimum performance standards, *capital requirements, or early warning level* may form the basis for Performance Committee remedial action against one or more specialists, specialist units, registered traders or brokers. Any member or member organization affected by a decision of the Performance Committee shall be informed in writing of the decision, which decision shall include the findings, conclusions, any remedial action to be taken (hereinafter ''written notification''). (f) through end. No Change.

* * * * *

Market Quality Committee

Rule 29. (a) No change.

(b) The Market Quality Committee shall evaluate the performance of specialists registered in securities admitted to dealings on an unlisted basis (''UTP Specialists'') with respect to, among other things: (1) Quality of markets, (2) competition with other market centers, (3) administrative matters, and (4) willingness to promote the Exchange as a marketplace. The Market Quality Committee may consider any relevant information, including but not limited to trading data, order flow statistics, market quality statistics, and such other factors and data pertaining to both the Amex and other market centers as may be relevant in the circumstances. *The Market Quality Committee also may review specialists, individually and/or collectively as units, with respect to capital requirements and the ''early warning level'' set forth in Commentary .06 to rule 171.* The Market Quality Committee may take one or more of the following actions if it finds that the performance of the UTP Specialist is inadequate relative to one or more of the above factors: (1) Send advisory letters, (2) counsel UTP Specialists on how to improve their market quality, (3) require UTP Specialists to adopt a performance improvement plan, (4) require the reallocation of securities, (5) suspend a

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b-4.

UTP Specialist's registration as a specialist for a specific period of time, or (6) prohibit a UTP Specialist from receiving allocations in a particular situation or for a specified period of time.

(c) No change.

(d) The Market Quality Committee may meet with a UTP Specialist that may have failed to meet minimum performance standards with respect to UTP Securities, *capital requirements, or the ''early warning level'' set forth in Commentary .06 to rule 171.* In such an event, the UTP Specialist shall be notified in writing of the grounds to be considered by the Market Quality Committee and afforded an opportunity to make a presentation of relevant information. Such UTP Specialist shall be given access to all written material to be reviewed by the Market Quality Committee, and all persons appearing before the Market Quality Committee may be represented by counsel. However, formal rules of evidence shall not apply in meetings of the Market Quality Committee. A failure to meet minimum standards relating to: (1) Quality of markets, (2) competition with other market centers, (3) administrative matters, [or] (4) willingness to promote the Exchange as a marketplace, *or (5) capital requirements, or early warning level* may form the basis for remedial action by the Market Quality Committee against a UTP Specialist. Any UTP Specialist affected by a decision of the Market Quality Committee shall be informed in writing of the decision, which decision shall include the findings, conclusions, and any remedial action to be taken (hereinafter ''written notification'').

(e) through end. No change.

* * * * *

Specialist Financial Requirements

Rule 171. Every registered specialist shall maintain [a cash or liquid asset position] *tentative net capital* in the amount of [$600,000] *$1,000,000* or in an amount sufficient to assume a position of sixty trading units of each security in which such specialist is registered, whichever amount is greater. In the event that two or more specialists are associated with each other and deal for the same specialists account, the above requirement of this rule shall apply to such specialists as one unit, rather than to each specialist individually.

Commentary

.01 through .03. No change.

.04 For each security in which a specialist is registered which is principally traded or priced in a U.S. marketplace other than the Exchange, such specialist shall maintain [a cash or net liquid asset position] *tentative net capital* sufficient to assume a position of twenty trading units of such security.

.05 The term ''tentative net capital'' means net capital, computed in accordance with Securities Exchange Act rule 15c3–1 before application of haircuts and undue concentration charges.

.06 Each specialist or specialist unit subject to this rule, shall promptly notify the Exchange in writing if the tentative net capital of such specialist or specialist unit after deduction of all capital withdrawals including maturities, if any, scheduled during the next six months, falls below 125% of the minimum dollar amount required hereby (the ''early warning level'').

.07 In the event the tentative net capital of any specialist or specialist unit subject to this rule falls below the early warning level, such specialist or specialist unit shall attempt to reach a written agreement with the Exchange's Financial Regulatory Services Department (FRSD) on a plan for raising the specialist or specialist unit's capital to an appropriate level or taking other appropriate action. In the event of the failure to reach such agreement within five business days following the initial response or involvement of FRSD, FRSD may refer such matter to the Committee on Floor Member Performance or the Market Quality Committee as appropriate to take such action as it shall decide is appropriate.

.08 For purposes of rule 171, the amount sufficient to assume a position of sixty trading units shall be equal to 15% of the current market value of the position.

* * * * *

Rules of General Applicability

Rule 950. (a) through (g). No change.

(h) The provisions of rule 171 and Commentary thereto shall apply to the trading of option contracts, however, the option specialist financial requirement shall be equal to a minimum of [$600,000] *$1,000,000* plus $25,000 for each option issue in excess of the initial [ten] *twenty-five* issues in which such specialist is registered.

.01 For an option specialist that is also an equity security specialist subject to the requirements of rule 171, the minimum [$600,000] *$1,000,000* referred to in rule 171 shall apply to the entirety of the specialist's business, in both equities and options. For example, a specialist maintaining a book in both equity securities and options that is allocated only one equity security and one option (assuming the cost to carry 60 units of the equity stock does not exceed [$600,000] *$1,000,000*) would be required to satisfy the minimum financial requirement of [$600,000] *$1,000,000.*

(i) through end. 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 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

Change in Specialist Capital Requirements. Amex rule 171 currently requires specialist units to maintain a cash or ''liquid asset position'' in the greater of $600,000 or an amount sufficient to assume a position of sixty trading units of each security in which such specialist unit is registered. In the case of options specialists, the requirements of Amex rule 171 are superceded by Amex rule 950(h), which requires option specialist units to maintain a cash or ''liquid asset position'' in the amount of $600,000 plus $25,000 for each option issue in excess of the initial ten issues in which the specialist unit is registered. The proposal would amend Amex rule 171 and Amex rule 950(h) to raise the minimum capital requirement for both equity and option specialists to $1,000,000.

For specialists whose position requirement already exceeds $1,000,000, this increase would be offset by reductions in the position requirements. Specifically, the proposal would reduce the position requirement for equity specialists from 25% of sixty trading units of each security in which such specialist is registered to 15% of such amount. In the case of option specialists, the proposal would reduce the position requirement from an additional $25,000 for each option issue in excess of the initial ten issues in which such specialist is registered to an additional $25,000 for each issue in excess of the initial 25.

Change in Specialist Capital Computation Method. The proposal would amend Amex rule 171, and indirectly Amex rule 950(h), to require that specialist units meet their capital requirements with ''tentative net capital,'' *i.e.*, net capital computed in accordance with Rule 15c3–1 of the Act,[3] before haircut and undue concentration charges, rather than with cash or liquid assets. Use of a tentative net capital standard would provide a better measure of a specialist unit's financial strength than the current ''cash or liquid asset'' requirement, since it would take into account all of the specialists' assets and liabilities—not just those held in the clearing account. Moreover, since all specialists on the Amex are now subject to the net capital rule, use of such a standard should not present any computational or operational difficulties for our specialists. Indeed, those Amex specialists who also act as specialists on the NYSE are already calculating their capital in a similar manner.

Creation of an Early Warning Level. As currently drafted, the Exchange's capital standards for specialists units suffer from an ''all or nothing'' approach. That is, a specialist either meets the financial requirements or it does not. The Exchange has little actual control or authority over a specialist that, although perhaps headed for financial difficulty, has not yet fallen below the minimum requirement.

Rather than the current ''all or nothing'' approach, the Exchange is proposing the creation of a so-called early warning level that, if triggered, would allow the Exchange to subject the breaching specialist unit to closer oversight and impose conditions on its operations. The proposed early warning level would be set at 125% of the actual financial requirement and would be calculated in a conservative manner by assuming that subordinated debt and other scheduled capital distributions coming due in less than 180 days have already been paid.

While the Exchange's Financial Regulatory Services Department (''FRSD'') would monitor for compliance with the early warning level, specialist units would also be required to provide the Exchange with notice in the event they breach the early warning level. In the event of such a breach, the specialist unit would have five business days to reach a written agreement with FRSD on an action plan for raising its capital to an appropriate level. The plan would specify a timetable for bringing capital above the early warning level or taking other appropriate actions.

In the event the specialist and FRSD are not able to reach agreement on a plan, FRSD would refer the specialist either to the Committee on Floor Member Performance or to the Market Quality Committee with respect to UTP securities. Either of these Committees would have the authority to impose a performance improvement plan on the specialist to increase the specialist's capital or take other appropriate action. In no event could a written action plan provide for capital requirements below, or otherwise violate, the Exchange's minimum requirements. A failure by the specialist to meet the conditions in the Committee's plan could result in disciplinary action, the reallocation of securities, and/or other remedial action to the extent necessary to bring the breaching specialist within continued compliance.

The proposed rule change would not go into effect until one year after approval by the Commission to give firms an opportunity to adjust to the changes.

2. Statutory Basis

The proposed rule change 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, in that 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 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 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 No. SR–Amex–2002–104 and should be submitted by April 4, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[6]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–6129 Filed 3–13–03; 8:45 am]

BILLING CODE 8010–01–P

[3] 17 CFR 240.15c3–1.

[4] 15 U.S.C. 78f(b).

[5] 15 U.S.C. 78f(b)(5).

[6] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47468; File No. SR–CHX–2003–03]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the Chicago Stock Exchange, Inc. Relating to Membership Dues and Fees

March 7, 2003.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the ''Act''),[1] and rule 19b–4 thereunder,[2] notice hereby is given that on February 26, 2003, the Chicago Stock Exchange, Inc. (''CHX'') filed with the Securities and Exchange Commission the proposed rule change as described in items I, II, and III below, which the CHX 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 CHX proposes to amend its membership dues and fees schedule effective March 1, 2003, to change the criteria under which its existing marketing fee would be assessed. The text of the proposed rule change is available at the CHX 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 CHX included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it had received regarding the proposed rule change. The text of these statements may be examined at the places specified in item IV below. The CHX 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 CHX currently assesses a marketing fee under a provision of the CHX fee schedule that, by its terms, expires on December 31, 2003.[3] The proposed change to the CHX fee schedule would modify, effective March 1, 2003, the criteria that govern the assessment of the CHX's marketing fee.

The CHX's marketing fee currently is assessed, in an amount equal to $.01 per share, when ''Subject Transactions''[4] in ''Subject Issues'' occur on the CHX's trading floor. A ''Subject Issue'' is any exchange-traded fund where (a) the average daily share volume in the issue exceeds 150,000 shares each month during a consecutive two month period and (b) market maker share participation in the issue exceeds 5% for each month during the same two-month period.

The CHX proposes to change the definition of Subject Issue by reducing the required market maker share participation from 5% to 1% of the shares traded in an issue. According to the CHX, when the marketing fee was initially adopted, the 5% market-maker participation threshold was included to minimize the administrative burden on the CHX by reducing the likelihood of issues sporadically and temporarily qualifying for the program.[5] The CHX now believes, however, that the 5% threshold may soon have the unintended consequence of sporadically and temporarily excluding from the program an exchange-traded fund (''ETF'') that has qualified for the program every month since the program began. While the CHX continues to believe that some minimum thresholds are needed, it proposes to reduce the monthly market-maker participation threshold to 1%. The CHX believes that this change will reduce the possibility that an ETF that consistently qualifies for the program might on occasion become temporarily disqualified and thereby increase an administrative burden that the threshold was designed to mitigate.

It is the CHX's intention that the marketing fee will equitably allocate the financial burden of seeking order flow for Subject Issues. According to the CHX, without the marketing fee, the CHX specialist trading a Subject Issue would be the sole bearer of the often-substantial costs associated with attracting order flow to the CHX, as well as licensing fees assessed by the licensor of the product.[6] Conversely, according to the CHX, market makers participating in transactions in Subject Issues do not currently share any of these costs. The proposed rule change would allow a specialist trading a Subject Issue to elect (or decline) assessment of the marketing fee in instances where the specialist believes that it is appropriate for at least a part of the financial burden of trading the Subject Issue to be allocated among those trading the Subject Issue. The CHX believes that the proposed rule change will provide specialists trading Subject Issues with sufficient incentive to continue their efforts to attract additional order flow and increase market share.

2. Statutory Basis

The CHX believes that the proposed rule change is consistent with Section 6(b)(4) of the Act[7] because it provides for the equitable allocation of reasonable dues, fees and other charges among its members.

B. Self-Regulatory Organization's Statement of Burden on Competition

The CHX does not believe that the proposed rule change will impose any inappropriate burden on competition.

C. Self-Regulatory Organization's Statement on Comments Regarding the Proposed Rule Change Received From Members, Participants or Others

The CHX has not received any written comments with respect to this change to the marketing fee.

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)

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] *See* Securities Exchange Act Release No. 44646 (August 2, 2001), 66 FR 41641 (August 8, 2001) (SR–CHX–2001–10) (announcing immediate effectiveness of the new marketing fee provision to the CHX fee schedule through December 31, 2001); Securities Exchange Act Release No. 45282 (January 15, 2002), 67 FR 3517 (January 24, 2002) (SR–CHX–2001–30) (extending program through June 30, 2002); Securities Exchange Act Release No. 46233 (July 19, 2002), 67 FR 48960 (July 26, 2002) (SR–CHX–2002–19) (extending program through July 31, 2002); Securities Exchange Act Release No. 46297 (August 1, 2002) 67 FR 51612 (August 8, 2002) (SR–CHX–2002–25) (extending program through December 31, 2002); and Securities Exchange Act Release No. 47163 (January 10, 2003), 68 FR 2597 (January 17, 2003) (CHX–2002–39) (extending program through December 31, 2003).

[4] ''Subject Transaction'' means (a) any trade with a customer, whether the contra party is a specialist or a market maker, where the order is delivered to the Exchange via the MAX system or where compensation is paid to induce the routing of the order to the Exchange; or (b) any trade between a specialist and a market maker in which the market maker is exercising rights under the market maker entitlement rules.

[5] In administering the program, the CHX must identify the issues and transactions covered by the fee, assess and collect the fee from CHX members, distribute the fee to the appropriate specialist firms and, where necessary, refund undistributed fees to the firms that have paid them. When issues move into and out of the program, the CHX is required to re-tool its systems that identify Subject Transactions and make other changes in its administrative procedures.

[6] The marketing fee is assessed only against ETF products, which often have an associated licensing fee.

[7] 15 U.S.C. 78(f)(b)(4).

of the Act[8] and rule 19b–4(f)(2) thereunder[9] because it establishes or changes a due, fee or other charge imposed by the CHX. At any time within 60 days after the filing of the 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 purpose 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 at the Commission's Public Reference Room. Copies of the filing will also be available for inspection and copying at the principal office of the CHX. All submissions should refer to File No. SR–CHX–2003–03 and should be submitted by April 4, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[10]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–6130 Filed 3–13–03; 8:45 am]

BILLING CODE 8010–01–P

[8] 15 U.S.C. 78s(b)(3)(A).

[9] 17 CFR 240.19b–4(f)(2).

[10] 17 CFR 200.30–3(a)(12).

SECURITIES AND EXCHANGE COMMISSION

[Release No. 34–47470; File No. SR–NASD–2003–31]

Self-Regulatory Organizations; Notice of Filing and Immediate Effectiveness of Proposed Rule Change by the National Association of Securities Dealers, Inc. To Extend a Pilot With Respect to Amendments to NASD Rule 2520, Margin Requirements for Security Futures Contracts

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 March 5, 2003, the National Association of Securities Dealers, Inc. (''NASD''), 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 NASD. NASD has designated the proposed rule change as constituting a ''non-controversial'' rule change under section 19(b)(3)(A)(iii) of the Exchange Act,[3] and paragraph (f)(6) of rule 19b–4 under the Act,[4] which renders the proposal effective upon receipt of this filing by the Commission.[5] 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 proposed rule change extends until March 20, 2003, the effectiveness of the pilot program (''Pilot'') amending NASD rule 2520 (''Margin Requirements'') to establish margin requirements for security futures contracts. On January 24, 2003, the Commission approved the amendments to NASD rule 2520 on a pilot basis ending March 6, 2003.[6]

[1] 15 U.S.C. 78s(b)(1).

[2] 17 CFR 240.19b–4.

[3] 15 U.S.C. 78s(b)(3)(A)(iii).

[4] 17 CFR 240.19b–4(f)(6).

[5] The NASD has requested that the Commission waive both the five-day pre-filing notification requirement and the 30-day operative delay, as specified in rule 19b–4(f)(6)(iii). 17 CFR 240.19b–4(f)(6)(iii).

[6] *See* Securities and Exchange Act Release No. 47244, 68 FR 5317 (February 3, 2003). Specifically, the Pilot allows NASD to facilitate the trading in security futures in securities accounts for those NASD members that are not also members of the NYSE while, at the same time, considering any comments it receives on the amendments to rule 2520 relating to margin requirements for security futures contracts.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, NASD 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. NASD 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

On November 15, 2002, NASD filed with the Commission a proposed rule change to amend NASD rule 2520 to establish margin rules for security futures contracts.[7] On January 15, 2003, NASD filed Amendment No. 2 to the proposed rule change requesting that the Commission approve the proposed rule change on a pilot basis under the same terms as the Commission approval on a pilot basis of the amendments to New York Stock Exchange, Inc. (''NYSE'') rule 431.[8] The SEC approved the proposed rule change, as amended, on a pilot basis until March 6, 2003.[9]

NASD proposes to extend this Pilot from March 6, 2003 until March 20, 2003, to allow NASD additional time to review comments it has received regarding the amendments[10] and also to ensure consistency with the amendments to NYSE rule 431 relating

[7] *See* Securities and Exchange Act Release No. 46995 (December 13, 2002), 67 FR 78543 (December 24, 2002) (Notice of Filing of a Proposed Rule Change and Amendment No. 1 to NASD Rule 2520 Relating to Margin Rule Amendments for Security Futures Contracts (SR–NASD–2002–166)). *See also* letter from Gary L. Goldsholle, Associate General Counsel, NASD, to Katherine A. England, Assistant Director, Division of Market Regulation, (''Division''), Commission, dated November 22, 2002 (''Amendment No. 1''). Amendment No. 1 made non-substantive technical changes to the proposed rule text.

[8] *See* letter from Gary L. Goldsholle, Associate General Counsel, NASD, to Katherine A. England, Assistant Director, Division, Commission, dated January 15, 2003 (''Amendment No. 2''). *See also* Securities and Exchange Act Release Nos. 46782 (November 7, 2002), 67 FR 69052 (November 14, 2002) (SR–NYSE–2002–53) and 47129 (January 3, 2003), 68 FR 2094 (January 15, 2003) (SR–NYSE–2003–01).

[9] *See supra* note 6.

[10] The Commission received one comment letter on NASD's proposed rule change. *See* letter from Edward J. Joyce, President and Chief Operating Officer, Chicago Board Options Exchange, Inc. (''CBOE''), to Jonathan G. Katz, Secretary, Commission, dated December 20, 2002.

to margin requirements for security futures contracts.[11]

2. Statutory Basis

NASD believes that the proposed rule change is consistent with the provisions of section 15A(b)(6) of the Act,[12] in that NASD's rules are designed to prevent fraudulent and manipulative acts and practices, to promote just and equitable principles of trade, and, in general, to protect investors and the public interest by establishing margin rules for security futures that are comparable with those developed by the NYSE.

B. Self-Regulatory Organization's Statement on Burden on Competition

NASD 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

NASD has received one written comment on the original proposed rule change that was filed with the Commission on November 15, 2002, and amended on January 15, 2003.[13] NASD is currently considering the comments.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Because the proposed rule change: (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 for 30 days (or such shorter time as the Commission may designate if consistent with the protection of investors and the public interest) after the date of the filing, the proposed rule change has become effective pursuant to section 19(b)(3)(A) of the Act[14] and rule 19b–4(f)(6) thereunder.[15] 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.

A proposed rule change filed under rule 19b–4(f)(6) normally must not become operative prior to 30 days after the date of the filing. In addition, a self-regulatory organization filing a proposed rule change under rule 19b–4(f)(6)(iii) normally must give the Commission written notice of its intent to file the proposed rule change five days prior to the date of filing. However, rule 19b–4(f)(6)(iii) permits the Commission to designate a shorter time if such action is consistent with the protection of investors and the public interest. NASD has requested that the Commission waive both the five-day pre-filing requirement and designate that the proposed rule change become operative immediately to allow the Pilot to continue in effect on an uninterrupted basis and for NASD to consider comments it has received on the Pilot.

The Commission believes it is consistent with the protection of investors and the public interest to waive the five-day pre-filing requirement and designate the proposal immediately operative.[16] Accelerating the operative date and waiving the pre-filing requirement should permit NASD to permit customers to continue to trade securities futures contracts in securities accounts on an uninterrupted basis while NASD considers the comments it has received on the Pilot. The Commission notes that NASD anticipates filing a new proposed rule change to adopt the Pilot on a permanent basis. Accordingly, the Commission designates the proposed rule change to be effective and operative upon filing with the Commission.

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 Room. Copies of such filing will also be available for inspection and copying at the principal office of NASD.

All submissions should refer to SR–NASD–2003–31 and should be submitted by April 4, 2003.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.[17]

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 03–6128 Filed 3–13–03; 8:45 am]

BILLING CODE 8010–01–P

[11] *See supra* note 8.

[12] 15 U.S.C. 78*o*–3(b)(6).

[13] *See supra* note 10.

[14] 15 U.S.C. 78s(b)(3)(A).

[15] 17 CFR 240.19b–4(f)(6).

[16] 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).

[17] 17 CFR 200.30–3(a)(12).

SMALL BUSINESS ADMINISTRATION

Reporting and Recordkeeping Requirements Under OMB Review

AGENCY: Small Business Administration.

ACTION: Notice of reporting requirements submitted for OMB review.

SUMMARY: Under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35), agencies are required to submit proposed reporting and recordkeeping requirements to OMB for review and approval, and to publish a notice in the **Federal Register** notifying the public that the agency has made such a submission.

DATES: Submit comments on or before April 14, 2003. If you intend to comment but cannot prepare comments promptly, please advise the OMB Reviewer and the Agency Clearance Officer before the deadline.

Copies: Request for clearance (OMB 83–1), supporting statement, and other documents submitted to OMB for review may be obtained from the Agency Clearance Officer.

ADDRESSES: Address all comments concerning this notice to: Agency Clearance Officer, Jacqueline White, Small Business Administration, 409 3rd Street, SW., 5th Floor, Washington, DC 20416; and OMB Reviewer, Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: Jacqueline White, Agency Clearance Officer, (202) 205–7044.

SUPPLEMENTARY INFORMATION:

Title: Re-Certification of Size for Multiple Award Schedule and Other Multiple Award Contract.

No: N/A.

Frequency: On Occasion.

Description of Respondents: Small Business Concerns.

Responses: 6,000.

Annual Burden: 3,000.

Jacqueline White,

Chief, Administrative Information Branch.

[FR Doc. 03–6120 Filed 3–13–03; 8:45 am]

BILLING CODE 8025–01–P

SMALL BUSINESS ADMINISTRATION

[Declaration of Disaster #3480]

State of Tennessee

Knox, Rhea and Sequatchie Counties and the contiguous counties of Anderson, Bledsoe, Blount, Cumberland, Grainger, Grundy, Hamilton, Jefferson, Loudon, Marion, Meigs, Roane, Sevier, Union, Van Buren and Warren in the State of Tennessee constitute a disaster area due to damages caused by heavy rains and flooding that began on February 14, 2003, and continued through February 16, 2003. Applications for loans for physical damage as a result of this disaster may be filed until the close of business on May 5, 2003 and for economic injury until the close of business on December 8, 2003 at the address listed below or other locally announced locations:

U.S. Small Business Administration, Disaster Area 2 Office, One Baltimore Place, Suite 300, Atlanta, GA 30308.

The interest rates are:

	Percent
For Physical Damage:	
Homeowners with credit available elsewhere	5.875
Homeowners without credit available elsewhere	2.937
Businesses with credit available elsewhere	6.378
Businesses and non-profit organizations without credit available elsewhere	3.189
Others (Including non-profit organizations) with credit available elsewhere	5.500
For Economic Injury:	
Businesses and small agricultural cooperatives without credit available elsewhere	3.189

The number assigned to this disaster for physical damage is 348006 and for economic damage is 9U4200.

(Catalog of Federal Domestic Assistance Program Nos. 59002 and 59008.)

Dated: March 6, 2003.

Hector V. Barreto,

Administrator.

[FR Doc. 03–6121 Filed 3–13–03; 8:45 am]

BILLING CODE 8025–01–P

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

Aviation Proceedings, Agreements Filed the Week Ending March 7, 2003

The following Agreements were filed with the Department of Transportation under the provisions of 49 U.S.C. sections 412 and 414. Answers may be filed within 21 days after the filing of the application.

Docket Number: OST–2003–14661.
Date Filed: March 6, 2003.
Parties: Members of the International Air Transport Association.
Subject:
PTC2 EUR–ME 0155 dated 6 March 2003
Mail Vote 270—TC2 Europe-Israel
Resolution 070iy Excursion Fares and Resolution 074ey
Pex Fares from Israel to Europe
Intended effective date: 1 April 2003

Docket Number: OST–2003–14669.
Date Filed: March 7, 2003.
Parties: Members of the International Air Transport Association.
Subject:
PTC2 EUR 0496 dated 11 March 2003
Mail Vote 271—TC2 Europe
Resolution 010r—TC2 Within Europe Special Passenger
Amending Resolution
Intended effective date: 20 March 2003

Dorothy Y. Beard,

Chief, Docket Operations & Media Management, Federal Register Liaison.

[FR Doc. 03–6184 Filed 3–13–03; 8:45 am]

BILLING CODE 4910–62–P

DEPARTMENT OF TRANSPORTATION

Maritime Administration

[DOCKET NO. MARAD–2003–14680]

Information Collection Available for Public Comments and Recommendations

ACTION: Notice and request for comments.

SUMMARY: In accordance with the Paperwork Reduction Act of 1995, this notice announces the Maritime Administration's (MARAD's) intentions to request extension of approval for three years of a currently approved information collection.

DATES: Comments should be submitted on or before May 13, 2003.

FOR FURTHER INFORMATION CONTACT: Taylor E. Jones II, Maritime Administration, 400 Seventh St., SW., Washington, DC 20590. Telephone: (202) 366–3423; FAX: (202)366–3128, or E-mail: *taylor.jones@marad.dot.gov.* Copies of this collection also can be obtained from that office.

SUPPLEMENTARY INFORMATION: *Title of Collection:* Request for Transfer of Ownership, Registry, and Flag, or Charter, Lease, or Mortgage of U.S. Citizen-Owned Documented Vessels.

Type of Request: Extension of currently approved information collection.

OMB Control Number: 2133–0006.

Form Numbers: MA–29, MA–29A, and MA–29B.

Expiration Date of Approval: Three years from date of approval.

Summary of Collection of Information: This collection provides information necessary for MARAD to approve the sale, transfer, charter, lease, or mortgage of U.S. documented vessels to non-citizens; or the transfer of such vessels to foreign registry and flag; or the transfer of foreign flag vessels by their owners as required by various contractual requirements.

Need and Use of the Information: The information will enable MARAD to determine whether the vessel proposed for transfer will initially require retention under the U.S.-flag statutory regulations.

Description of Respondents: Respondents are vessel owners who have applied for foreign transfer of U.S.-flag vessels.

Annual Responses: 100 responses.

Annual Burden: 200 hours.

Comments: Comments should refer to the docket number that appears at the top of this document. Written comments may be submitted to the Docket Clerk, U.S. DOT Dockets, Room PL–401, 400 Seventh Street, SW., Washington, DC 20590. Comments may also be submitted by electronic means via the Internet at *http://dmses.dot.gov/submit.* Specifically address whether this information collection is necessary for proper performance of the functions of the agency and will have practical utility, accuracy of the burden estimates, ways to minimize this burden, and ways to enhance the quality, utility, and clarity of the information to be collected. All comments received will be available for examination at the above address between 10 a.m. and 5 p.m. EDT (or EST), Monday through Friday, except Federal Holidays. An electronic version of this document is available on the World Wide Web at *http://dms.dot.gov.*

Dated: March 11, 2003.

By Order of the Maritime Administrator.

Joel C. Richard,

Secretary, Maritime Administration.

[FR Doc. 03–6170 Filed 3–13–03; 8:45 am]

BILLING CODE 4910–81–P

DEPARTMENT OF TRANSPORTATION

Surface Transportation Board

[STB Finance Docket No. 30186 (Sub–No. 3)]

Tongue River Railroad Co.—Construction and Operation—Western Alignment

AGENCY: Surface Transportation Board, Transportation.

ACTION: Notice of Decision Allowing Supplemental Pleadings To Be Filed in Construction and Operation Application.[1]

SUMMARY: The Board is giving notice that it is allowing the Tongue River Railroad Company (TRRC) to supplement its application,[2] filed on April 27, 1998, to construct and operate 17.3 miles of track, called the Western Alignment, to be built between Decker, MT, and a point 17.3 miles north of Decker. The track would connect with a rail line previously approved for construction in *Tongue River Railroad Company—Rail Construction and Operation—Ashland to Decker, Montana,* Finance Docket No. 30186 (Sub-No. 2) (STB served Nov. 8, 1996) (*Tongue River II*). The proceeding has been held in abeyance at applicant's request since March 2, 2000. The Board will permit TRRC to tender supplemental evidence. The Board will establish a procedural schedule for replies after TRRC has filed its evidence and the agency has had an opportunity to review it.

DATES: The Board's decision is effective on March 11, 2003.

ADDRESSES: Send an original and 10 copies of all pleadings referring to STB Finance Docket No. 30186 (Sub-No. 3) to: Surface Transportation Board, 1925 K Street, NW., Washington, DC 20423–0001. All filings must be concurrently served on all parties of record and TRRC's representative: Betty Jo Christian, Esq., Steptoe & Johnson LLP, 1330 Connecticut Avenue, NW., Washington, DC 20036, (202) 429–3000, FAX (202) 429–3902.

FOR FURTHER INFORMATION CONTACT: Joseph H. Dettmar, (202) 565–1600. [Federal Relay Information Service (FIRS) for the hearing impaired: 1–800–877–8339.]

Copies of the application are available for public inspection at the offices of either the Surface Transportation Board or the applicant, Tongue River Railroad Company, 550 North 31st Street, Suite 250, P.O. Box 1181, Billings, MT 59102.

Board decisions and notices are available on our Web site at *http://www.stb.dot.gov.*

This decision will not significantly affect either the quality of the human environment or the conservation of energy resources.

Decided: March 10, 2003.

By the Board, Chairman Nober, Vice Chairman Burkes, and Commissioner Morgan.

Vernon A. Williams,

Secretary.

[FR Doc. 03–6176 Filed 3–13–03; 8:45 am]

BILLING CODE 4915–00–P

[1] Notice of this application and an initial procedural schedule were published in the **Federal Register** on June 23, 1998.

[2] The supplemental information TRRC submits will not address any of the environmental issues raised in this proceeding. These matters will be considered separately in the environmental review process, which will be conducted by the Board's Section of Environmental Analysis (SEA). SEA intends to reinstitute shortly the environmental review process by publishing an appropriate notice in the **Federal Register**.

DEPARTMENT OF TRANSPORTATION

Bureau of Transportation Statistics

[Docket BTS–2002–13790]

Notice of Request To Renew Approval of Information Collection; Collection: OMB No. 2139–0003 (Financial and Operating Statistics for Motor Carriers of Passengers)

AGENCY: Bureau of Transportation Statistics (BTS), U.S. DOT.

ACTION: Notice and request for comments.

OMB Control Numbers: 2139–0003 (Form MP–1, Quarterly and Annual Reports).

SUMMARY: This notice announces that the information collection request (ICR) to renew approval for the information collection, the Annual and Quarterly Reports for Class I Motor Carriers of Passengers (Form MP–1) has been sent to the Office of Management and Budget (OMB) for review and approval. This information collection is necessary to ensure that motor carriers comply with financial and operating statistics requirements as prescribed in the BTS regulations (49 CFR 1420). The **Federal Register** notice allowing for a 60-day comment period on this information collection was published on November 15, 2002 (67 FR 69300). This notice is required under the Paperwork Reduction Act (PRA).

DATES: Comments must be submitted to OMB on or before April 14, 2003.

ADDRESSES: Send comments to the Office of Information and Regulatory Affairs, Office of Management and Budget, New Executive Office Building, NW., Room 10202, Washington, DC 20502, ATTN: Desk Officer for the Bureau of Transportation Statistics. Comments should identify the docket number, BTS–2002–13790, and be submitted in duplicate. OMB requests comments by April 14, 2003 to process the information collection request expeditiously.

FOR FURTHER INFORMATION CONTACT: Paula R. Robinson, Compliance Program Manager, Office of Motor Carrier Information, K–13, Bureau of Transportation Statistics, 400 Seventh Street, SW., Washington, DC 20590–0001; (202) 366–2984; fax: (202) 366–3364; e-mail: *paula.robinson@bts.gov.*

SUPPLEMENTARY INFORMATION:

Electronic Access

An electronic copy of this document may be downloaded by using a computer, modem, and suitable communications software from the Government Printing Office's Electronic Bulletin Board Services at (202) 512–1661. Internet users may reach the Office of the Federal Register's Home Page at: *http://www.nara.gov/fedreg* and the Government Printing Office's database at: *http://www.access.gpo.gov/nara.* You can also view and download this document by going to the Web page of the Department's Docket Management System (*http://dms.dot.gov/*). On that page, click on ''search.'' On the next page, type the last five digits of the docket number shown in the heading of this document. Then click on ''search.''

The public should be aware that anyone may search the electronic form of all comments received in the Department's Docket Management System by using the name of the individual submitting the comment (or signing the comment, if submitted on behalf of an association, business, labor union, etc.). You may review DOT's complete Privacy Act Statement in the **Federal Register** published on April 11, 2000 (Volume 65, Number 70; Pages 19477–78) or you may visit *http://dms.dot.gov.*

Background

The Quarterly and Annual Report of Motor Carriers of Passengers (Form MP–1) is a mandated reporting requirement for any for-hire Class I motor carriers of passengers that have annual operating

reviews that are $5,000,000 dollars or more. Motor carriers required to comply with the BTS regulations are classified on the basis of their annual gross carrier operating revenues (including interstate and intrastate). Under the financial and operating statistics (F&OS) program, the BTS collects balance sheet and income statement data along with information on tonnage, mileage, employees, transportation equipment, and other related data. These regulations were formerly administered by Interstate Commerce Commission (ICC), the Interstate Commerce Act, 49 U.S.C. 11145, 49 U.S.C. 11343(d)(1) and the Bus Regulatory Act of 1982 and later transferred to the Secretary of Transportation under 49 U.S.C. 14123 and BTS' implementing regulations (49 CFR part 1420).

Comment to the Docket

The BTS published in the **Federal Register** the required notice offering a 60-day comment period on November 15, 2002 (67 FR 69300). The agency received one comment to the docket from the Central Analysis Bureau, Inc., (CAB). The CAB is a private organization within the insurance industry that provides services to motor carriers of passengers and property.

In their comments, CAB supports the agency's need for the data collection and the agency's combined use of the form both as a quarterly and annual report for passenger carriers, however, it recommends that the agency revise its existing MP–1 Form and initiate efforts to prescribe a new MP–1 Form that complies with governing statutes. CAB believes that the current MP–1 Form does not meet statutory requirements, in that it lacks sufficient details in the balance sheet and income statement information. CAB further states that in order to permit a proper evaluation of a passenger carrier's ability to operate with sufficient capital that the agency must require more detailed information. They suggest a new form, which would include more meaningful financial and safety information. Secondly, CAB suggests that if the quarterly report were supplemental to an improved annual report for passenger carriers, the form would have greater utility.

The CAB believes that proper motor carrier financial reporting continues to be a crucial safety issue because ''almost every safety study, such as the General Accounting Office's April 1991 report, ''Freight Trucking: Promising Approach for Predicting Carriers' Safety Risks'' has found that financially weak motor carriers have more accidents. The CAB believes that a financially weak motor carrier will sometimes cut back on safety engineering services, including maintenance, employee hiring standards, and other safety related aspects.

CAB also recommends that the agency conduct a survey of all passenger carriers to determine their qualifying revenues. Currently, motor carriers of passengers with annual operating revenues of $5 million dollars or more are required to file the Form MP–1. Under the CAB proposal, the reporting threshold would be lowered to $3 million dollars in annual operating revenues.

BTS Response

BTS reviewed the CAB comment. It should be noted that the comment contained multiple proposals that would require the agency to conduct a rulemaking. The BTS is deferring rulemaking action, at this time, because the benefits of increasing the reporting requirements do not appear to outweigh the costs of the increased regulatory burden. The agency will consider CAB's proposal in any future rulemaking to revise the agency's reporting requirements.

The agency will consider CAB's proposal for the agency to survey passenger carriers about their qualifying revenues as a long-term action. The agency believes that it is not practical at this time to conduct a survey because it does not have the resources and/or necessary approval from OMB.

In the meantime, the agency will continue to work with motor carriers of passengers and others within the bus and transportation community to collect F&OS data and to conduct and facilitate useful analysis. Although no additional comments were received to the docket, specifically from the regulated community, the agency believes that the present regulations are not burdensome. Therefore, BTS without any additional data or information bus carriers or other affected parties as to the extent of the burden, will not proceed with the CAB's recommendation at this time. BTS will continue to work with CAB and others in the future on ways to reduce the burden on the motor carrier industry and improve the reporting process.

Information Collected for a Non-Statistical Purpose

Respondents are hereby notified by this notice that BTS uses the information it collects under this OMB approval for non-statistical purposes including, but not limited to, publication of both Respondent's identity and its data. There may be reports of this information to agencies outside BTS for review, analysis, and other possible non-statistical uses.

The Data Collection

The Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35; as amended) and 5 CFR part 1320 require each Federal agency to obtain an OMB approval to continue an information collection activity for which the agency received prior approval. BTS is seeking OMB' approval for the following BTS information collection activity.

Title: Class I Quarterly and Annual Reports of Motor Carriers of Passengers.

OMB Control Number: 2139–0003.

Form Number: BTS Form MP–1.

Type of Review: Extension of a currently approved collection.

Respondents: Class I Motor Carriers of Passengers.

Number of Respondents: 26.

Estimated Time Per Response: 1.5 hours.

Expiration Date: February 28, 2003.

Frequency: Quarterly and Annually.

Total Annual Burden: 195 hours.

Abstract: This report provides financial and operating data. The Department of Transportation uses this information to assess the health of the industry and identify industry changes that may affect national transportation policy. The data also show company financial stability and traffic.

For additional information regarding this data collection, interested parties may review the supporting statements the agency submitted to OMB.

Issued on: March 10, 2003 in Washington, DC.

Russell B. Capelle, Jr.,

Assistant BTS Director for Motor Carrier Information, Department of Transportation.

[FR Doc. 03–6185 Filed 3–13–03; 8:45 am]

BILLING CODE 4910–FE–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Proposed Information Collection for Public Comment: Community Development Financial Institutions Fund, Bank Enterprise Award Program, 2003–2004 Application

AGENCY: Community Development Financial Institutions Fund, Department of the Treasury.

ACTION: Notice and request for comments.

SUMMARY: The proposed information collection requirement, concerning the Community Development Financial

Institutions Fund (the Fund) Bank Enterprise Award (BEA) Program 2003–2004 Application, pursuant to which insured depository institutions (as defined by 12 U.S.C. 1813(c)(2)) may apply to the Fund for awards for performing certain qualified activities (as defined by 12 CFR 1806.103(mm)), will be submitted to the Office of Management and Budget (OMB) for review as required by the Paperwork Reduction Act. The Fund is soliciting public comments on the subject proposal.

DATES: Written and electronic comments on the subject proposal must be submitted to the Fund by May 13, 2003.

ADDRESSES: Interested persons are invited to submit comments regarding the subject proposal. Comments should refer to the proposal by name and should be sent by mail to: Margaret Nilson, Depository Institutions Manager, CDFI Fund, 601 Thirteenth Street, NW., Suite 200, Washington DC 20005; by e-mail to *cdfihelp@cdfi.treas.gov;* or by facsimile at (202) 622–8244. This is not a toll free number.

FOR FURTHER INFORMATION CONTACT: Margaret Nilson, Depository Institutions Manager, CDFI Fund, 601 Thirteenth Street, NW., Suite 200, Washington DC 20005; telephone number: (202) 622–8917. This is not a toll free number. Copies of the proposed application form and other available information may be obtained from Ms. Nilson, or on the BEA page of the Fund's Web site, at: *http://www.cdfifund.gov.*

SUPPLEMENTARY INFORMATION: The Fund will submit the proposed information collection to OMB for review, as required by the Paperwork Reduction Act of 1995 (44 U.S.C. Chapter 35, as amended). This notice is soliciting comments from members of the public and affected organizations concerning the proposed collection of information to: (1) Evaluate whether the proposed collection of information is necessary to insure proper performance of the functions of the Fund, including whether the information will have practical utility; (2) evaluate the accuracy of the Fund's estimate of the burden of the proposed collection of information; (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 use of appropriate automated collection techniques or other forms of information technology, *e.g.*, permitting electronic submission of responses. Please note: The fund may not consider public comments in the event that OMB determines that modifications to the proposed information collection are not substantive and thus do not require that the Fund obtain public comments prior to issuing the 2003–2004 BEA Application.

This Notice also lists the following information:

Title of Proposal: Community Development Financial Institutions Fund Bank Enterprise Award Program 2003–2004 Application.

Description of the need for information and proposed use: The Fund, a wholly owned government corporation within the Department of the Treasury, is administering the FY 2003 and FY 2004 funding rounds of its BEA Program, pursuant to that certain Notice of Funds Availability (NOFA), published in the **Federal Register**, on February 4, 2003, at 68 FR 5727 (2003). As provided in the NOFA, the Fund will make awards to insured depository institutions, based upon such institutions' completion of certain qualified activities, as reported in the application. The application will solicit information concerning: applicants' eligibility to participate in the BEA Program; the character and quantity (value) of applicants' activities, and the extent to which such activities may be qualified activities; and appropriate supporting documentation. The questions that the application contains, and the information generated thereby, will enable the Fund to evaluate applicants' activities and determine the extent of applicants' eligibility for a BEA Program award.

Members of the affected public: Every insured depository institution that applies to the Fund for an award under the BEA Program will be required to submit an application. One hundred fifty-nine (159) such insured depository institutions applied to participate in the FY 2002 funding round.

Estimation of the total number of hours needed to prepare the information collection including number of respondents, frequency of response, and hours of response: The Fund estimates that completing each application will take 15 hours, for a total maximum burden hour estimate of 2,385 hours (based upon the number of applicants to the BEA Program in the FY 2002 funding round) .

Total Estimated Annual Burden Hours: 2,385 hours.

Status of the proposed information collection: Pending OMB approval.

Authority: The Paperwork Reduction Act of 1995, 44 U.S.C. Chapter 35, as amended; 12 U.S.C. 1834a; 12 U.S.C. 4713.

Dated: March 10, 2003.

Tony T. Brown,

Director, Community Development Financial Institutions Fund.

[FR Doc. 03–6147 Filed 3–13–03; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF THE TREASURY

Community Development Financial Institutions Fund

Notice of Funds Availability Inviting Applications for the Community Development Financial Institutions Fund—Bank Enterprise Award Program: Change of Application Deadlines; Corrections

AGENCY: Community Development Financial Institutions Fund, Department of the Treasury.

ACTION: Change of application deadlines; corrections.

Change of Application Deadlines: On February 4, 2003, the Community Development Financial Institutions Fund (the ''Fund'') announced in a NOFA for the BEA Program (68 FR 5727 (2003)) that the deadline for applications for BEA Program awards was July 17, 2003, for those applicants that opt to apply under the 6-month baseline/assessment period, as defined in 12 CFR 1806.103(k) and (f), respectively, and as further specified in the NOFA (the ''6-month option'').

This notice is to announce that the Fund is extending until 5 p.m., July 23, 2003 the deadline for the submission of applications for BEA Program awards for those applicants that apply under the 6-month option, for the FY 2003 funding round.

Correction

Section X of the February 4, 2003 NOFA states incorrectly that the award percentage applicable to an Equity Investment in CDFI shall be 15 percent for if the applicant is CDFI, and 5 percent if the applicant is not a CDFI. 68 FR 5730 (2003). The correct award percentage for an Equity Investment in a CDFI shall be 15 percent for all applicants, whether such applicant is a CDFI, or not.

All other information and requirements set forth in the February 4, 2003 NOFA for the BEA Program shall remain effective, as published.

FOR FURTHER INFORMATION, CONTACT: If you have any questions about the programmatic requirements for this program, contact the Depository Institutions Manager. If you have questions regarding administrative

requirements, contact the Fund's Awards Manager. The Depository Institutions Manager and the Awards Manager may be reached by e-mail at *cdfihelp@cdfi.treas.gov*, by telephone at (202) 622–6355, by facsimile at (202) 622–7754, or by mail at CDFI Fund, 601 13th Street, NW., Suite 200 South, Washington, DC 20005.

These are not toll free numbers.

Authority: 12 U.S.C. 1834a, 4703, 4703 note, 4704, 4706, 4707, 4713, 4717; 12 CFR part 1806.

Dated: March 10, 2003.

Tony T. Brown,

Director, Community Development Financial Institutions Fund.

[FR Doc. 03–6148 Filed 3–13–03; 8:45 am]

BILLING CODE 4810–70–P

DEPARTMENT OF TREASURY

Fiscal Service

Financial Management Service; Proposed Collection of Information: ACH Vendor/Miscellaneous Payment Enrollment Form

AGENCY: Financial Management Service, Fiscal Service, Treasury.

ACTION: Notice and request for comments.

SUMMARY: The Financial Management Service, as part of its continuing effort to reduce paperwork and respondent burden, invites the general public and other Federal agencies to take this opportunity to comment on a continuing information collection. By this notice, the Financial Management Service solicits comments concerning the SF 3881 ''ACH Vendor/Miscellaneous Payment Enrollment Form.''

DATES: Written comments should be received on or before May 13, 2003.

ADDRESSES: Direct all written comments to Financial Management Service, 3700 East West Highway, Records and Information Management Staff, Room 135, Hyattsville, Maryland 20782.

FOR FURTHER INFORMATION CONTACT: Requests for additional information or copies of the form(s) and instructions should be directed to Carolyn Dunston, Program Assistance Division, 401 14th Street, SW., Washington, DC 20227, (202) 874–7491.

SUPPLEMENTARY INFORMATION: Pursuant to the Paperwork Reduction Act of 1995, (44 U.S.C. 3506(c)(2)(A)), the Financial Management Service solicits comments on the collection of information described below.

Title: ACH Vendor/Miscellaneous Payment Enrollment Form.

OMB Number: 1510–0056.

Form Number: SF 3881.

Abstract: This form is used to collect payment data from vendors doing business with the Federal Government. The Treasury Department, Financial Management Service, will use the information to electronically transmit payments to vendors' financial institutions.

Current Actions: Extension of currently approved collection.

Type of Review: Regular.

Affected Public: Business or other for-profit institutions.

Estimated Number of Respondents: 80,000.

Estimated Time Per Respondent: 15 minutes.

Estimated Total Annual Burden Hours: 20,000.

Comments: Comments submitted in response to this notice will be summarized and/or included in the request for Office of Management and Budget approval. All comments will become a matter of public record. Comments are invited on: (a) Whether the collection 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 collection of information; (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 respondents, including through the use of automated collection techniques or other forms of information technology; and (e) estimates of capital or start-up costs and costs of operation, maintenance and purchase of services to provide information.

Bettsy Lane,

Assistant Commissioner, Federal Finance.

[FR Doc. 03–6115 Filed 3–13–03; 8:45 am]

BILLING CODE 4810–35–M

Federal Register

Friday,
March 14, 2003

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 310, 312, et al.
Safety Reporting Requirements for Human Drug and Biological Products; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 310, 312, 314, 320, 600, 601, and 606

[Docket No. 00N–1484]

RIN 0910–AA97

Safety Reporting Requirements for Human Drug and Biological Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend its pre- and postmarketing safety reporting regulations for human drug and biological products to implement definitions and reporting formats and standards recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and by the World Health Organization's (WHO's) Council for International Organizations of Medical Sciences (CIOMS); codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed drugs and licensed biological products; require that certain information, such as domestic reports of medication errors, be submitted to the agency in an expedited manner; clarify certain requirements; and make other minor revisions. FDA is also proposing to amend its postmarketing annual reporting regulations for human drug and licensed biological products by revising the content for these reports. FDA is taking this action to strengthen its ability to monitor the safety of human drugs and biological products. The intended effect of these changes is to further worldwide consistency in the collection of safety information and submission of safety reports, increase the quality of safety reports, expedite FDA's review of critical safety information, and enable the agency to protect and promote public health. These proposed changes would be an important step toward global harmonization of safety reporting requirements and additional efforts are underway within the Department of Health and Human Services to harmonize the reporting requirements of U.S. Federal agencies (*e.g.*, FDA and the National Institutes of Health (NIH) are continuing to work together to address the best ways to streamline information sharing and harmonize, to the extent possible, the safety reporting requirements of the two agencies).

DATES: Submit written comments by July 14, 2003. Submit written 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, e-mail: *FDADockets@oc.fda.gov* or to the Internet at *http://www.accessdata.fda.gov/scripts/oc/dockets/comments/commentdocket.cfm.* FAX written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, Attn: Stuart Shapiro, Desk Officer for FDA, 202–395–6974.

FOR FURTHER INFORMATION CONTACT:

For information concerning human drug products: Audrey A. Thomas, Center for Drug Evaluation and Research (HFD–7), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–594–5626.

For information concerning human biological products: Miles Braun, Center for Biologics Evaluation and Research (HFM–220), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852–1448, 301–827–6079.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Previous Safety Reporting Rulemaking and Current Guidances
II. Introduction
A. Persons Subject to the Safety Reporting Regulations
1. Premarketing Expedited Safety Reporting Regulations
2. Postmarketing Safety Reporting Regulations
3. Terms Used in This Document
B. Rationale for This Proposal
1. International Standards
2. Quality of Postmarketing Safety Reports
3. New Postmarketing Expedited Safety Reports
a. Medication errors
b. Unexpected SADRs with unknown outcome
c. Always expedited reports
d. Blood and blood component safety reports
4. Bioavailability and Bioequivalence Studies Not Subject to an Investigational New Drug Application (IND)
C. New Safety Reporting Abbreviations
D. Highlights of Proposed Changes to FDA's Safety Reporting Regulations
III. Description of the Proposed Rule
A. Definitions
1. Suspected Adverse Drug Reaction (SADR)
2. A Life-Threatening SADR
3. Serious SADR, Nonserious SADR, and SADR With Unknown Outcome
4. Contractor
5. Minimum Data Set and Full Data Set for an Individual Case Safety Report
6. Active Query
7. Spontaneous Report
8. Medication Error
9. Company Core Data Sheet, Company Core Safety Information (CCSI), Listed SADR, Unlisted SADR, and Unexpected SADR
10. Data Lock Point and International Birth Date
B. IND Safety Reports
1. Review of Safety Information
2. Written IND Safety Reports
a. Minimum data set
b. Serious and unexpected SADRs
c. Information sufficient to consider product administration changes
d. Reporting format
3. Telephone Safety Reports
4. IND Safety Reporting for Drugs Marketed in the United States
5. Investigator Reporting
C. Postmarketing Safety Reporting
1. Prescription Drugs Marketed for Human Use Without an Approved Application
2. Review of Safety Information
3. Reporting Requirements
4. Request for Alternative Reporting Frequency
5. Determination of Outcome, Minimum Data Set, and Full Data Set
6. Spontaneous Reports and Reports From Clinical Trials
7. Lack of Efficacy Reports
D. Postmarketing Expedited Reports
1. Serious and Unexpected SADRs
2. Information Sufficient to Consider Product Administration Changes
3. Unexpected SADRs With Unknown Outcome
4. Always Expedited Reports
5. Medication Errors
6. Followup Reports
7. Supporting Documentation
8. Scientific Literature
9. Contractors and Shared Manufacturers
10. Prescription Drugs Marketed for Human Use Without an Approved Application
11. Class Action Lawsuits
12. Blood and Blood Component Safety Reports
E. Postmarketing Periodic Safety Reporting
1. Traditional Periodic Safety Reports (TPSRs)
a. Narrative summary and analysis of individual case safety reports
b. Individual case safety reports
c. Increased frequency reports
d. Safety-related actions to be taken
e. Summary tabulations
f. History of safety-related actions taken
g. Location of safety records
h. Contact person
2. Periodic Safety Update Reports (PSURs)
a. Title page, table of contents, and introduction
b. Worldwide marketing status
c. Actions taken for safety reasons

d. Changes to CCSI
e. Worldwide patient exposure
f. Individual case safety reports
i. Line listings
ii. Summary tabulations
g. Safety studies
h. Other information
i. Overall safety evaluation
j. Conclusion
k. Appendices
i. Company core data sheet
ii. U.S. labeling
iii. Spontaneous reports submitted to the applicant by an individual other than a health care professional
iv. SADRs with unknown outcome
v. Class action lawsuits
vi. Lack of efficacy reports
vii. Information on resistance to antimicrobial drug products
viii. Medication errors
ix. U.S. patient exposure
x. Location of safety records
xi. Contact person
3. Interim Periodic Safety Reports (IPSRs)
4. Semiannual Submission of Individual Case Safety Reports
5. Reporting Requirements
a. Reporting intervals
b. Submission date
c. Cover letter
d. International birth date for combination products
F. Reporting Format
1. Forms Versus Narrative Format
2. Medical Dictionary for Regulatory Activities (MedDRA)
3. Single Form for Each Identifiable Patient
4. Contact Person
5. Computer-Generated Facsimile of FDA Form 3500A or Vaccine Adverse Event Reporting System (VAERS) Form
6. Other Revisions
G. Patient Privacy
H. Recordkeeping
I. Abbreviated New Drug Application (ANDA) Products
J. Postmarketing Approved New Drug Application (NDA) and Biologics License Application (BLA) Annual Reports
K. Safety Reporting for In Vivo Bioavailability and Bioequivalence Studies
L. Proposed Implementation Scheme
IV. Environmental Impact
V. Analysis of Impacts
A. Background and Summary
B. Market Failure
C. Benefits
1. Expanded Safety Information
2. Improved Uniformity and Quality of Safety Information
3. Potential Savings from Reduced SADR-Related Hospitalizations
a. Reduced rate of SADR-related hospitalizations
b. Reduced rate of in-hospital SADRs
c. Indirect benefits of reducing the hospital costs of SADRs
d. Sum of SADR-related costs
4. Cost Savings and More Efficient Use of Resources
a. Savings related to maintaining and building data bases of SADRs and intercompany transfers of drug safety data
b. Savings related to greater ease in entering into intercompany agreements
c. Savings related to eventual international harmonization to the PSUR format
d. Potential savings in clinical trial management
e. Leveraging specialized knowledge
f. Total benefits
D. Costs of Compliance
1. Costs of New Recordkeeping and Reporting Requirements
a. Number of reports
b. New time burden
i. Expedited reports
ii. Followup reports
iii. Blood products
iv. IND and bioavailability/bioequivalence safety reports
v. Semiannual submissions of postmarketing individual case safety reports
vi. Postmarketing period safety reports (TPSR, PSUR, and IPSR)
vii. Other reports
c. Annual cost of the reporting and recordkeeping provisions
2. Costs of MedDRA
a. One-time costs
i. Planning and coordination
ii. Development of information technology support structure
iii. Purchase or development of an autoencoder
iv. Conversion of legacy safety data
v. Training of personnel
vi. Revision of standard operating procedures (SOPs)
b. Recurring costs
i. MedDRA core subscription
ii. MedDRA versions and quarterly updates
iii. Maintenance of existing dictionaries
E. Small Business Analysis
1. Need for and Objectives of the Rule
2. Description and Estimate of Small Entities
3. Projected Reporting, Recordkeeping, and Other Compliance Requirements
a. Reporting and recordkeeping requirements
b. Implementing MedDRA
4. Alternatives and Steps to Minimize the Impact on Small Entities
a. Do nothing
b. Do not require a medical dictionary
c. Do not require medication errors as expedited reports
d. Do not require blood establishments to submit reports for all serious SADRs associated with blood collection and transfusion
e. Do not require certain bioavailability and bioequivalence reports as expedited reports
f. Waivers for economic hardship
g. Small business outreach, training, and assistance
F. Unfunded Mandates Reform Act of 1995
G. References
VI. Paperwork Reduction Act of 1995
A. Expedited Safety Reporting
B. Periodic Safety Reports
C. Other Reports
D. Recordkeeping
VII. Executive Order 13132: Federalism

I. Previous Safety Reporting Rulemaking and Current Guidances

FDA has undertaken a major effort to clarify and revise its regulations regarding pre- and postmarketing safety reporting for human drug and biological products. Since 1990, several rules and guidances have been issued regarding these regulations. Some of these guidances have been issued by international organizations (*i.e.*, ICH and CIOMS), while others have been issued by FDA. In figure 1 of this document, FDA illustrates how these rules and guidances relate to the current proposed rule.

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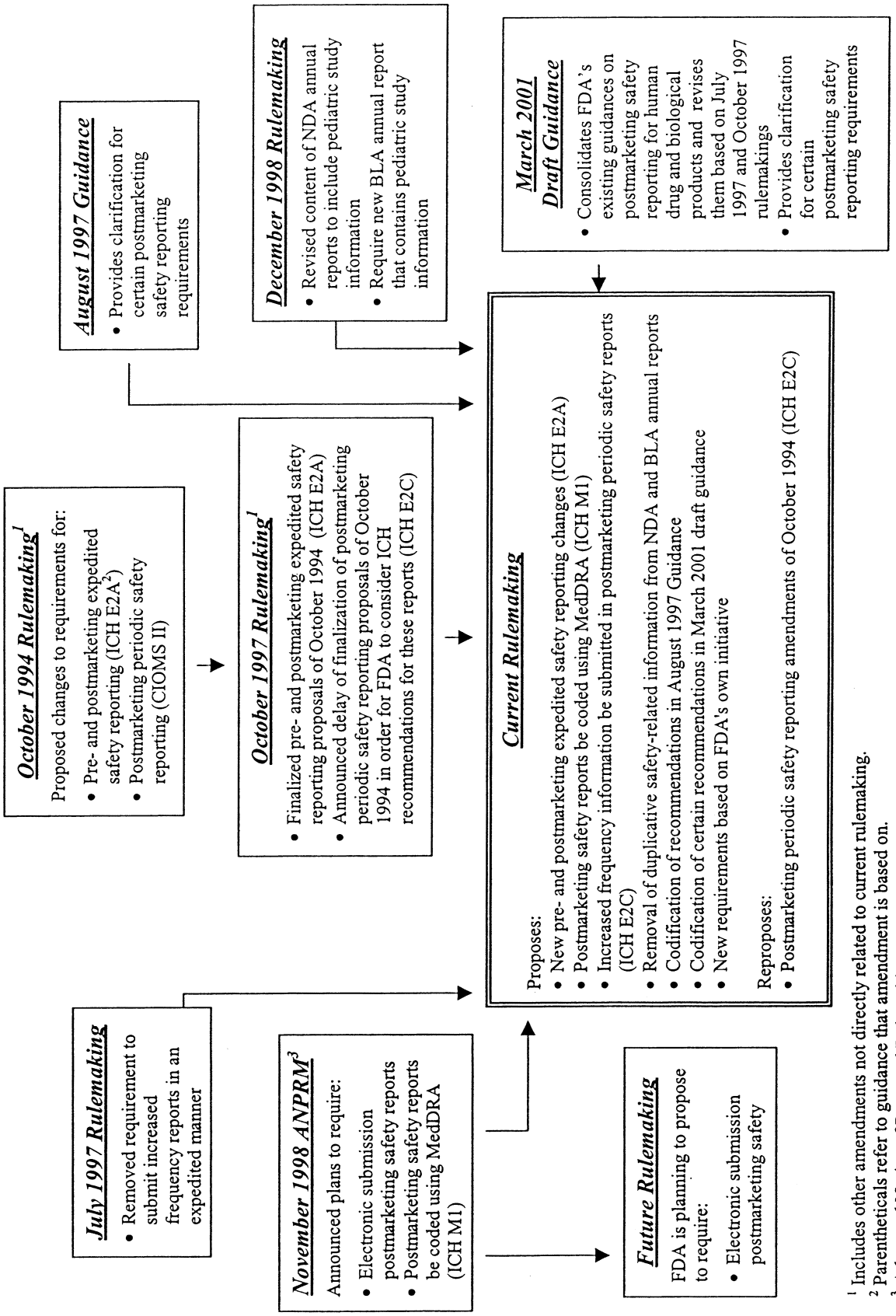
Figure 1. Safety Reporting Rulemaking and Guidances Related to Current Proposed Rule



[1] Includes other amendments not directly related to current rulemaking.
[2] Parentheticals refer to guidance that amendment is based on.
[3] Advanced Notice of Proposed Rulemaking.

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In the **Federal Register** of October 27, 1994 (59 FR 54046), FDA published a proposed rule to amend its expedited and periodic pre- and postmarketing safety reporting regulations for human drug and biological products (the October 1994 proposal). In the **Federal Register** of October 7, 1997 (62 FR 52237), FDA published a final rule amending its expedited pre- and postmarketing safety reporting regulations for human drug and biological products (the October 1997 final rule). The October 1997 final rule implemented certain international standards recommended in an ICH guidance entitled ''Clinical Safety Data Management: Definitions and Standards for Expedited Reporting'' (60 FR 11284, March 1, 1995) (the ICH E2A guidance). FDA is now proposing additional amendments to its expedited pre- and postmarketing safety reporting regulations based on recommendations in the ICH E2A guidance that were not included in the October 1994 proposal. Although the ICH E2A guidance pertains to expedited safety reporting during the premarketing phase of drug development, the agency has determined that many of the definitions and standards also should apply to FDA's expedited postmarketing safety reporting requirements.

The proposed amendments to the postmarketing periodic safety reporting requirements in the October 1994 proposal were based on recommendations in a CIOMS II report issued in 1992 (''International Reporting of Periodic Drug-Safety Update Summaries'') (Ref. 28). As explained in the October 1997 final rule, the agency decided not to finalize these proposed amendments (62 FR 52237 and 52238) until FDA considered ICH's recommendations on this topic. These recommendations were published in an ICH final guidance entitled ''Clinical Safety Data Management: Periodic Safety Update Reports for Marketed Drugs'' ''(PSURs) (the ICH E2C guidance) (62 FR 27470, May 19, 1997). After review of the ICH E2C guidance, FDA decided to repropose the postmarketing periodic safety reporting amendments in the October 1994 proposal. These amendments are being reproposed in this rulemaking based on recommendations in the ICH E2C guidance and comments submitted in response to the October 1994 proposal.

An addendum to the ICH E2C guidance has been prepared by ICH based on experience gained over the past 5 years in preparation of PSUR reports by companies and review of them by regulators (the ICH V1 draft guidance) (67 FR 79939; December 31, 2002). FDA is interested in harmonizing, to the extent possible, its postmarketing periodic safety reporting regulations with the recommendations in the ICH V1 draft guidance. In this regard, FDA is interested in comment from the public on whether the agency should implement these recommendations (*e.g.*, permit use of summary bridging reports, include an executive summary in PSURs, permit use of different versions of reference safety information within a reporting interval or use of the version in effect at the end of the reporting interval).

Some of the comments submitted in response to the October 1994 proposal noted that several of the proposed amendments to the postmarketing periodic safety reporting regulations would result in duplicative reporting of information currently required in postmarketing approved new drug application (NDA) annual reports. The comments questioned the value of submitting similar information to FDA in two different reports and requested that the agency require inclusion of this information in either one report or the other, but not in both of them. In light of these comments, FDA is proposing to revoke the requirement for safety-related information in postmarketing approved NDA annual reports.

In the **Federal Register** of December 2, 1998 (63 FR 66632), FDA issued a final rule amending its postmarketing approved NDA annual reports regulations to require reporting of specific information regarding studies in pediatric populations (the 1998 pediatric final rule). The 1998 pediatric final rule also required a new annual report for biological products with approved biologics license applications (BLAs) that contains the same type of information on studies of licensed biological products in pediatric populations. FDA is proposing to amend the annual reporting requirements for licensed biological products to revoke the requirement to submit safety-related information in these reports. This proposal is consistent with the proposed amendments to the postmarketing approved NDA annual reporting requirements.

In the **Federal Register** of June 25, 1997 (62 FR 34166), FDA published a final rule revoking the postmarketing safety reporting requirement for submission of increased frequency reports in an expedited manner (the increased frequency reports final rule). These reports contained information regarding a significant increase in frequency of an adverse drug experience (synonymous with adverse experience) that is both serious and expected for marketed human drug and licensed biological products. FDA is now proposing to amend its regulations to require submission of increased frequency type information for marketed human drugs and licensed biological products in postmarketing periodic safety reports.

In the **Federal Register** of August 27, 1997 (62 FR 45425), FDA published a notice of availability of a guidance for industry entitled ''Postmarketing Adverse Experience Reporting for Human Drug and Licensed Biological Products; Clarification of What to Report'' (the clarification guidance of 1997). This guidance clarifies the agency's policy concerning certain postmarketing safety reporting requirements for human drugs and licensed biological products. The guidance: (1) Describes the information that should be obtained before an individual case safety report (*i.e.*, FDA Form 3500A, CIOMS I Form, Vaccine Adverse Event Reporting System (VAERS) Form) of an adverse experience should be considered for submission to FDA; (2) clarifies how solicited safety information from planned contacts with patients should be handled; and (3) informs applicants that FDA will entertain waiver requests for periodic submission of individual case safety reports for adverse experiences that are determined to be nonserious and expected.

FDA received 28 comments from medical centers, physicians, and consumers regarding the clarification guidance of 1997. All of these comments pertained to the item regarding waiver requests for periodic submission of individual case safety reports for adverse experiences that are determined to be nonserious and expected. The agency considered these comments in developing this proposed rule. All of the comments requested that FDA postpone granting these waivers until this new policy receives more complete public scrutiny and debate. The comments stated that the new waiver policy would deprive the public of access to important safety information about adverse reactions to approved drugs and biological products. The comments noted that, in some cases, adverse reactions classified as ''nonserious'' may, in fact, be related to very serious reactions. The comments also indicated that the new waiver policy provides industry with an incentive to classify serious reactions as ''nonserious'' so that the reactions would not have to be reported to FDA.

Even though applicants may currently request waivers for submission of individual case safety reports for nonserious, expected adverse experiences, the agency should continue to receive information regarding these experiences. The clarification guidance

of 1997 provides that summary tabulations of nonserious, expected adverse experiences be included in postmarketing periodic safety reports. If warranted, FDA could request submission of an individual case safety report for any nonserious, expected adverse experience. Thus, even if a waiver is granted, the agency will continue to receive sufficient information to monitor the safety of marketed drugs and licensed biological products. FDA is now proposing amendments to its postmarketing periodic safety reporting regulations that would require that nonserious, expected adverse experiences [1] be submitted to the agency in summary tabulations consistent with the clarification guidance of 1997. At this time, FDA is also proposing to codify the other recommendations in the clarification guidance of 1997 (*i.e.*, require a minimum data set for individual case safety reports, describe how solicited safety information from planned contacts with patients must be handled).

In the **Federal Register** of March 12, 2001 (66 FR 14391), FDA published a notice of availability of a draft guidance for industry entitled ''Postmarketing Safety Reporting for Human Drug and Biological Products Including Vaccines'' (the draft guidance of 2001). The draft guidance of 2001 represents the agency's current thinking on reporting of postmarketing adverse drug experiences for human marketed drug and biological products including vaccines in accordance with FDA's postmarketing safety reporting regulations for these products in effect at the time the draft guidance of 2001 was issued. The draft guidance of 2001 consolidates the agency's existing guidances on this topic and revises them based on the October 1997 final rule and the increased frequency reports final rule. The draft guidance of 2001, once finalized, will replace FDA's guidances entitled ''Postmarketing Reporting of Adverse Drug Experiences'' (57 FR 61437, December 24, 1992) (the guidance of 1992), ''Adverse Experience Reporting for Licensed Biological Products'' (the guidance of 1993), and the clarification guidance of 1997. The agency will issue a final guidance for industry on this topic after considering the comments received on the draft guidance of 2001.

FDA is now proposing to codify certain expectations described in the draft guidance of 2001 to improve the quality of postmarketing safety reports submitted to the agency for human marketed drug and biological products, and also to clarify certain postmarketing safety reporting requirements. Once this proposed rule is finalized, the draft guidance of 2001, as finalized, will be updated to provide industry with assistance in fulfilling the new safety reporting requirements for human marketed drug and biological products.

In June 2001, CIOMS issued a new report entitled ''Current Challenges in Pharmacovigilance: Pragmatic Approaches'' (CIOMS V report) (Ref. 29). This report provides recommendations for simplification, clarification, and harmonization of certain drug safety practices. Many of these recommendations serve to provide guidance for industry and would not be subject to requirements of individual regulatory authorities (*e.g.*, FDA). Those that are the subject of our proposed rule are essentially consistent with what we are proposing. However, in some cases, there may be differences (see section III.A.6 of this document for discussion of use of active query and written requests for acquisition of followup information).

In the **Federal Register** of November 5, 1998 (63 FR 59746), FDA published an advance notice of proposed rulemaking announcing that it is considering a proposal to require persons subject to the postmarketing safety reporting regulations to submit postmarketing expedited individual case safety reports and individual case safety reports contained in postmarketing periodic safety reports to the agency electronically using a standardized medical terminology, standardized data elements, and electronic transmission standards recommended by the ICH. Under the auspices of ICH, standard medical terminology for regulatory purposes, MedDRA, the medical dictionary for regulatory activities (ICH M1), has been developed (63 FR 59746 at 59748). On November 24, 1998, an international maintenance and support services organization (MSSO) was established to maintain and update MedDRA in response to medical/scientific advances and regulatory changes and to serve as the licensing agent for distribution of MedDRA. This proposed rule on safety reporting would require that postmarketing individual case safety reports be coded using MedDRA prior to submission to the agency. In a separate rulemaking, FDA plans to propose that postmarketing individual case safety reports be submitted to the agency electronically using standardized data elements and electronic transmission standards. The proposed amendments for electronic submissions are beyond the scope of this proposed rule.

II. Introduction

II.A. Persons Subject to the Safety Reporting Regulations

II.A.1. Premarketing Expedited Safety Reporting Regulations

Section 312.32 (21 CFR 312.32), requires expedited reports of premarketing adverse experiences associated with the use of an investigational human drug or biological product (see table 1). Sponsors of INDs are subject to the premarketing expedited safety reporting regulations.

TABLE 1.—CURRENTLY REQUIRED PREMARKETING EXPEDITED SAFETY REPORTS

Safety report	Type of information	21 CFR section	Submission timeframe	Persons with reporting responsibility
Written IND safety report	• Serious and unexpected adverse experience associated with the use of the drug. • Findings from tests in laboratory animals that suggest a significant risk for humans.	312.32	15 calendar days	Sponsors.
Telephone and facsimile transmission safety report.	Unexpected fatal or life-threatening experience associated with the use of the drug.	312.32	7 calendar days	Sponsors.

[1] Adverse experiences are proposed to be called suspected adverse drug reactions (SADRs) in this proposed rule; see section III.A.1 of this document; the term ''adverse experiences'' or ''adverse drug experiences'' will be used in this document when discussions pertain to FDA's current regulations and the term ''SADR'' will be used in this document when discussions pertain to proposals in this rule.

II.A.2. Postmarketing Safety Reporting Regulations

Sections 310.305, 314.80, 314.98, and 600.80 (21 CFR 310.305, 314.80, 314.98, and 600.80) require expedited reports of postmarketing adverse drug experiences (see table 2). The following persons are subject to these postmarketing expedited safety reporting regulations:

• Applicants with approved NDAs (§ 314.80) and abbreviated new drug applications (ANDAs) (§ 314.98);

• Licensed manufacturers with approved BLAs (§ 600.80);

• Manufacturers, packers, and distributors (also shared manufacturers, joint manufacturers, or any other participant involved in divided manufacturing for § 600.80) whose name appears on the label of a product with an approved NDA, ANDA, or BLA (§§ 314.80, 314.98 and 600.80); and

• Manufacturers, packers, and distributors whose name appears on the label of a prescription drug product marketed without an approved NDA or ANDA (§ 310.305). In this document, the term ''applicant'' will be used instead of the term ''licensed manufacturer'' for persons with approved BLAs.

TABLE 2.—CURRENTLY REQUIRED POSTMARKETING SAFETY REPORTS

Type of report	Safety report	Type of information	21 CFR section	Submission timeframe	Persons with reporting responsibility
Expedited report.	15-day Alert report ..	Serious and unexpected adverse drug experience [1].	310.305, 314.80, 314.98, 600.80.	15 calendar days ...	Manufacturers [2] and applicants [3].
	15-day Alert report-followup.	New information for 15-day Alert report.	310.305, 314.80, 314.98, 600.80.	15 calendar days ...	Manufacturers [2] and applicants [3].
	Reports to manufacturer instead of FDA.	Serious adverse drug experiences [1].	310.305	5 calendar days	Packers and distributors.
	Reports to applicant instead of FDA.	Serious adverse experiences [1].	314.80, 314.98, 600.80.	5 calendar days	Manufacturers, packers, and distributors (§§ 314.80, 314.98, and 600.80) and joint manufacturers, shared manufacturers, or any participant involved in divided manufacturing (§ 600.80).
Expedited report.	Blood safety report ..	Fatalities	606.170	As soon as possible (oral or written) and 7 days (written).	Blood establishments.
Periodic report.	Periodic adverse drug experience report.	• Narrative summary and analysis of adverse drug experiences that occurred during the reporting interval including 15-day Alert reports previously submitted to FDA [1]. • Individual case safety report for each adverse drug experience not submitted to FDA as a 15-day Alert report, excluding reports from postmarketing studies, reports in the scientific literature, and foreign marketing experience [1]. • History of actions taken..	314.80, 314.98, 600.80.	Quarterly for 3 years from the date of U.S. approval of the application and then annually thereafter.	Applicants.

[1] For spontaneous reports, adverse drug experiences are submitted whether or not they are considered drug related; for study reports, adverse drug experiences are submitted if there is a reasonable possibility that the drug caused the adverse drug experience.
[2] Section 310.305 also includes packers and distributors.
[3] Sections 314.80 and 314.98 also include manufacturers, packers and distributors. Section 600.80 also includes manufacturers, packers, distributors, joint manufacturers, shared manufacturers, or any participant involved in divided manufacturing.

Applicants with approved NDAs, ANDAs, and BLAs must also submit periodic reports of postmarketing adverse drug experiences under §§ 314.80, 314.98 and 600.80 (see table 2). Manufacturers of prescription drug products marketed without an approved NDA or ANDA are not required to submit periodic reports of postmarketing adverse drug experiences (§ 310.305).

Existing regulations, under § 606.170 (21 CFR 606.170), require expedited reports of fatalities associated with

blood collection or transfusion (see table 2). The report must be submitted to FDA by the collecting facility in the event of a donor reaction and by the facility that performed the compatibility tests in the event of a transfusion reaction.

Current safety reporting regulations under §§ 310.305, 314.80, 314.98, 600.80 and 606.170, as well as the provisions of this proposed rule, do not apply to voluntary reporting of adverse drug experiences to companies or regulatory authorities (*e.g.*, FDA) by an individual (*e.g.*, health care professional, consumer).

II.A.3. Terms Used in This Document

The terms ''sponsors,'' ''manufacturers,'' and ''applicants'' are used in this proposed rule to describe, as appropriate, persons with safety reporting responsibilities. ''Sponsors'' is used to describe persons subject to the premarketing safety reporting regulations. ''Manufacturers'' is used, unless otherwise specified, to describe persons subject to the postmarketing safety reporting regulations under § 310.305 for prescription drug products marketed without an approved NDA or ANDA. ''Applicants'' is used to describe persons subject to the postmarketing safety reporting regulations under §§ 314.80, 314.98, and 600.80 for products with an approved NDA, ANDA, or BLA; for § 600.80, ''applicants'' includes participants involved in divided manufacturing.

II.B. Rationale for This Proposal

II.B.1. International Standards

Many of the amendments that are being proposed in this rulemaking are intended to harmonize our safety reporting requirements with international standards developed by CIOMS and ICH (see table 4 of this document). These organizations were formed to facilitate international consideration of issues, particularly safety issues, concerning the use of global data in the development and use of drugs and biological products.

The CIOMS working groups have been comprised of representatives from regulatory authorities, including FDA, and the pharmaceutical industry. These groups have worked to develop recommendations for standardization of international reporting of postmarketing adverse reactions by the pharmaceutical industry to regulatory authorities.

ICH was organized to provide an opportunity for tripartite harmonization initiatives to be developed with input from regulatory and industry representatives. ICH has worked to promote the harmonization of technical requirements for the registration of pharmaceutical products among three regions: The European Union, Japan, and the United States. The six ICH sponsors are the European Commission; the European Federation of Pharmaceutical Industry Associations; the Japanese Ministry of Health and Welfare; the Japanese Pharmaceutical Manufacturers Association; FDA; and the Pharmaceutical Research and Manufacturers of America.

One ICH initiative is to harmonize certain safety reporting requirements of the three regions. Through the ICH process, recommendations have been developed regarding the content, format, and reporting frequency for expedited and periodic safety reports for human drugs and biological products (the ICH E2A and E2C guidances). In addition, a standard medical terminology for regulatory purposes, MedDRA, has been developed (ICH M1). Worldwide implementation of this initiative is in process. FDA, which has been actively involved in the development of these recommendations, has implemented some of them (the October 1997 final rule) and is proposing to implement others in this rulemaking.

FDA believes the changes recommended by ICH and CIOMS will result in more effective and efficient safety reporting to regulatory authorities worldwide. For example, postmarketing periodic safety reports are, for the most part, currently submitted to regulatory authorities in the three regions at different times with different formats and content. International harmonization efforts are beginning to decrease some of these differences, but harmonization of the format and content, as well as the reporting frequency, of these reports by all countries in the three regions is essential to eliminate unnecessary reporting burdens on industry so that companies can focus on the safety profiles of their products and not on the different reporting requirements of different regions. The PSUR recommended for postmarketing periodic safety reporting in the ICH E2C guidance provides regulatory authorities with a comprehensive overview of the safety profile of a product along with other relevant information such as estimates of worldwide patient exposure and worldwide marketing status of the product. In this rulemaking, FDA is proposing to require submission of PSURs for certain products (see sections III.E.2 and III.E.5.a of this document). FDA is also interested in receipt of additional information and is proposing to require that such information be submitted with these reports as appendices (*e.g.*, copy of current U.S. approved labeling, information on medication errors, resistance to antimicrobial drug products and class action lawsuits) (see section III.E.2.k of this document). Thus, companies can prepare the same core document for all three regions and any additional information required by FDA would simply be attached to this document.

Another international harmonization effort is standardization of medical terminology used for regulatory purposes. As noted previously, ICH has developed MedDRA for this purpose. Currently, companies use various medical terminologies for safety reporting purposes (*e.g.*, WHO's Adverse Reaction Terminology (WHOART), Coding Symbols for a Thesaurus of Adverse Reaction Terms (COSTART), Japan's Adverse Reaction Terminology (J-ART)). The established terminologies have been criticized for a number of reasons, including: Lack of specificity, limited data retrieval options, and an inability to effectively handle complex combinations of signs and symptoms (syndromes). In addition, use of different terminologies at different stages in the development and use of products complicates data retrieval and analysis of information and makes it difficult to effectively cross-reference data through the lifetime of a product. Internationally, communication is impaired between regulatory authorities because of the delays and distortions caused by the translation of data from one terminology to another.

Use of different terminologies also has significant consequences for pharmaceutical firms. Companies operating in more than one jurisdiction have had to adjust to subsidiaries or clinical research organizations that use different terminologies because of variations in data submission requirements. The difficulty of analyzing data comprehensively may be compounded by use of incompatible terminologies and could lead to delays in recognizing potential public health problems.

For these reasons, it is critical that a single medical terminology be used internationally for coding postmarketing safety reports. FDA is proposing to use MedDRA for this purpose (see section III.F.2 of this document). MedDRA is the best choice because it was developed with input from regulatory authorities and industry and the problems associated with the other terminologies were taken into consideration during development of MedDRA. Some companies have begun to voluntarily

submit their postmarketing safety reports to FDA coded using MedDRA.

Even though FDA is proposing to use MedDRA as the standard medical terminology for reporting purposes under this rule, the agency recognizes that alternative standard classification systems for clinical information exist in the United States and supports the national health data standardization initiatives underway in the United States under the Health Insurance Portability and Accountability Act.

Although this proposed rule does not impose reporting requirements on health care providers, the agency recognizes that clinicians, medical centers, hospitals and others may report safety information to pharmaceutical companies. These third parties may employ clinical terminology standards that differ from those proposed here. Therefore, the agency invites comment on the unintended potential impact of this proposed rule on those parties not subject to FDA's safety reporting requirements. The agency also invites comment on the potential strategies and approaches for facilitating seamless cross-standard communications, such as mapping between alternative terminologies and MedDRA.

II.B.2. Quality of Postmarketing Safety Reports

In light of the recommendations of ICH and CIOMS, FDA has reviewed its postmarketing safety reporting regulations for human drugs and licensed biological products and identified additional changes that the agency believes would further enhance surveillance of marketed products. Many of the postmarketing safety reports that FDA receives are complete and of very high quality. Others are incomplete, of mediocre or poor quality or both, making it difficult to ascertain the significance of these reports. In the latter cases, FDA is unnecessarily spending considerable amounts of time trying to collect additional information for the reports.

To address this problem, FDA is proposing amendments to its postmarketing safety reporting requirements. For most of these amendments, a risk-based approach is being proposed (*i.e.*, greater emphasis and effort would be required for reports of serious adverse drug experiences while less information would be required for nonserious adverse drug experiences (adverse drug experiences proposed to be called SADRs in this proposed rule; see section III.A.1 of this document)). For example, FDA is proposing that complete information be submitted for reports of serious SADRs (see section III.C.5 of this document). If complete information is not available, in some cases, a followup report would be required (*e.g.*, for serious, unexpected SADRs) (see section III.D.6 of this document). On the other hand, for SADRs that are determined to be nonserious, not as much information would need to be acquired (see section III.C.5 of this document).

Another amendment would require direct contact with the initial reporter of an SADR by a health care professional at the company for collection of certain postmarketing safety information (*e.g.*, collection of followup information for a serious SADR) (see section III.A.6 of this document). Currently, some companies use this approach for collecting information, whereas others send the initial reporter a letter. The latter case is a passive approach which, in FDA's experience, results in limited acquisition of new information. In most cases, the initial reporter simply does not respond to the letter. Instead, using an active approach, as proposed by FDA, companies would more likely obtain the additional information needed for an SADR. Thus, use of this approach should result in submission of higher quality reports to FDA for review.

Another amendment would require that a licensed physician at the company be responsible for the content of postmarketing safety reports submitted to FDA (see sections III.E.1.h, III.E.2.k.xi, and II.F.4 of this document). As in the previous examples, some companies currently use licensed physicians for this purpose, whereas others have their postmarketing safety reports prepared and submitted by clerical personnel with no health care training. The medical significance of postmarketing safety reports warrants review by a licensed physician. The agency believes that licensed physicians would ensure submission of high quality reports to FDA that articulately conveys all clinically relevant information associated with an SADR.

II.B.3. New Postmarketing Expedited Safety Reports

FDA currently requires postmarketing expedited safety reports for serious and unexpected adverse drug experiences (adverse drug experiences proposed to be called SADRs in this proposed rule; see section III.A.1 of this document). To facilitate identification of significant safety problems, FDA is proposing that additional safety information be submitted expeditiously to the agency for marketed drugs and biological products. Some of this information is currently submitted to the agency but not in an expedited manner. In other cases, the information is not currently required to be submitted to the agency.

II.B.3.a. *Medication errors.* In 1999, the Institute of Medicine (IOM) issued a report, ''To Err is Human: Building a Safer Health System,'' that cited studies and articles estimating the number of Americans dying each year as a result of medical mistakes to be between 44,000 and 98,000 (Ref. 10). The IOM report concluded that preventable adverse drug events impose significant medical, personal, and economic costs to the United States.

Requiring medication errors to be reported in an expedited manner to a centralized location would provide a systematic approach for collecting comprehensive information on these errors and result in timely assessment of the information. Various organizations and health care professional associations, including the 1999 IOM report, have advocated mandatory medication error reporting efforts, as well as encouragement of voluntary efforts, aimed at making sure the system continues to be made safer for patients. Such a system would provide the public with a higher level of protection by assuring that the most serious errors are investigated and reported, and that appropriate followup action is taken both by FDA and the company whose product is associated with the error. Second, it would provide companies with an incentive to improve patient safety regarding medication errors associated with their products. Finally, it would require that FDA and the pharmaceutical industry make some level of investment in preventing medication errors and improving patient safety. In some instances, information gathered through this type of a reporting system and analyzed for root causes can lead to various changes within the health care system to prevent or minimize recurrence.

Currently, FDA maintains both a voluntary adverse event reporting system for health care professionals, through MedWatch (the Medical Products Reporting Program), and a mandatory adverse event reporting system for companies subject to the agency's postmarketing safety reporting regulations. Through these systems, FDA receives only about 3,000 reports of medication errors annually. FDA believes that these safety reporting systems do not adequately address the nature and extent of problems caused by medication errors. In most cases, safety reports associated with a medication error are not identified in the report as being associated with an error. Instead, the report only highlights the effect of

the medication error (*e.g.*, patient experienced a seizure). This information is not sufficient for FDA to identify medication errors that could be avoided in the future. For cases that involve a medication error, the safety report needs to be identified as a suspected medication error so that the report can be appropriately analyzed and addressed. FDA concludes that an explicit requirement for reporting medication errors by companies subject to the agency's postmarketing safety reporting regulations is needed to adequately assess and respond to the problem.

FDA is therefore proposing to require that these companies submit to the agency expeditiously all domestic reports of actual and potential medication errors (see section III.D.5 of this document). FDA would review information about suspected medication errors to determine an appropriate risk management plan (*e.g.*, changes to the proprietary name, labels, labeling or packaging of the drug or biological product or educational initiatives to protect public health). This proposal, which is consistent with one of the Department of Health and Human Services' major health initiatives, would allow FDA to form the framework for building a comprehensive risk assessment and management system for preventable SADRs. This proposal is also responsive to the 1999 IOM report, which states that ''the Food and Drug Administration (FDA) should increase attention to the safe use of drugs in both pre- and postmarketing process'' by ''establishing appropriate responses to problems identified through post-marketing surveillance, especially for concerns that are perceived to require immediate response to protect the safety of patients.''

II.B.3.b. *Unexpected SADRs with unknown outcome.* FDA is also proposing to require that companies subject to the agency's postmarketing safety reporting regulations submit to FDA in an expedited report SADRs that are unexpected and for which a determination of serious or nonserious cannot be made (*i.e.*, SADR with unknown outcome) (see section III.D.3 of this document). This information is currently submitted to FDA, but, in most cases, not in an expedited manner. A company that receives a report of an adverse drug experience is able, in most cases, to determine if it is serious or nonserious (*i.e.*, whether it meets the regulatory definition of serious), but in some cases, this may not be possible. Currently, most companies that are not able to make this determination designate the adverse drug experience as nonserious and include it in their next quarterly or annual postmarketing periodic safety report. In some of these cases, the adverse drug experience is, in fact, serious even though the company was not able to make this determination. FDA needs to receive reports of SADRs with unknown outcome expeditiously if the SADR is unexpected so that the agency can evaluate the report in light of other data and information available to FDA to attempt to determine if the SADR is serious. FDA would do this by comparing information on the unexpected SADR with unknown outcome with information on other similar unexpected SADRs with a known serious outcome that are on file with the agency.

II.B.3.c. *Always expedited reports.* FDA is also proposing that companies subject to the agency's postmarketing safety reporting regulations always submit to FDA in an expedited report certain SADRs, which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject (*e.g.*, ventricular fibrillation, liver necrosis, transmission of an infectious agent by an approved product) (see section III.D.4 of this document). Currently, all of these adverse drug experiences are submitted to the agency for review, but only some of them are submitted in an expedited safety report (*i.e.*, if the adverse drug experience is serious and unexpected). FDA is proposing that all of them be submitted expeditiously whether the SADR is unexpected or expected and whether or not the SADR leads to a serious outcome. This is because of the medical gravity of these SADRs. For example, even though the labeling for a product indicates that ventricular fibrillation may be associated with use of the product and thus not subject to expedited reporting to FDA (*i.e.*, SADR is expected), the agency needs to review each new report of ventricular fibrillation for this product as quickly as possible to ascertain if there is a qualitative or quantitative change in the nature of the SADR. Information from these reports could result in either new studies being undertaken to evaluate the SADR or appropriate regulatory action by FDA (*e.g.*, labeling change, distribution of Dear Health Care Professional letter, restriction on distribution of product, withdrawal of product from the market).

II.B.3.d. *Blood and blood component safety reports.* With regard to blood and blood components (*e.g.*, red blood cells, plasma, platelets, cryoprecipitated AHF), FDA is proposing that blood establishments submit reports to the agency for all serious SADRs associated with blood collection and transfusion, in addition to their current requirement at § 606.170(b) (21 CFR 606.170(b)) to submit reports of fatalities (see section III.D.12 of this document). This proposed safety reporting requirement would not impose significant new burdens on blood establishments. This is because under § 606.170(a) (21 CFR 606.170(a)) blood collection and transfusion facilities are currently required to conduct investigations and prepare and maintain reports of all adverse events associated either with the collection or transfusion of blood or blood components. The proposal would simply require that reports of serious SADRs that are currently maintained by the facility, be submitted to the agency within 45 calendar days of occurrence rather than only having these reports be reviewed by FDA at the time of an inspection. Thus, not all serious SADRs are reported to FDA for blood and blood components. FDA believes that it is critical that we receive all such reports to enhance donor safety and also to ensure the safety, purity and potency of blood and blood components for administration to patients.

In the past, the agency has received some voluntary reports that have helped to identify errors in manufacturing and defects in products used to collect blood. For example, in 1997, FDA received reports from a blood establishment of allergic adverse reactions to red blood cells that had been leukoreduced using a bedside filtration method in hematology or oncology patients receiving multiple transfusions. The reactions were related to several lots of Hemasure Leukonet filters. The symptoms included bilateral conjunctival edema, severe headaches, eye pain, nausea sometimes associated with vomiting and joint pain. After investigation and analysis of the reports by FDA, the manufacturer discontinued production of the filter. Voluntary reporting of the adverse reactions by the blood establishment brought the issue to the attention of FDA. However, the time to resolution may have been shortened had these been required to be reported to FDA from all blood centers.

With regard to the safety of donors, FDA review of adverse event reports is important and has resulted in detection and correction of problematic collection procedures. During an inspection, FDA field officers identified a blood collection center that had numerous donors with vasovagal reactions that required treatment by emergency medical personnel. In some of these cases, the donors had to be transported to a hospital emergency room for treatment. Upon investigation, FDA

determined that the center had failed to establish a lower limit for blood pressure measurements for donors as required by 21 CFR 640.3. Had these serious adverse events been required to be reported to FDA, immediate analysis of them is likely to have identified the problem sooner.

Thus, required reporting of all serious SADRs related to blood collection and transfusion would enhance FDA's ability to take appropriate action to protect the blood supply more consistently. Currently, there is no assurance that FDA will receive reports of serious SADRs that have the potential to adversely affect both the donors and recipients of the nation's blood supply. Such information is essential for evaluating the agency's scientific and regulatory policies and for monitoring industry practices and their implications on blood safety.

II.B.4. Bioavailability and Bioequivalence Studies Not Subject to an Investigational New Drug Application (IND).

FDA is also proposing to amend its bioavailability and bioequivalence regulations under part 320 (21 CFR part 320) (see section III.K of this document). Under the existing regulations at § 320.31, persons conducting a bioavailability or bioequivalence study in humans are only required to comply with the IND requirements of part 312 (21 CFR part 312) for certain products or for certain types of studies. This proposed rule would require submission of expedited safety reports for serious, unexpected adverse experiences (adverse experiences proposed to be called SADRs in this proposed rule; see section III.A.1 of this document) as prescribed under § 312.32 for human bioavailability and bioequivalence studies that are not being conducted under an IND. FDA believes that bioavailability and bioequivalence studies that are not being conducted under an IND are, in general, safe. However, the agency is occasionally made aware of safety-related information associated with these types of studies. This information could either reflect a problem with the drug product being evaluated or with the study design being used. Timely review of serious, unexpected SADRs from these studies is critical to ensure the safety of study subjects. FDA would use this information to determine if the study design needs to be altered or if the study needs to be stopped.

II.C. New Safety Reporting Abbreviations

Table 3 provides a list of new safety reporting abbreviations that are used in this document.

TABLE 3.—NEW SAFETY REPORTING ABBREVIATIONS

Phrase	Abbreviation	Reference in section III of this document
Company core safety information	CCSI	A.9
Interim periodic safety report	IPSR	E.3
Medical dictionary for regulatory activities	MedDRA	F.2
Periodic safety update report	PSUR	E.2
Suspected adverse drug reaction	SADR	A.1
Traditional periodic safety report	TPSR	E.1

II.D. Highlights of Proposed Changes to FDA's Safety Reporting Regulations

Specific changes to FDA's safety reporting requirements, as described in this proposed rule, are identified in table 4.

TABLE 4.—HIGHLIGHTS OF PROPOSED CHANGES TO FDA'S SAFETY REPORTING REQUIREMENTS

21 CFR Section	Proposed Change (reference in section III of this document)	Is the change based on ICH (ICH guidance)?
Changes apply to: 310.305, 312.32, 314.80, 314.98, and 600.80.[1]	• "Associated with the use of the drug" and "adverse drug experience" changed to "suspected adverse drug reaction (SADR)" and "adverse experience" changed to "suspected adverse reaction (SAR)" (A.1).	Yes (E2A)
	• Minimum data set required for all individual case safety reports of SADRs (A.5, B.2.a, C.5, E.4).	Yes (E2A)
	• Reporting requirements for lack of efficacy reports revised (B.2.c, C.7, D.2, E.1.c, E.2.h, E.2.k.vi).	Yes (E2A and E2C)
	• Sources of safety information revised (B.1, C.2, D.8)	No
	• Individual case safety reports from clinical trials based on opinion of either the sponsor/applicant or investigator (B.2.b, B.3, C.6).	Yes (E2A)
	• Narrative format required for safety reports of overall findings or data in the aggregate (B.2.d, F.1).	No
Changes only apply to 312.32	• Determination of a life-threatening SADR based on opinion of either sponsor or investigator (A.2).	Yes (E2A)
	• Expedited reports of findings from tests in laboratory animals revised to include other information sufficient to consider product administration changes (B.2.c).	Yes (E2A)
Changes only apply to 310.305, 314.80, 314.98, 600.80.	*New Safety Reports*	Yes (E2A)
	• Expedited report for information sufficient to consider product administration changes (D.2).	
	• Expedited report for unexpected SADRs with unknown outcome (A.3, D.3).	No

TABLE 4.—HIGHLIGHTS OF PROPOSED CHANGES TO FDA'S SAFETY REPORTING REQUIREMENTS—Continued

21 CFR Section	Proposed Change (reference in section III of this document)	Is the change based on ICH (ICH guidance)?
	• Always expedited reports for certain medically significant SADRs whether unexpected or expected and whether or not the SADR leads to a serious outcome (D.4).	No
	• Expedited report for medication errors (D.5)	No
	• 30-day followup report for initial serious and unexpected SADR reports, always expedited reports, and medication error reports that do not contain a full data set (D.6).	No
	Other Changes	No
	• Active query required to acquire certain safety information (A.6, C.5, D.6, D.7).	
	• Full data set required for reports of serious SADRs, always expedited reports, and medication error reports (A.5, C.5, D.1, D.4, D.5, E.4).	No
	• Safety reporting requirements for contractors and shared manufacturers (A.4, D.9).	No
Changes only apply to 310.305, 314.80, 314.98, and 600.80.	• Reporting requirements for spontaneous reports codified (A.7, C.6)	Yes (E2A and E2C)
	• Supporting documentation required for expedited reports concerning a death or hospitalization (D.7).	No
	• FDA request for submission of safety reports at times other than prescribed by regulations (C.4).	No
	• Individual case safety reports required to be coded using MedDRA (F.2).	Yes (M1)
	• SADR information from class action lawsuits (A.7, E.1.e, E.2.k.v, E.3)	No
	• Contact person for postmarketing safety reports (E.1.h, E.2.k.xi, E.3, F.4)	No
	• Use of computer-generated facsimile of FDA Form 3500A or VAERS form permitted without approval by FDA (F.5).	No
	• Location of safety records (D.10, E.1.g, E.2.k.x, E.3)	No
	• FDA request for submission of safety related records (D.7, H).	No
Changes only to apply to 314.80, 314.98 and 600.80.	*New or Revised Safety Reports*	No
	• Semiannual submission of certain spontaneously reported individual case safety reports (E.4, E.5.a).	No
	• TPSR, PSUR, or IPSR for applications approved prior to January 1, 1998 (E.1, E.2, E.3, E.5.a).	No
	• PSUR/IPSR for applications approved on or after January 1, 1998 (E.2, E.3, E.5.a).	Yes (E2C)
	• PSUR/IPSR for pediatric use supplements (E.5.a)	No
	Other Changes	Yes (E2C)
	• Periodicity of periodic safety reports (E.5.a, I)	
	• Submission date for periodic safety reports (A.10, E.5.b, I)	Yes (E2C)
	• CCSI for determination of listed and unlisted SADRs for certain periodic safety reports (A.9, E.2, E.3, E.4).	Yes (E2C)
	• Information in addition to the minimum data set not required to be acquired for nonserious SADRs, except for nonserious SADRs resulting from a medication error, which require a full data set (A.3, C.5, E.4).	No
	• Individual case safety reports forwarded to applicant by FDA required to be included in comprehensive safety analysis (C.2).	No
	• Information on resistance to antimicrobial drug products (E.2.k.vii, E.3)	No
	• Number of copies of periodic safety reports required to be submitted to FDA (C.3).	No
Change only applies to 314.81 and 601.28 [2].	• Requirement to submit safety-related information in postmarketing annual report revoked (J).	No
Change only applies to 312.64(b) [3]	• Investigator safety reporting requirements revised	No
Change only applies to 320.31(d) [4]	• Submission of expedited safety reports required for human bioequivalence and bioavailability studies which are exempt from submission of an IND (K).	No
Change only applies to 606.170 [5]	• All serious SARs required to be submitted to FDA for blood and blood products (D.12).	No

[1] Section 310.305 describes postmarketing safety reporting regulations for prescription drug products marketed for human use without an approved application; § 312.32 describes premarketing safety reporting regulations for investigational drugs and biological products; § 314.80 describes postmarketing safety reporting regulations for human drugs with approved NDAs; § 314.98 describes postmarketing safety reporting regulations for human drugs with approved ANDAs; and § 600.80 describes postmarketing safety reporting regulations for human licensed biological products with approved BLAs.

[2] Section 314.81 describes postmarketing annual reporting regulations for human marketed drugs with approved NDAs; § 601.28 describes postmarketing annual reporting regulations for pediatric studies of human licensed biological products with approved BLAs.

[3] Section 312.64(b) describes requirements for safety reporting to sponsors by investigators.

[4] Section 320.31 (d) describes bioequivalence and bioavailability requirements for studies which are exempt from submission of an IND.

[5] Section 606.170 describes safety reporting and recordkeeping requirements for blood and blood products.

III. Description of the Proposed Rule

III.A. Definitions

III.A.1. Suspected Adverse Drug Reaction (SADR)

FDA's existing premarketing safety reporting regulations in § 312.32(a) define ''associated with the use of the drug'' to mean: ''There is a reasonable possibility that the experience may have been caused by the drug.''

FDA's existing postmarketing safety reporting regulations in §§ 310.305(b), 314.80(a), and 600.80(a) define ''adverse drug experience (''adverse experience'' for § 600.80(a))'' to mean:

> Any adverse event associated with the use of a drug (''biological product'' for § 600.80(a)) in humans, whether or not considered drug (''product'' for § 600.80(a)) related, including the following: An adverse event occurring in the course of the use of a drug (''biological'' for § 600.80(a)) product in professional practice; an adverse event occurring from drug overdose (''from overdose of the product'' for § 600.80(a)) whether accidental or intentional; an adverse event occurring from drug abuse (''from abuse of the product'' for § 600.80(a)), an adverse event occurring from drug withdrawal (''from withdrawal of the product'' for § 600.80(a)); and any failure of expected pharmacological action.

Proposed § 312.32(a) would replace the term ''associated with the use of the drug'' with the term ''suspected adverse drug reaction (SADR).'' Proposed §§ 310.305(a) and 314.80(a) would replace the term ''adverse drug experience'' with the term ''suspected adverse drug reaction (SADR)'' (see section III.C.1 of this document regarding reorganization of § 310.305). Proposed § 600.80(a) would replace the term ''adverse experience'' with the term ''suspected adverse reaction (SAR).'' In this document the term ''adverse drug experience'' is synonymous with the term ''adverse experience'' and the abbreviation ''SADR'' will be used for both ''SADR'' and ''SAR,'' except when reference is only being made to an ''SAR,'' in which case the abbreviation ''SAR'' will be used. Proposed §§ 310.305(a), 312.32(a), 314.80(a), and 600.80(a) would also replace the definitions for ''associated with the use of the drug,'' ''adverse drug experience'' and ''adverse experience'' with the following definition for ''SADR'':

> A noxious and unintended response to any dose of a drug (''biological'' for proposed § 600.80(a)) product for which there is a reasonable possibility that the product caused the response. In this definition, the phrase ''a reasonable possibility'' means that the relationship cannot be ruled out.

The phrase ''the relationship cannot be ruled out'' clarifies which individual cases would be reported to FDA. Classifying a case as ''probably related,'' ''possibly related,'' ''remotely related,'' or ''unlikely related'' to the drug or biological product would signify that a causal relationship between the product and an adverse event could not be ruled out and, thus, the adverse event would be considered an SADR. For example, in some cases an adverse event may most probably have occurred as a result of a patient's underlying disease and not as a result of a drug or biological product the patient was taking, but it cannot usually be said with certainty that the product did not cause the adverse event. Therefore, such an adverse event would be classified as an SADR because there would be at least a ''reasonable possibility'' that the drug or biological product may have caused the adverse event. Of course, this classification would not establish causality (attributability) by itself, it would only indicate that causality could not be ruled out with certainty.

These proposed changes are consistent with the ICH E2A guidance (60 FR 11284 at 11285), which defines ''adverse drug reaction'' as:

> All noxious and unintended responses to a medicinal product related to any dose should be considered adverse drug reactions. The phrase ''response to medicinal products'' means that a causal relationship between a medicinal product and an adverse event is at least a reasonable possibility, *i.e.*, the relationship cannot be ruled out.

These proposed amendments would harmonize the agency's premarketing and postmarketing safety reporting definition for SADR, as well as safety reporting worldwide.

Even though FDA has harmonized its proposed definition of SADR with the definition of adverse drug reaction recommended by ICH, the agency would like comment on an alternative definition for SADR: ''A noxious and unintended response to any dose of a drug product for which a relationship between the product and the response to the product cannot be ruled out''. The alternative and proposed definitions for SADR have the same meaning (*i.e.*, a response to a product is an SADR unless one is sure that the product did not cause the response). The difference between these definitions is that the alternative definition of SADR does not include the phrase ''a reasonable possibility.'' This is because use of this phrase is potentially confusing. The phrase ''a reasonable possibility'' might be interpreted differently than the phrase ''the relationship cannot be ruled out.'' The agency defines ''a reasonable possibility'' as ''the relationship cannot be ruled out'' to be consistent with ICH. FDA seeks comment as to whether the agency should use the alternative definition of SADR instead of the proposed definition of SADR. The agency also requests comment from sponsors, manufacturers and applicants if their interpretation of these definitions is different than FDA's interpretation.

As explained in the following paragraphs, FDA believes that the proposed definition of SADR would not affect the number of safety reports that are currently submitted to FDA from spontaneous sources, but it could increase the number of safety reports that would be submitted from clinical studies. FDA seeks comment as to whether use of the proposed or alternative definition of SADR would lead to significant increases in reporting to the agency beyond what FDA has identified in the following paragraphs. FDA is particularly interested in learning of examples of events beyond those identified by the agency that are not currently reported to FDA but would be required to be reported under these definitions.

Although FDA is proposing to remove the definition for ''adverse drug experience'' from its postmarketing safety reporting regulations and replace it with the proposed definition for ''SADR,'' this change would not affect the number of safety reports from spontaneous sources that would be submitted to the agency because every spontaneous report currently must be submitted to FDA, irrespective of whether the manufacturer or applicant considers it to be drug related (see current definition of adverse drug experience at §§ 310.305(c), 314.80(c), and 600.80(c)). Under this proposed rule, every spontaneous report would continue to be submitted to FDA, because, for spontaneous reports, manufacturers and applicants would always be required to assume, for safety reporting purposes only, that there was at least a reasonable possibility in the opinion of the initial reporter that the drug or biological product caused the spontaneously reported event (see sections III.A.7 and III.C.6 of this document for the proposed definition of spontaneous report and for discussion of the proposed reporting requirement for SADRs from spontaneous sources).

On the other hand, with regard to clinical studies of investigational and marketed drugs and biological products, the proposed definition of SADR is likely to result in an increase in the number of safety reports that are currently submitted to FDA from some

studies. Current regulations at §§ 310.305(c)(1)(ii), 312.32(c)(1), 314.80(e)(1), and 600.80(e)(1) require that serious, unexpected adverse experiences from a study be reported to FDA only if there is a reasonable possibility that the drug caused the adverse experience. The phrase ''reasonable possibility'' is typically interpreted by sponsors, manufacturers and applicants to mean that there is a possible causal relationship between an adverse experience and a drug or biological product. It would not include adverse experiences considered to be unlikely or remotely related to the product. The proposed definition of SADR maintains the phrase ''reasonable possibility'' as part of the definition, but defines the phrase to mean that the relationship between a product and a response to the product cannot be ruled out. In some cases, this proposed change would result in submission of more safety reports to FDA. For example, under the current regulations if a sponsor or applicant concludes that the existence of a causal relationship between a drug and an adverse event is unlikely or remote, but not impossible, (*e.g.*, because the event is a recognized consequence of the patient's underlying disease) it would not submit a safety report to FDA. In contrast, under the proposed rule, the sponsor or applicant would be required to submit a safety report to the agency for this SADR, because, although the relationship of the adverse event to the drug is unlikely or remote because of the patient's underlying disease, a causal relationship cannot, nonetheless, be ruled out. FDA is proposing the new definition for SADR to minimize situations in which an adverse event that proves ultimately to be due to a drug or biological product is not reported as soon as possible to the agency because the etiology of the adverse event is attributed to the patient's underlying disease by the sponsor, manufacturer or applicant (*e.g.*, a patient's hepatic deterioration is judged to be related to the patient's viral hepatitis and not to the hepatotoxicity of the drug the patient received.)

FDA recognizes, however, that particularly for those patients who have certain diseases (*e.g.*, fatal diseases such as cancer), the proposed definition of SADR may result in submission of numerous safety reports to the agency for which the reported SADR is not informative as a single report because it is very likely to have been a consequence of the patient's disease. This would be true, for example, for most non-acute deaths in a clinical trial evaluating a drug in cancer patients. These deaths would have to be reported to FDA as SADRs because a relationship between the drug and the deaths could not be ruled out with certainty. Because such ''over-reporting'' may make it more difficult for FDA and the sponsor, manufacturer or applicant to recognize adverse events that are really caused by a drug or biological product, the agency wants to minimize receipt of this type of safety report, but in a way that does not compromise receipt of useful safety reports that are perceived as remotely related to an administered drug or biological product but that occur, in fact, as a result of the product. If sponsors, manufacturers or applicants believe that, in a specific situation, there is an alternative way(s) to handle adverse events occurring during clinical studies that would minimize ''over-reporting'' while assuring that reporting of SADRs would not be compromised, they are invited to propose any such alternative(s) reporting method to the agency. In such situations, if FDA does not oppose the proposed alternative reporting method, the sponsor, manufacturer or applicant would be permitted to report SADRs to the agency according to the alternative method. For example, one such alternative would be to include in study protocols or other documentation a list of known consequences of the disease that would not be submitted to FDA in an expedited manner as individual case safety reports (*e.g.*, events that are the endpoints of the study). These adverse events would, however, be monitored by the sponsor, manufacturer, or applicant and, if they indicated in the aggregate by comparison to a control group or historical experience, that the product in the clinical study may be causing these events, the information would be submitted to FDA in an expedited manner as an information sufficient to consider product administration changes report (see sections III.B.2.c and III.D.2 of this document for discussion of this type of report). FDA invites comment from the public on this alternative and requests suggestions for other alternatives as well that would minimize ''over-reporting'' of uninformative events and assure submission of meaningful reports of unexpected events. FDA also invites comment on reporting of these types of clinical events that occur in studies not being conducted under an IND (*e.g.*, drug or biological product is marketed in the United States for a particular indication and being investigated in a clinical trial abroad for the same or other indication).

The proposed definition of SADR may result in submission to FDA of some reports from clinical studies and the scientific literature in which the reported SADR is suspected to be associated with the product, but, in fact, it is ultimately demonstrated not to be due to the product. This is also true for reports from spontaneous sources in which manufacturers and applicants must always assume, for safety reporting purposes, that there is at least a reasonable possibility that the drug or biological product caused the spontaneously reported event and submit the report to FDA. Thus, SADR reports are required to be submitted to FDA based on a suspected, not established, causal relationship between an adverse event and a drug. This type of reporting program allows the agency to determine more quickly which SADRs warrant regulatory action by FDA to protect public health (*e.g.*, change in product labeling, withdrawal of product from the market). FDA receives hundreds of thousands of such reports each year, most of which do not result in any regulatory action. But for those reports that do represent a significant change in the benefit-to-risk profile of a product, this system is critical for developing a signal necessitating further evaluation of an SADR.

Some members of the public have maintained that submission of voluntary SADR reports by health care professionals or consumers to manufacturers or to FDA might be discouraged because of concern that a person or entity might be implicated in a product liability action. In addition, industry has expressed its concern that these reports, taken out of context and used in a manner for which they were never intended, can create a product liability vulnerability. FDA is concerned that such liability misuse of these reports could imperil the credibility and functionality of this critical public health reporting system.

Our current safety reporting regulations at §§ 310.305(g), 312.32(e), 314.80(k), and 600.80(l) provide manufacturers, applicants, and sponsors with a disclaimer that permits them to deny that the safety report or other information required to be submitted to FDA under these regulatory provisions constitutes an admission that the drug or biological product caused or contributed to an adverse effect. For example, § 314.80(k) currently reads in pertinent part:

Disclaimer. A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a

conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an adverse effect. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an adverse effect.

Additionally, a ''disclaimer'' is included on the first page of the voluntary reporting form used by health care professionals and consumers, FDA Form 3500, stating ''Submission of a report does not constitute an admission that medical personnel or the product caused or contributed to the event.'' A similar disclaimer is included on the mandatory reporting form used by manufacturers and applicants, FDA Form 3500A. In its notice of availability announcing FDA Form 3500 and 3500A, the agency reiterated that ''Although the underlying information may be relevant to product liability issues, submitting the form itself, as is clearly stated on the form, does not constitute an admission that the product caused the adverse event'' (58 FR 31596 at 31600, June 3, 1993).

FDA seeks comment as to whether these ''disclaimers'' are sufficient to protect manufacturers, applicants, and sponsors, from the use of SADR reports in product liability actions. For instance, perhaps the agency should consider also prohibiting use of SADR reports the agency receives in product liability actions. Accordingly, FDA seeks comment on the need for any further action to promote submission of SADR reports to the agency and guard against their misuse, as well as FDA's legal authority to take any such action.

FDA is proposing to remove the current provisions in §§ 310.305(c)(1)(ii), 314.80(e)(1), and 600.80(e)(1). The agency is proposing this amendment because the information contained in these paragraphs is included in the proposed definition of SADR.

III.A.2. A Life-Threatening SADR

FDA's existing premarketing safety reporting regulations at § 312.32(a) define a life-threatening adverse drug experience as:

Any adverse drug experience that places the patient or subject, in the view of the investigator, at immediate risk of death from the reaction as it occurred, *i.e.*, it does not include a reaction that, had it occurred in a more severe form, might have caused death.

FDA is proposing to amend this definition by adding the phrase ''or sponsor'' after the word ''investigator.'' Thus, reports of life-threatening SADRs would be based on the opinion of either the investigator or sponsor. In some cases, the opinions of the investigator and sponsor may be discordant. In these situations, the sponsor would submit an IND safety report to FDA for the life-threatening SADR and include in the report the reason(s) for any differences in opinions. This proposed revision is consistent with the ICH E2A guidance (60 FR 11286): ''Causality assessment is required for clinical investigation cases. All cases judged by either the reporting health care professional or the sponsor as having a reasonable suspected causal relationship to the medicinal product qualify as ADR's [adverse drug reactions].''

FDA's existing postmarketing safety reporting regulations at §§ 310.305(b), 314.80(a), and 600.80(a) define a ''life-threatening adverse drug experience'' as:

Any adverse [drug] experience that places the patient, in the view of the initial reporter, at immediate risk of death from the adverse [drug] experience as it occurred, *i.e.*, it does not include an adverse [drug] experience that, had it occurred in a more severe form, might have caused death.

Proposed §§ 310.305(a), 312.32(a), 314.80(a), and 600.80(a) would amend the premarketing and postmarketing definition of life-threatening adverse drug experience by making minor revisions. FDA is proposing to move the phrase ''places the patient'' (''patient or subject'' for proposed § 312.32(a)) before the phrase ''at immediate risk of death'' and also to replace the phrase ''adverse drug experience'' with the abbreviation ''SADR.''

III.A.3. Serious SADR, Nonserious SADR, and SADR With Unknown Outcome

FDA's existing premarketing and postmarketing safety reporting regulations at §§ 310.305(b), 312.32(a), 314.80(a), and 600.80(a) define a serious adverse drug experience as:

Any adverse [drug] experience occurring at any dose that results in any of the following outcomes: Death, a life-threatening adverse [drug] experience, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. * * *

Proposed §§ 310.305(a), 312.32(a), 314.80(a), and 600.80(a) would amend this definition by removing the phrase ''occurring at any dose,'' because the proposed definition of SADR includes the phrase ''response to any dose of a drug (''biological'' for proposed § 600.80(a)) product'' and it is unnecessary to refer to ''any dose'' in both definitions. FDA is also proposing to amend this definition by replacing the phrase ''adverse drug experience'' with the abbreviation ''SADR'' for consistency as proposed previously.

Under proposed §§ 310.305(a), 314.80(a), and 600.80(a), FDA would amend its postmarketing safety reporting regulations to define the term ''nonserious SADR'' to mean: ''Any SADR that is determined not to be a serious SADR.'' FDA is proposing to add this definition to clarify what constitutes a nonserious SADR. SADRs would only be classified as ''nonserious'' if manufacturers and applicants have determined that the reaction does not meet the definition of a serious SADR. If the outcome for an SADR is not known, a determination of seriousness cannot be made; the SADR would not default to a ''nonserious'' designation, but would rather be classified as an ''SADR with unknown outcome'' as described below.

Under proposed §§ 310.305(a), 314.80(a), and 600.80(a), FDA would amend its postmarketing safety reporting regulations to define the term ''SADR with unknown outcome'' to mean: ''An SADR that cannot be classified, after active query, as either serious or nonserious.'' FDA is proposing to define this term to describe those SADRs for which an outcome (*i.e.*, classification as either serious or nonserious) cannot be determined. FDA believes that, in most cases, manufacturers and applicants are usually able to determine the outcome of an SADR. However, in a few cases, this may not be possible, even after active query, and these SADRs would be designated as ''SADR with unknown outcome'' (see section III.A.6 of this document for proposed definition of active query).

III.A.4. Contractor

Under proposed § 310.305(a), FDA would amend its postmarketing safety reporting regulations to define the term ''contractor'' to mean:

Any person (*e.g.*, packer or distributor whether or not its name appears on the label of the product; licensee; contract research organization) that has entered into a contract with the manufacturer to manufacture, pack, sell, distribute, or develop the drug or to maintain, create, or submit records regarding SADRs or medication errors.

Under proposed § 314.80(a), the term ''contractor'' is defined as persons (*e.g.*, manufacturer, packer, or distributor whether or not its name appears on the label of the product; licensee; contract research organization) that have entered into a contract with the applicant. Under proposed § 600.80(a), the term ''contractor'' is defined as persons (*e.g.*,

manufacturer, joint manufacturer, packer, or distributor whether or not its name appears on the label of the product; licensee; contract research organization) that have entered into a contract with the applicant (includes participants involved in divided manufacturing). FDA would define this term to specify which contractors would be subject to the agency's postmarketing safety reporting requirements under proposed §§ 310.305(c)(2)(xi), 314.80(c)(2)(x), and 600.80(c)(2)(x) (see section III.D.9 of this document). Persons under contract to manufacture, pack, sell, distribute, or develop the drug or licensed biological product, or to maintain, create, or submit records regarding SADRs or medication errors (whether or not the medication error results in an SADR; see section III.A.8 of this document) would have postmarketing safety reporting responsibilities.

III.A.5. Minimum Data Set and Full Data Set for an Individual Case Safety Report

Proposed §§ 310.305(a), 312.32(a), 314.80(a), and 600.80(a), would amend FDA's premarketing and postmarketing safety reporting regulations to define the term ''minimum data set.'' A ''minimum data set'' for an individual case safety report of an SADR would include: an identifiable patient, an identifiable reporter, a suspect drug (biological for proposed § 600.80(a)) product, and an SADR.

Proposed §§ 310.305(a), 314.80(a), and 600.80(a), would also amend FDA's postmarketing safety reporting regulations to define the term ''full data set.'' A ''full data set'' for a postmarketing individual case safety report would include:

> Completion of all the applicable elements on FDA Form 3500A (or the Vaccine Adverse Event Reporting System (VAERS) form for proposed § 600.80(a)) (or on a Council for International Organizations of Medical Sciences (CIOMS) I form for reports of foreign SADRs) including a concise medical narrative of the case (*i.e.*, an accurate summary of the relevant data and information pertaining to an SADR or medication error).

The proposed rule would define these terms to clarify the type of information that manufacturers and applicants would be required to submit to FDA for SADRs and medication errors. The proposed rule would, as described below, require at least a minimum data set for all individual case safety reports, except for certain reports of medication errors (see sections III.B.2.a and III.C.5 of this document). In addition, a full data set would be required for postmarketing individual case safety reports of serious SADRs, always expedited reports, and medication error reports (see sections III.C.5, III.D.1, III.D.4, III.D.5, and III.E.4 of this document). Reports of nonserious SADRs with a minimum data set would include all safety information received or otherwise obtained by the manufacturer or applicant for the SADR. However, except for reports of nonserious SADRs resulting from a medication error, information in addition to the minimum data set would not be required to be acquired by the manufacturer or applicant (see sections III.C.5 and III.E.4 of this document). Manufacturers and applicants would be required to submit a full data set for reports of nonserious SADRs resulting from a medication error (see sections III.C.5 and III.D.5 of this document).

As noted previously, for each individual case safety report, a suspect product would be required to be identified. Reports from blinded clinical studies (*i.e.*, the sponsor and investigator are blinded to individual patient treatment) should be submitted to FDA only after the code is broken for the patient or subject that experiences an SADR. The blind should be broken for each patient or subject who experiences a serious, unexpected SADR unless arrangements have been made otherwise with the FDA review division that has responsibility for review of the IND (*e.g.*, the protocol or other documentation clearly defines specific alternative arrangements for maintaining the blind). Exceptions to breaking the blind for a study usually involve situations in which mortality or certain serious morbidities are indeed the clinical endpoint of the study. This is consistent with the discussion of managing blinded therapy cases in the ICH E2A guidance (60 FR 11266):

> * * * Although it is advantageous to retain the blind for all patients prior to final study analysis, when a serious adverse reaction is judged reportable on an expedited basis, it is recommended that the blind be broken only for the specific patient by the sponsor even if the investigator has not broken the blind. * * * However, when a fatal or other ''serious'' outcome is the primary efficacy endpoint in a clinical investigation, the integrity of the clinical investigation may be compromised if the blind is broken. Under these and similar circumstances, it may be appropriate to reach agreement with regulatory authorities in advance concerning serious events that would be treated as disease-related and not subject to routine expedited reporting.

In addition to the exception for breaking the blind mentioned above, FDA is also interested in considering whether the blind should be broken for other serious SADRs that are not the clinical endpoint of the study, but occur at a rate high enough that the overall study blind would be threatened if each such case were individually unblinded. FDA invites comment from the public on how reporting of these SADRs should be handled.

III.A.6. Active Query

Under proposed §§ 310.305(a), 314.80(a), and 600.80(a), FDA would amend its postmarketing safety reporting regulations to define the term ''active query'' to mean:

> Direct verbal contact (*i.e.*, in person or by telephone or other interactive means such as a videoconference) with the initial reporter of a suspected adverse drug reaction (SADR) or medication error by a health care professional (*e.g.*, physician, physician assistant, pharmacist, dentist, nurse, any individual with some form of health care training) representing the manufacturer (applicant for proposed §§ 314.80(a) and 600.80(a)). For SADRs, active query entails, at a minimum, a focused line of questioning designed to capture clinically relevant information associated with the drug product (licensed biological product for proposed § 600.80(a)) and the SADR, including, but not limited to, information such as baseline data, patient history, physical exam, diagnostic results, and supportive lab results.

The agency would define this term to describe the process that manufacturers and applicants would be required to use to acquire safety information expeditiously. Active query would be used to:

- Determine whether an SADR is serious or nonserious if the manufacturer or applicant is not able to immediately make this determination (see section III.C.5 of this document),
- Obtain at least the minimum data set for all SADRs and the minimum information for medication errors that do not result in an SADR if the manufacturer or applicant is not able to immediately obtain this information (see section III.C.5 of this document),
- Obtain a full data set for individual case safety reports of serious SADRs, always expedited reports, and medication error reports if a full data set is not available for the report (see section III.C.5 of this document), and
- Obtain supporting documentation for a report of a death or hospitalization (*e.g.*, autopsy report, hospital discharge summary) (see section III.D.7 of this document).

Active query would entail direct verbal contact either in person or by telephone or other interactive means (*e.g.*, a videoconference) with the initial reporter of an SADR or medication error. FDA believes that, in many cases, use of active query during initial contact with these reporters would provide

manufacturers and applicants with adequate safety information and could eliminate or decrease followup time expended by manufacturers, applicants, and the agency. The agency does not believe that it is sufficient for manufacturers and applicants just to send a letter to reporters of SADRs and medication errors requesting further information. These reporters could, however, submit written materials to manufacturers and applicants to clarify or provide support for verbal discussions.

Even though the agency is not proposing that manufacturers and applicants request followup information for SADR and medication error reports in writing, the CIOMS V report describes instances when it might be appropriate to do so. FDA seeks comment as to whether the agency should permit written requests for followup information and, if so, in which situations should these requests be permitted.

Active query would be conducted by a health care professional, such as a physician, physician's assistant, pharmacist, dentist, nurse, or any individual with some form of health care training. The agency believes that a health care professional would be able to understand better the medical consequences of a case and ask reporters of SADRs and medication errors appropriate questions to acquire more complete safety information effectively and rapidly.

The proposed definition of active query would provide that, at a minimum, a focused line of questioning be used to acquire further information on SADRs. For this purpose, questions would be designed to capture clinically relevant information associated with the drug or licensed biological product and the SADR. This information would include, but would not be limited to, baseline data, patient history, physical exam, diagnostic results, and supportive lab results.

III.A.7. Spontaneous Report

Under proposed §§ 310.305(a), 314.80(a), and 600.80(a), FDA would amend its postmarketing safety reporting regulations to define the term ''spontaneous report'' to mean:

> A communication from an individual (*e.g.*, health care professional, consumer) to a company or regulatory authority that describes an SADR or medication error. It does not include cases identified from information solicited by the manufacturer or contractor (applicant or contractor for proposed § 314.80(a); applicant, shared manufacturer, or contractor for proposed § 600.80(a)), such as individual case safety reports or findings derived from a study, company-sponsored patient support program, disease management program, patient registry, including pregnancy registries, or any organized data collection scheme. It also does not include information compiled in support of class action lawsuits.

The agency would define this term to clarify which reports would be considered ''spontaneous.'' Over the years, changes in marketing practices in the United States have led to expanded contacts between consumers and manufacturers, applicants, contractors, and shared manufacturers. This has resulted in the acquisition of new types of solicited safety information. Under the proposed rule, only unsolicited safety information from an individual, such as a health care professional or consumer, to a company or regulatory authority would be considered a ''spontaneous report.''

Cases identified from information solicited by companies, such as individual case safety reports or findings obtained from a study, company-sponsored patient support program, disease management program, patient registry, including pregnancy registries, or any organized data collection scheme would not be considered spontaneous. Instead, safety information from these sources would be considered ''study'' information and would be handled according to the postmarketing safety reporting requirements for a ''study.'' As proposed, study information would be subject to reporting as discussed below:

- Expedited reports for serious and unexpected SADRs from a study (see section III.D.1 of this document),
- Expedited reports for information from a study that would be sufficient to consider product administration changes (see section III.D.2 of this document),
- Expedited reports for an unexpected SADR with unknown outcome from a study (see section III.D.3 of this document),
- Always expedited reports from a study (see section III.D.4 of this document),
- Medication error reports from a study (see section III.D.5 of this document),
- Summary tabulations of all serious SADRs from studies or individual patient INDs in PSURs (see section III.E.2.f.ii of this document), and
- Discussion of important safety information from studies in PSURs and IPSRs (see sections III.E.2.g and III.E.3 of this document).

The proposed rule would consider SADR information compiled in support of class action lawsuits to be neither spontaneous nor ''study'' information. FDA believes that the vast majority of SADR information from class action lawsuits is duplicative (*i.e.*, the same SADR information is reported by multiple individuals). In many cases, information in addition to the minimum data set is not available for these SADR reports and followup is unlikely to result in acquisition of new information. For these reasons, the agency is proposing to require in TPSRs, PSURs and IPSRs summary information for SADRs from class action lawsuits (see sections III.E.1.e, III.E.2.k.v, and III.E.3 of this document).

Any safety information obtained from an individual (*e.g.*, health care professional, consumer) who has initiated contact with a company or regulatory authority would be considered spontaneous. For example, if an individual calls a company and asks if a particular SADR has been observed with one of the company's drug or licensed biological products because the individual or someone the individual knows has experienced such an SADR, the call would be considered spontaneous. The agency would consider these calls spontaneous because the individual making the call has a belief or suspicion that the drug or licensed biological product may have caused the SADR.

The proposed definition for spontaneous report is consistent with the definition of ''spontaneous report or spontaneous notification'' in the ICH E2C guidance (62 FR 27475)):

> An unsolicited communication to a company, regulatory authority, or other organization that describes an adverse reaction in a patient given one or more medicinal products and which does not derive from a study or any organized data collection scheme.

III.A.8. Medication Error

Proposed §§ 310.305(a), 314.80(a), and 600.80(a) would amend FDA's postmarketing safety reporting regulations to define the terms ''medication error,'' ''actual medication error,'' and ''potential medication error.'' A ''medication error'' would be defined as:

> Any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: Prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

An ''actual medication error'' would be defined as:

A medication error that involves an identifiable patient whether the error was prevented prior to administration of the product or, if the product was administered, whether the error results in a serious SADR, nonserious SADR, or no SADR.

A ''potential medication error'' would be defined as:

An individual case safety report of information or complaint about product name, labeling, or packaging similarities that does not involve a patient.

The proposed rule would define these terms to clarify what would be considered a medication error. The proposed definition for ''medication error'' was developed by the National Coordinating Council for Medication Error Reporting and Prevention, of which FDA is a member. FDA would not consider a case in which a patient deliberately took an overdose of a drug to be a ''medication error'' because the agency does not believe that this type of situation is ''preventable.'' Instead, it would be considered a ''non-accidental overdose.''

The proposed definitions for actual and potential medication errors were developed by FDA. Actual medication errors involve an identifiable patient whether or not the product is administered and, if the product is administered, whether or not an SADR occurs. Potential medication errors do not involve a patient, but rather describe information or complaint about product name, labeling, or packaging similarities that could result in a medication error in the future.

III.A.9. Company Core Data Sheet, Company Core Safety Information (CCSI), Listed SADR, Unlisted SADR, and Unexpected SADR

Proposed §§ 314.80(a) and 600.80(a) would amend FDA's postmarketing safety reporting regulations to define the terms ''company core data sheet,'' ''company core safety information (CCSI),'' ''listed SADR,'' and ''unlisted SADR.'' The ''company core data sheet'' would be defined as:

A document prepared by the applicant containing, in addition to safety information, material relating to indications, dosing, pharmacology, and other information concerning the drug substance (biological product for proposed § 600.80(a)). The only purpose of this document is to provide the company core safety information (CCSI) for periodic safety update reports (PSURs), interim periodic safety reports (IPSRs), and certain individual case safety reports—semiannual submissions (*i.e.*, if PSURs are submitted for the product).

The ''CCSI'' would be defined as:

All relevant safety information contained in the company core data sheet that the applicant proposes to include in the approved product labeling in all countries where the applicant markets the drug substance (biological product for proposed § 600.80(a)). It is the reference information by which an SADR is determined to be ''listed'' or ''unlisted'' for PSURs, IPSRs, and certain individual case safety reports—semiannual submissions (*i.e.*, if PSURs are submitted for the product).

A ''listed SADR'' would be defined as: ''an SADR whose nature, specificity, severity, and outcome are consistent with the information in the CCSI.''

An ''unlisted SADR'' would be defined as: ''an SADR whose nature, specificity, severity, or outcome is not consistent with the information included in the CCSI.''

The proposed rule would define these terms to help applicants determine which SADRs must be reported in PSURs, IPSRs, and certain individual case safety reports—semiannual submissions (*i.e.*, if PSURs are submitted for the product) (see sections III.E.2, III.E.3, and III.E.4 of this document). For this purpose, the CCSI would be used as the reference document by which an SADR would be judged as ''listed'' or ''unlisted.''

Company core data sheets would usually be prepared by applicants for a drug substance rather than a drug product because postmarketing PSURs and IPSRs would be based on a drug substance. Under the existing regulations at § 314.3(b) (21 CFR 314.3(b)), a drug substance is defined as:

An active ingredient that is intended to furnish pharmacological activity or other direct effect in the diagnosis, cure, mitigation, treatment, or prevention of disease or to affect the structure or any function of the human body, but does not include intermediates use[d] in the synthesis of such ingredient.

Under these same regulations, a drug product is defined as:

a finished dosage form, for example, tablet, capsule, or solution, that contains a drug substance, generally, but not necessarily, in association with one or more other ingredients.

Thus, drug substances refer to active moieties of drug products.

In the United States, the company core data sheet would be used only to provide the CCSI for a drug or biological product to determine whether an SADR is listed or unlisted. Company core data sheets would not require approval from FDA, unlike the U.S. labeling for a marketed drug or licensed biological product which does require approval from FDA. Company core data sheets would not be used in the United States as the labeling for an approved drug or licensed biological product. FDA believes that preparation of a company core data sheet would not impose a new burden on most applicants because it codifies a common practice in the pharmaceutical industry (see the ICH E2C guidance, 62 FR 27470 at 27472).

Postmarketing PSURs may be submitted by applicants to multiple countries, and the drug or licensed biological product may have different approved labeling in the different countries. The CCSI for the product should not be a compilation of all the safety information contained in the various approved labelings for the product. Instead, the CCSI should contain the critical safety information for the product that would be relevant in all countries where the product is approved for marketing. In some cases, the CCSI and an approved labeling for the product would contain the same safety information (*i.e.*, all the safety information in an approved labeling for the product is relevant in all countries where the product is approved for marketing or the product is only approved for marketing in one country). In other cases, an approved labeling for a product may contain more safety information than the CCSI for the product because the labeling may contain safety information specific to the country in which the product is approved for marketing (*e.g.*, safety information regarding a specific indication for which the product is approved for marketing in one country but not other countries). In these cases, the use of the CCSI as the reference document for determining whether an SADR is listed or unlisted for the postmarketing PSURs may result in overreporting of some SADRs to FDA as ''unlisted'' when they actually are ''expected'' by the approved U.S. labeling.

This proposal would not affect the reference document used to determine expectedness (*i.e.*, unexpected or expected SADR) for SADRs reported in premarketing IND safety reports, postmarketing expedited reports, postmarketing TPSRs, and certain postmarketing individual case safety reports—semiannual submissions (*i.e.*, if TPSRs are submitted for the product) (see table 5 and sections III.B, III.D, III.E.1, and III.E.4 of this document). Under the existing regulations at §§ 310.305(b), 314.80(a), and 600.80(a), the definition of ''unexpected adverse drug experience'' designates the current approved labeling for the drug or licensed biological product as the reference document to be used to determine what would be considered

''unexpected.'' Proposed §§ 310.305(a), 314.80(a), and 600.80(a) would include in the definition of ''unexpected SADR'' the abbreviation ''U.S.'' before the word ''labeling'' to clarify that the approved U.S. labeling would be used to determine whether or not an SADR is ''unexpected.'' FDA would also amend this definition by replacing the word ''event'' with the word ''reaction'' and by clarifying that the phrase ''differ from the event because of greater severity or specificity'' refers to a ''labeled reaction.'' Under proposed §§ 310.305(a), 312.32(a), 314.80(a), and 600.80(a), the agency would also replace the word ''listed'' with the word ''included'' in the definition of ''unexpected SADR'' to minimize confusion with ''listed SADRs'' in the CCSI. FDA would also revise the sentence ''Unexpected, as used in this definition, refers to an SADR that has not been previously observed * * * rather than from the perspective of such reaction not being anticipated from the pharmacological properties of the drug product'' in this definition for clarity.

TABLE 5.—PROPOSED REFERENCE DOCUMENTS FOR SAFETY REPORTS

Marketing status	Safety report	Reference document
Premarketing	IND safety report	Investigator's brochure. If not available, risk information in general investigational plan or elsewhere in the current application.
Postmarketing	Expedited reports	U.S. labeling.
	TPSRs	U.S. labeling.
	PSURs and IPSRs	CCSI.
	Individual case safety reports—semiannual submission:	
	If TPSR is submitted for the product	U.S. labeling.
	If PSUR is submitted for the product	CCSI.

These proposed amendments are consistent with the ICH E2C guidance (62 FR 27470 at 27472):

For purposes of periodic safety reporting, CCSI forms the basis for determining whether an ADR is already Listed or is still Unlisted, terms that are introduced to distinguish them from the usual terminology of ''expectedness'' or ''labeledness'' that is used in association with official labeling. Thus, the local approved product information continues to be the reference document upon which labeledness/expectedness is based for the purpose of local expedited postmarketing safety reporting.

Under proposed §§ 310.305(a), 312.32(a), 314.80(a), and 600.80(a), FDA would include the following sentence in the definition of ''unexpected SADR:''

SADRs that are mentioned in the U.S. labeling (investigator's brochure for proposed § 312.32(a)) as occurring with a class of drugs (products for proposed § 600.80(a)) but not specifically mentioned as occurring with the particular drug (product for proposed § 600.80(a)) are considered unexpected.

This information is currently included in the draft guidance of 2001. FDA is now proposing to codify this information to clarify which SADRs would be considered ''unexpected.''

III.A.10. Data Lock Point and International Birth Date

Proposed §§ 314.80(a) and 600.80(a) would amend FDA's postmarketing safety reporting requirements to define the terms ''data lock point'' and ''international birth date.'' The ''data lock point'' would be defined as:

The date designated as the cut-off date for data to be included in a postmarketing periodic safety report.

The ''international birth date'' would be defined as:

The date the first regulatory authority in the world approved the first marketing application for a human drug product containing the drug substance (human biological product for proposed § 600.80(a)).

The agency would define these terms to help standardize the submission date (*i.e.*, month and day of submission) for postmarketing periodic safety reports (*i.e.*, PSURs, IPSRs, TPSRs, individual case safety reports—semiannual submissions). The data lock point would signify the end of a reporting period for data to be included in a specific postmarketing periodic safety report. The month and day of the international birth date would serve as a reference point for determining the data lock point. On the date of the data lock point, safety information that is available to applicants would be reviewed and evaluated prior to being submitted to FDA. Postmarketing periodic safety reports would be submitted to FDA within 60 days of the data lock point (see section III.E.5.b of this document). For example, for a drug or biological product approved by FDA on June 15 with a 6-month periodic reporting period and an international birth date of April 1, the first data lock point would be October 1, which is less than 6 months after FDA approval, but is the 6-month anniversary of the international birth date. Therefore, the first postmarketing periodic safety report would cover the period from April 1 through October 1 even though the product had only been approved in the United States on June 15. The second periodic report would cover the period from October 2 through April 1.

An international birth date would be determined and declared by applicants. Applicants would determine an international birth date for a product based on the date of approval of the first marketing application in the world for a human drug product containing the drug substance or a biological product. A single international birth date would encompass all different dosage forms, formulations, or uses (*e.g.*, indications, routes of administration, populations) of a drug substance or licensed biological product. Thus, postmarketing periodic safety reports for different drug products containing the same drug substance would be submitted to FDA at the same time.

The month and day of the international birth date would be used, as noted previously, to determine the data lock point (*i.e.*, month and day) for postmarketing periodic safety reports. It would not, except as noted below, be used to determine the frequency for submission of these reports (*i.e.*, 6-month intervals or multiples of 6 months). Instead, the date (*i.e.*, year) of U.S. approval of the application for the drug or biological product (*e.g.*, NDA, ANDA, BLA) would be used to determine the frequency for submission of postmarketing periodic safety reports to FDA (see section III.E.5.a of this document). The international birth date would be used to determine both the data lock point and reporting frequency for postmarketing periodic safety reports only when the U.S. approval date is used to determine the international birth date (*e.g.*, FDA is the first

regulatory authority in the world to approve the human drug product containing the drug substance or biological product for marketing).

The use of a standardized submission date (*i.e.*, month and day), which is consistent with the ICH E2C guidance (62 FR 27470 at 27472), would enable applicants to submit a single core report (PSUR excluding appendices) to regulatory authorities worldwide. Currently, different regulatory authorities require submission of postmarketing periodic safety reports on varying time schedules. The submission of a single core report to multiple regulatory authorities would significantly reduce the time spent preparing these reports, thereby permitting more time for the evaluation of the medical significance of any safety information reported.

III.B. IND Safety Reports

III.B.1. Review of Safety Information

Current IND safety reporting regulations in § 312.32(b) require that sponsors promptly review all information relevant to the safety of the drug under investigation obtained or otherwise received by the sponsor from any source, foreign or domestic. Sources of information include any clinical or epidemiological investigations, animal investigations, commercial marketing experience, reports in the scientific literature, and unpublished scientific papers, and reports from foreign regulatory authorities that have not already been previously reported to FDA by the sponsor. FDA is proposing to amend this requirement by adding ''in vitro studies'' to the list of examples because some in vitro studies report relevant safety-related information (*e.g.*, carcinogenicity studies performed in cell lines). FDA is also proposing to move the phrase ''commercial marketing experience'' to the end of the list and to revise it to read ''and reports of foreign commercial marketing experience for drugs that are not marketed in the United States'' to clarify that sponsors are not required to review safety information from commercial marketing experience for drugs that are marketed in the United States and are being further studied under an IND. Safety reports from commercial marketing experience for these drugs would be reviewed for safety information as prescribed by FDA's postmarketing safety reporting regulations (see section III.C.2 of this document). This proposed revision is consistent with existing regulations at § 312.32(c)(4) and proposed amendments to § 312.32(c)(4) described below (see section III.B.4 of this document). The proposed amendments would further clarify some of the types of safety information that must be examined to determine whether the information must be submitted in an IND safety report.

III.B.2. Written IND Safety Reports

Current IND safety reporting regulations at § 312.32(c)(1)(i) require sponsors to notify FDA and all participating investigators in a written IND safety report of any adverse experience associated with the use of the drug that is both serious and unexpected or any finding from tests in laboratory animals that suggests a significant risk for human subjects, including reports of mutagenicity, teratogenicity, or carcinogenicity. These written IND safety reports must be made as soon as possible and in no event later than 15 calendar days after the sponsor's initial receipt of the information. For clarity, FDA is proposing to amend § 312.32(c)(1) by reorganizing and renumbering this paragraph.

III.B.2.a. *Minimum data set.* FDA is proposing to amend § 312.32(c) to state that sponsors must not submit an IND safety report for an SADR to the agency if the report does not contain a minimum data set (*i.e.*, identifiable patient, identifiable reporter, suspect drug or biological product, and SADR). If a minimum data set is not available, a sponsor would be required to maintain records of any information received or otherwise obtained for the SADR along with a record of its efforts to obtain a minimum data set for the IND safety report. This proposed amendment would clarify for sponsors that, at a minimum, certain information must be submitted to FDA for each IND safety report of an SADR to allow an initial evaluation of the significance of the SADR. This proposed revision is consistent with the ICH E2A guidance (60 FR 11284 at 11287):

> The minimum information required for expedited reporting purposes is: an identifiable patient; the name of a suspect medicinal product; an identifiable reporting source; and an event or outcome * * *.

III.B.2.b. *Serious and unexpected SADRs.* FDA is also proposing to amend § 312.32(c)(1)(i) by replacing the phrase ''any adverse experience associated with the use of the drug that is both serious and unexpected'' with the phrase ''any SADR that, based on the opinion of the investigator or sponsor, is both serious and unexpected, as soon as possible, but in no case later than 15 calendar days after receipt by the sponsor of the minimum data set for the serious, unexpected SADR.'' This proposed amendment would require that the determination of the possibility of causality (attributability) of an SADR to an investigational drug be based on the opinion of either the investigator or sponsor, which is consistent with the ICH E2A guidance (60 FR 11284 at 11286):

> Causality assessment is required for clinical investigation cases. All cases judged by either the reporting health care professional or the sponsor as having a reasonable suspected causal relationship to the medicinal product qualify as ADR's.

In situations in which a sponsor does not believe that there is a reasonable possibility that an investigational drug caused a response, but an investigator believes that such a possibility exists, the proposed rule would require that the sponsor submit a written IND safety report to FDA for the SADR. In the opposite situation, the same would also be true.

The proposed rule would also require that written IND safety reports be submitted to FDA no later than 15 calendar days after receipt by the sponsor of the minimum data set for the serious, unexpected SADR. This proposed revision would clarify when the 15 calendar day timeframe would begin. FDA expects sponsors to use due diligence to acquire immediately the minimum data set for a report and to determine the outcome (whether the SADR is serious or nonserious) and expectedness of an SADR upon initial receipt of the SADR. Sponsors should include in any written IND safety reports subsequently filed with FDA a chronological history of their efforts to acquire this information if there is a delay in obtaining the information (it is not necessary to include the chronological history in IND safety reports sent to investigators). This proposed amendment is consistent with the ICH E2A guidance (60 FR 11284 at 11286):

> Information for final description and evaluation of a case report may not be available within the required timeframes for reporting * * *. Nevertheless, for regulatory purposes, initial reports should be submitted within the prescribed time as long as the following minimum criteria are met: An identifiable patient; a suspect medicinal product; an identifiable reporting source; and an event or outcome that can be identified as serious and unexpected, and for which, in clinical investigation cases, there is a reasonable suspected causal relationship. * * *

FDA is also proposing to amend § 312.32(c)(1)(i) by removing the following sentence: ''Each notification shall be made as soon as possible and

in no event later than 15 calendar days after the sponsor's initial receipt of the information.'' The agency is proposing this revision because the information in this sentence is redundant with a provision of proposed § 312.32(c)(1)(i).

III.B.2.c. *Information sufficient to consider product administration changes.* Under proposed § 312.32(c)(1)(ii), FDA would amend § 312.32(c)(1)(i) by replacing the phrase ''Any finding from tests in laboratory animals that suggests a significant risk for human subjects including reports of mutagenicity, teratogenicity, or carcinogenicity'' with the sentence:

> The sponsor must also notify FDA and all participating investigators in a written IND safety report of information that, based upon appropriate medical judgment, might materially influence the benefit-risk assessment of an investigational drug or that would be sufficient to consider changes in either product administration or in the overall conduct of a clinical investigation. The sponsor must submit this information to FDA and all participating investigators as soon as possible, but in no case later than 15 calendar days after determination by the sponsor that the information qualifies for reporting under this paragraph. Examples of such information include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an IND, that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity or reports of a lack of efficacy with a drug product used in treating a life-threatening or serious disease.

This proposed amendment is consistent with the ICH E2A guidance (60 FR 11284 at 11286):

> There are situations in addition to single case reports of ''serious'' adverse events or reactions that may necessitate rapid communication to regulatory authorities; appropriate medical and scientific judgment should be applied for each situation. In general, information that might materially influence the benefit-risk assessment of a medicinal product or that would be sufficient to consider changes in medicinal product administration or in the overall conduct of a clinical investigation represents such situations. Examples include:
>
> a. For an ''expected, serious ADR, ['']an increase in the rate of occurrence which is judged to be clinically important.
>
> b. A significant hazard to the patient population, such as lack of efficacy with a medical product used in treating life-threatening disease.
>
> c. A major safety finding from a newly completed animal study (such as carcinogenicity).

In contrast to the ICH recommendations, the proposed rule would not require reports of an increase in the rate of occurrence of expected, serious SADRs to be submitted to the agency in an expedited manner. However, sponsors should report this information to FDA in their IND annual reports under § 312.33(b)(1). Proposed § 312.32(c)(1)(ii) would be consistent with the increased frequency reports final rule that revoked the postmarketing safety reporting requirement for submission of increased frequency reports in an expedited manner. Although the increased frequency reports final rule pertains to postmarketing expedited safety reporting, FDA has decided to apply this rule to its requirements for premarketing expedited safety reports because of the limited reliability of increased frequency reports. See the increased frequency reports final rule (62 FR 34166) for a discussion of the limited reliability of increased frequency reports. With regard to premarketing clinical trials in progress, FDA does not believe that baseline incidence rates would be available for serious expected SADRs which would make it difficult for sponsors to predict an increase in the rate of occurrence of these SADRs.

III.B.2.d. *Reporting format.* Current IND safety reporting regulations at § 312.32(c)(1)(i) require sponsors to submit written IND safety reports from animal or epidemiological studies in a narrative format. Proposed § 312.32(c)(1)(iii) would amend these regulations by replacing the phrase ''reports from animal or epidemiological studies'' with the phrase ''reports of overall findings or data in the aggregate from published and unpublished in vitro, animal, epidemiological, or clinical studies.'' The proposed rule would require sponsors to submit reports of overall findings or data in the aggregate in a narrative format rather than on FDA Form 3500A because the form is designed for reporting safety information for an individual case.

III.B.3. Telephone Safety Reports

Current IND safety reporting regulations at § 312.32(c)(2) require sponsors to notify FDA by telephone or by facsimile transmission of any unexpected fatal or life-threatening experience associated with the use of an investigational drug as soon as possible but in no event later than 7 calendar days after the sponsor's initial receipt of the information. FDA is proposing to amend this requirement to read:

> The sponsor must also notify FDA by telephone or by facsimile transmission of any unexpected fatal or life-threatening SADR based on the opinion of the investigator or sponsor as soon as possible but in no case later than 7 calendar days after receipt by the sponsor of the minimum data set for the unexpected fatal or life-threatening SADR.

These proposed revisions are consistent, as described previously, with the proposed amendments to § 312.32(c)(1)(i) for written IND safety reports and the ICH E2A guidance (60 FR 11284 at 11286).

III.B.4. IND Safety Reporting for Drugs Marketed in the United States

Current IND safety reporting regulations at § 312.32(c)(4) state that a sponsor of a clinical study of a marketed drug is not required to make a safety report for any adverse experience associated with the use of the drug that is not from the clinical study itself. FDA is proposing to amend this regulation by making the following revisions:

> A sponsor of a clinical study under an IND for a drug marketed in the United States is only required to submit IND safety reports to FDA (review division that has responsibility for the IND) for SADRs from the clinical study itself, whether from domestic or foreign study sites of the IND. The sponsor must also submit to FDA safety information from these clinical studies as prescribed by the postmarketing safety reporting requirements under §§ 310.305, 314.80, and 600.80 of this chapter.

FDA is proposing this change to clarify, for sponsors investigating under an IND drugs and biological products that are already marketed in the United States, what SADRs must be reported in IND safety reports under § 312.32. The agency notes that sponsors investigating under an IND drug and biological products that are not marketed in the United States are required, under § 312.32, to report to FDA safety information obtained or otherwise received for the product from any source, domestic or foreign, including safety information from foreign commercial marketing experience (see section III.B.1 of this document). Proposed § 312.32(c)(4) also clarifies that sponsors investigating under an IND drugs and biological products that are already marketed in the United States must submit safety information for these clinical studies as prescribed by the postmarketing safety reporting requirements in §§ 310.305, 314.80, and 600.80.

III.B.5. Investigator Reporting

Current investigator safety reporting regulations at § 312.64(b) state that the investigator shall promptly report to the sponsor any adverse effect that may reasonably be regarded as caused by, or probably caused by, the drug. If the adverse effect is alarming, the investigator shall report the adverse

effect immediately. FDA is proposing to revise this requirement as follows:

> An investigator must report to the sponsor any serious SADR (as defined in § 312.32(a)) immediately and any other SADR (as defined in § 312.32(a)) promptly unless the protocol or investigator's brochure specifies a different timetable for reporting the SADR.

FDA is proposing this revision to be consistent with the proposed definition for SADR and to clarify what information investigators must submit to sponsors expeditiously.

III.C. Postmarketing Safety Reporting

III.C.1. Prescription Drugs Marketed for Human Use Without an Approved Application

Current regulations (§ 310.305) require manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved NDA or ANDA to establish and maintain records of and report to FDA all serious, unexpected adverse drug experiences associated with the use of their drug products. The proposed rule would amend these regulations by revising the language in this section to be consistent with the language for the postmarketing expedited safety reporting requirements under § 314.80. FDA is also proposing to reorganize and renumber § 310.305 to be consistent with § 314.80. FDA is proposing these revisions to harmonize, to the extent possible, the postmarketing expedited safety reporting requirements for human marketed drugs with approved applications (*i.e.*, NDAs, ANDAs) and prescription drugs marketed for human use without an approved application.

III.C.2. Review of Safety Information

Current postmarketing safety reporting regulations under §§ 314.80(b) and 600.80(b) require applicants to promptly review all safety information obtained or otherwise received from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiological/surveillance studies, reports in the scientific literature, and unpublished scientific papers. FDA is proposing to amend these regulations by adding ''animal and in vitro studies,'' ''electronic communications with applicants via the Internet (*e.g.*, e-mail),'' and ''reports from foreign regulatory authorities that have not been previously reported to FDA by the applicant'' to the list of examples. FDA is proposing to add animal and in vitro studies to the list of examples because many of these studies report relevant safety-related information (*e.g.*, carcinogenicity, mutagenicity, teratogenicity).

FDA is proposing to add electronic communications with applicants via the Internet (*e.g.*, e-mail) to the list of examples to clarify for applicants what safety information on the Internet would be required to be reviewed. An applicant would be required to review information received on an Internet site(s) that it sponsors, but would not be required to review Internet sites that it does not sponsor. However, if an applicant becomes aware of safety information on an Internet site that it does not sponsor, the applicant would be responsible for reviewing the information.

FDA would not expect applicants to review safety data bases generated by foreign regulatory authorities. However, proposed §§ 314.80(b)(1) and 600.80(b)(1) would require that any safety information acquired or received from a foreign regulatory authority be reviewed to determine whether the information must be reported to FDA. The agency is proposing these amendments to further clarify some of the types of safety information that must be examined to determine whether the information must be submitted in postmarketing safety reports.

Proposed § 310.305(b)(1) would amend FDA's postmarketing safety reporting regulations for prescription drugs marketed for human use without an approved application by adding the following sentence:

> Each manufacturer of a prescription drug product marketed for human use without an approved application must promptly review all safety information pertaining to its product obtained or otherwise received by the manufacturer from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiology/surveillance studies, animal or in vitro studies, electronic communications with manufacturers via the Internet (*e.g.*, e-mail), reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not been previously reported to FDA by the manufacturer.

This proposed amendment would further clarify some of the types of safety information that must be examined to determine whether the information must be submitted in postmarketing expedited safety reports (see section III.D of this document). This proposed revision would provide uniformity between FDA's safety reporting requirements for human marketed drugs with approved applications (*i.e.*, NDAs, ANDAs) and prescription drugs marketed for human use without an approved application (*i.e.*, without an approved NDA or ANDA).

Current postmarketing safety reporting regulations in §§ 314.80(b) and 600.80(b) state that applicants are not required to resubmit to FDA safety reports forwarded to the applicant by FDA; however, applicants must submit all followup information on such reports. Proposed §§ 314.80(b)(2) and 600.80(b)(2) would amend these regulations to state that individual case safety reports forwarded to the applicant by FDA must not be resubmitted to the agency by applicants. FDA is proposing this revision to prevent duplicate reports from being entered into the agency's safety reporting database. Applicants that inadvertently resubmit such reports to FDA will be informed not to do so in the future.

Proposed §§ 314.80(b)(2) and 600.80(b)(2) would also amend these regulations to require that applicants include information from individual case safety reports forwarded to the applicant by FDA in any comprehensive safety analysis subsequently submitted to the agency. This proposed amendment, which was discussed in the preamble but inadvertently omitted from the codified section of the October 1994 proposal (59 FR 54046 at 54053), would clarify how safety information received from FDA must be handled.

Current postmarketing safety reporting regulations at §§ 314.80(b) and 600.80(b) state that applicants must develop written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing adverse drug experiences to FDA. FDA is proposing to amend this provision by adding the phrase ''and maintain'' after the phrase ''must develop.'' This proposed amendment would clarify that applicants must maintain records of the written procedures for review by FDA. FDA would review the written procedures either upon request by the agency (proposed §§ 314.80(f) and 600.80(f)) or during inspections by the agency. FDA is also proposing to replace the phrase ''adverse drug experiences'' with the phrase ''postmarketing safety information.'' For organizational purposes, FDA is proposing to move the written procedures provision to proposed §§ 314.80(g) and 600.80(g). FDA is proposing the same type of amendments to § 310.305.

Current § 314.80(b) applies to applicants having an approved application under § 314.50 or, in the case of a 505(b)(2) application, an effective approved application. FDA is proposing to amend this provision by replacing the phrase ''under § 314.50 or,

in the case of a 505(b)(2) application, an effective approved application'' with the phrase ''under section 505(c) of the act.'' Although NDAs, including those referred to in section 505(b)(2) of the Federal Food, Drug and Cosmetic Act (the act) (21 U.S.C. 355(b)(2)) are filed under section 505(b)(1) of the act, they are approved under section 505(c) of the act. FDA is proposing to use the phrase ''section 505(c) of the act'' because it more appropriately references the cite for approval of NDAs.

The agency is proposing to remove the phrase ''in the case of a 505(b)(2) application, an effective approved application'' because FDA no longer issues approvals with a delayed effective date for 505(b)(2) applications, as it did at the time this regulation was issued. The agency now issues tentative approvals for 505(b)(2) applications when the (final) approval is blocked by patent or exclusivity rights. As described in the preamble to the final rule on ''Abbreviated New Drug Application Regulations; Patent and Exclusivity Provisions'' (59 FR 50338 at 50351 to 50352, October 3, 1994), a 505(b)(2) application that has a tentative approval is not approved for marketing until a final approval letter for the drug product is received from FDA. Thus, applicants having a 505(b)(2) application with a tentative approval would not be subject to the postmarketing safety reporting requirements under § 314.80 until final approval of the application is in effect. For consistency, FDA is proposing a similar change to § 314.98(a).

III.C.3. Reporting Requirements

Current postmarketing safety reporting requirements at §§ 310.305(c), 314.80(c), and 600.80(c) state that persons subject to these requirements shall report to FDA adverse drug experience information as described under these sections. FDA is proposing to remove these provisions from its postmarketing safety reporting regulations because they are redundant (see proposed §§ 310.305(c), 314.80(c), and 600.80(c)).

Current postmarketing safety reporting requirements at §§ 314.80(c) and 600.80(c) state that two copies of each report must be submitted to FDA. For drug products, proposed § 314.80(c) would require that applicants submit to FDA two copies of each postmarketing expedited report and one copy of each postmarketing periodic safety report of an individual case safety reports—semiannual submission pertaining to its product (see tables 6 and 7 for proposed postmarketing expedited and periodic safety reports). For nonvaccine biological products, proposed § 600.80(c) would require that applicants submit to FDA two copies of each postmarketing expedited report and each postmarketing periodic safety report of an individual case safety reports—semiannual submission pertaining to its product. For drugs and nonvaccine biologics, proposed §§ 314.80(c) and 600.80(c) would also require that one copy of a PSUR, IPSR, or TPSR be submitted to FDA along with one copy for each approved application for a human drug or licensed biological product (*e.g.*, NDA, ANDA, BLA) covered by the report (see table 7 for proposed postmarketing periodic safety reports). For vaccines, proposed § 600.80(c) would require that applicants submit to VAERS two copies of each safety report required under § 600.80 and pertaining to its product. These proposed amendments would provide FDA with enough copies of safety reports for efficient review by the agency. Electronic submission of these reports will obviate the need for submission of two copies. At this time, manufacturers and applicants can voluntarily submit certain postmarketing safety reports in an electronic format (see Docket 92S–0251 regarding postmarketing expedited and periodic individual case safety reports; available on the Internet at *http://www.fda.gov/ohrms/dockets/dockets/92s0251/92s0251.htm).* Capabilities for electronic submission of other postmarketing safety reports (*e.g.*, safety reports for vaccines) will be available in the future.

TABLE 6.—PROPOSED POSTMARKETING EXPEDITED SAFETY REPORTS

Expedited Safety Report	Type of Information	Submission to FDA—Timeframe	Persons with Reporting Responsibility	Reference in Section III of this Document
Serious & unexpected SADRs.	Individual case safety reports.	15 calendar days.	Manufacturers and applicants.	D.1
Information sufficient to consider product administration changes.	Information based upon appropriate medical judgment. For example, any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study that suggests a significant human risk.	15 calendar days.	Manufacturers and applicants.	D.2
Unexpected SADRs with unknown outcome.	Individual case safety reports of unexpected SADRs for which a determination of serious or nonserious cannot be made..	45 calendar days.	Manufacturers and applicants.	D.3
Always expedited reports.	Individual case safety reports of certain medically significant SADRs whether unexpected or expected and whether or not the SADR leads to a serious outcome.	15 calendar days.	Manufacturers and applicants.	D.4
Medication errors	All domestic reports of medication errors, whether actual or potential..	15 calendar and days.	Manufacturers and applicants.	D.5
30-day followup	Followup report for initial serious and unexpected SADR reports, always expedited reports and medication error reports that do not contain a full data set.	30 calendar days.	Manufacturers and applicants.	D.6
15-day followup	New information for expedited or followup reports, except initial expedited reports for which 30-day followup reports must be submitted.	15 calendar days.	Manufacturers and applicants.	D.6
SADR reports to manufacturer.	All SADRs	5 calendar days to manufacturer.	Contractors	D.9
SADR reports to applicant.	All SADRs	5 calendar days to applicant.	Contractors and shared manufacturers.	D.9

TABLE 6.—PROPOSED POSTMARKETING EXPEDITED SAFETY REPORTS—Continued

Expedited Safety Report	Type of Information	Submission to FDA—Timeframe	Persons with Reporting Responsibility	Reference in Section III of this Document
Blood safety—oral or written.	Fatalities	As soon as possible.	Blood establishments.	D.12
Blood safety—written.	Fatalities	7 calendar days		
	All serious SARs except fatalities	45 calendar days.		

TABLE 7.—PROPOSED POSTMARKETING PERIODIC SAFETY REPORTS

Periodic safety report	Type of information	Submission to FDA—timeframe	Persons with reporting responsibility	Reference in section III of this document
Individual case safety reports—semiannual submission.	• Serious, expected SADRs (domestic and foreign) and nonserious, unexpected SADRs (domestic) if TPSR is submitted for the product.[1]. • Serious, listed SADRs (domestic and foreign) and nonserious, unlisted SADRs (domestic) if PSUR is submitted for the product.[2]	Every 6 months after U.S. approval of application.[3].	Applicants	E.4
TPSR—for applications approved before January 1, 1998.[4].	• Narrative summary and analysis of individual case safety reports • Increased frequency reports • Safety-related actions to be taken • Summary tabulations of individual case safety reports • History of safety-related actions taken • Location of safety records • Contact person information	At 5, 7.5, 10, 12.5, and 15 years after U.S. approval of application and then every 5 years thereafter.[3].	Applicants	E.1
PSUR—for applications approved on or after January 1, 1998.	Core Document • Introduction • Worldwide marketing status • Actions taken for safety reasons • Changes to CCSI • Worldwide patient exposure • Summary tabulations • Safety studies • Other information • Overall safety evaluation • Conclusion Appendices • Company core data sheet • U.S. labeling • Spontaneous reports from individuals other than health care professionals • SADRs with unknown outcome • SADRs from class action lawsuits • Lack of efficacy reports • Information on resistance to antimicrobial drug products • Medication errors • U.S. patient exposure • Location of safety records • Contact person	Every 6 months after U.S. approval of application for 2 years, annually for the next 3 years, and then every 5 years thereafter.[3].	Applicants	E.2
IPSR—for applications approved on or after January 1, 1998.	An ''abbreviated PSUR;'' same information as PSUR excluding summary tabulations.	At 7.5 and 12.5 years after U.S. approval of application.[3].	Applicants	E.3

[1] Nonserious, expected SARs (domestic) and expected SARs with unknown outcome (domestic) would also be submitted for vaccines.
[2] Nonserious, listed SARs (domestic) and listed SARs with unknown outcome (domestic) would also be submitted for vaccines.
[3] The data lock point for the report would be the month and day of the international birth date or any other month and day agreed on by the applicant and FDA. The submission date for the report would be within 60 calendar days of the data lock point.
[4] A PSUR may be submitted in lieu of a TPSR if an applicant so desires.

Current §§ 310.305(c), 314.80(c), 314.98(b), and 600.80(c) provide mailing addresses for the submission of postmarketing safety reports. FDA is proposing to remove the mailing addresses from §§ 310.305(c), 314.80(c), 314.98(b), and 600.80(c) because this information is provided in the draft guidance of 2001.

III.C.4. Request for Alternative Reporting Frequency

FDA is proposing to amend its postmarketing safety reporting regulations at §§ 310.305(c), 314.80(c), and 600.80(c) to state that, upon written notice, the agency may require, when appropriate, that manufacturers and applicants submit postmarketing safety reports (*i.e.*, expedited, followup, or periodic safety reports) to FDA at times other than prescribed by the regulations (see tables 8 and 9 regarding proposed reporting frequencies for postmarketing safety reports). In most cases, FDA would not request alternative reporting periods for these safety reports. In some cases, however, FDA may need to receive reports more frequently (*e.g.*, marketed product approved for a new indication, dosage form, or population) or less frequently (*e.g.*, product on the market for over 30 years with no new safety concerns identified).

TABLE 8.—PROPOSED REPORTING FREQUENCY FOR POSTMARKETING EXPEDITED SAFETY REPORTS

Submit as soon as possible	Submit within 5 calendar days	Submit within 7 calendar days	Submit within 15 calendar days	Submit within 30 calendar days	Submit within 45 calendar days
• Blood safety report— telephone (fatality) (D.12).[1]	• Individual case safety reports from contractors to manufacturer (D.9). • Individual case safety reports from contractors and shared manufacturers to applicant (D.9).	• Blood safety report—written (fatality) (D.12).	• Serious and unexpected SADR report (D.1). • Information sufficient to consider product administration changes (D.2). • Always expedited report (D.4). • Medication error report (D.5). • 15-day followup report (D.6).	• 30-day followup report (D.6).	• Unexpected SADR with unknown outcome (D.3). • Blood safety report—written (all serious SARs except fatalities) (D.12).

[1] References in parentheses refer to location in section III of this document.

TABLE 9.—PROPOSED REPORTING FREQUENCY FOR POSTMARKETING PERIODIC SAFETY REPORTS

Persons with reporting responsibility	Submit every 6 months	Submit at 0.5, 1, 1.5, 2, 3, 4, and 5 years	Submit at 7.5 and 12.5 years	Submit at 10 years and every 5 years thereafter
Applicants with NDAs[1] or BLAs approved on or after 1/1/98 and applicants with approved pediatric use supplements.	Individual case safety reports—semiannual submission (E.4)[2].	PSUR (E.2)	IPSR (E.3)	PSUR.
Applicants with NDAs or BLAs approved before 1/1/98.	Individual case safety reports—semiannual submission.	NA	TPSR (E.1) or IPSR.	TPSR or PSUR.

[1] Applicants with approved ANDAs would determine the type of postmarketing periodic safety report required to be submitted to FDA (*i.e.*, TPSR, PSUR, IPSR) and the frequency of submission for these reports based on the U.S. approval date of the application for the innovator NDA product (see section III.I of this document).
[2] References in parentheses refer to section III of this document.

FDA is also proposing to amend its postmarketing safety reporting regulations at §§ 314.80(c) and 600.80(c) to state that applicants who wish to submit postmarketing safety reports at times other than prescribed by these regulations may request a waiver for this purpose under §§ 314.90 or 600.90. This proposed revision does not represent a new provision, but rather provides a cross-reference to the existing waiver requirements under §§ 314.90 and 600.90.

FDA is also proposing to amend its postmarketing periodic safety reporting regulations at §§ 314.80(c)(2)(i) and 600.80(c)(2)(i) by removing the third and fourth sentences in these paragraphs. These sentences state that, upon written notice, FDA may request submission of periodic safety reports at different times than stated under §§ 314.80(c)(2)(i) and 600.80(c)(2)(i) (*e.g.*, following the approval of a major supplement). FDA is proposing to remove these sentences because this information would now be stated under proposed §§ 314.80(c) and 600.80(c). This proposed revision represents an organizational change that clarifies that FDA may request a different time period for submission of not only postmarketing periodic safety reports, but also postmarketing expedited safety reports.

III.C.5. Determination of Outcome, Minimum Data Set, and Full Data Set

Proposed §§ 310.305(c)(1)(i)(A), 314.80(c)(1)(i)(A), and 600.80(c)(1)(i)(A) would amend FDA's postmarketing safety reporting regulations to require that manufacturers and applicants immediately, upon initial receipt of an SADR report, determine the outcome for the SADR (whether the SADR is serious or nonserious) and at least the minimum data set for the individual case safety report (*i.e.,* identifiable patient, identifiable reporter, suspect drug or biological product, and SADR). If the manufacturer or applicant is not able to immediately determine this information, active query would be required to be used by the manufacturer or applicant to obtain the information as soon as possible. FDA is proposing this change to clarify that timely acquisition of information is critical to determine whether an SADR must be submitted to FDA and, for those reactions that would be reported, whether the SADR would be submitted in a postmarketing expedited safety report or a postmarketing periodic safety report.

Proposed §§ 310.305(c)(1)(i)(A), 314.80(c)(1)(i)(A), and 600.80(c)(1)(i)(A) would also require manufacturers and applicants to immediately determine the

minimum information for actual medication errors that do not result in an SADR and potential medication errors (minimum information described below and at proposed §§ 310.305(c)(1)(iii)(B) and (c)(1)(iii)(C), 314.80(c)(1)(iii)(B) and (c)(1)(iii)(C), and 600.80(c)(1)(iii)(B) and (c)(1)(iii)(C)). If the manufacturer or applicant is not able to immediately determine this information, active query would be required to be used by the manufacturer or applicant to obtain the information as soon as possible.

Proposed §§ 310.305(c)(1)(ii), 314.80(c)(1)(ii), and 600.80(c)(1)(ii) would require manufacturers and applicants who are unable to immediately determine the outcome of an SADR (whether the SADR is serious or nonserious) to continue to use active query to attempt to determine the outcome within 30 calendar days after initial receipt of the SADR report by the manufacturer or applicant. The proposed rule would require that manufacturers and applicants maintain records of their efforts to obtain this information. These proposed revisions clarify that due diligence must be used to obtain the outcome for SADRs. Unknown outcomes should not be classified arbitrarily as nonserious SADRs. Instead, each of the outcomes in the definition of serious SADR should be considered as a possibility.

Under proposed §§ 310.305(c)(1)(iii)(A), 314.80(c)(1)(iii)(A), and 600.80(c)(1)(iii)(A), individual case safety reports for SADRs that do not contain a minimum data set would not be submitted to the agency. Instead, the proposed rule would require that manufacturers and applicants maintain records of any information received or otherwise obtained for the SADR along with a record of their efforts to obtain a minimum data set for the individual case safety report. These proposed amendments are consistent with proposed revisions to the premarketing safety reporting regulations at proposed § 312.32(c) (see section III.B.2.a of this document). This change would clarify that, at a minimum, certain information must be submitted to FDA to provide the agency with enough information to allow an initial evaluation of the significance of an SADR.

Proposed §§ 310.305(c)(1)(iii)(B), 314.80(c)(1)(iii)(B), and 600.80(c)(1)(iii)(B) would require that reports of actual medication errors that do not result in an SADR be submitted to FDA even though the report does not contain a minimum data set (*i.e.,* does not have an SADR). In these cases, individual case safety reports would be required to contain at least an identifiable patient, an identifiable reporter, and a suspect drug or biological product.

Proposed §§ 310.305(c)(1)(iii)(C), 314.80(c)(1)(iii)(C), and 600.80(c)(1)(iii)(C) would require that reports of potential medication errors be submitted to FDA even though the report does not contain a minimum data set (*i.e.,* does not have an identifiable patient or an SADR). In these cases, individual case safety reports would be required to contain at least an identifiable reporter and a suspect drug or biological product.

FDA is requiring submission of individual case safety reports for actual medication errors that do not result in an SADR and potential medication errors because of their potential significance and the need for intervention to minimize future errors. For example, if an adult is given the wrong medication, no SADR may occur, but if the same error occurs with a child, an SADR may occur. Also, if an error is prevented prior to administration of a product, this information could be used to prevent the error from occurring in other situations. For example, the proprietary name, label, labeling or packaging of the product could be changed if sufficient evidence suggests such a change is warranted, or education announcements could be communicated to health care professionals and/or consumers.

Proposed §§ 310.305(c)(1)(iv), 314.80(c)(1)(iv), and 600.80(c)(1)(iv) state that, for reports of serious SADRs, always expedited reports, and medication error reports, manufacturers and applicants would be required to submit a full data set for the report (see section III.D.4 of this document for discussion of always expedited reports and section III.D.5 of this document for discussion of medication error reports). If a full data set is not available for the report, the manufacturer or applicant would be required to use active query to obtain this information. If a full data set is not available, after active query, the manufacturer or applicant would provide the following information:

- All safety information, received or otherwise obtained, for the report;
- The reason(s) for their inability to acquire a full data set; and
- Documentation of their efforts to obtain a full data set (*i.e.*, description of unsuccessful steps taken to obtain this information).

In some cases, the agency has received incomplete safety reports for serious SADRs, making interpretation of their significance difficult. This proposed amendment would require submission of complete information for reports of serious SADRs, always expedited reports, and medication error reports, which would facilitate their expeditious review.

Proposed §§ 310.305(c)(1)(v), 314.80(c)(1)(v), and 600.80(c)(1)(v) state that:

> For a serious SADR that was not initially reported to the manufacturer (applicant for proposed §§ 314.80(c)(1)(v) and 600.80(c)(1)(v)) by a health care professional (*e.g.*, report from a consumer), the manufacturer (applicant for proposed §§ 314.80(c)(1)(v) and 600.80(c)(1)(v)) must contact the health care professional associated with the care of the patient using active query to gather further medical perspective on the case and to acquire a full data set for the report. If the manufacturer (applicant for proposed §§ 314.80(c)(1)(v) and 600.80(c)(1)(v)) is unable to contact the health care professional, it must include in the report for the serious SADR: (A) The reason(s) for its inability to contact the health care professional and (B) a description of its efforts to contact the health care professional.

The agency believes that contact with a health care professional is warranted for serious SADRs because of the critical nature of these reactions. However, in those situations in which a manufacturer or applicant is unable to contact the health care professional (*e.g.*, health care professional does not return phone calls, consumer does not permit manufacturer or applicant to contact its health care provider), it would include in its report to FDA the reason(s) for its inability to contact the health care professional and a description of its efforts to contact the health care professional.

For nonserious SADRs with a minimum data set, proposed §§ 314.80(c)(1)(vi) and 600.80(c)(1)(vi) would require applicants to submit to FDA all safety information received or otherwise obtained. Applicants would not be required to acquire information in addition to the minimum data set, except that reports of nonserious SADRs resulting from a medication error would require a full data set. Thus, followup would not be required for reports of nonserious SADRs that contain a minimum data set and do not occur because of a medication error.

III.C.6. Spontaneous Reports and Reports From Clinical Trials

Proposed §§ 310.305(c)(1)(i)(B), 314.80(c)(1)(i)(B), and 600.80(c)(1)(i)(B) would require that, for spontaneous reports, manufacturers and applicants must always assume, for safety reporting purposes only, that there is at least a reasonable possibility, in the opinion of the initial reporter, that the drug or

biological product caused the spontaneously reported event. Proposed §§ 310.305(c)(1)(i)(C), 314.80(c)(1)(i)(C), and 600.80(c)(1)(i)(C) state that, for a clinical trial, the possibility that the drug or biological product caused the SADR or that a medication error has occurred would be assumed if either the investigator or the applicant/manufacturer believes that such a reasonable possibility exists.

These proposed changes would clarify that all spontaneous reports received by manufacturers and applicants that contain a minimum data set (minimum information for a report of a medication error that does not result in SADR) would be reported to FDA (*i.e.*, as an individual case safety report and/or in a summary tabulation). These changes are consistent with the premarketing safety reporting requirements described in section III.B.2.b of this document (*i.e.*, determination of the possibility of causality (attributability) of an SADR to the drug or biological product in a clinical investigation would be based on the opinion of either the applicant/sponsor or investigator). These proposed amendments are also consistent with the ICH E2A guidance (60 FR 11284 at 11286):

> Causality assessment is required for clinical investigation cases. All cases judged by either the reporting health care professional or the sponsor as having a reasonable suspected causal relationship to the medicinal product qualify as ADR's. For purposes of reporting, adverse event reports associated with marketed drugs (spontaneous reports) usually imply causality.

III.C.7. Lack of Efficacy Reports

With regard to reports of a lack of efficacy for an approved drug or biological product, the guidance of 1992 and guidance of 1993 advise applicants to submit all individual cases of such reports that occur in the United States in postmarketing periodic safety reports. In this proposed rule, FDA would not require submission of individual case safety reports for reports of a lack of efficacy. Instead, applicants would be required to submit to FDA expedited reports of information sufficient to consider a product administration change, based upon appropriate medical judgement, for any significant unanticipated safety finding or data in the aggregate from a study that suggests a significant human risk. For example, applicants would be required to submit information concerning reports of a lack of efficacy with a drug or biological product used in treating a life-threatening or serious disease (see section III.D.2 of this document). In addition, applicants would be required to include in postmarketing periodic safety reports (*i.e.*, TPSRs, PSURs, IPSRs) an assessment of whether it is believed that the frequency of lack of efficacy reports is greater than would be predicted by the premarketing clinical trials for the drug or biological product (see sections III.E.1.c, III.E.2.k.vi, and III.E.3 of this document). This assessment would be provided for reports of a lack of efficacy whether a serious SADR, nonserious SADR, or no SADR occurs. Applicants that submit PSURs and IPSRs to FDA would also include in these reports a discussion of medically relevant lack of efficacy reports (*e.g.*, might represent a significant hazard to the treated population) for a product(s) used to treat serious or life-threatening diseases (see sections III.E.2.h and III.E.3 of this document).

III.D. Postmarketing Expedited Reports

Current postmarketing expedited safety reporting regulations at §§ 310.305(c), 314.80(c), and 600.80(c) require submission of ''15-day Alert reports'' to FDA. FDA is proposing to amend these regulations by removing the term ''15-day Alert report'' and replacing it with the term ''expedited report'' to be consistent with terminology used in the ICH E2A guidance. FDA is also proposing the following revisions to its postmarketing expedited safety reporting regulations.

III.D.1. Serious and Unexpected SADRs

Under the existing postmarketing expedited safety reporting regulations at § 310.305(c)(1)(i), persons subject to this requirement must report to FDA each adverse drug experience received or otherwise obtained that is both serious and unexpected as soon as possible, but in no case later than 15 calendar days of initial receipt of the information by the person. Under the existing postmarketing expedited safety reporting regulations at §§ 314.80(c)(1)(i) and 600.80(c)(1)(i), persons subject to these requirements must report each adverse drug experience that is both serious and unexpected, whether foreign or domestic, as soon as possible, but in no case later than 15 calendar days of initial receipt of the information by the person.

FDA is proposing minor revisions to these regulations for consistency. Proposed § 310.305(c)(2)(i) would amend § 310.305(c)(1)(i) by adding the phrase ''whether foreign or domestic'' after the phrase ''that is both serious and unexpected.'' Proposed §§ 314.80(c)(2)(i) and 600.80(c)(2)(i) would amend §§ 314.80(c)(1)(i) and 600.80(c)(1)(i) by adding the phrase ''to FDA'' after the word ''report'' and by adding the phrase ''received or otherwise obtained'' before the phrase ''that is both serious and unexpected.''

Proposed §§ 310.305(c)(2)(i), 314.80(c)(2)(i), and 600.80(c)(2)(i) would amend §§ 310.305(c)(1)(i), 314.80(c)(1)(i), and 600.80(c)(1)(i) by removing the phrase ''of initial receipt of the information by the person whose name appears on the label (''by the applicant'' for § 314.80(c)(1)(i), and ''by the licensed manufacturer'' for § 600.80(c)(1)(i)) and replacing it with the phrase ''after receipt by the manufacturer (''applicant'' for proposed §§ 314.80(c)(2)(i), and 600.80(c)(2)(i)) of the minimum data set for the serious, unexpected SADR.'' This proposed amendment is consistent with proposed revisions to the premarketing expedited safety reporting regulations at proposed § 312.32(c)(1)(i) (see section III.B.2.b of this document). The amendment would clarify that the 15 calendar day timeframe would begin as soon as manufacturers and applicants have knowledge of the minimum data set for an SADR that is serious and unexpected. Manufacturers and applicants must use due diligence to acquire this information. For this purpose, they would be required, as described in section III.C.5 of this document, to use active query to determine the outcome for the SADR (whether the SADR is serious or nonserious) and acquire at least the minimum data set for the individual case safety report if they are not able to immediately obtain this information. Manufacturers and applicants should include in postmarketing expedited safety reports a chronological history of their efforts to acquire a minimum data set and to determine the seriousness and expectedness of an SADR if there is a delay in obtaining such information.

Proposed §§ 310.305(c)(2)(i), 314.80(c)(2)(i) and 600.80(c)(2)(i) state that if a full data set is not available for a serious and unexpected SADR report at the time of initial submission of the report to FDA, manufacturers and applicants must submit the information required under proposed §§ 310.305(c)(1)(iv), 314.80(c)(1)(iv) and 600.80(c)(1)(iv) as described in section III.C.5 of this document and also submit a 30-day followup report as described in section III.D.6 of this document. FDA is proposing this action to clarify the importance of acquiring complete information for serious SADRs.

III.D.2. Information Sufficient To Consider Product Administration Changes

Proposed §§ 310.305(c)(2)(ii), 314.80(c)(2)(ii), and 600.80(c)(2)(ii) would require that manufacturers and applicants submit to FDA information, received or otherwise obtained, whether foreign or domestic, that would be sufficient, based upon appropriate medical judgment, to consider changes in product administration. Manufacturers and applicants would be required to submit this information to the agency as soon as possible, but in no case later than 15 calendar days after the manufacturer or applicant determines that the information qualifies for expedited reporting. Examples of such information include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an IND, that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a drug or biological product used in treating a life-threatening or serious disease. The proposed rule would require that manufacturers and applicants maintain records of their efforts to determine whether information that they have received or otherwise obtained would qualify for expedited reporting under this proposed requirement. This proposed requirement is consistent with the proposed revisions to the premarketing expedited safety reporting regulations at proposed § 312.32(c)(1)(ii) (see section III.B.2.c of this document) and with the ICH E2A guidance (60 FR 11284 at 11286). The proposed amendment would further clarify some of the types of safety information that must be submitted to FDA in an expedited manner.

III.D.3. Unexpected SADRs With Unknown Outcome

FDA expects that, in most cases, manufacturers and applicants will be able to determine the outcome for an SADR (whether the SADR is serious or nonserious). However, in those few cases where a determination may not be possible, FDA would require submission of unexpected SADRs with unknown outcome in an expedited manner (proposed §§ 310.305(c)(2)(iii), 314.80(c)(2)(iii), and 600.80(c)(2)(iii)). Expedited safety reports for unexpected SADRs with unknown outcome would be submitted to FDA within 45 calendar days after initial receipt by the manufacturer or applicant of the minimum data set for the unexpected SADR. FDA is proposing this action to expedite review of potentially serious SADRs.

The proposed rule would require that manufacturers and applicants reporting an unexpected SADR with unknown outcome include in the expedited safety report the reason(s) for their inability to classify an SADR as either serious or nonserious (*i.e.*, unknown outcome). For this purpose, manufacturers and applicants should include in the expedited report a chronological history of their efforts to determine the outcome of the SADR.

Manufacturers and applicants reporting an unexpected SADR with unknown outcome must exercise due diligence to determine the expectedness for the SADR and to acquire at least the minimum data set for the individual case safety report. For this purpose, these persons would be required to use active query to acquire this information (see section III.C.5 of this document). These persons should include in postmarketing expedited safety reports a chronological history of their efforts to acquire this information if there is a delay in obtaining it.

III.D.4. Always Expedited Reports

Proposed §§ 310.305(c)(2)(iv), 314.80(c)(2)(iv), and 600.80(c)(2)(iv) would require manufacturers and applicants to submit to FDA individual case safety reports for SADRs, received or otherwise obtained, whether foreign or domestic, that are the subject of an always expedited report. These always expedited reports would be submitted to the agency as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer (''applicant'' for proposed §§ 314.80(c)(2)(iv), and 600.80(c)(2)(iv)) of the minimum data set for the report. The following medically significant SADRs, which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject, would be subject to an always expedited report:

- Congenital anomalies,
- Acute respiratory failure,
- Ventricular fibrillation,
- Torsades de pointe,
- Malignant hypertension,
- Seizure,
- Agranulocytosis,
- Aplastic anemia,
- Toxic epidermal necrolysis,
- Liver necrosis,
- Acute liver failure,
- Anaphylaxis,
- Acute renal failure,
- Sclerosing syndromes,
- Pulmonary hypertension,
- Pulmonary fibrosis,
- Confirmed or suspected transmission of an infectious agent by a marketed drug or biological product,
- Confirmed or suspected endotoxin shock, and
- Any other medically significant SADR that FDA determines to be the subject of an always expedited report (*i.e.*, may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject).

These SADRs would be submitted to the agency in an expedited manner whether unexpected or expected and whether or not the SADR leads to a serious outcome. The medical gravity of these SADRs requires expedited reporting.

The agency is proposing that a confirmed or suspected transmission of an infectious agent by a marketed drug or biological product would be the subject of an always expedited report. Examples of such transmissions include human immunodeficiency virus (HIV) transmission by anti-hemophilic factor, hepatitis C transmission by intravenous immunoglobulin, bacterial contamination of albumin leading to sepsis, and parvovirus contamination of anti-hemophilic factor causing an SADR. These SADRs indicate a public health problem that requires expedited review by the agency.

The proposal provides that the agency could make a new SADR the subject of an always expedited report. Such an SADR would only become the subject of these reports if FDA determines that the SADR is medically significant (*i.e.*, may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject). New SADRs that become the subject of always expedited reports would be included in the agency's current guidance for industry on postmarketing safety reporting for human drugs and licensed biological products.

Proposed §§ 310.305(c)(2)(iv)(B), 314.80(c)(2)(iv)(B), and 600.80(c)(2)(iv)(B) would require that if a full data set is not available for always expedited reports at the time of initial submission of the report to FDA, manufacturers and applicants would submit the information required under proposed §§ 310.305(c)(1)(iv), 314.80(c)(1)(iv) and 600.80(c)(1)(iv) as described in section III.C.5 of this document and also submit a 30-day followup report as described in section III.D.6 of this document. FDA is proposing this action to clarify the importance of acquiring complete information for medically significant SADRs that are the subject of always expedited reports.

III.D.5. Medication Errors

Proposed §§ 310.305(c)(2)(v)(A), 314.80(c)(2)(v)(A), and 600.80(c)(2)(v)(A) would require that each domestic report of an actual medication error, received or otherwise obtained, be submitted to the agency as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer (''applicant'' for proposed §§ 314.80(c)(2)(v)(A) and 600.80(c)(2)(v)(A)) of the minimum data set for a report of an SADR or, if an SADR does not occur, the minimum information for the report as described in section III.C.5 of this document (*i.e.*, an identifiable patient, an identifiable reporter, and a suspect drug or biological product). For postmarketing safety reporting purposes, all reports of medication errors would be considered unexpected. FDA is proposing this new type of expedited report to protect public health.

Proposed §§ 310.305(c)(2)(v)(B), 314.80(c)(2)(v)(B), and 600.80(c)(2)(v)(B) would require that reports of potential medication errors, received or otherwise obtained, be submitted to the agency as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer (''applicant'' for proposed §§ 314.80(c)(2)(v)(B) and 600.80(c)(2)(v)(B)) of the minimum information described in section III.C.5 of this document (*i.e.*, an identifiable reporter and a suspect drug or biological product). FDA is proposing submission of this information to the agency in an expedited manner to attempt to prevent actual medication errors.

Proposed §§ 310.305(c)(2)(v)(C), 314.80(c)(2)(v)(C), and 600.80(c)(2)(v)(C) state that if a full data set is not available for an actual or potential medication error report at the time of initial submission of the report to FDA, manufacturers and applicants would submit the information required under proposed §§ 310.305(c)(1)(iv), 314.80(c)(1)(iv) and 600.80(c)(1)(iv) as described in section III.C.5 of this document and also submit a 30-day followup report as described in section III.D.6 of this document. FDA is proposing this action to clarify the importance of acquiring complete information for reports of medication errors.

III.D.6. Followup Reports

Current postmarketing expedited safety reporting regulations at §§ 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii) require persons subject to these regulations to promptly investigate all serious, unexpected adverse drug experiences that are the subject of expedited reports and to submit followup reports within 15 calendar days of receipt of new information or as requested by FDA. If additional information is not obtainable, records should be maintained of the unsuccessful steps taken to seek additional information. Thus, followup reports are currently only required to be submitted to FDA if requested by the agency or if new information is obtained or otherwise received by the manufacturer or applicant for an adverse drug experience previously reported to FDA.

In this rulemaking, FDA continues to require submission of these followup reports. In addition, as described in the following paragraph, a 30-day followup report would be required to be submitted in certain cases (*i.e.*, initial serious and unexpected SADR reports, always expedited reports and medication error reports that do not contain a full data set). If a 30-day followup report is required and no new information is available for the report, then the manufacturer or applicant would still be required to submit the 30-day followup report, indicate in the report that no new information was available and include a description of the reason(s) for its inability to acquire complete information and its efforts to obtain complete information. In all other cases, if there is no new information to report to FDA on a previously submitted SADR no followup report would be required to be submitted to the agency.

Proposed §§ 310.305(c)(2)(vi), 314.80(c)(2)(vi), and 600.80(c)(2)(vi) would require manufacturers and applicants to use active query to obtain additional information for any serious and unexpected SADR submitted to FDA in an expedited report under proposed §§ 310.305(c)(2)(i), 314.80(c)(2)(i), and 600.80(c)(2)(i) that does not contain a full data set. The proposed amendment would also require these persons to use active query to obtain additional information for any always expedited report under proposed §§ 310.305(c)(2)(iv), 314.80(c)(2)(iv), and 600.80(c)(2)(iv) or any medication error report under proposed §§ 310.305(c)(2)(v), 314.80(c)(2)(v), and 600.80(c)(2)(v) that does not contain a full data set. This information would be submitted to the agency in a followup report within 30 calendar days after initial submission of the expedited report to FDA by the manufacturer or applicant (30-day followup report). This proposed amendment would provide the agency with timely acquisition of more complete information for SADRs and medication errors that are the subject of these reports.

Proposed §§ 310.305(c)(2)(vi), 314.80(c)(2)(vi), and 600.80(c)(2)(vi) would also state that:

> * * * If a full data set is still not obtainable, the 30-day followup report must contain the information required under paragraph (c)(1)(iv) of this section. Any new safety information in the 30-day followup report must be highlighted. Any new information, received or otherwise obtained, after submission of a 30-day followup report must be submitted to FDA as a 15-day followup report under paragraph (c)(2)(vii) of this section.

This proposed amendment would clarify the information that would be required in a 30-day followup report if a full data set is still not available for the report. It would also clarify that FDA would require a 15-day followup report, as described in the paragraphs that follow, for any new information obtained or otherwise received for the report after submission of the 30-day followup report. The proposed amendment would ensure that manufacturers and applicants would exercise due diligence to obtain complete information for SADRs that are the subject of 30-day followup reports.

Proposed §§ 310.305(c)(2)(vii), 314.80(c)(2)(vii), and 600.80(c)(2)(vii) would amend §§ 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii) to clarify that manufacturers and applicants must submit 15-day followup reports to FDA of any new information received or otherwise obtained for any expedited or followup report (except for initial expedited reports under proposed §§ 310.305(c)(2)(i), (c)(2)(iv), and (c)(2)(v), 314.80 (c)(2)(i), (c)(2)(iv), and (c)(2)(v), and 600.80(c)(2)(i), (c)(2)(iv), and (c)(2)(v) that do not contain a full data set) within 15 calendar days of initial receipt of new information by the manufacturer or applicant. Proposed §§ 310.305(c)(2)(vii), 314.80(c)(2)(vii), and 600.80(c)(2)(vii) would also state that:

> * * * Expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set at the time of initial submission of the report to FDA are subject to the 30-day followup reporting requirements under paragraph (c)(2)(vi) of this section rather than the 15-day followup reporting requirements under this paragraph.

Thus, 15-day followup reports would be submitted for the following types of expedited and followup reports:

- Serious and unexpected SADR reports that contain a full data set,
- Information sufficient to consider product administration changes,

- Unexpected SADRs with unknown outcomes,
- Always expedited reports that contain a full data set,
- Actual and potential medication error reports that contain a full data set,
- 30-day followup reports, and
- 15-day followup reports.

These proposed revisions clarify the types of expedited reports that would be subject to the 15-day followup reporting requirements.

FDA notes that a 15-day followup report, rather than a serious and unexpected SADR report, should be submitted to FDA for an SADR that is initially reported to the agency as serious and expected or nonserious and unexpected, but is subsequently determined to be serious and unexpected. In these cases, manufacturers and applicants should include in the 15-day followup report a chronological history describing the events that transpired which resulted in determination of the serious and unexpected character of the SADR.

FDA is proposing to amend its postmarketing expedited safety reporting regulations at §§ 310.305(c)(2), 314.80(c)(1)(ii), and 600.80(c)(1)(ii) by removing the second sentence in these paragraphs regarding maintaining records if additional information is not obtainable for a serious and unexpected adverse drug experience. The agency is proposing this amendment because postmarketing safety reporting requirements for serious and unexpected SADR reports that do not contain a full data set are now prescribed under proposed §§ 310.305(c)(1)(iv) and (c)(2)(vi), 314.80(c)(1)(iv) and (c)(2)(vi), and 600.80(c)(1)(iv) and (c)(2)(vi).

III.D.7. Supporting Documentation

Proposed §§ 310.305(c)(2)(viii)(A), 314.80(c)(2)(viii)(A), and 600.80(c)(2)(viii)(A) would require that manufacturers and applicants submit to FDA, if available, a copy of the autopsy report if the patient dies. If an autopsy report is not available, the proposed rule would require that manufacturers and applicants submit a death certificate to FDA. If an autopsy report becomes available after the manufacturer or applicant has submitted a death certificate to the agency, the manufacturer or applicant must submit the autopsy report to FDA. If the patient was hospitalized, manufacturers and applicants would be required to submit to FDA, if available, a copy of the hospital discharge summary. If any of these documents is not in English, an English translation of the document would be required. FDA is proposing that manufacturers and applicants submit these documents to provide the agency with complete information for SADRs that result in a death or hospitalization.

Proposed §§ 310.305(c)(2)(viii)(A), 314.80(c)(2)(viii)(A), and 600.80(c)(2)(viii)(A) would require that manufacturers and applicants use active query to obtain the documents required to be submitted to FDA under this paragraph. These documents would be required to be submitted to FDA as 15-day followup reports (see section III.D.6 of this document) within 15 calendar days of initial receipt of the document by the manufacturer or applicant. In instances when a document is not submitted to FDA in a 15-day followup report within 3 months after submission of the initial expedited report for the death or hospitalization, the agency would assume that active query by the manufacturer or applicant did not result in access to these documents. In this case, a record of the reason(s) for the lack of documentation and the effort that was made to obtain the documentation would be required to be maintained by the manufacturer and applicant.

Proposed §§ 310.305(c)(2)(viii)(B), 314.80(c)(2)(viii)(B), and 600.80(c)(2)(viii)(B) would require that each expedited report contain in the narrative a list of other relevant documents (*e.g.*, medical records, laboratory results, data from studies) regarding the report that are maintained by manufacturers and applicants. FDA may require, when appropriate, that copies of one or more of these documents be submitted to the agency within 5 calendar days after receipt of the request. FDA would usually request such records in response to a suspected safety problem associated with the use of a drug or licensed biological product.

III.D.8. Scientific Literature

Current postmarketing expedited safety reporting regulations at §§ 314.80(d)(1) and 600.80(d)(1) require that expedited reports based on information from the scientific literature be accompanied by a copy of the published article. These regulations apply only to reports found in scientific and medical journals either as case reports or as the result of a formal clinical trial. Proposed §§ 314.80(c)(2)(ix) and 600.80(c)(2)(ix) would amend the current regulations by removing the phrase ''either as case reports or as the result of a formal clinical trial'' to clarify that all reports from the scientific literature, including case reports, and results of a formal clinical trial, epidemiological study, in vitro study, or animal study, that qualify for expedited reporting under proposed §§ 314.80(c)(2) and 600.80(c)(2) would be required to be submitted to FDA.

The proposed rule would also remove §§ 314.80(d)(2) and 600.80(d)(2). These paragraphs provide that reports based on the scientific literature must be submitted on FDA Form 3500A or comparable format prescribed by the regulations and that, in cases where persons subject to the postmarketing safety reporting regulations believe that preparing the FDA Form 3500A constitutes an undue hardship, arrangements can be made with the agency for use of an acceptable alternative reporting format. FDA is proposing to remove these paragraphs because the reporting format for reports based on information in the scientific literature would be specified under proposed §§ 314.80(c)(4) and 600.80(c)(4) (see section III.F of this document).

For organizational purposes, FDA is proposing to move §§ 314.80(d) and 600.80(d), as revised by this proposed rule, to proposed §§ 314.80(c)(2)(ix) and 600.80(c)(2)(ix). Proposed § 310.305(c)(2)(ix) would amend § 310.305(c) by adding the paragraph:

> *Scientific literature.* An expedited report based on information from the scientific literature applies only to reports found in scientific and medical journals. These expedited reports must be accompanied by a copy of the published article.

This proposed amendment would clarify for prescription drug products marketed for human use without an approved application the types of safety information found in scientific literature that would qualify for expedited reporting. The proposed amendment would also require that these reports include a copy of the published article that is the subject of the expedited report. The proposed amendment would provide the agency with more complete information for review of safety information from the scientific literature and would also provide uniformity between FDA's postmarketing expedited safety reporting requirements for prescription drugs marketed for human use without an approved application and marketed drugs with an approved application.

III.D.9. Contractors and Shared Manufacturers

Current regulations at §§ 310.305(c)(1)(i) and (c)(3), 314.80(c)(1)(iii), and 600.80(c)(1)(iii) require any person whose name appears on the label of a marketed drug product or licensed biological product as a packer or distributor to submit either

expedited reports of serious and unexpected adverse drug experiences directly to FDA or reports of all serious adverse drug experiences to the manufacturer (§ 310.305(c)(3) or applicant (§§ 314.80(c)(1)(iii) and 600.80(c)(1)(iii)) instead of FDA in 5 calendar days. This provision also applies to manufacturers for §§ 314.80(c)(1)(iii) and 600.80(c)(1)(iii) and to shared manufacturers, joint manufacturers, and any participants involved in divided manufacturing for § 600.80(c)(1)(iii). Proposed §§ 310.305(c)(2)(xi)(A), 314.80(c)(2)(x)(A), and 600.80(c)(2)(x)(A) would amend these regulations to require contractors, as defined in proposed §§ 310.305(a), 314.80(a) and 600.80(a) (see section III.A.4 of this document), to submit to the manufacturer (proposed § 310.305(c)(2)(xi)(A)) or applicant (proposed §§ 314.80(c)(2)(x)(A) and 600.80(c)(2)(x)(A)) safety reports of all SADRs (serious and nonserious) and medication errors for the manufacturer's (proposed § 310.305(c)(2)(xi)) or applicant's (proposed §§ 314.80(c)(2)(x) and 600.80(c)(2)(x)) drug or biological product, obtained or otherwise received, within 5 calendar days of initial receipt of the report by the contractor. This provision would also apply to shared manufacturers of licensed biological products for proposed § 600.80(c)(2)(x)(A) (*i.e.*, all SARs and medication errors would be required to be submitted to the applicant within 5 calendar days). The contractor would be required to submit a report of an SADR to the manufacturer (proposed § 310.305(c)(2)(xi)(A)) or applicant (proposed §§ 314.80(c)(2)(x)(A) and 600.80(c)(2)(x)(A)) even if the report does not contain a minimum data set. Contractors and shared manufacturers would only be required to convey to manufacturers (proposed § 310.305(c)(2)(xi)(A)) or applicants (proposed §§ 314.80(c)(2)(x)(A) and 600.80(c)(2)(x)(A)) whatever safety information was obtained or otherwise received. They would not be required to use active query to acquire safety information, to conduct followup, or to submit postmarketing safety reports to FDA. Upon receipt of a safety report from a contractor or shared manufacturer, the manufacturer (proposed § 310.305(c)(2)(xi)(A)) or applicant (proposed §§ 314.80(c)(2)(x)(A) and 600.80(c)(2)(x)(A)) would be required to comply with the postmarketing safety reporting requirements under proposed §§ 310.305, 314.80 and 600.80 (*e.g.*, use active query, if necessary, to acquire safety information, conduct followup, submit postmarketing safety reports to FDA). These proposed amendments would provide manufacturers and applicants with complete safety information regarding its products.

Proposed §§ 310.305(c)(2)(xi)(B), 314.80(c)(2)(x)(B), and 600.80(c)(2)(x)(B) would require that contracts between manufacturers and contractors (§ 310.305(c)(2)(xi)(B)) and applicants and contractors (§§ 314.80(c)(2)(x)(B) and 600.80(c)(2)(x)(B)) specify the postmarketing safety reporting responsibilities of the contractor. Although contractors and shared manufacturers have postmarketing safety reporting responsibilities, the manufacturer (proposed § 310.305(c)(2)(xi)(B)) or applicant (proposed §§ 314.80(c)(2)(x)(B) and 600.80(c)(2)(x)(B)) would be responsible for ensuring that the contractors and shared manufacturers of its products comply with these postmarketing safety reporting responsibilities. FDA believes that, in general, this proposal represents a practice that is already customary and usual in the pharmaceutical industry because contractors are typically considered agents of the manufacturer or applicant.

Proposed §§ 310.305(c)(2)(xi)(C), 314.80(c)(2)(x)(C), and 600.80(c)(2)(x)(C) would require that contractors and shared manufacturers maintain records of SADR reports and medication errors. This proposal is consistent with current postmarketing safety reporting requirements.

Proposed §§ 310.305(c)(2)(xi)(D), 314.80(c)(2)(x)(D), and 600.80(c)(2)(x)(D) state that the recordkeeping, written procedures, and disclaimer provisions under proposed §§ 310.305, 314.80 and 600.80 would apply to contractors and shared manufacturers. This proposal clarifies for contractors and shared manufacturers which of the postmarketing safety reporting provisions would apply to them.

III.D.10. Prescription Drugs Marketed for Human Use Without an Approved Application

Proposed § 310.305(c)(2)(x) would amend § 310.305(c)(1)(i) to require that expedited reports for prescription drugs marketed for human use without an approved application be accompanied by a list of the current addresses where all safety reports and other safety-related records for the drug product are maintained by manufacturers and contractors. In the October 1994 proposal, FDA proposed to include, under §§ 314.80(c)(2) and 600.80(c)(2), a section in its postmarketing periodic safety reports on location of adverse drug experience records (59 FR 54046 at 54061). FDA is now reproposing this amendment for its postmarketing periodic safety reports (see sections III.E.1.g, III.E.2.k.x, and III.E.3 of this document). The agency is also proposing to require the list of addresses in expedited reports for drugs covered under § 310.305 because manufacturers of these drugs are not required to submit postmarketing periodic safety reports to FDA. The list of addresses would provide rapid access to safety-related records for FDA inspections and for requests by FDA for additional information concerning safety issues.

III.D.11. Class Action Lawsuits

Manufacturers and applicants should not submit SADRs from class action lawsuits to FDA in an expedited report. The agency believes that SADRs from class action lawsuits would be submitted to FDA from other sources (*e.g.*, spontaneous reports) prior to initiation of the class action lawsuit. Summary tabulations of SADRs from class action lawsuits would be required in postmarketing periodic safety reports (see sections III.E.1.e and III.E.2.k.v of this document).

III.D.12. Blood and Blood Component Safety Reports

Current § 606.170(a) requires a blood establishment to thoroughly investigate any complaint of an adverse reaction arising as a result of blood collection or transfusion and to prepare and maintain a written report of the investigation, including followup and conclusions, as part of the record for that lot or unit of final product. If appropriate, the report must be forwarded to the manufacturer of the blood or blood component or the collection facility. Under § 606.170(b), a complication of a blood collection or blood transfusion resulting in a fatality must be reported to FDA as soon as possible by telephone or other rapid means of communication, and a written report of the investigation must be submitted to FDA within 7 days of the fatality. Each year, in accordance with § 606.170(b), FDA receives between 50 and 80 reports of fatalities.

Current § 606.171 requires licensed manufacturers of blood and blood components, unlicensed registered blood establishments and transfusion services to report biological product deviations. A biological product deviation is an event that represents either: (1) A deviation from current good manufacturing practices, applicable regulations, applicable standards, or established specifications that may affect the safety, purity, or potency of a product; or (2) an unexpected or

unforseeable event that may affect the safety, purity, or potency of a product. In some cases, a biological product deviation reportable under § 606.171 may actually result in an adverse reaction in the transfusion recipient. In many other cases, the biological product deviation may be discovered before the affected products are administered or administration of the product may not result in an adverse reaction.

Although manufacturers of blood and blood components are currently exempt from the safety reporting requirements under § 600.80, FDA receives reports of fatal adverse reactions related to blood and blood components and may receive some additional information through biological product deviation reporting. However, the agency does not currently receive adequate information to monitor and assess safety-related information concerning the collection and transfusion of blood and blood components. Such information is essential for evaluating the agency's scientific and regulatory policies and for monitoring industry practices and their implications on blood safety. For these purposes, FDA is proposing to amend § 606.170 to require the reporting of all serious SARs, in addition to fatalities, that are related to the collection or transfusion of blood and blood components (*e.g.*, red blood cells, plasma, platelets, and cryoprecipitate). For fatal SARs, proposed § 606.170(c) would continue the current requirement that a fatal SAR be reported immediately by telephone, facsimile, express mail, or electronically transmitted mail and in a written report within 7 calendar days of the fatality. Because blood establishments are already required to investigate all complaints of an adverse reaction related to the collection and transfusion of blood and blood components and many of these reactions are well recognized and understood by blood establishments and by FDA, the agency is not proposing to require the submission of postmarketing periodic safety reports (*i.e.*, TPSRs, PSURs, IPSRs and individual case safety reports—semiannual submissions).

Specifically, FDA is proposing to amend § 606.170 by revising the title of the section to read ''Suspected adverse reaction investigation and reporting''; by making editorial changes to § 606.170(a), which prescribes requirements for the investigation and recording of any complaint of an SAR related to the collection or transfusion of blood or blood components; by adding a new requirement for reporting of serious SARs related to transfusion or collection procedures (proposed § 606.170(b)); and by redesignating current § 606.170(b) as § 606.170(c) and revising the paragraph as discussed below. FDA is also proposing that the terms ''SAR'' and ''serious SAR,'' as used in proposed § 606.170, have the same meaning as defined in proposed § 600.80(a)(see sections III.A.1 and III.A.3 of this document).

In general, FDA believes that any SAR related to blood donation or transfusion that requires immediate medical intervention or followup medical attention should be reported. For the purpose of reporting serious SARs related to blood collection, FDA interprets the term to include:

- Vasovagal reactions with syncope (hypotension and bradycardia) requiring medical intervention;
- Citrate reactions requiring significant medical intervention;
- Anaphylaxis or any major allergic reactions;
- Seizure of any type or duration;
- Cerebrovascular accidents;
- Cardiac arrhythmia, angina of any duration, myocardial infarction, or cardiac arrest;
- Clinically significant hypotension;
- Bronchospasm, respiratory insufficiency;
- Arterial puncture, air embolus;
- Phlebotomy-related nerve damage; and,
- Thrombophlebitis, phlebitis, or any procedure-related infection.

For SARs related to donation, FDA interprets the term ''serious SAR'' not to include:

- Self-limited vasovagal reactions (hemodynamically stable);
- Self-limited citrate reactions;
- Localized hematoma, uncomplicated; and,
- Localized skin irritation, uncomplicated.

For the purposes of reporting serious SARs related to receipt of a blood transfusion, FDA interprets the term to include:

- Any complication from the use of an unsuitable unit, including infusion of hemolyzed blood;
- Any complication from improper blood administration, including failure to use a standard blood filter (*e.g.*, air embolism);
- Induced hemolysis, acute or delayed;
- Transmitted infections, including bacterial infections;
- Associated graft versus host disease;
- Related hypersensitivity with respiratory insufficiency and/or hypotension (*e.g.*, anaphylaxis);
- Transfusion-related acute lung injury (TRALI);
- Induced alloimmunization which prevents effective transfusion therapy (*e.g.*, posttransfusion purpura);
- Induced congestive heart failure; and
- Induced cardiac arrhythmias, including those resulting from metabolic imbalance.

For SARs related to receipt of a blood transfusion, FDA interprets the term ''SAR'' not to include:

- Febrile nonhemolytic transfusion reactions;
- Related hypersensitivity without respiratory insufficiency nor hypotension;
- Induced alloimmunization which does not prevent effective transfusion therapy;
- Infections not clinically significant to the recipient, such as cytomegalovirus (CMV) infection in an immunocompetent adult; and,
- Induced hemochromatosis.

FDA is proposing to require that for a serious SAR related to blood collection, the establishment performing the blood collection be responsible for reporting the serious SAR to FDA, and for a serious SAR related to transfusion, the establishment responsible for the compatibility testing be responsible for reporting the serious SAR to FDA (proposed § 606.170(b)). FDA is proposing to require that reports of serious SARs, including fatal SARs under proposed § 606.170(c), be reported to FDA using the reporting format described in proposed § 600.80(c)(4). Thus the reporting facility would be required to submit a report for each individual patient on FDA Form 3500A or a computer-generated facsimile of FDA Form 3500A using the appropriate ''preferred term'' in the latest version of MedDRA (see section III.F of this document).

Current § 606.171 requires reports of biological product deviations be submitted as soon as possible, but not to exceed 45 calendar days. Because there will be instances when an SAR occurs and a biological product deviation may have contributed to an SAR, FDA is proposing to require reporting of serious SARs to the agency within 45 calendar days (for fatal SARs, within 7 calendar days) of the determination that a serious SAR related to blood collection or transfusion has occurred. This will permit a blood establishment to investigate and report both a biological product deviation and an SAR related to the biological product deviation at the same time and will limit the reporting burden. In the case of a reported serious SAR that subsequently results in a fatality, FDA would not require two separate reports,

one reporting the serious SAR and the other reporting the fatality. However, if the fatality occurs after the report of the serious SAR is submitted to the agency, the blood establishment should update the initial report to report the fatality.

III.E. Postmarketing Periodic Safety Reporting

The proposed rule would require all applicants to submit to FDA semiannually on an FDA Form 3500A (VAERS form for vaccines, CIOMS I Form, if desired, for foreign SADRs) certain spontaneously reported SADRs (see tables 7 and 9 and section III.E.4 of this document regarding individual case safety reports—semiannual submissions). Applicants would also be required to submit other postmarketing periodic safety reports (*i.e.*, traditional periodic safety reports (TPSRs), periodic safety update reports (PSURs), or interim periodic safety reports (IPSRs)) to FDA with a frequency as described in section III.E.5.a of this document (see tables 7 and 9). PSURs, IPSRs, and TPSRs would provide FDA with an overview or summary of the safety profile of a drug or licensed biological product (excluding individual case safety reports). A TPSR would essentially contain the same format and content as the periodic safety report currently required by the agency's postmarketing periodic safety reporting regulations (see table 10 and section III.E.1 of this document). A PSUR would essentially be consistent with the format and content of the periodic safety report described in the ICH E2C guidance (see section III.E.2 of this document), and an IPSR would represent an abbreviated form of a PSUR (see section III.E.3 of this document). Applicants with drugs and licensed biological products approved prior to January 1, 1998, would have the option to submit either a TPSR or PSUR to FDA, whereas applicants with products approved on or after January 1, 1998, would be required to submit a PSUR (see tables 7 and 9 and section III.E.5.a of this document). FDA is proposing to require submission of periodic safety reports in a PSUR format for products approved on or after January 1, 1998, to be consistent with the ICH E2C guidance. FDA is not proposing to require submission of PSURs for products approved prior to January 1, 1998, because the agency recognizes that the most significant new safety information on a product is usually acquired in the first few years after it has been on the market. It is not necessary for applicants to reformat periodic safety reports for products approved prior to January 1, 1998. In addition, in some cases, it will be sufficient for FDA to review an abbreviated form of the PSUR (*i.e.*, at 7.5 and 12.5 years after U.S. approval of a product). For these cases, the agency is proposing to require submission of an IPSR instead of a PSUR (see tables 7 and 9 and sections III.E.3 and III.E.5.a of this document).

III.E.1. Traditional Periodic Safety Reports (TPSRs)

Current regulations (§§ 314.80(c)(2)(ii)(*a*) through (c)(2(ii)(*c*) and 600.80(c)(2)(ii)(A) through (c)(2)(ii)(C)) require the submission of postmarketing periodic adverse drug experience reports that contain:

- A narrative summary and analysis of the information in the report and an analysis of the 15-day postmarketing Alert reports submitted during the reporting period (all 15-day Alert reports being appropriately referenced by the applicant's patient identification number, adverse reaction term(s), and date of submission to FDA);
- An FDA Form 3500A describing each adverse drug experience not previously reported (with an index consisting of a line listing of the applicant's patient identification number and adverse reaction term(s)); and
- A history of actions taken since the last periodic report.

Proposed §§ 314.80(c)(3)(i) and 600.80(c)(3)(i) would amend these regulations by replacing the term ''periodic adverse drug experience report'' with the term ''traditional periodic safety report (TPSR).'' FDA is proposing this revision to differentiate the existing postmarketing periodic safety report from the proposed new postmarketing periodic safety reports (*i.e.*, PSURs and IPSRs, see sections III.E.2 and III.E.3 of this document).

III.E.1.a. *Narrative summary and analysis of individual case safety reports.* Proposed §§ 314.80(c)(3)(i)(A) and 600.80(c)(3)(i)(A) would amend §§ 314.80(c)(2)(ii)(*a*) and 600.80(c)(2)(ii)(A) by providing paragraph headings and reorganizing and revising these paragraphs. Proposed §§ 314.80(c)(3)(i)(A)(*1*) and 600.80(c)(3)(i)(A)(*1*) would amend §§ 314.80(c)(2)(ii)(*a*) and 600.80(c)(2)(ii)(A) by replacing the phrase ''the information in the report'' with the following:

> serious, expected SADRs and nonserious, unexpected SADRs occurring in the United States that were submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals) (with an index consisting of a line listing of the applicant's manufacturer report number and SADR term(s)). The narrative summary and analysis would include spontaneous reports submitted to the applicant by health care professionals and other individuals (*e.g.*, consumers).

Proposed §§ 314.80(c)(3)(i)(A)(*2*) and 600.80(c)(3)(i)(A)(*2*) would amend §§ 314.80(c)(2)(ii)(*a*) and 600.80(c)(2)(ii)(A) by replacing the phrase ''an analysis of the 15-day Alert reports * * * date of submission to FDA)'' with the phrase:

> An analysis of the expedited reports submitted during the reporting period under paragraphs (c)(2)(i) through (c)(2)(vii) of this section (all expedited reports must be appropriately referenced by the applicant's manufacturer report number, SADR term(s), if appropriate, and date of submission to FDA),

Current regulations at §§ 314.80(c)(2)(iii) and 600.80(c)(2)(iii) state that periodic reporting, except for information regarding 15-day Alert reports, does not apply to adverse drug experience information obtained from postmarketing studies (whether or not conducted under an IND), from reports in the scientific literature, and from foreign marketing experience. FDA is proposing to remove this statement because proposed §§ 314.80(c)(3)(i)(A)(*1*) and 600.80(c)(3)(i)(A)(*1*) specifies the type of information that FDA would require in a TPSR.

III.E.1.b. *Individual case safety reports.* FDA is also proposing to remove §§ 314.80(c)(2)(ii)(*b*) and 600.80(c)(2)(ii)(B) from these regulations. FDA is proposing this change because the requirement to submit individual case safety reports to FDA on FDA Form 3500A (VAERS form for vaccines) would be required in a separate submission on a semiannual basis (see section III.E.4 of this document).

III.E.1.c. *Increased frequency reports.* Proposed §§ 314.80(c)(3)(i)(A)(*3*) and 600.80(c)(3)(i)(A)(*3*) would amend §§ 314.80(c)(2)(ii)(*a*) and 600.80(c)(2)(ii)(A) to require applicants to include in TPSRs a discussion of any increased reporting frequency of serious, expected SADRs, including comments on whether it is believed that the data reflect a meaningful change in SADR occurrence. Even though the agency has revoked the requirement to submit increased frequency reports in an expedited manner (62 FR 34166), FDA is interested in reviewing periodically information on increased frequencies of serious, expected SADRs and is proposing that this type of information be submitted to the agency in TPSRs.

The proposed rule would also require that this section of the TPSR include an assessment of whether it is believed that the frequency of lack of efficacy reports, obtained or otherwise received during the reporting period, is greater than would be predicted by the premarketing clinical trials for the drug or biological product. This assessment would be provided whether a serious SADR, nonserious SADR, or no SADR occurs as a result of a lack of efficacy of the product.

III.E.1.d. *Safety-related actions to be taken.* Proposed §§ 314.80(c)(3)(i)(A)(*4*) and 600.80(c)(3)(i)(A)(*4*) would require applicants to include in TPSRs the applicant's conclusion as to what, if any, safety-related actions should be taken based on the analysis of the safety data in the TPSR (*e.g.*, labeling changes, studies initiated). FDA is proposing this amendment to highlight safety-related actions that may be necessary.

III.E.1.e. *Summary tabulations.* Proposed §§ 314.80(c)(3)(i)(B), and 600.80(c)(3)(i)(B) would require that a new section of summary tabulations (*i.e.*, lists of all SADR terms and counts of occurrences) be included in TPSRs for all serious, expected SADRs; nonserious, unexpected SADRs; nonserious, expected SADRs; and expected SADRs with unknown outcome occurring in the United States that are submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals). These tabulations would include SADRs that were previously submitted to FDA in an expedited report (*i.e.*, serious, unexpected SADRs, unexpected SADRs with unknown outcome, and always expedited reports) and reports of SADRs not previously submitted to FDA by applicants (*e.g.*, reports submitted to applicants by FDA; reports obtained from FDA from freedom of information requests at the discretion of applicants; reports from class action lawsuits). The proposed rule would require that cumulative data be provided for SADRs that are determined to be both serious and unexpected (*i.e.*, all cases reported to date). These summary tabulations would be presented by body system or standard organ system classification scheme (*e.g.*, cardiovascular, central nervous system, endocrine, renal). The proposed rule would also require summary tabulations for all domestic reports of actual medication errors (*i.e.*, serious SADRs, nonserious SADRs, no SADRs) and potential medication errors (*i.e.*, number of reports for specific errors) that were previously submitted to the agency as an expedited report.

In the guidance of 1992, FDA advises applicants to include in their postmarketing periodic safety reports a listing by body system of all adverse drug experience terms and counts of occurrences submitted during the reporting period. FDA is now proposing to clarify and codify this expectation.

III.E.1.f. *History of safety-related actions taken.* Proposed §§ 314.80(c)(3)(i)(C), and 600.80(c)(3)(i)(C) would amend §§ 314.80(c)(2)(ii)(*c*) and 600.80(c)(2)(ii)(C) by adding the phrase ''safety-related'' before the word ''actions'' and by removing the phrase ''because of adverse drug experiences.'' FDA is proposing these changes because actions may be taken for safety-related reasons other than SADRs. The proposed rule would also amend these regulations by adding the phrase ''periodic safety'' before the word ''report'' for clarification.

III.E.1.g. *Location of safety records.* Proposed §§ 314.80(c)(3)(i)(D) and 600.80(c)(3)(i)(D) would require another new section in TPSRs that would contain a list of the current address(es) where all safety reports and other safety-related records for the drug product or licensed biological product are maintained. FDA is proposing to require a list of these addresses to provide rapid access to safety-related records for FDA inspections and for requests by FDA for additional information concerning safety issues.

III.E.1.h. *Contact person.* Proposed §§ 314.80(c)(3)(i)(E) and 600.80(c)(3)(i)(E) would require another new section in TPSRs that would contain the name and telephone number of the licensed physician or licensed physicians responsible for the content and medical interpretation of the data and information contained within the TPSR. The fax number and e-mail address for the licensed physician would also be included, if available. This proposal would provide the agency with someone to contact with any questions that may arise during review of a TPSR. FDA is proposing that the contact persons be licensed physicians because of their crucial knowledge of the medical significance of the information provided in a TPSR.

Table 10 highlights the differences in content between the currently required postmarketing periodic adverse drug experience reports and proposed TPSRs.

TABLE 10.—DIFFERENCES BETWEEN THE CURRENT REQUIREMENT FOR THE CONTENT OF POSTMARKETING PERIODIC ADVERSE DRUG EXPERIENCE REPORTS AND THE PROPOSED CONTENT OF TPSRS.

Content of periodic adverse drug experience report	Proposed revisions to content of periodic adverse drug experience report (proposed TPSRs)
Narrative summary and analysis of the information contained in the report.	Excludes nonserious expected SADRs. Includes discussion of increased frequency of serious expected SADRs and lack of efficacy reports. Includes applicant's recommendations for safety-related actions to be taken.
Analysis of expedited reports submitted to FDA during the reporting interval.	Not revised.
FDA Form 3500A (VAERS form for vaccines) for each adverse drug experience not submitted to FDA as an expedited report.	Revoked requirement. [1]
Index consisting of a line listing of the applicant's patient identification number and adverse reaction term(s).	Not revised.
History of actions taken since the last report because of adverse drug experiences.	Not revised. Require submission summary tabulations.[2] New section added for location of safety records. New section added for contact information for licensed physician responsible for information in TPSR.

[1] Individual case safety reports would be submitted to FDA separately on a semiannual basis (see section III.E.4 of this document).

[2] Summary tabulations are currently requested (see the guidance of 1992) but not required for postmarketing periodic adverse drug experience reports.

III.E.2. Periodic Safety Update Reports (PSURs)

Proposed §§ 314.80(c)(3)(ii) and 600.80(c)(3)(ii) would amend FDA's postmarketing periodic safety reporting regulations by adding a new type of postmarketing periodic safety report. This new report would be identified as a ''periodic safety update report (PSUR).'' The proposed content and format for the PSUR, as described below, are consistent with the ICH E2C guidance (62 FR 27470) and would enable applicants to submit a single core document (PSUR excluding appendices) to regulatory authorities worldwide. All dosage forms, formulations, and indications for which applicants hold an approved application (*i.e.*, NDA, ANDA, BLA) for a given drug substance or licensed biological product should usually be covered in one PSUR. The PSUR may include separate presentations of these data as well as other data (*e.g.*, populations) if such presentations would facilitate review of the PSUR. FDA is proposing that a PSUR contain the following information:

III.E.2.a. *Title page, table of contents, and introduction.* The title page would include, at a minimum, the following information:

- Name and international birth date of the drug substance or licensed biological product that is the subject of the PSUR,
- Various dosage forms and formulations of the drug substance or biological product covered by the PSUR,
- Name and address of the applicant,
- Reporting period covered by the PSUR, and
- Date of the PSUR.

The introduction would provide a brief description of how this PSUR relates to previous reports and circumstances, would reference relevant drug products, drug substances, or biological products reported in other periodic safety reports (*e.g.*, a combination product reported in a separate PSUR), and would indicate any data duplication with other PSURs. If two or more companies co-market the same drug substance or licensed biological product, the safety reporting responsibilities of each of the companies should be specified clearly in the introduction.

III.E.2.b. *Worldwide marketing status.* This section of the PSUR would contain a table of the chronological history of the worldwide marketing status of the drug or biological product(s) covered by the PSUR from the date the product was first approved (*i.e.*, the international birth date) through its current status (*i.e.*, cumulative information). The table would include:

- Dates of drug or biological product approval and renewal,
- Safety-related restrictions on product use,
- Indications for use and special populations covered by the drug or biological product approval,
- Lack of approval of the drug substance or biological product in any dosage form or for any indication for use by any regulatory authority(ies),
- Withdrawal of a pending drug or biological product marketing application by the applicant for safety- or efficacy-related reasons,
- Dates of market launches, and
- Trade name(s).

Drug or biological products that are approved in a country for a particular indication, population, or dosage form that may result in different types of patient exposure in that country should be identified, particularly if there are meaningful differences in the safety information reported in the PSUR due to the difference in patient exposures.

III.E.2.c. *Actions taken for safety reasons.* This section of the PSUR would contain details on regulatory authority-initiated (*e.g.*, FDA) and/or applicant-initiated actions related to safety that were taken during the period covered by the PSUR and between the data lock point and PSUR submission (*i.e.*, ''late-breaking'' safety concerns) including:

- Withdrawal or suspension of product approval or indication for use approval,
- Failure to obtain a marketing authorization renewal or to obtain an approval for a new indication for use,
- Restrictions on distribution (*e.g.*, products recalled for safety reasons),
- Clinical trial suspension,
- Dosage modification,
- Changes in target population or indications, and
- Formulation changes.

This section of the PSUR would also contain a narrative identifying the safety-related reasons that led to these actions with relevant documentation appended when appropriate. Any communication with health care professionals (*e.g.*, Dear Healthcare Professional letters) resulting from such actions would also be described with copies appended.

III.E.2.d. *Changes to CCSI.* This section of the PSUR would describe changes to the CCSI (*e.g.*, new contraindications, precautions, warnings, SADRs, or interactions) made during the period covered by the PSUR. A copy of any modified section of the CCSI would be included. Applicants would use the CCSI in effect at the beginning of the reporting period for the PSUR. The revised CCSI would be used as the reference document for the next reporting period.

III.E.2.e. *Worldwide patient exposure.* This section of the PSUR would include, for the reporting period, an estimate of the worldwide patient exposure to the drug or biological product(s) covered by the PSUR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). In many cases, accurate patient exposure data for a reporting period may be difficult to obtain. However, applicants should exercise due diligence to obtain an estimate of this exposure. The method used to estimate patient exposure would always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions would be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, could be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales could be used with estimates of what such numbers may mean in terms of patient exposure.

When possible, data broken down by gender and age (especially pediatric versus adult) would be provided. Data for the pediatric population would be reported, if possible, by age group (*e.g.*, neonates, infants, children, adolescents). If these data are not available, an explanation for the lack of such information would be included. In addition, when a pattern of reports indicates a potential problem, details by country (with locally recommended dosage regimens) or other segmentation (*e.g.*, indication, dosage form) would also be presented.

Patient exposure for clinical studies should also be provided when SADR data from these types of studies are included in the PSUR. For ongoing or blinded clinical studies, an estimate of patient exposure should be provided.

III.E.2.f. *Individual case safety reports.*

III.E.2.f.i. *Line listings.* Individual line listings of various data points from individual case safety reports are included as part of the format for international PSURs agreed to by ICH (ICH E2C guidance, 62 FR 27470 at 27473 and 27474). FDA will not require submission of such line listings in PSURs because, instead, the agency is proposing to require a separate

semiannual submission of certain individual case safety reports on FDA Form 3500A (VAERS form for vaccines, CIOMS I form, if desired, for foreign SADRs) (*see* section III.E.4 of this document). However, FDA is willing to accept line listings in PSURs as described in the ICH E2C guidance if applicants wish to include them. FDA believes that such an approach will help further the goal of harmonizing PSUR generation, formatting, and submission globally.

III.E.2.f.ii. *Summary tabulations.* This section of the PSUR would consist of summary tabulations of individual case safety reports (*e.g.*, serious unlisted SADRs, serious listed SADRs, nonserious unlisted SADRs, nonserious listed SADRs) for the following SADRs obtained or otherwise received during the reporting period:

- All serious and nonserious SADRs from spontaneous sources that were submitted to applicants by a health care professional,
- All serious SADRs from studies, individual patient INDs, or, in foreign countries, from named-patient ''compassionate'' use,
- All serious SADRs and nonserious unlisted SADRs from the scientific literature,
- All serious SADRs from regulatory authorities, and
- Serious SADRs from other sources such as reports created by poison control centers and epidemiological data bases.

These summary tabulations would be made up of lists by body system or standard organ system classification scheme (*e.g.*, cardiovascular, central nervous system, endocrine, renal) of all SADR terms and counts of occurrences. For SADRs that are determined to be both serious and unlisted, cumulative data would also be provided (*i.e.*, all cases reported to date). Applicants may provide information for this section of the PSUR in a narrative rather than a summary tabulation if the number of cases is small or the information is inadequate for any of the tabulations.

As noted previously, FDA would consider ''study'' information to include the following: safety information from company-sponsored patient support programs, disease management programs, patient registries, including pregnancy registries, or any organized data collection scheme (*see* section III.A.7 of this document). FDA is proposing to include summary tabulations for serious listed SADRs from study information in PSURs to be consistent with the ICH E2C guidance (62 FR 27470 at 27474), even though the agency indicated in the clarification guidance of 1997 that only serious and unexpected adverse drug experiences for which there is a reasonable possibility that the drug or biological product caused the adverse drug experience should be reported to FDA from studies.

This section of the PSUR would also contain a brief discussion of the individual case data in the summary tabulations (*e.g.*, discussion of medical significance or mechanism). This section of the PSUR should be used to comment on specific cases rather than to provide an overall assessment of the cases.

III.E.2.g. *Safety studies.* This section of the PSUR would contain a discussion (not just a listing of the studies) of nonclinical, clinical, and epidemiological studies concerning important safety information including:

- All applicant-sponsored studies newly analyzed during the reporting period;
- New studies specifically planned, initiated, or continuing during the reporting period that examine a safety issue, whether actual or hypothetical; and
- Published safety studies in the scientific and medical literature, including relevant published abstracts from meetings (provide citations for all reports from the literature).

As noted previously, FDA would consider ''study'' information to include the following: safety information from company-sponsored patient support programs, disease management programs, patient registries, including pregnancy registries, or any organized data collection scheme (*see* section III.A.7 of this document).

The study design and results of newly analyzed studies should be clearly and concisely presented with attention to the usual standards of data analysis and description that are applied to nonclinical and clinical study reports. Copies of full reports for these studies should be appended only if new safety issues are raised or confirmed. FDA may request copies of other studies, if necessary.

For new or ongoing studies, the objective, starting date, projected completion date, number of subjects (planned and enrolled), and protocol abstract for each study should be provided. When possible and relevant, interim results of ongoing studies should be presented.

III.E.2.h. *Other information.* This section of the PSUR would contain a discussion of medically relevant lack of efficacy reports (*e.g.*, might represent a significant hazard to the treated population) for a product(s) used to treat serious or life-threatening diseases, or any important new information received after the data lock point (*e.g.*, significant new cases).

III.E.2.i. *Overall safety evaluation.* This section of the PSUR would contain a concise, yet comprehensive, analysis of all of the safety information provided in the PSUR, including new information provided under the section entitled ''Other Information.'' In addition, the section would include an assessment by applicants of the significance of the data collected during the reporting period, as well as from the perspective of cumulative experience. Applicants would highlight any new information on:

- Serious, unlisted SADRs;
- Increased reporting frequencies of listed SADRs, including comments on whether it is believed that the data reflect a meaningful change in SADR occurrence;
- A change in characteristics of listed SADRs (*e.g.*, severity, outcome, target population); and
- Nonserious, unlisted SADRs.

As part of the overall safety evaluation, applicants would also explicitly address any new safety issue including but not limited to the following:

- Drug interactions;
- Experience with overdose, whether deliberate or accidental, and its treatment;
- Drug abuse or intentional misuse;
- Positive or negative experiences during pregnancy or lactation;
- Effects with long-term treatment; and
- Experience in special patient groups (*e.g.*, pediatric population evaluated, if possible, by age group; geriatric; organ impaired).

Applicants would note a lack of significant new information for any of these categories.

III.E.2.j. *Conclusion.* This section of the PSUR would indicate new safety information that is not in accord with previous cumulative experience and with the CCSI in use at the beginning of the reporting period (*e.g.*, new evidence that strengthens a possible causal relationship between the drug or biological product and an SADR, such as positive rechallenge, an epidemiological association, or new laboratory studies). This section of the PSUR would also specify and justify any action recommended or initiated, including changes in the CCSI.

III.E.2.k. *Appendices.* This section of the PSUR would include the following information as appendices:

III.E.2.k.i. *Company core data sheet.* A copy of the company core data sheet covered by the PSUR (*i.e.*, in effect at the beginning of the period covered by the PSUR) would be provided. The company core data sheet would be numbered and dated and include the date of last revision. In addition, a copy of the company core data sheet for the next reporting period would be provided.

III.E.2.k.ii. *U.S. labeling.* A copy of the current approved U.S. labeling would be provided. Any safety information that is included in the CCSI but not in the U.S. labeling would be identified and an explanation for the discrepancy provided. Any safety-related changes or proposed changes to the U.S. labeling made during the reporting period would be described, including the supplement numbers and dates of submission for the supplements. Any suggested change or changes in the U.S. labeling that should be considered based on the safety analysis in the PSUR would also be described. (If appropriate, a supplemental application would be filed with FDA concerning those changes as prescribed under §§ 314.70 or 601.12.)

III.E.2.k.iii. *Spontaneous reports submitted to the applicant by an individual other than a health care professional.* This appendix would contain summary tabulations (*e.g.*, serious unlisted SADRs, serious listed SADRs, nonserious unlisted SADRs, nonserious listed SADRs) for all spontaneously reported serious SADRs, whether domestic or foreign, and all spontaneously reported nonserious SADRs occurring in the United States, obtained or otherwise received during the reporting period by the applicant from an individual other than a health care professional (*e.g.*, SADR reports from consumers). These summary tabulations would consist of lists by body system or by standard organ system classification scheme (*e.g.*, cardiovascular, central nervous system, endocrine, renal) of all SADR terms and counts of occurrences. For those SADRs that are determined to be both serious and unlisted, cumulative data (*i.e.*, all cases reported to date by individuals other than a health care professional) would also be provided. The impact of these spontaneous reports on the overall safety evaluation would be discussed briefly. FDA may require applicants to submit to the agency, when appropriate, SADR reports (*e.g.*, FDA Form 3500As), within 5 calendar days after receipt of the request, for any or all of the SADRs contained within this appendix (*see* section III.H of this document).

III.E.2.k.iv. *SADRs with unknown outcome.* This appendix would contain summary tabulations for unlisted and listed SADRs with unknown outcome from all spontaneous sources (*i.e.*, health care professionals and other individuals), obtained or otherwise received by the applicant during the reporting period. These summary tabulations would consist of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. The impact of these spontaneous reports on the overall safety evaluation would be discussed briefly. FDA may require applicants to submit to the agency, when appropriate, individual case safety reports (*e.g.*, FDA Form 3500As), within 5 calendar days after receipt of the request, for any or all of the listed SADRs with unknown outcome contained within this appendix (*see* section III.H of this document).

III.E.2.k.v. *Class action lawsuits.* This appendix would contain summary tabulations (*e.g.*, serious unlisted SADRs, serious listed SADRs, nonserious unlisted SADRs, nonserious listed SADRs) for all SADRs obtained or otherwise received during the reporting period by the applicant from class action lawsuits. These summary tabulations would consist of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. For SADRs that are both serious and unlisted, cumulative data would also be provided. The impact of these reports on the overall safety evaluation would be discussed briefly. FDA may require applicants to submit to the agency, when appropriate, individual case safety reports (*e.g.*, FDA Form 3500As), within 5 calendar days after receipt of the request, for any or all of the SADRs contained within this appendix (see section III.H of this document).

III.E.2.k.vi. *Lack of efficacy reports.* This appendix would contain an assessment of whether it is believed that the frequency of lack of efficacy reports, obtained or otherwise received during the reporting period, is greater than would be predicted by the premarketing clinical trials for the drug or biological product. This assessment would be provided whether a serious SADR, nonserious SADR, or no SADR results from a lack of efficacy of the product.

III.E.2.k.vii. *Information on resistance to antimicrobial drug products.* This appendix would contain information, received or otherwise obtained by the applicant, on resistance to antimicrobial drug products intended to treat infectious diseases. Information would include:

- Changes in U.S. microbial in vitro susceptibility,
- The relationship of changes in U.S. microbial in vitro susceptibility and clinical outcomes,
- Therapeutic failure that may possibly be due to resistance to the antimicrobial drug product, and
- Whether the U.S. labeling should be revised because of the information on antimicrobial resistance learned during the period covered by the report.

III.E.2.k.viii. *Medication errors.* This appendix would contain summary tabulations for all domestic reports of medication errors submitted during the reporting period as an expedited report. For actual medication errors, summary tabulations would be provided for serious SADRs, nonserious SADRs, and no SADRs. For serious SADRs, cumulative data (*i.e.*, all cases reported to date) would also be provided. For potential medication errors, the number of reports for specific errors would be provided. If an SADR occurs, the summary tabulations would consist of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. The impact of these reports on the overall safety evaluation would be discussed briefly.

III.E.2.k.ix. *U.S. patient exposure.* This appendix would contain, for the reporting period, an estimate of the U.S. patient exposure to the drug product(s) or biological product(s) covered by the PSUR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure would always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions would be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

III.E.2.k.x. *Location of safety records.* This appendix would contain a list of the current address(es) where all safety reports and other safety-related records for the drug product or licensed biological product are maintained. The list of addresses would provide rapid access to safety-related records for FDA inspections and for requests by FDA for additional information concerning safety issues.

III.E.2.k.xi. *Contact person.* The name and telephone number of the licensed

physician or licensed physicians responsible for the content and medical interpretation of the data and information contained within the PSUR would be provided. The fax number and e-mail address of the licensed physician would also be included, if available. This proposal would provide the agency with someone to contact with any questions that may arise during review of a PSUR. FDA is proposing that the contact persons be licensed physicians because of their crucial knowledge of the medical significance of the information provided in a PSUR.

The PSUR excluding appendices, as proposed in this rule, would represent a harmonized core document for worldwide postmarketing periodic safety reporting for marketed drugs and licensed biological products.

III.E.3. Interim Periodic Safety Reports (IPSRs)

Proposed §§ 314.80(c)(3)(iii) and 600.80(c)(3)(iii) would amend FDA's postmarketing periodic safety reporting regulations by adding another new type of postmarketing periodic safety report. FDA is proposing that this new report be identified as an ''interim periodic safety report (IPSR).'' An IPSR would contain the same information as a PSUR, except that the following information would not be provided:

- Summary tabulations for individual case safety reports, obtained or otherwise received during the reporting period and brief discussion of the data concerning these reports (*see* section III.E.2.f.ii of this document),
- Any important new information received after the data lock point (*e.g.*, significant new cases) (*see* section III.E.2.h of this document),
- Summary tabulations for spontaneous reports of SADRs submitted to the applicant by an individual other than a health care professional (see section III.E.2.k.iii of this document),
- Summary tabulations for spontaneous reports of SADRs with unknown outcome submitted to the applicant by health care professionals and other individuals (*see* section III.E.2.k.iv of this document),
- Summary tabulations for reports of SADRs from class action lawsuits (*see* section III.E.2.k.v of this document),
- Summary tabulations of domestic reports of medication errors (*see* section III.E.2.k.viii of this document).

The IPSR would provide the agency with an overview of the safety profile of a drug product containing a drug substance or biological product without requiring summary information on individual case safety reports.

III.E.4. Semiannual Submission of Individual Case Safety Reports

Currently, postmarketing periodic safety reporting regulations (§§ 314.80(c)(2)(ii)(*b*) and 600.80(c)(2)(ii)(B)) require applicants to submit to FDA in periodic adverse drug experience reports an FDA Form 3500A (VAERS form for vaccines) for each spontaneously reported adverse drug experience occurring in the United States that has not been submitted to the agency as an expedited report (*i.e.*, serious, expected adverse drug experiences and all nonserious adverse drug experiences, whether unexpected or expected). FDA is proposing to remove this requirement (*see* section III.E.1.b of this document). Instead, under proposed §§ 314.80(c)(3)(v) and 600.80(c)(3)(v), the agency would require applicants to submit semiannually a separate report to FDA consisting of a compilation of FDA Form 3500As (VAERS forms for vaccines, CIOMS I forms, if desired, for foreign SADRs) for certain spontaneously reported individual case safety reports as described in the following explanation. This report would be identified as ''Individual Case Safety Reports—Semiannual Submission.''

The semiannual submission from applicants that submit TPSRs for a drug or licensed biological product would include an individual case safety report for each serious, expected SADR, whether domestic or foreign, and each nonserious, unexpected SADR occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals). The semiannual submission for vaccines would also include an individual case safety report for each nonserious, expected SADR and each expected SADR with unknown outcome occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources. For drugs and licensed biological products that are not vaccines, nonserious, expected SADRs and expected SADRs with an unknown outcome would not be submitted as individual case safety reports in a semiannual submission. Instead, they would be reported as part of a summary tabulation in a TPSR (*see* section III.E.1.e of this document).

The semiannual submission from applicants that submit PSURs for a drug product containing a drug substance or licensed biological product would include an individual case safety report for each serious, listed SADR, whether domestic or foreign, and each nonserious, unlisted SADR occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources. The semiannual submission for vaccines would also include an individual case safety report for each nonserious, listed SADR and each listed SADR with unknown outcome occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources. For drugs and licensed biological products that are not vaccines, nonserious, listed SADRs and listed SADRs with an unknown outcome would not be submitted as individual case safety reports in a semiannual submission. Instead, they would be reported as part of a summary tabulation in a PSUR (*see* sections III.E.2.f.ii and III.E.2.k.iii of this document). The semiannual submission should not include individual case safety reports for serious, listed SADRs that were previously submitted to FDA as a serious, unexpected SADR in an expedited report (*i.e.*, the agency does not want to receive duplicative reports for the same SADR).

FDA needs to continue to receive information on serious, expected/listed SADRs and nonserious SADRs, whether unexpected/unlisted or expected/listed, to monitor the safety profile of marketed products to determine if studies need to be undertaken to evaluate a particular issue and/or to take appropriate regulatory action (*e.g.*, labeling change, distribution of Dear Healthcare Professional letter, restriction on distribution of product, withdrawal of product from the market). Reports of serious, expected/listed SADRs are used to monitor changes in the frequency of occurrence or severity of a serious, expected/listed SADR (*e.g.*, frequency of serious, expected/listed SADR increases because product interacts with a new approved product that is frequently used concomitantly with the product). The agency's proposal to require submission of spontaneously reported serious, expected/listed SADRs from foreign sources would provide FDA with important information that the agency currently does not receive (*e.g.*, reports from foreign countries in which the product is approved for more indications than in the United States or the product results in exposure to certain populations that are limited in the United States).

Reports of nonserious, unexpected/unlisted SADRs are used to identify new nonserious SADRs that are associated with the use of a product (*e.g.*, sedation, sexual dysfunction, gastrointestinal distress). This information is valuable

for individuals taking the product because, if one of these SADRs occurs, the individual might suspect that it was due to the product and not due to the onset of a new disorder. These reports may also serve to signal the emergence of a serious, unexpected/unlisted SADR (*e.g.*, an aggregate of reports of decreased white blood cell counts may be an early indicator of a serious condition such as bone marrow suppressive disorder).

The reports (*i.e.*, individual case safety reports for vaccines or summary tabulations for drugs and licensed biological products that are not vaccines) of nonserious, expected/listed SADRs are used to monitor changes in the frequency of occurrence or severity of a nonserious, expected/listed SADR. Such information could indicate a potential safety problem that is worthy of further investigation (*e.g.*, a new drug or food interaction not previously associated with use of the product).

Proposed changes to FDA's current reporting requirements for these types of SADRs include: (1) Different reporting frequencies for the SADRs, (2) receipt of spontaneously reported serious, expected/listed SADRs from foreign sources and (3) submission of nonserious, expected/listed SADRs in a summary tabulation instead of as individual case safety reports for drugs and licensed biological products that are not vaccines. With regard to different reporting frequencies, some SADRs would be reported less frequently (*e.g.*, semiannually rather than every 3 months) and others would be reported more frequently (*e.g.*, semiannually rather than annually). FDA seeks comment on these proposed changes.

The current approved U.S. labeling would be used as the reference document to determine whether an SADR is unexpected or expected, and the CCSI would be used to determine whether an SADR is unlisted or listed.

As described previously, a minimum data set would be required for all individual case safety reports of an SADR (*see* section III.C.5 of this document). In addition, a full data set would be required for reports of serious, expected SADRs and serious, listed SADRs. If a full data set is not available for these SADR reports, the information required under proposed §§ 314.80(c)(1)(iv) and 600.80(c)(1)(iv) would be provided. For nonserious SADRs with a minimum data set, the proposal would require that all safety information received or otherwise obtained be submitted. The proposal would not require that information in addition to the minimum data set be acquired. Thus, followup would not be required for nonserious SADRs that contain a minimum data set.

Followup information on SADRs submitted in an individual case safety report—semiannual submission may be submitted in the next individual case safety report—semiannual submission, unless such information changes the classification of the SADR to a serious, unexpected SADR. In these cases, the followup information would be submitted to FDA as an expedited 15-day followup report (*see* section III.D.6 of this document).

Applicants should not submit any reports of lack of efficacy in an individual case safety report—semiannual submission. As noted previously, applicants would be required to submit to FDA in an expedited manner information regarding certain lack of efficacy reports for the product (*i.e.*, expedited reports of information sufficient to consider product administration changes) and also to provide in postmarketing periodic safety reports an assessment of all lack of efficacy reports for the product as compared to premarketing clinical trials for the product (see section III.C.7 of this document).

Applicants should not submit SADRs from class action lawsuits to FDA in an individual case safety report—semiannual submission. The agency believes, as noted previously, that SADRs from class action lawsuits would be submitted to FDA from other sources (*e.g.*, spontaneous report) prior to initiation of the class action lawsuit (*see* section III.D.11 of this document). Summary tabulations of these SADRs would be required to be included in postmarketing periodic safety reports (*see* sections III.E.1.e and III.E.2.k.v of this document).

Applicants should not submit reports of medication errors in an individual case safety report—semiannual submission. These reports would be submitted, as previously noted, as an expedited report (*see* section III.D.5 of this document).

III.E.5. Reporting Requirements

III.E.5.a. *Reporting intervals.* Current regulations (§§ 314.80(c)(2)(i) and 600.80(c)(2)(i)) require the submission of postmarketing periodic safety reports at quarterly intervals for 3 years from the date of approval of the application in the United States and then annually thereafter. Quarterly safety reports must be submitted within 30 days of the close of the quarter (the first quarter beginning on the date of U.S. approval of the application); annual safety reports must be submitted within 60 days of the anniversary date of U.S. approval of the application. FDA is proposing revisions to these reporting requirements. The proposals are consistent with the recommendations of ICH (62 FR 27470 at 27472): ''Therefore, it is recommended that the preparation of PSUR's for all regulatory authorities should be based on data sets of 6 months or multiples thereof.''

Products approved before January 1, 1998. Proposed §§ 314.80(c)(3)(i) and 600.80(c)(3)(i) would require applicants holding an NDA, ANDA, or BLA that was approved for initial marketing of a drug product containing a drug substance or licensed biological product *before* January 1, 1998, to submit either a TPSR or a PSUR every 5 years after U.S. approval of the application. The proposed rule would also require these applicants to submit a TPSR or an IPSR 7.5 years and 12.5 years after U.S. approval of the application. Under proposed §§ 314.80(c)(3)(iii) and 600.80(c)(3)(iii), the reporting period for an IPSR would cover the period between the last PSUR or TPSR and the data lock point for the IPSR (*e.g.*, between years 5 and 7.5 for an IPSR with a data lock point at 7.5 years after U.S. approval of the application).

Products approved on or after January 1, 1998. Under proposed §§ 314.80(c)(3)(ii) and 600.80(c)(3)(ii), applicants holding an NDA, ANDA, or BLA that was approved for initial marketing of a drug product containing a drug substance or licensed biological product on or after January 1, 1998, would be required to submit a PSUR to FDA with the following schedule:

- Semiannually (*i.e.*, every 6 months) for 2 years after U.S. approval of the application,
- Annually for the next 3 years, and then
- Every 5 years thereafter.

The proposed rule would also require applicants to submit an IPSR 7.5 years and 12.5 years after U.S. approval of the application.

Products with approved pediatric use supplements. Proposed §§ 314.80(c)(3)(iv) and 600.80(c)(3)(iv) would require applicants holding an approved pediatric use supplement to an approved application (*i.e.*, a supplement for use of the human drug or biological product in the pediatric population) to submit a PSUR to FDA with the following schedule:

- Semiannually (*i.e.*, every 6 months) for 2 years after U.S. approval of the supplement,
- Annually for the next 3 years, and
- Then every 5 years thereafter.

The proposed rule would also require these applicants to submit an IPSR 7.5

years and 12.5 years after U.S. approval of the supplement. These applicants would be required to submit PSURs and IPSRs to FDA even if the pediatric use supplement or original application was approved prior to January 1, 1998. FDA is proposing this action to harmonize acquisition of new safety information regarding pediatric populations for timely review by the agency.

All products. Under proposed §§ 314.80(c)(3)(v) and 600.80(c)(3)(v), applicants holding an NDA, ANDA, or BLA would be required to submit an individual case safety reports—semiannual submission to FDA every 6 months after U.S. approval of an application. The 6-month interval for these reports would coincide with the reporting interval (6-month or multiples of 6 months) for TPSRs, PSURs or IPSRs.

Alternative reporting frequency. Proposed §§ 314.80(c) and 600.80(c) would provide that, when appropriate, FDA may require in writing that applicants submit postmarketing periodic safety reports at time intervals other than prescribed by the regulations (see section III.C.4 of this document). Usually such variations would occur if new safety concerns arose requiring more timely reporting (*e.g.*, approval of a new indication or dosage form for the product, approval for use of the product in a new population, new safety issues in individual case safety reports submitted to FDA for the product). When anticipated, FDA would state the revised reporting interval in the approval letter for the new indication, new population, or new dosage form. In other cases, such revisions to the reporting interval would be conveyed to applicants in a written letter from the director of the responsible review division in FDA with an explanation of why such a new reporting time interval is required.

III.E.5.b. *Submission date.* Proposed §§ 314.80(c)(3) and 600.80(c)(3) would require that the data lock point for postmarketing periodic safety reports be the month and day of the international birth date of the drug product (proposed §§ 314.80(c)(3)(i) and 314.80(c)(3)(v)), drug substance (proposed §§ 314.80(c)(3)(ii), 314.80(c)(3)(iii), and 314.80(c)(3)(iv)) or licensed biological product (proposed §§ 600.80(c)(3)(i) through 600.80(c)(3)(v)) or any other month and day agreed on by the applicant and FDA. For example, applicants that are submitting PSURs on an every 5 year basis may, in agreement with FDA, change the data lock point to facilitate international reporting so long as there is never a time period of greater than 5 years in which FDA has not received a PSUR. Or, the applicant and FDA may agree to change the data lock point to the month and day of U.S. approval of the application if this date would result in better use of the applicant's resources.

Proposed §§ 314.80(c)(3) and 600.80(c)(3) would require that all postmarketing periodic safety reports be submitted to FDA within 60 calendar days after the data lock point for the report. As noted previously, the data lock point (*i.e.*, month and day) for postmarketing periodic safety reports would be based on the month and day of the international birth date for the product and the frequency for submission of these reports would be based on the product's date (*i.e.*, year) of U.S. approval (*see* section III.A.10 of this document).

III.E.5.c. *Cover letter.* Proposed §§ 314.80(c)(3) and 600.80(c)(3) would require that applicants include a cover letter with all postmarketing periodic safety reports (*i.e.*, TPSRs, PSURs, IPSRs, individual case safety reports—semiannual submissions). This cover letter would contain a list of the NDA and/or ANDA numbers for the human drug products or BLA numbers for the human biological products covered by the report.

III.E.5.d. *International birth date for combination products.* Proposed §§ 314.80(c)(3) and 600.80(c)(3) would also state that the international birth date for combination products would be the international birth date of the human drug product containing the drug substance or licensed biological product that was most recently approved for marketing. For combination products that are also marketed individually, applicants may submit either a separate PSUR for the combination product or include information for the combination product as a separate presentation in the PSUR for one of the individual components.

III.F. Reporting Format

Current postmarketing safety reporting regulations at §§ 310.305(d)(1), 314.80(f)(1), and 600.80(f)(1) require persons subject to these requirements to submit an FDA Form 3500A (VAERS form for vaccines) for each report of an adverse drug experience. Foreign SADRs, including those associated with the use of vaccines, may be submitted on an FDA Form 3500A or, if preferred, on a CIOMS I form.

III.F.1. Forms Versus Narrative Format

Proposed §§ 310.305(d)(1), 314.80(c)(4)(i), and 600.80(c)(4)(i) would amend the current postmarketing safety reporting format regulations by reorganizing these regulations and by adding new information. Proposed §§ 310.305(d)(1)(i) would prescribe, except as provided in the regulations, that:

> * * * the manufacturer must complete an FDA Form 3500A for each individual case safety report of an SADR. Reports based on information about individual cases or case series in the scientific literature must be submitted on an FDA Form 3500A(s).

Proposed §§ 314.80(c)(4)(i)(A) and 600.80(c)(4)(i)(A) would prescribe the same requirements for submission of postmarketing individual case safety reports by applicants. Proposed § 600.80(c)(4)(i)(A) would also describe requirements for use of the VAERS form for vaccines. Proposed §§ 310.305(d)(1)(ii), 314.80(c)(4)(i)(B) and 600.80(c)(4)(i)(B) would prescribe that:

> Foreign SADRs may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form (foreign SARs for vaccines, may be submitted either on a VAERS form, or, if preferred, on a CIOMS I form, for proposed § 600.80(c)(4)(i)(B)).

Proposed §§ 310.305(d)(1)(iii), 314.80(c)(4)(i)(C) and 600.80(c)(4)(i)(C) would prescribe that:

> Each domestic report of an actual or potential medication error must be submitted on an FDA Form 3500A (or, for vaccines, on a VAERS form for proposed § 600.80(c)(4)(i)(C)).

Proposed §§ 310.305(d)(1)(iv), 314.80(c)(4)(i)(D) and 600.80(c)(4)(i)(D) would prescribe that:

> Reports of overall findings or data in the aggregate from published and unpublished in vitro, animal, epidemiological, or clinical studies must be submitted in a narrative format.

These proposed amendments would clarify the reporting format that would be required for individual case safety reports or other safety information (*i.e.*, overall findings or data in the aggregate). Reports of actual and potential medication errors would be required to be submitted on an FDA Form 3500A (or VAERS form, as appropriate) because these reports describe an individual case even if an SADR does not occur or a patient is not identifiable. Reports of overall findings or data in the aggregate would be submitted in a narrative format rather than on FDA Form 3500A because FDA Form 3500A has been designed for reporting of data from an individual case.

III.F.2. Medical Dictionary for Regulatory Activities (MedDRA)

ICH has developed an international medical terminology, MedDRA (the

medical dictionary for regulatory activities), to support the computerization and transmission of information related to many aspects of the regulation of medical products (ICH M1). Use of a single medical terminology internationally would facilitate global communication of safety information for human drug and biological products (*see* section II.B.1 of this document).

Proposed §§ 310.305(d)(2), 314.80(c)(4)(ii), and 600.80(c)(4)(ii) would require that each SADR in an individual case safety report be coded on the FDA Form 3500A, CIOMS I Form, or VAERS Form using the appropriate ''preferred term'' in the latest version of MedDRA in use at the time the manufacturer or applicant becomes aware of the individual case safety report. FDA is proposing to require use of MedDRA to be consistent with ICH M1.

Proposed §§ 310.305(d)(2), 314.80(c)(4)(ii), and 600.80(c)(4)(ii) would also require that each individual case safety report of a medication error be coded both as a medication error and, if applicable, with the preferred term for any SADRs associated with the medication error. The proposal clarifies how actual and potential medication errors would be coded.

MedDRA must be licensed for a fee from an international MSSO. TRW was selected as the MSSO by ICH and the International Federation of Pharmaceutical Manufacturers Associations (IFPMA) through a contract process that involved bids from companies globally. FDA was involved in this process. The costs that would be imposed on industry to license MedDRA was a consideration in the selection of the MSSO.

Companies may license the latest version of MedDRA 5.1 by contacting TRW in Reston, VA, toll free number 877–258–8280 (703–345–7799 in Washington, DC area), FAX 703–345–7755, e-mail *subscrib@meddramsso.com,* Internet at *www.meddramsso.com.* Updated versions of MedDRA will be provided to subscribers as part of the annual licensing fee.

MedDRA is a hierarchical system composed of various levels of terminology (*i.e.*, system organ class, high level group term, high level term, preferred term, lower level term). The agency is proposing to require use of the preferred term for reporting to FDA because each preferred term represents a unique medical concept accepted internationally, which will aid in the transmission and translation of reports from various parts of the world. The preferred term provides medically validated representations of colloquial terms, which will result in fewer misrepresentations and misunderstandings of colloquial reports from various parts of the world. The preferred term also provides medically validated representations of noncurrent terms in other previously widely used coding terminologies such as COSTART and WHOART.

FDA believes that use of MedDRA, a standardized medical terminology, will be welcomed by most of industry. However, for some manufacturers and applicants, use of MedDRA may result in a significant economic hardship. Applicants may request, under §§ 314.90 or 600.90, that FDA waive the requirement that each SADR in an individual case safety report be coded using MedDRA. If FDA finds that this requirement is economically burdensome for a small company, the agency intends to grant the company a waiver. A large company may also be granted a waiver if, for instance, it only markets a single product that generates a few safety reports a year. FDA intends to grant all reasonable waiver requests. This determination will be made on a case-by-case basis.

III.F.3. Single Form for Each Identifiable Patient

Current postmarketing safety reporting regulations, at §§ 310.305(d)(2), 314.80(f)(2), and 600.80(f)(2), state that each completed FDA Form 3500A, VAERS Form, or CIOMS I Form should refer only to an individual patient or a single attached publication. Under proposed §§ 310.305(d)(3), 314.80(c)(4)(iii), and 600.80(c)(4)(iii) FDA would remove the phrase ''or a single attached publication'' and replace the word ''patient'' with the word ''case.'' This proposed amendment would clarify that an FDA Form 3500A should be completed for each identifiable patient described in a scientific article (*e.g.*, six FDA Form 3500As should be completed for an article describing six patients experiencing a particular SADR). This would also clarify that an FDA Form 3500A would be used to describe a potential medication error that does not involve a patient.

III.F.4. Contact Person

Proposed §§ 310.305(d)(4), 314.80(c)(4)(iv), and 600.80(c)(4)(iv) would state:

> Each completed FDA Form 3500A (VAERS Form for proposed § 600.80(c)(4)(iv)) or CIOMS I Form must include the name and telephone number (and fax number and e-mail address, if available) for the licensed physician responsible for the content and medical interpretation of the data contained within the form (*i.e.*, contact person for the company).

This information should be provided on FDA Form 3500A under the ''contact office'' box (box G1 on FDA Form 3500A). This proposed revision would provide FDA with a person to contact with any questions that may arise during review of an individual case safety report. The agency believes that the potential medical significance of these safety reports warrants oversight by a licensed physician.

III.F.5. Computer-Generated Facsimile of FDA Form 3500A or Vaccine Adverse Event Reporting System (VAERS) Form

Current §§ 310.305(d)(3), 314.80(f)(3), and 600.80(f)(3) state that instead of using an FDA Form 3500A, manufacturers and applicants may use a computer-generated FDA Form 3500A or other alternative format provided that the content of the alternative format is equivalent in all elements to those specified in FDA Form 3500A and the format is agreed to in advance by MedWatch: The FDA Medical Products Reporting Program. Alternative formats to the Center for Biologics Evaluation and Research's VAERS Form must be approved by the Division of Biostatistics and Epidemiology (§ 600.80(f)(3)).

Proposed §§ 310.305(d)(5), 314.80(c)(4)(v), and 600.80(c)(4)(v) would remove the use of alternative formats to FDA Form 3500A and the requirement to obtain preapproval by MedWatch for use of a computer-generated FDA Form 3500A. Proposed § 600.80(c)(4)(v) would also remove the use of alternative formats to the VAERS Form and the requirement to obtain preapproval by the Division of Biostatistics and Epidemiology for use of a computer-generated VAERS Form. Instead, the proposed rule would permit manufacturers and applicants to use a computer-generated facsimile of FDA Form 3500A (or VAERS Form for vaccines) provided that it is readable, includes appropriate identifying information and contains all the elements (*i.e.*, format, sections, blocks, titles, descriptors within blocks, text for disclaimer) of FDA Form 3500A (or the VAERS Form for vaccines) in the identical enumerated sequence of the form. The proposed rule would also permit use of a one-page FDA Form 3500A for individual case safety reports in which no suspect medical device is involved. For one-page reports, the box, Section D. *Suspect Medical Device,* on the front page of FDA Form 3500A would be replaced with the box, Section

G. *All Manufacturers,* located on the back page of the form.

To be considered ''readable'' by FDA, the computer-generated facsimile should be formatted as follows.

- The facsimile should have at least a ¼ inch margin around the entire form so that information is not lost during scanning, copying, or faxing of the document. The left-hand margin may be increased up to ½ inch to permit binding (*e.g.*, hole-punching) of the form; all other margins should continue to be at least ¼ inch.
- The data and text that is contained within the boxes should be in a font size of not less than 10 point.
- The data and text that is contained within the boxes should be in a font type that is easy to read (*e.g.*, CG Times, Arial) and not condensed, because the form may be copied or faxed multiple times. For visual contrast, the font type that is used for the data and text should, if possible, be different than the font type used to create the FDA Form 3500A or VAERS Form.
- All data and text should be contained within each of the boxes, *e.g.*, an ''x'' mark should be centered within the box, and narratives should include margins so that letters of the text are not obscured or made ambiguous by lines defining a box.

FDA would consider ''appropriate identifying information'' to include:

- The name of the company centered on the top of the front page;
- In the lower left hand corner of the front page, the phrase ''3500A Facsimile'' instead of the phrase ''FDA Form 3500A (date of form [*e.g.*, 6/93])'' or the phrase ''VAERS facsimile'' instead of the phrase ''Form VAERS–1'';
- The phrase ''continued'' at the end of each field that has additional information continued onto another page; and
- On each continuation page containing additional information, the page number identified as Page____of____, the manufacturer report number in the upper right corner, the name of the company in the upper right corner, and the section and block number (*e.g.*, Block B5) for each narrative entry.

This information is included in the draft guidance of 2001. Any revisions to these parameters would be included in updated versions of the guidance.

III.F.6. Other Revisions

The proposed rule would remove §§ 310.305(d)(4), 314.80(f)(4), and 600.80(f)(4). These paragraphs provide manufacturers and applicants with addresses for obtaining copies of FDA Form 3500A and instructions for completing the form. FDA is proposing to remove these paragraphs because the addresses are provided in the draft guidance of 2001.

The proposed rule would also remove §§ 314.80(e)(2) and 600.80(e)(2). These paragraphs state that persons subject to the postmarketing safety reporting regulations must separate and clearly mark reports of adverse drug experiences that occur during a postmarketing study as being distinct from those experiences that are being reported spontaneously to the person. FDA is proposing this revision because this information would be submitted to the agency in a completed FDA Form 3500A under the box for ''Report source'' (box G3 on FDA Form 3500A).

III.G. Patient Privacy

Current postmarketing safety reporting regulations at §§ 310.305(e), 314.80(h), and 600.80(h) state that persons subject to these requirements should not include the names and addresses of individual patients in reports and, instead, should assign a unique code number to each report, preferably not more than eight characters in length. Proposed §§ 310.305(e), 314.80(e), and 600.80(e) would amend these regulations by removing the word ''number.'' This proposed amendment would clarify that the code selected to identify a patient need not be limited to numbers (*i.e.*, it could contain letters or a mixture of letters and numbers).

III.H. Recordkeeping

Current postmarketing safety recordkeeping regulations at § 314.80(i) require applicants to maintain for a period of 10 years records of all adverse drug experiences known to the applicant, including raw data and any correspondence relating to the adverse drug experiences. Under proposed § 314.80(f), FDA would amend these regulations to read:

> The applicant must maintain for a period of 10 years records of all safety information pertaining to its drug product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SADRs or medication errors not submitted to FDA or only provided to FDA in a summary tabulation. The applicant must also retain for a period of 10 years any records required to be maintained under this section. When appropriate, FDA may require an applicant to submit any or all of these records to the agency within 5 calendar days after receipt of the request.

This proposed revision clarifies the type of safety records that applicants would be required to maintain for its drug products. With regard to a request for these records by FDA, the agency would usually make such a request either in response to a suspected safety problem associated with the use of a drug or to determine a company's compliance with the postmarketing safety reporting requirements. Under proposed § 600.80(f), the agency is proposing similar revisions to the recordkeeping requirements for licensed biological products at § 600.80(i). FDA is proposing these revisions to clarify what types of postmarketing safety reporting records must be maintained.

Current § 310.305(f)(1) requires manufacturers, packers, and distributors to maintain for a period of 10 years records of all adverse drug experiences required under § 310.305, including raw data, any correspondence relating to adverse drug experiences, and the records required to be maintained under § 310.305. FDA is proposing to amend these regulations to be consistent with the postmarketing safety recordkeeping regulations at proposed §§ 314.80(f) and 600.80(f).

III.I. Abbreviated New Drug Application (ANDA) Products

Current § 314.98 requires applicants holding an approved ANDA to comply with the postmarketing safety reporting requirements under § 314.80. The proposed amendments to § 314.80 in this rule would apply to applicants holding an approved ANDA. For postmarketing periodic safety reporting purposes, proposed § 314.98(a) would require applicants holding an approved ANDA to determine the data lock point (*i.e.*, month and day of the international birth date or any other month and day agreed by the applicant and FDA) for their periodic safety reports based on the data lock point of postmarketing periodic safety reports for other drug products containing the same drug substance (*i.e.*, innovator NDA product that is the same drug product as the ANDA product or other ANDA products with the same drug substance if the innovator NDA product is no longer on the market). Thus, postmarketing periodic safety reports from different applicants for drug products containing the same drug substance would be submitted to FDA at the same time. Applicants holding an approved ANDA may contact FDA, if necessary, for assistance in determining the data lock point for postmarketing periodic safety reports.

Proposed § 314.98(a) would also state that applicants holding an approved ANDA would determine the type of postmarketing periodic safety report that would be required to be submitted to FDA (*i.e.*, TPSR, PSUR, or IPSR)

based on the U.S. approval date of the application for the innovator NDA product. If the innovator NDA product (even if no longer on the market) was approved for marketing before January 1, 1998, applicants holding an approved ANDA for the drug product would have the option of submitting either TPSRs or PSURs and IPSRs to FDA. In these cases, an applicant holding an approved ANDA may choose to submit TPSRs to FDA even though other applicants with approved applications for the drug product submit PSURs and IPSRs. If the innovator NDA product was approved for marketing on or after January 1, 1998, applicants holding an approved ANDA for the drug product would be required to submit PSURs and IPSRs to FDA.

Proposed § 314.98(a) also provides that applicants holding an approved ANDA would determine the frequency of submission for postmarketing periodic safety reports based on the U.S. approval date of the application for the innovator NDA product. For example, if the innovator NDA product is the first human drug product containing the drug substance approved in the world and the application is approved for marketing on June 15, 1980, applicants of the innovator NDA product and all ANDA products with the same drug product would either submit a TPSR or PSUR to FDA every 5 years based on the U.S. approval date of the innovator NDA product (*e.g.*, data lock point of June 15, 2000, June 15, 2005). In this case, an applicant with an ANDA approved on January 1, 1999, would have a data lock point of June 15, 2000, even though the reporting period for the drug product is less than 5 years; the next reporting period for the drug product would cover a 5-year period (*i.e.*, June 16, 2000 through June 15, 2005). If the first human drug product containing the drug substance was approved for marketing in Europe on February 1, 1980, and the same drug product was approved in the United States on June 15, 1980, applicants of this drug product and all ANDA products with the same drug product would either submit a TPSR or PSUR to FDA with a 5-year frequency based on the U.S. approval date and with a date lock point based on the European approval date (*e.g.*, February 1, 2000, February 1, 2005).

All applicants holding an approved NDA or ANDA would be required to submit postmarketing individual case safety reports—semiannual submissions to FDA every 6 months (*see* section III.E.4 in this document). Thus, even though the agency would not be receiving TPSRs, PSURs, and IPSRs for drug products with approved ANDAs frequently after approval of the product, FDA would receive in a timely manner individual case safety reports for the product (*i.e.*, expedited reports, individual case safety reports—semiannual submission) that would identify any potential problems associated with the formulation of the product. It is not necessary to receive TPSRs, PSURs, or IPSRs for drugs with approved ANDAs more frequently because the innovator NDA product has been evaluated for a number of years.

III.J. Postmarketing Approved New Drug Application (NDA) and Biologics License Application (BLA) Annual Reports

Current § 314.81(b)(2) requires applicants of marketed drug products subject to an NDA to submit an annual report to FDA within 60 days of the anniversary date of U.S. approval of the application. This annual report must contain a brief summary of significant new information from the previous year that might affect the safety, effectiveness, or labeling of the drug product and a description of actions the applicant has taken or intends to take as a result of new information, such as submitting a labeling supplement, adding a warning to the labeling, or initiating a new study (§ 314.81(b)(2)(i)). This summary section must also contain, in accordance with the 1998 pediatric final rule, a statement of whether labeling supplements for pediatric use were submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population were initiated. The 1998 pediatric final rule also requires that the summary section include, where possible, an estimate of the patient exposure to the drug product, with special reference to the pediatric population (neonates, infants, children, and adolescents), including dosage form. The annual report also must contain a section on nonclinical laboratory studies that includes copies of unpublished reports and summaries of published reports of new toxicological findings in animal studies and in vitro studies (*e.g.*, mutagenicity) conducted by, or otherwise obtained by, the applicant concerning the ingredients in the drug product (§ 314.81(b)(2)(v)). The applicant must submit a copy of a published report if requested by FDA. The annual report also must contain a section on clinical data that includes, among other data, published clinical trials on safety of the drug (or abstracts of them) and reports of clinical experience pertinent to safety (for example, epidemiological studies or analyses of experience in a monitored series of patients) conducted by or otherwise obtained by the applicant (§ 314.81(b)(2)(vi)). The clinical data section also must contain, in accordance with the 1998 pediatric final rule, an analysis of available safety and efficacy data in the pediatric population, changes proposed in the labeling based on this information, and an assessment of data needed to ensure appropriate labeling for the pediatric population.

Current § 601.28 requires applicants of licensed biological products to submit an annual report to FDA within 60 days of the anniversary date of U.S. approval of the application. This annual report must contain, among other information, a brief summary stating whether labeling supplements for pediatric use were submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population were initiated (§ 601.28(a)). This summary section also must contain, where possible, an estimate of the patient exposure to the product, with special reference to the pediatric population (neonates, infants, children, and adolescents), including dosage form. The annual report also must contain a section on clinical data that includes an analysis of available safety and efficacy data in the pediatric population and changes proposed in the labeling based on this information (§ 601.28(b)). This clinical data section also must contain an assessment of data needed to ensure appropriate labeling for the pediatric population.

As noted in section I of this document, FDA received comments on the October 1994 proposal that noted that the proposed amendments to the agency's postmarketing safety reporting requirements would duplicate certain information required in postmarketing approved NDA annual reports. In light of these comments, FDA is proposing to revoke the requirement for safety-related information in postmarketing approved NDA and BLA annual reports to eliminate duplicative reporting.

FDA is proposing to remove the requirement in § 314.81(b)(2)(i) to report safety information or safety-related labeling changes in the summary section of approved NDA annual reports. FDA is also proposing to remove the requirement in §§ 314.81(b)(2)(i) and 601.28(a) to submit an estimate of patient exposure to the drug product with special reference to the pediatric population. FDA is also proposing to remove the requirement in § 314.81(b)(2)(v) to include the section on nonclinical laboratory studies in approved NDA annual reports. FDA is

also proposing to remove the requirement in §§ 314.81(b)(2)(vi) and 601.28(b) to submit safety-related information in the clinical data section of approved NDA and BLA annual reports. FDA is proposing these changes because this safety-related information for a drug or licensed biological product would be provided to the agency in postmarketing safety reports (*i.e.*, expedited reports, TPSRs, PSURs, IPSRs, individual case safety reports—semiannual submissions). For example, proposed §§ 314.80(c)(2)(ii) and 600.80(c)(2)(ii) would require postmarketing expedited reports for certain information that would be sufficient, based on appropriate medical judgment, to consider changes in product administration (*e.g.*, any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an IND, that suggests a significant human risk such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a drug or biological product used in treating a life-threatening or serious disease). Under proposed §§ 314.80(c)(3)(ii)(E), 314.80(c)(3)(iii)(E), 600.80(c)(3)(ii)(E), and 600.80(c)(3)(iii)(E), PSURs and IPSRs would contain a section on worldwide patient exposure that includes, when possible, data broken down by gender and age (especially pediatric versus adult). Under proposed §§ 314.80(c)(3)(ii)(G), 314.80(c)(3)(iii)(F), 600.80(c)(3)(ii)(G) and 600.80(c)(3)(iii)(F), PSURs and IPSRs would include a section on safety studies that would contain a discussion of nonclinical, clinical, and epidemiological studies that contain important safety information. This safety studies section would include all applicant-sponsored studies newly analyzed during the reporting period; new studies specifically planned, initiated, or continuing during the reporting period; and published safety studies in the scientific and medical literature.

III.K. Safety Reporting for In Vivo Bioavailability and Bioequivalence Studies

FDA's existing in vivo bioavailability and bioequivalence study regulations, under § 320.31(a), require submission of an IND, as prescribed under part 312, for certain studies in humans (*i.e.*, studies that involve a new chemical entity, a radioactively labeled drug product, or a cytotoxic drug product). Section 320.31(b) requires an IND for certain studies in humans using a drug product that contains an already approved, non-new chemical entity (*i.e.*, a single-dose study where either the maximum single or total daily dose exceeds that specified in the approved labeling for the drug product, a multiple-dose study where either the single or total daily dose exceeds that specified in the approved labeling of the drug product, a multiple-dose study on a controlled release product on which no single-dose study has been completed). Section 320.31(d) exempts all other in vivo bioavailability and bioequivalence studies in humans from the requirements of part 312 if certain conditions are satisfied (*i.e.*, samples of any test article and reference standard are reserved by the person conducting the study and released to FDA upon request, studies are conducted in compliance with the requirements for institutional review set forth in 21 CFR part 56 and informed consent set forth in 21 CFR part 50).

FDA believes that drug products that are being investigated in human bioavailability and bioequivalence studies that are not subject to an IND are, in general, safe. However, as noted in section II.B.4 of this document, FDA receives some safety information periodically regarding drugs in these studies, thus making the agency uncertain whether it is receiving all necessary safety information regarding the specificity and severity of SADRs related to these drugs or any new SADRs that may be related to them. FDA has determined that a more comprehensive and orderly system for collecting safety information for these studies is needed. For this purpose, the agency is proposing to require persons conducting human bioavailability and bioequivalence studies that are not subject to an IND to submit expedited safety reports to FDA to alert the agency to potential safety problems quickly. The proposed rule would not require these persons to submit an IND to FDA for the studies.

FDA believes that this new proposed safety reporting requirement will result in submission of minimal reports to the agency (~ 200/year; *see* table 13 for estimate). FDA seeks comment on the reasonableness of this estimate and requests that comments provide information to support any alternative estimates.

The act provides authority to FDA to require safety reports for human bioavailability and bioequivalence studies that are not subject to an IND. Section 505(i) of the act provides broad authority for FDA to issue regulations governing the clinical investigation of new drugs to protect the rights, safety, and welfare of human subjects and otherwise to protect the public health. In addition, section 701 of the act (21 U.S.C. 371) provides that the agency has authority to issue regulations for the efficient enforcement of the act.

FDA is proposing to amend its regulations at § 320.31(d) to require persons conducting human bioequivalence and bioavailability studies that are not subject to an IND to submit safety reports to FDA as prescribed under § 312.32 for drug products subject to an IND. Under proposed § 312.32(c)(1), a written safety report must be submitted within 15 calendar days to FDA and all participating investigators for any SADR that, based on the opinion of the investigator or sponsor, is both serious and unexpected and for information that, based upon appropriate medical judgment, might materially influence the benefit-risk assessment of an investigational drug, or that would be sufficient to consider changes in either product administration or in the overall conduct of a clinical investigation. Examples of reportable information would include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an IND, that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a drug or biological product used in treating a life-threatening or serious disease. In addition, under proposed § 312.32(c)(2), a telephone or facsimile transmission safety report must be submitted within 7 calendar days to FDA for any unexpected fatal or life-threatening SADR.

Proposed § 320.31(d)(3) would require that these safety reports be transmitted to all participating investigators and the appropriate FDA division in the Center for Drug Evaluation and Research. Thus, safety reports for the reference listed drug would be sent to the new drug review division responsible for that drug; safety reports for the investigational drug product would be sent to the Director, Division of Bioequivalence, Office of Generic Drugs. The proposed rule would also require that each written notification bear prominent identification of its contents, *i.e.*, ''Bioavailability/Bioequivalence Safety Report.'' Each report should clearly identify the sponsor of the bioavailability or bioequivalence study and the contract research organization, if applicable. In each written Bioavailability/Bioequivalence Safety Report, the sponsor would be required

to identify all safety reports previously filed for the bioavailability or bioequivalence study concerning a similar SADR and to analyze the SADR in light of previous similar reports, as required under proposed § 312.32(c)(1)(i) for IND safety reports.

An unexpected adverse drug experience is currently defined, under § 312.32(a), as:

> Any adverse drug experience, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. * * *

For reporting purposes under proposed § 320.31(d), an unexpected SADR would be any SADR, the specificity or severity of which is not consistent with the U.S. labeling for the reference listed drug. FDA is proposing use of the U.S. labeling for the reference listed drug for this purpose because studies that are not subject to an IND are unlikely to have an investigator brochure for use as a reference document.

Under proposed § 312.32(c)(4), a sponsor of a clinical study under an IND for a drug marketed in the United States is only required to submit IND safety reports to FDA (review division that has responsibility for the IND) for SADRs that occur during the clinical study itself, whether from domestic or foreign study sites of the IND. Proposed § 312.32(c)(4) would apply to human bioavailability and bioequivalence studies that are the subject of proposed § 320.31(d). In these cases, the reference listed drug would be the marketed drug and persons conducting human bioequivalence and bioavailability studies that are not subject to an IND would only be required to submit safety reports to FDA from their studies.

III.L. Proposed Implementation Scheme

FDA proposes that any final rule that may be issued regarding the proposal to require that SADRs in individual case safety reports be coded using MedDRA become effective 1 year after its date of publication in the **Federal Register**. FDA proposes that any final rule that may be issued based on all other proposals become effective 180 days after its date of publication in the **Federal Register**.

IV. Environmental Impact

The agency has determined under 21 CFR 25.30(h) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

V. Analysis of Impacts

V.A. Background and Summary

FDA has examined the impacts of the proposed rule under Executive Order 12866, the Regulatory Flexibility Act (5 U.S.C. 601–612), and the Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1501 *et seq.*). 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). Under the Regulatory Flexibility Act, if a rule has a significant impact on a substantial number of small entities, an agency must analyze regulatory options that would minimize any significant impact of the rule on small entities. Title II of the Unfunded Mandates Reform Act of 1995 requires that agencies prepare a written assessment of anticipated costs and benefits before proposing any rule that may result in an expenditure by State, local, and tribal governments, in the aggregate, or by the private sector, of $100 million in any one year (adjusted annually for inflation). Section 205 of the Unfunded Mandates Reform Act also requires that the agency identify and consider a reasonable number of regulatory alternatives and from those alternatives select the least costly, most cost-effective, or least burdensome alternative that achieves the objective of the rule.

The following analysis, in conjunction with the remainder of this document, demonstrates that this proposed rule is consistent with the regulatory philosophy and principles identified in Executive Order 12866 and in the other two statutes. The proposed rule would amend current safety reporting requirements for human drug and biological products. Based on the analysis below, as summarized in table 11, FDA projects that the annual benefits would exceed the costs if this proposed rule resulted in a 2 percent reduction in hospital-related SADRs. The agency believes that a reduction in hospital related SADRs of at least 2 percent is a reasonable and likely outcome of this rule. The agency has determined that the proposed rule is an economically significant rule as described in the Executive Order. As required by the Regulatory Flexibility Act, the agency's Initial Regulatory Flexibility Analysis is included in this section. Because the rule may impose a mandate on the private sector that will result in a 1-year expenditure of $110 million or more (the current inflation adjusted threshold), FDA has conducted a cost-benefit analysis according to the Unfunded Mandates Reform Act. The relationship of this proposed rule with other agency rulemaking is described in the background section (*e.g.*, reproposal of postmarketing periodic safety reporting requirements) (*see* section I of this document).

The proposed rule covers a small part of a broader based set of international initiatives (ICH and CIOMS) that, taken collectively, have the potential to generate substantial benefits, savings, and efficiencies for consumers, manufacturers, and regulators. The full benefits of this proposed rule will accrue when international regulatory inconsistencies are addressed, safety reporting submission requirements are harmonized internationally, and electronic information exchange is uniform and compatible for the major participants involved in monitoring drug safety. A primary objective of the proposed rule is the harmonization of FDA's safety reporting requirements with international initiatives. The proposed rule would also improve the quality of information contained in postmarketing individual case safety reports for human drug and biological products. By providing more complete information for individual case safety reports, the revised reports would enhance the ability of the drug and biologics manufacturers and the agency to identify, monitor, and communicate the risks and benefits of marketed drug and biological products. Monitoring these risks and benefits is especially critical for newly approved products introduced to large and diverse patient populations.

Specifically, the proposed rule would clarify and codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed human drug and biological products. The proposed rule would expand postmarketing expedited safety reporting to include unexpected SADRs that cannot be classified as either serious or nonserious, information that is sufficient to consider changes in product administration, certain medically significant SADRs, and actual and potential medication errors as specified in the proposal. The proposed rule would require that each SADR in postmarketing individual case safety reports be coded using a single medical

dictionary, MedDRA. The proposed rule would also require applicants to conduct a more thorough review and analysis of the safety profile of marketed drug and biological products. Finally, the proposed rule would codify current best practices in postmarketing safety reporting.

The proposed rule would also amend FDA's regulation on postmarketing annual reports for human drugs and licensed biological products to revoke the requirement for submission of safety-related information. The agency would also require the submission of expedited safety reports for certain bioavailability and bioequivalence studies that are exempt from submission of an IND.

The summary of the costs and benefits of this proposed rule are presented in table 11. The total one-time costs of $144.2 million are primarily for adopting MedDRA and include planning for implementation of the MedDRA requirements, purchasing materials, and converting existing systems to the new dictionary. Firms would also incur annual operating costs of about $106.6 million for complying with the revised safety reporting and recordkeeping requirements and $28.5 million for maintaining the new MedDRA system. Total annualized costs are $155.6 million (assuming a 10-year regulatory period and a 7 percent discount rate). A 10-year regulatory period for annualizing the costs and benefits of this proposed rule was selected as a reasonable time frame to adjust for investments, returns and savings given the potential for unforseen advances in both medical and information technology. In addition, by the fourth year savings and costs remain constant.

The expected health benefits of the rule would result from the improved timeliness and quality of the safety reports and analyses. Submission of more complete safety information would reduce the number and duration of hospitalizations due to SADRs. If the proposed rule reduced the incidence of SADR-related hospitalizations by 2 percent, these annual savings could be $368.5 million (*see* table 11). A 1 percent reduction in hospital related events would save $184 million annually; a 3 percent reduction would save $553 million annually. In addition, industry will experience economic benefits due to the more efficient allocation of resources permitted by the international harmonization of the safety reporting requirements. The annualized present value of these savings is $28.5 million assuming a 7 percent discount over 10 years (*see* table 11). The agency believes this represents only a partial estimate of future industry savings.

TABLE 11.—SUMMARY OF THE COSTS AND BENEFITS

[$ million]

Benefits assuming a 2 percent reduction in hospital related SADRs	Annual
Reducing hospital costs	368.5
More efficient use of resources	[1] 28.5
Total benefits	397.0

[1] This is the annualized present value of the estimated savings assuming a 7 percent discount over 10 years.

Costs	One-Time	Annual	Annualized
Safety Reporting and Recordkeeping:			
Expedited reports (Except medication errors)	.....	29.0	29.0
Expedited reports—medication errors	.....	68.0	68.0
Periodic/other reports	.....	9.6	9.6
Implementing MedDRA	144.2	28.5	49.0
Total	144.2	135.1	155.6

V.B. Market Failure

The host of international requirements and procedures that currently govern safety reporting for drugs and biologics creates substantial economic inefficiencies for firms. Manufacturers of drug and biological products operating in global markets must meet the regulatory safety reporting requirements of each country in which the product is marketed. In many cases, these safety reporting requirements, in particular submission timeframes for SADR reports, vary substantially among countries. Thus, drug and biologics manufacturers must devote considerable resources to reformatting the data and information pertaining to each SADR according to specific national requirements. Also, because the timing of report submissions is typically determined by product approval dates for each country, manufacturers must submit reports to different countries at different intervals. Such activities impose substantial costs on both industry and regulatory authorities. Moreover, product safety can be compromised due to the difficulty of analyzing SADR reports based on the inconsistent use of terms derived from multiple dictionaries.

Despite the general recognition that manufacturers could realize substantial gains if safety reporting and terminologies were standardized globally, companies currently have limited incentives to invest capital and resources in standardized reporting systems (*e.g.*, MedDRA) unless the standards are required by regulation. This shortfall in industry incentives occurs because the economic gains of harmonization cannot be attained by individual firms acting alone. Although most regulatory authorities have agreed in principal to implement international standardized reporting procedures, formal procedures have not yet been established. A few companies have voluntarily invested in the standardized process, but in the absence of global standards, these firms are uncertain of potential gains. FDA believes that the proposed rule is a necessary step toward achieving the desired international standardization and its corresponding economic and health benefits.

Industry would benefit from FDA action to reduce uncertainties associated with investments in harmonization and from the ability to more efficiently allocate resources associated with safety reporting. Society would benefit from the improved quality of adverse event information that is a critical component to reducing health care costs associated with avoidable SADRs. More timely and

improved information on SADRs is needed to ensure the safe use of products and to monitor early warnings and unexpected risks associated with drugs, drug-drug interactions, drug-food interactions, and risks to certain patient populations.

V.C. Benefits

The benefits of the proposed rule would result both from the public health gains attributable to the improved scope, uniformity, and quality of information and analyses submitted in safety reports and the economic savings attributable to the more efficient use of industry and regulatory resources.

This proposed rule would require improved factual and analytic data underlying safety reporting and analysis, provide for more timely safety information for certain serious SADRs, and would require a common medical dictionary, MedDRA.

The timely identification of SADRs is critical to managing risk information and to the safe prescribing and use of new drugs. Accurate and timely risk information is especially significant in the early months after product launch to develop appropriate prescribing and use behaviors as health care practitioners and consumers are learning about the product safety and use. Newly approved product use can quickly grow from a few thousand patients (the population in clinical trials) to many thousands or millions. Rare but serious SADRs are detected only after exposure to very large patient populations. Forty percent of SADR reports are for drugs approved within the last 3 years. Compounding this need for timely serious SADR information, U.S. patients are increasingly the first in the world to have access to new medications (49 percent of new drugs were first approved in the United States between 1996 and 1998, compared with 31 percent in 1991–1995).

More timely and improved factual information would also enhance the identification of other important factors associated with the risks of SADRs. These factors include subpopulations that may differ from clinical trial participants, patients taking multiple medications or medications that require therapeutic monitoring, and patients with concurrent comorbidities.

This rule would require affected entities to complete either a minimum or full set of data in safety reports, reflecting levels of risk. That is, more detail is required for higher risk events and reduced reporting for lower risk events. This rule would also require the use of MedDRA, a medical dictionary developed by the ICH, in coding SADR terms. MedDRA will provide a uniform, consistent and specific presentation of medical terms. By eliminating the use of multiple dictionaries, MedDRA would facilitate the retrieval, presentation, and summarization of SADR data and enhance the global communication and acceptance of safety information and reports. The use of a single dictionary will substantially upgrade the quality of safety analysis by incorporating uniformity of terms. MedDRA will aid in more expeditious and broader international drug use comparisons within a class, and prescribing and use decisions. Providing more complete information and more timely safety assessments would enhance the ability of the manufacturers to more quickly identify, monitor, and communicate the potential risks and benefits of marketed drugs and biologics.

It is well recognized that drug safety information is a critical element in the risk management of marketed drugs and biologics. In addition, the medical literature provides substantial documentation of avoidable hospitalizations associated with SADRs. Improving the quality and timeliness of safety information and accelerating the communication of risk information will enable health care practitioners and consumers to take appropriate corrective actions (in the case of medication errors) and to make more informed decisions about treatments. Moreover, the management of risk information is an essential component of risk-based decisions that determine the continued marketing or withdrawal of effective products with newly identified serious SADRs. We discuss benefits more fully below and show that a small reduction in the number of hospitalizations due to SADRs (as low as 0.85 percent), due to improved prescribing and use decisions, would result in the annual benefits outweighing the total costs.

V.C.1. Expanded Safety Information

New drug approval decisions are based on safety and testing information derived from clinical trials that typically include several thousands of patients. However, the number of individuals tested in preapproval trials is not sufficiently large to reliably detect rare, serious SADRs. Patient exposure can quickly grow from thousands to millions after product launch. Thus, especially in the first few years after product launch, postmarketing surveillance is a critical component of the overall continuing review and assessment of drug safety (Ref. 1). Recent studies have identified common factors associated with increased risks of SADRs. These factors include subpopulations who differ from the clinical trial participants, *e.g.*, the elderly, patients taking multiple medications or medications that require therapeutic monitoring, and patients with concurrent comorbidities (Refs. 2 through 5). The proposed rule would require companies to collect proactively more complete safety information, improving the factual and analytical data underlying the safety analyses. This expanded risk information would enable health care practitioners and consumers to take appropriate corrective actions (in cases of avoidable medication errors) and to make more informed decisions about treatments.

V.C.2. Improved Uniformity and Quality of Safety Information

For years, numerous health care organizations, teaching hospitals, health care professionals, and educators have recognized the importance to public health of monitoring SADRs. Substantial evidence demonstrates that effective monitoring and analyzing of SADRs facilitate the identification of trends and warning signals that result in improved medication use and patient care (Refs. 6 through 10). Yet, the current drug and biologics safety reporting system, encompassing raw material suppliers, manufacturers, health care providers, and consumers, is fragmented with respect to its oversight and lacks common reporting procedures and tools for evaluating SADRs. For example, FDA oversees mandatory safety reporting by manufacturers of drug and biological products and voluntary reporting from health care providers and consumers. Health care facilities, on the other hand, may be subject to safety reporting oversight by individual state regulatory programs, although not all states have oversight systems. The Joint Commission on Accreditation of Health Care Organizations (JCAHO), which accredits health care facilities, has had standards for establishing SADR reporting systems for hospitalized patients for many years. Hospitals may establish their own systems independently and almost all conform to the JCAHO standards (Ref. 11). Despite growing evidence that avoidable SADRs and serious SADRs are important public health problems and widespread acknowledgment that monitoring SADRs provides public health benefits, FDA continues to receive reports of only a small percentage of the serious and avoidable SADRs that occur in health care facilities (Ref. 12). This proposed rule would improve safety reporting by drug

and biologics manufacturers, which may serve to provide a national framework for improved data collection and analysis of safety reports from a variety of sources.

The proposed rule would also require the use of MedDRA, a single, medical terminology developed by ICH that can be used for the coding of SADR terms. MedDRA is a broad-based dictionary, developed for international use, that combines both SADR and morbidity terminology to provide a uniform, consistent, and specific presentation of medical terms. By eliminating the use of multiple dictionaries, MedDRA would facilitate the retrieval, presentation, and summarization of SADR data and enhance the global communication and acceptance of safety information and reports. In addition, the use of a single comprehensive medical dictionary by drug safety reporters and reviewers would substantially upgrade the quality of safety analysis by incorporating uniformity of terms. Standardizing the terms and improving the quality of the roughly 250,000 safety reports submitted annually to FDA would lead to better and more timely safety assessments and to improved communication of risk information. The widespread use and acceptance of standardized SADR information by regulators would ultimately enhance drug comparisons within a class and drug prescribing and use decisions.

V.C.3. Potential Savings From Reduced SADR-Related Hospitalizations

Improved timeliness and analysis of SADR data would lead to a better understanding and a more rapid communication of the risks of SADRs. By providing such improvements, the proposed rule would reduce the incidence of SADRs. An agency estimate of the potential economic benefits of the rule is presented below and reflects the value of the expected hospital cost savings and the avoided lost wages that might result from reduced numbers of SADRs.

V.C.3.a. *Reduced rate of SADR-related hospitalizations.* Numerous studies have documented drug-related hospitalizations (60 FR 44182 at 44232, August 24, 1995). A comprehensive review of 36 articles focused specifically on SADRs as the primary cause of hospitalization. This study counted the number of reactions attributed to unintended consequences of drug therapy, excluding admissions due to overdose, intentional poisoning, attempted suicides, drug abuse, or intoxication. The percentage of hospitalizations due to SADRs ranged from 0.2 to 22 percent, with a mean of 5.5 percent. FDA adjusted this figure to 5 percent to remove over-the-counter drugs (Ref. 13). Based on 27.8 million hospital admissions reported in 1997, excluding obstetrical admissions (Ref. 14), the agency estimates the annual number of SADR-related hospitalizations at about 1.4 million (5 percent × 27.8 million). Absent available data, the agency assumes the costs associated with SADR-related hospitalizations are similar to the average cost of a hospital stay, but requests comments and supporting data on this assumption. Therefore, applying an estimated cost of $9,177 for an average hospital stay (Ref. 15) implies total annual SADR-related hospital admission costs of about $12 billion ($9,177 × 1.4 million).

If the improved reporting and analyses of SADRs led to the avoidance of only 2 percent of these hospitalizations, the economic savings would amount to $252.2 million annually.

V.C.3.b. *Reduced rate of in-hospital SADRs.* Bates et al. conducted a random sample of nonobstetrical admissions to two large tertiary care hospitals in Massachusetts over a 6-month period (Ref. 16). His prospective investigation of SADRs included interviews with medical staff and daily reviews of all medical charts. He estimated the incidence of all SADRs, including medical errors, at 6.5 percent with an average increase in hospital costs of $2,595 per case. Extrapolating these findings, FDA estimated the annual number of in-hospital SADRs at 1.8 million and the total additional hospital cost at $4.7 billion annually. If this proposed rule led to a 2 percent reduction, the economic benefits would be $93.6 million annually.

In a comprehensive review of studies that estimated the incidence of SADRs and/or the magnitude of hospital costs due to SADRs, the U.S. General Accounting Office cited substantial variation in estimates (Ref. 17). These differences may be due to inconsistent definitions of SADRs, different study methodologies (active prospective investigation versus retrospective review of patient records), representativeness of the samples, and particular methods used to extrapolate study findings to a national level. For example, Lazarou *et al.* and Classen *et al.* estimated the incidence of serious SADRs using the WHO definition of SADR and excluding other factors such as poisonings, intentional overdoses, and therapeutic failure (Refs. 18 and 19). These two studies had findings similar to Bates *et al.* On the other hand, Thomas *et al.* reviewed randomly selected hospital discharge records in two states and found a lower incidence of ''drug injury''. However, he used a particularly restrictive definition of SADR, one that resulted in prolonged hospitalization or disability at discharge (Ref. 20). Despite the uncertainties of estimating the incidence and cost of hospital related SADRs, FDA believes that the $4.7 billion estimate for in-hospital SADRs derived above provides a plausible estimate.

V.C.3.c. *Indirect benefits of reducing the hospital costs of SADRs.* The indirect benefits of reduced drug-related illnesses are derived from estimates of the costs of missed work or reduced productivity. Several studies on SADR-related hospital admissions stratified findings by patient age. Roughly 58 percent of SADR admissions were for patients aged 20 to 59. The remaining 42 percent were for patients under 20 years (less than 10 percent) and over 59 years old (Refs. 21 through 23). To calculate productivity losses, the agency assumed 56 hours per admission for patients aged 20 to 59 years (40 hours of lost work per hospitalization plus 16 additional hours for recovery and followup doctor visits) [2] and 14 hours for the remaining groups (to account for lost volunteer time or for time away from work for the care givers of dependent patients). The wage rates used are the average hourly production workers earnings of $15.96 for patients aged 20 to 59 ($12.28 plus 30 percent for benefits), and $12.28 for the remaining patients or their care givers (Ref. 14). The estimated value of this lost productivity is $812 million.

To estimate similar indirect benefits for in-hospital SADRs, the agency assumed the same distribution of patient ages. Related productivity losses are assumed to be 16 and 6 additional hours respectively, for patients aged 20 to 59, and for the remaining groups. The estimated value of this lost productivity is $323 million.

A 2 percent reduction in costs of SADR-related hospitalizations and prolonged hospitalizations would yield indirect benefit savings of $22.7 million. These estimates may somewhat overstate the value of lost productivity for the 20 to 59 age group because all patients are assumed to be employed. On the other hand, indirect benefits for the remaining age groups are understated because many of these patients are in the workforce and for those who are not, data are inadequate to measure their contribution to society.

[2] The agency used 40 hours to estimate work productivity losses. This estimate is consistent with current hospital discharge data and with the length of stay for drug-related hospitalizations (Ref. 21).

V.C.3.d. *Sum of SADR-related costs.* Summing these estimates, the total annual direct and indirect benefits of reducing avoidable SADR-related hospitalizations and longer hospital stays by 2 percent would lead to economic benefits of $368.5 million per year. Varying the assumption of a 2 percent reduction in hospital costs with a 1, 3, and 5 percent reduction, would yield annual benefits of $184 million, $553 million, and $921 million, respectively. A reduction of only 0.85 percent in the hospital costs associated with SADRs would be needed to outweigh the annualized industry costs of $155 million. Furthermore, under any of these scenarios, the total SADR-related hospital savings would outweigh the costs of this rule. With a 2 percent or greater reduction, the annual benefits would outweigh the costs beginning in the first year. Nonetheless, the agency seeks comment on our estimates of expected reductions in hospital-related costs, including the potential for reducing the incidence and length of stay of hospital-related SADRs.

In contrast to focusing only on hospital costs of SADRs, one study estimated the direct costs of drug-related morbidity and mortality for the ambulatory population at $76.6 billion annually, with the largest component $47.4 billion for drug-related hospitalizations (Ref. 24). The remaining cost components included: $14.4 billion for long-term care, $7.5 billion for physician visits, $5.3 billion for emergency department visits, and $1.9 billion for additional prescriptions. Again, assuming a 2 percent reduction, savings are approximately $948 million annually.

V.C.4. Cost Savings and More Efficient Use of Resources

The proposed rule is intended to complement and formalize international efforts by industry representatives and major international regulatory bodies to achieve a more uniform and global approach to safety reporting. The content, analyses, and timing of SADR report submissions would closely align with international initiatives and recommendations. To the extent that U.S. requirements become harmonized within a global context, companies that compete internationally would benefit from this proposed rule. Multiple international due dates for safety report submissions and reformatting of the same information to meet different regulatory requirements represent opportunity costs that could be allocated elsewhere. Companies would accrue savings through a substantial reduction or elimination of the reformatting of postmarketing periodic safety report information to meet varying international requirements and by synchronizing report frequencies and due dates internationally. Thus, as the international community harmonizes, companies would achieve efficiencies, eliminate duplicative processes, and reallocate those resources more efficiently.

The agency contracted with the Eastern Research Group, Inc. (ERG), an economics consulting firm, to estimate the potential benefits that would accrue to drug and biologics companies in the long run, as international harmonization efforts align and generate cost savings. These savings include more efficient regulatory safety reporting, more efficient sharing of safety information, and a common medical terminology. ERG estimated the following specific categories of benefits: More efficient management of drug safety data, more efficient intercompany agreements, and international harmonization of the postmarketing periodic safety report format (*i.e.*, use of PSUR format). ERG applied estimates of savings by category and firm size to the number of affected firms within each affected industry. The methodologies and procedures for deriving these estimates are fully presented in ERG's final report (Ref. 25).

V.C.4.a. *Savings related to maintaining and building data bases of SADRs and intercompany transfers of drug safety data.*

Drug and biologics companies maintain safety data bases of all domestic and foreign SADRs involving their products. The management of these data bases can be quite complex depending on the individual circumstances of manufacturing and marketing. Companies may have foreign subsidiaries, domestic and foreign manufacturing sites, and varied licensing agreements with other companies for marketing products. Foreign subsidiaries and licensees generally submit SADR reports to U.S. companies by fax. U.S. companies then reenter the reports into their own databases. Use of standardized safety report formats and content internationally will lend itself to electronic transmission of safety information. In these cases, intercompany and intracompany sharing of safety information will be substantially facilitated. ERG estimated these benefits at $3.1 million annually.

V.C.4.b. *Savings related to greater ease in entering into intercompany agreements.* As requirements for drug and biologics safety reporting become harmonized, drug and biologics companies will find it easier to coordinate safety reporting efforts when entering into various agreements with other manufacturers or sales organizations. In the current organizational structure of the industry, companies are frequently negotiating licensing agreements, mergers, joint ventures, and other contractual matters with other companies. For these arrangements, companies must develop, share, and merge drug safety reports from around the world. At present, negotiation of drug safety data sharing is often complicated by reporting formats and requirements that differ between regions. ERG estimated the potential savings that would accrue from simplified negotiation of licensing agreements due to standardized reporting formats and requirements at $4.2 million annually.

V.C.4.c. *Savings related to eventual international harmonization to the PSUR format.* ERG estimated the potential savings to industry of preparing a single PSUR that would be accepted by regulatory authorities internationally on the same date. Currently, companies are faced with many inconsistent requirements and must meet the individual requirements and timeframes of each country. ERG estimated these savings at $24.3 million annually.

V.C.4.d. *Potential savings in clinical trial management.* Some companies noted that they would convert medical terms from clinical trials to MedDRA whether or not it was required by FDA. Assuming that this transition will gradually apply to future clinical trials, a single medical terminology, internationally developed, accepted, and applied, would allow companies to more easily transmit, integrate, and analyze clinical trial data from global sites. Subsequent reductions in time and resources would contribute to reduced costs during drug development. Based on input from industry, ERG developed a narrow focus of savings associated with clinical trial data management valued at $7.2 million annually.

V.C.4.e. *Leveraging specialized knowledge.* This proposed rule also provides the groundwork for establishing focused centers of technical information on drug safety. Global companies and regulatory agencies will have the opportunity to create economies of expertise by concentrating specialized knowledge of global drug use and product risks and benefits in centralized locations. To the extent that safety information is better managed, understood, and shared with interested parties, substantial benefits will accrue. Neither ERG nor FDA could quantify these benefits.

V.C.4.f. *Total benefits.* ERG estimated the total industry savings from more efficient use of resources to be $38.8 million annually. This estimate, however, accounts for only a modest portion of the potential benefits of the broader set of initiatives that enhance electronic submissions and global harmonization of safety reporting. Table 12 summarizes the estimated annual benefits of this proposed rule. The agency recognizes, however, that the industry savings component will not be fully realized until safety reporting requirements are harmonized internationally. The agency believes that these benefits could be achieved in a relatively short period after this rule becomes final. The agency is ready to accept PSUR formats and the use of MedDRA for coding of individual case safety reports at the present time (*see* draft guidance of 2001). In addition, the European Union and Japan currently accept PSUR formats and the use of MedDRA.

TABLE 12.—SUMMARY OF THE ANNUAL BENEFITS

Savings category	$ Million (annually)
Public health benefits for a 2 percent reduction in SADR-related hospital costs:	
Reduced SADR-related hospital admissions	252.2
Reduced in-hospital SADRs	93.6
Indirect benefits from reduced hospitalizations	22.7
Total hospital-related savings	368.5
Expanded safety information on product approvals	([2])
Improved risk communication and product selection	([2])
Future Industry Savings:	
Efficiencies in database maintenance	3.1
Facilitation of PSUR submissions	24.3
Facilitation of intercompany negotiations	4.2
Clinical trial management	7.2
Total Industry Savings	[1] 38.8
Economies of Managing Drug Expertise	([2])

[1] Assuming ⅓ of these savings begin in year 2 ($11.6 million), ⅔ in year 3 ($23.3 million), and $38.8 million in years 4 through 10, the annualized present value is $28.5 million, discounted at 7 percent over 10 years. The 10-year time horizon allows a reasonable projection of current information given the unforseen progress and impacts of medical and computer technology.

[2] Not estimated.

V.D. Costs of Compliance

This section presents the estimated compliance costs of the proposed requirements. As explained in the following paragraphs, the proposed rule clarifies and expands existing requirements for submitting premarketing expedited reports, postmarketing expedited initial and followup reports, and postmarketing periodic safety reports to FDA. Drug and biologics manufacturers would be required to use direct verbal contact to collect information sufficient to determine the nature, severity, and outcome of SADRs and to evaluate and describe the safety profile or changes in the safety profile of marketed drugs. The proposed regulation also specifies criteria for reporting individual case safety reports and designates data elements that must be completed as a condition for initial and followup reporting. Each SADR in a postmarketing individual case safety report for human drugs and biologics must be coded using the appropriate ''preferred term'' in the latest version of MedDRA. The proposal also requires a physician to review the postmarketing expedited and periodic safety reports. The proposed rule would codify the data elements, analyses, and report format of the required postmarketing periodic safety report submissions and harmonize many of these requirements with ICH initiatives. Applicants holding an approved marketing application would be required to submit semiannual individual case safety reports and more detailed postmarketing periodic safety reports that contain cumulative and comprehensive data, analyses, tabulations, summaries, and other information. The proposed rule also includes revisions to IND safety reporting requirements and bioavailability and bioequivalence study requirements.

V.D.1. Costs of New Recordkeeping and Reporting Requirements

V.D.1.a. *Number of reports.* In 1998, manufacturers and applicants of human drug and biological products submitted approximately 230,000 individual case safety reports of SADRs to FDA. Data from about 130,000 of these individual case safety reports in the agency's Adverse Event Reporting System (AERS) were analyzed to estimate the annual number of future SADR reports expected to be included as revised expedited and new semiannual submissions. However, not enough data exists to predict the number of new expedited reports the agency may expect each year. For this analysis, estimates of new expedited reports for human drugs and biological products were based on counts of similar reports received by the agency during 1998. The estimated number of expedited reports for blood products is derived from published studies (Refs. 26 and 27).

The agency does not know how many TPSRs, and PSURs and IPSRs would be submitted annually, because applicants with pre-1998 drug approvals can submit either format. In addition, applicants with ANDAs approved on or after January 1, 1998, may choose to submit a TPSR rather than a PSUR or IPSR if the innovator NDA was approved before January 1, 1998. Despite this uncertainty, this analysis estimates the number of new filings of postmarketing periodic safety reports based on average counts of pre- and post-1998 drug approvals.

The number of affected reports for prescription drugs marketed for human use without an approved application, IND safety reports, bioavailability/bioequivalence safety reports, and other reports were projected from counts of similar reports received by FDA. Estimates for the total number of reports affected by the proposed rule are shown in table 13.

TABLE 13.—NUMBER OF AFFECTED REPORTS BY REGULATORY STATUS

Type of report	Drugs marketed without an approved application	NDA/AND	Biologics	Blood products	IND	Bioavailability and bioequivalence	Total
Expedited:							
Serious and unexpected SADRs	350	50,000	3,000	0	0	0	53,350
Always expedited report	50	1,500	100	0	0	0	1,650
Unexpected SADR with unknown outcome	46	912	25	0	0	0	983
Information sufficient to consider product administration changes	5	300	4	0	0	0	309
Medication errors	1,000	100,000	10,000	0	0	0	111,000
30-day followup	340	43,000	3,000	0	0	0	46,340
Serious SARs—blood products	0	0	0	7,000	0	0	7,000
IND Safety							
Information sufficient to consider product administration changes	0	0	0	0	600	0	600
Bioavailability/bioequivalence safety report	0	0	0	0	0	200	200
Periodic:							
TPSR	0	1,400	35	0	0	0	1,435
PSUR	0	2,500	35	0	0	0	2,535
ISUR	0	350	3	0	0	0	353
Individual case safety reports—semiannual submission	0	4,726	480	0	0	0	5,206
Other:							
Reports to manufacturer or applicant	4	4,548	100	0	0	0	4,652
Submit safety records to FDA upon request	2	15	4	0	0	0	21
Annual reports	0	2,363	69	0	0	0	2,432

V.D.1.b. *New time burden.* The proposed rule requires manufacturers and applicants to use active query to acquire the outcome (*i.e.,* whether an SADR is serious or nonserious) and required data set for any spontaneously reported individual case safety report that they receive pertaining to their marketed human drug or biological product. Furthermore, the proposed rule requires that every individual case safety report submitted to the agency be assigned an appropriate MedDRA code. Although individual case safety reports are currently submitted for most SADRs, depending on the type of SADR, the proposed rule may impose an additional burden on health professional personnel if active query is not already used routinely by a manufacturer or applicant. Regulatory affairs personnel working with the health professional may spend additional time assigning the MedDRA code and documenting the active query. The agency seeks comment on the reasonableness of the estimates of the time burden and the type of employee anticipated to fulfill the new requirements detailed in the following paragraphs.

V.D.1.b.i. *Expedited reports.* The nature of the SADR (*i.e.,* whether the SADR is expected or unexpected) and whether the outcome is known (*i.e.,* SADR is serious or nonserious) will determine the data needed and when and if an individual case safety report should be submitted to FDA. At present, individual case safety reports of SADRs that are both serious and unexpected are submitted as 15-day alert reports.

The proposed rule adds conditions for determining expedited reports (*e.g.,* minimum data set required). In addition, it specifies that an expedited report for an individual case safety report must contain a full data set, including MedDRA codes, and that supporting documentation such as hospital discharge records, autopsy reports, or death certificates must be submitted, if available. This aspect of the proposal may impose a new burden estimated at 1 hour each for health professionals and regulatory affairs personnel (see table 14).

The proposal defines new criteria for determining when expedited reports should be submitted. Certain medically significant SADRs as listed in the proposal, whether unexpected or expected, and all domestic reports of actual and potential medication errors would be required to be submitted to FDA in an expedited manner. Furthermore, when the outcome of a spontaneous, unexpected SADR cannot be determined, an expedited report must be submitted to the agency. In these circumstances, manufacturers and applicants are assumed to allocate from 16 to 24 hours more time for health professionals and regulatory affairs and clerical personnel to prepare and submit these new reports. Table 14 lists the additional hours each type of employee may spend complying with these new requirements.

In addition to individual case safety reports, manufacturers and applicants may receive safety information from domestic or foreign studies that is judged to be sufficient to consider a change in product administration. In this case, the proposed rule requires that a narrative report of these findings be submitted to the agency as an expedited report. Preparing and submitting this new report may take up to 8 hours of time from health professionals and regulatory affairs and clerical personnel as shown in table 14.

V.D.1.b.ii. *Followup reports.* The proposed rule establishes timeframes and data elements required for submission of expedited individual case safety reports. If required data elements were not submitted with the initial filing of an expedited report of a serious SADR or a medication error report, then the applicant must continue to use active query to obtain the additional information. This information must be submitted to FDA in a followup report

within 30 calendar days of the previous filing. If the full data set is still not obtainable, the 30-day followup report must include all safety information obtained, highlighting new information and stating the reasons for the inability to obtain complete information. The agency estimates that 8 additional hours, as shown in table 14, are needed for these followup reports.

Applicants must also submit any new safety information to FDA for any other expedited or followup report within 15 days of receipt of the new information. This provision is currently required; therefore, no additional hours are allocated to this provision.

V.D.1.b.iii. *Blood products.* Collection and transfusing facilities are currently required to investigate, prepare, and maintain written reports of complaints of SARs arising as a result of blood collection or transfusion. Furthermore, if a fatality occurs as a complication of blood collection or transfusion, facilities must notify FDA as soon as possible and follow up with a written report within 7 calendar days after the fatality occurs. The proposed rule will require that all written reports submitted to the agency use the individual case safety report format. This change in reporting format is not expected to increase the time needed to prepare and submit reports of fatalities. In addition, the proposed rule will require that any serious nonfatal SAR related to collection or transfusion of blood and blood components be submitted as a expedited report within 45 calendar days. As shown in table 14, blood facilities may spend up to 16 hours more preparing and submitting each of these expedited reports.

V.D.1.b.iv. *IND and bioavailability/bioequivalence safety reports.* Sponsors of an IND are currently required to submit written and telephone safety reports. The proposed rule will add some conditions for reporting and require that reportable SADRs include the minimum data set. Sponsors of INDs will be required to submit written safety reports to FDA and all participating investigators of: (1) Any SADR that, based on the opinion of either the sponsor or investigator, is both serious and unexpected and (2) any information that might materially influence the benefit-risk assessment of an investigational drug or that would be sufficient to consider a change in either product administration or in the overall conduct of a clinical investigation. The agency is also expanding the current requirement for telephone and facsimile transmission of safety reports of unexpected death or life-threatening SADRs to include those that meet these criteria based on the opinion of either the sponsor or investigator. In addition, the agency is making minor changes to align current IND safety reporting requirements with the proposed changes to postmarketing safety reporting.

The agency anticipates that very few investigator-initiated reports would be submitted under the proposed rule. Because the number of new reports (*i.e.*, approximately 10 per year) would represent less than 0.2 percent of all individual IND safety reports submitted to the agency in a year, no additional burden is estimated. However, up to 4 hours may be needed for sponsors to accommodate the new requirements for written safety reports for information sufficient to consider a change in product administration (see table 14).

In addition, the agency would require submission of expedited safety reports for certain bioavailability and bioequivalence studies that are exempt from submission of an IND. The agency estimates 14 hours per report are needed to comply (see table 14).

V.D.1.b.v. *Semiannual submissions of postmarketing individual case safety reports.* The current regulations require that postmarketing individual case safety reports from domestic marketing experience for serious expected adverse drug experiences, nonserious unexpected adverse drug experiences, and nonserious expected adverse drug experiences be submitted to the agency in postmarketing periodic safety reports. Under the proposed rule, most individual case safety reports not submitted to FDA as an expedited report would be submitted as a separate report twice a year. All reports of actual or potential medication errors, whether or not an SADR occurs, would be submitted as expedited reports and not submitted semiannually. Individual case safety reports of nonserious SADRs that are expected or listed would no longer be submitted to the agency. Exceptions, for vaccines, would be reports of nonserious, expected SARs and expected SARs with an unknown outcome, which would be submitted semiannually. Nevertheless, applicants would be expected to maintain these reports and include them in tabular summaries provided in the postmarketing periodic safety reports (*e.g.*, PSURs).

Whereas the current postmarketing periodic safety reporting regulations do not apply to foreign reports of SADRs, the proposed rule would require that foreign individual case safety reports of serious and expected or listed SADRS be submitted semiannually. The agency is unable to predict how many foreign reports may be submitted. For the purpose of this analysis, therefore, the number of nonserious and expected or listed individual case safety reports is assumed to be equal to the number of serious and expected or listed foreign reports, and the overall number of individual case safety reports submitted in a year would remain unchanged.

Although the number of individual case safety reports submitted annually as a postmarketing periodic safety report is expected to remain stable, the timing of these submissions may change. Reports will be submitted less frequently (semiannually rather than quarterly) for products that have been on the market for less than 3 years and more frequently (semiannually rather than annually) for products that have been on the market for more than 3 years. Furthermore, additional time may be needed for an active query to obtain a full data set for reports of serious and expected or listed SADRs and a minimum data set for all SADRs. Based on reports to AERS in 1998, the agency estimates that, on average, approximately 35 individual case safety reports may be submitted semiannually for each drug product. Regulatory affairs personnel and health professionals might spend up to 10 additional hours each to obtain and process information for each semiannual submission (see table 14).

TABLE 14.—ESTIMATED NEW BURDEN FOR EXPEDITED AND SEMIANNUAL REPORTS

Type of report	New or revised	New burden (hours)			
		Health professional	Regulatory affairs	Clerical	Total
Expedited:					
Serious and unexpected SADR	Revised	1	1	0	2
Always expedited report	New	2	12	2	16
Unexpected SADR with unknown outcome	New	3	18	3	24

TABLE 14.—ESTIMATED NEW BURDEN FOR EXPEDITED AND SEMIANNUAL REPORTS—Continued

Type of report	New or revised	New burden (hours)			
		Health professional	Regulatory affairs	Clerical	Total
Information sufficient to consider product administration changes.	New	3	3	2	8
Medication errors	New	2	12	2	16
30-day followup	New	3	4	1	8
Serious SARs—blood products	Revised	2	12	2	16
IND Safety:					
Information sufficient to consider product administration changes.	Revised	1	2	1	4
Bioavailability/bioequivalence safety report	New	1	11	2	14
Individual case safety reports—semiannual submission.	Revised	10	10	0	20

V.D.1.b.vi. *Postmarketing periodic safety reports (TPSR, PSUR, and IPSR).* Current agency regulations require applicants to submit postmarketing periodic safety reports at specified intervals. Each periodic safety report must contain a narrative summary and analysis of adverse drug experiences received since the last periodic report. The proposed regulation would require applicants to provide more thorough review and analysis of the safety profile for certain drugs.

For all applications approved on or after January 1, 1998, these reports would be in the PSUR format (with some variation) that is currently accepted by other regulatory authorities. These applications would be submitted semiannually for 2 years after the U.S. approval date, annually for the next 3 years, and every 5 years thereafter. In contrast to current regulations, postmarketing periodic safety reports would have to contain a more comprehensive analysis of the product's safety record. Specifically, applicants would be required to submit, as described in chart 1, summary tabulations of SADRs (*i.e.*, all SADR terms and counts of occurrences) received since the last periodic report categorized by body system or standard organ system classification scheme.

CHART 1.—REQUIRED SUMMARY TABULATIONS OF SADRS FOR PSURS

Source	Outcome
Spontaneous submissions from health care professionals	All serious and nonserious.
Studies or individual patient INDs	All serious.
Scientific literature	All serious; all nonserious unlisted.
Regulatory authorities	All serious.
Other (*e.g.* poison control centers, epidemiological data bases)	All serious.

In addition, applicants would have to submit cumulative summary tabulations for SADRs that are both serious and unlisted. Applicants would be required to include a discussion of these data including the medical significance or mechanism.

Applicants would be required to submit a discussion of safety information from applicant-sponsored studies (either planned or initiated) and published safety studies and abstracts. Furthermore, applicants would be required to include a discussion of certain lack of efficacy reports and important new information received after the data lock point. In addition to analysis of individual case safety reports and studies, applicants would be required to submit a comprehensive analysis of other safety information specified in the proposal, such as increased frequencies of listed SADRs, specific populations, and drug interactions.

Applicants would also be required to provide other relevant safety and baseline information as specified in the proposal. This information would include worldwide marketing status, changes to the CCSI, actions taken for safety reasons, and worldwide patient exposure. Appendices would include additional safety information as specified in the proposal including information related to the current (or proposed changes) in the U.S. labeling and safe use of the product, summary tabulations of spontaneous individual case safety reports from individuals other than a health care professional, summary tabulations of individual case safety reports of SADRs with unknown outcome and medication errors, summary tabulations of SADRs from class action lawsuits, U.S. patient exposure, assessments of lack of efficacy reports and new information on resistance to antimicrobial drug products. In addition, the name and telephone number of the licensed physicians responsible for the content and medical interpretation of the information in the PSUR and the addresses where all safety reports and other safety related records are maintained would be included.

The proposal also requires IPSRs for approvals on or after January 1, 1998. While following a similar format as the PSUR, the IPSR is less comprehensive than the PSUR (*i.e.*, does not require submission of summary tabulation information). This report would be submitted 7.5 and 12.5 years after the U.S. approval date.

Under the proposed regulation, TPSRs would be required for applications approved before January 1, 1998. Although less comprehensive than the PSUR, the TPSR would have to contain product safety information, including summary tabulations and a narrative summary and analysis of individual case safety reports, and a history of safety-related actions taken during the

reporting period. The timing for these report submissions would be at 5, 7.5, 10, 12.5, and 15 years after U.S. approval of the product and then every 5 years thereafter. Applicants would have the option to file using the PSUR and IPSR formats.

The additional times required to complete the proposed changes to postmarketing periodic safety report submissions are shown in table 15. The agency estimates that the new burdens would be 16 hours for TPSRs, 40 hours for PSURs, and 30 hours for IPSRs. These times represent estimates of the average time per report, recognizing that preparation times for each postmarketing periodic safety reports may take as little as a day for products with few or no SADRs or as much as several months for other products that are more complex or associated with many SADRs. Based on reports received by the agency, a few products account for the majority of the reports of SADRs. For example, 1998 AERS data showed that approximately 75 percent of the postmarketing periodic safety reports for drug products included 10 or fewer individual case safety reports, accounting for only about 5 percent of all of those reports submitted with postmarketing periodic safety reports. The other 25 percent of postmarketing periodic safety reports included the remaining 95 percent of individual case safety reports submitted in 1998.

TABLE 15.—ESTIMATED NEW BURDEN FOR PERIODIC SAFETY REPORTS AND OTHER REPORTS

Type of report	New or revised	New burden (hours)			
		Health professional	Regulatory affairs	Clerical	Total
Periodic:					
TPSR—application approved before 1/1/95	Revised	3	9	4	16
PSUR—application approved on or after 1/1/95	New	8	24	8	40
IPSR—application approved on or after 1/1/95	New	6	18	6	30
Other:					
Reports of nonserious SADRs and certain medication errors to manufacturer or applicant.	New	0	1	0	1
Submit safety records to FDA upon request	New	0	4	4	8
Annual reports	Revised	[1] (3)	(7.5)	(3)	(14)

[1] Values in parentheses represent an estimate of the decrease in burden.

V.D.1.b.vii. *Other reports.* Currently, persons submitting postmarketing safety reports may elect to submit reports of serious adverse drug experiences to the manufacturer or applicant rather than submitting serious unexpected adverse drug experiences directly to FDA. The proposed rule would require submission of all safety reports (*i.e.*, serious and nonserious SADRs and medication errors) to the manufacturer or applicant within 5 calendar days of initial receipt of the information. Contractors may need to allocate up to 1 additional hour to prepare and submit each report of a nonserious SADR or medication error that does not result in an SADR (see table 15).

Persons maintaining records of SADRs may be asked to submit any or all records to FDA within 5 calendar days. The agency estimates that 21 such requests for SADR records would be made in a given year. This new reporting requirement may take regulatory affairs and clerical personnel up to 4 hours each to fulfill each request (see table 15).

FDA will no longer require that applicants subject to an NDA or BLA submit certain safety related information with annual reports. This reduction in reporting requirements will decrease the burden on these applicants. To prepare and submit each annual report, applicants may save an estimated 13.5 hours annually (see table 15).

V.D.1.c. *Annual cost of the reporting and recordkeeping provisions.* Hourly compensation estimates for personnel implicated in the proposed changes to safety reports are shown in table 16. The additional cost of the proposed changes for each type of affected report and the total annual cost of the proposed rule are summarized in table 17. However, because the annual costs depend on the actual number and type of reports submitted to FDA, these costs are uncertain and may fluctuate from year to year. For example, if there are 50 percent fewer reports than estimated, annual costs would be approximately $52.2 million instead of $106.6 million. If the number of reports submitted is 50 percent more than shown in table 17, the annual costs would be about $159.9 million. The agency seeks comments on the reasonableness of its estimates of number of reports, burden hours, and costs.

TABLE 16.—HOURLY COMPENSATION

Health Practitioner[1]	Regulatory Affairs[2 3]	Clerical[2]
$67.31	$36.92	$17.39

[1] Hourly compensation derived from the annual salary range for clinical research physicians in the pharmaceutical industry from http://careers.yahoo.com. Hourly compensation includes benefits equal to 40 percent of hourly wage.
[2] U.S. Department of Labor, BLS, ''Employer Costs for Employee Compensation, Table 12,'' March 1999.
[3] Includes biostatisticians.

TABLE 17.—TOTAL ANNUAL COST OF NEW REPORTING BURDEN

Type of report	Number of affected reports	Per report cost of new burden	Annual cost ($ mil)
Expedited:			
Serious and unexpected SADRs	53,350	$104.23	$5.6
Always expedited reports	1,650	612.44	1.0
Unexpected SADR with unknown outcome	983	918.65	0.9
Information sufficient to consider product administration changes	309	$347.46	0.1
Medication errors	111,000	612.44	68.0
30-day followup	46,340	366.99	17.0
Serious SARs—blood products	7,000	612.44	4.3
IND Safety:			
Information sufficient to consider product administration changes	600	158.54	0.1
Bioavailability/bioequivalence safety report	200	508.21	0.1
Periodic:			
TPSR	1,435	603.76	0.9
PSUR	2,535	1,563.66	4.0
IPSR	353	1,172.75	0.4
Individual case safety reports—semiannual submission	5,206	1,042.28	5.4
Other:			
Reports of nonserious SADRs and certain medication errors to manufacturer or applicant	4,652	36.92	0.2
Submit safety records to FDA upon request	21	217.24	0.0
Annual reports	2,432	[1] (530.99)	(1.3)
Total Annual Cost of New Reporting Burden			$106.60

[1] Values in parentheses represent an estimate of cost savings.

V.D.2. Costs of MedDRA

FDA contracted with ERG to estimate the industry cost of using MedDRA terms to code individual case safety reports. In the fall of 1999, ERG and FDA staff visited three drug companies and conducted telephone interviews with several more companies and industry consultants. The purpose of the interviews was to collect information to assist in estimating the major cost components of implementing MedDRA. ERG's complete report is on file with the hearing clerk (Ref. 25).

Companies were asked to describe costs incurred or projected based on company experiences. Companies identified major cost elements that include one-time implementation costs such as planning and coordination of the conversion, converting existing data and information systems, and training. Recurring costs include MedDRA subscription and maintenance costs.

ERG applied estimates of cost by category and firm size to the number of affected firms within each industry. Estimates of affected drug and biologic product manufacturers are derived by applying data from 1998 FDA Adverse Drug Event Reports and Vaccine Adverse Event Reports to aggregate firm data from the Small Business Administration, Census of Manufactures and the National Science Foundation. Estimates of affected blood facilities are derived from the FDA Center for Biologics Evaluation and Research database of licensed and/or registered establishments, the National Blood Data Research Center and the Census Bureau.

Limitations on ERG cost estimation include the complexities associated with firms' abilities to separate incremental costs from factors that substantially influence expenditures, such as integrating operations of one or more newly merged corporations, isolating U.S. corporate policies and operations from global corporate policies and operations, and reaching consensus on the extent and timing of the conversion of historical SADRs and data.

V.D.2.a. *One-time costs*

V.D.2.a.i. *Planning and coordination.* Companies will need to allocate time to plan and coordinate the conversion of MedDRA across their affected operations. Planning costs are affected by the extent of decentralization of coding and pharmacovigilance work within the corporate structure. Managers for drug and biologics firms are expected to spend from 240 hours for very small firms to 1,400 hours for very large firms (greater than 750 or 500 employees respectively for drug and biologics firms) for planning and coordination. Costs per company ranged from $10,800 to $64,500 for drug and biologics firms. In contrast to drug and biologics firms, blood facilities have a limited range of products, do not need to convert legacy data, and typically operate only in the United States. Therefore, ERG judged that compliance costs for blood facilities would be 4 to 5 percent of equivalent-sized drug and biologics firms. Estimated costs per firm range from $450 to $2,260 for very small and very large firms, respectively.

V.D.2.a.ii. *Development of information technology support structure.* Companies reported that information technology (IT) personnel will need to modify existing database systems to:

- Accommodate adding a new medical dictionary,
- Allow for MedDRA's complex hierarchical structure and wider field widths,
- Reconcile the comparability of existing dictionaries with MedDRA (in the short term),
- Integrate a Web browser, and
- Install or modify an autoencoder system.

IT personnel are estimated to need from 720 hours for very small firms to 1,920 hours for very large firms to develop and validate computer data systems that will accommodate MedDRA. Costs are estimated to range from $25,850 to $68,900 for drug and biologics firms. No costs were forecast for blood facilities.

V.D.2.a.iii. *Purchase or development of an autoencoder.* Companies reported that they currently use an existing database such as COSTART or WHOART and supplement these dictionaries with their own medical vocabulary. Autoencoders assist with the automated conversion of existing medical terms to MedDRA. Companies

may purchase autoencoders, adapt existing in-house versions, or use outside contractors. Converting existing terms to MedDRA is estimated to cost from $20,000 to $100,000 for drug and biologics firms. Costs are not applicable to blood facilities.

V.D.2.a.iv. *Conversion of legacy safety data.* Some companies reported that they would convert virtually all of their legacy data into MedDRA terms even though it is not required by this proposed rule. Some companies maintain that this conversion includes information from clinical trials. Nonetheless, some companies may not convert their legacy drug safety data into MedDRA or may convert only some of their products, based on criteria associated with experience and history of the drug. ERG estimated that 75 percent of companies would incur conversion costs to allow for the range of company responses. The number of terms that are converted automatically (with autoencoders) or manually will affect conversion costs. Estimated costs per company for converting existing legacy data range from about $16,500 (for converting 15,000 terms) for very small firms to $275,000 (for converting roughly 250,000 terms) for very large drug firms. Costs for biologics firms of corresponding size range from $3,300 (for 3,000 terms) to $55,000 (for about 50,000 terms). Costs are not applicable to blood facilities.

V.D.2.a.v. *Training of personnel.* Companies reported that staff most likely to receive MedDRA training include medical coders, biostatisticians, and pharmacovigilance, IT, and regulatory affairs personnel. In addition to formal training, medical data coders will require several months of experience before they become proficient with coding in MedDRA. Training costs are dependent on the number of employees that must be trained in MedDRA and the level of training needed for their relevant duties. Training costs were estimated to range from $9,300 to $330,300 for very small to very large drug manufacturers and from $9,300 to $90,600 for biologics firms of corresponding size. ERG estimated training costs from $1,300 to $4,300 for very small to very large blood facilities.

V.D.2.a.vi. *Revision of standard operating procedures (SOPs).* Companies will revise a substantial group of SOPs in implementing MedDRA. Affected procedures include dictionary/coding, IT, and drug safety/pharmacovigilance. Drug and biologics firms are expected to need from 130 to 1,300 hours for very small to very large firms to revise their SOPs for MedDRA, with costs ranging from $5,900 to $59,200. ERG allocated 8 to 50 hours for developing or revising SOPs for blood facilities. Per firm costs for SOPs are estimated to range from $370 to $2,260 for very small to very large blood facilities.

V.D.2.b. Recurring costs

V.D.2.b.i. *MedDRA core subscription.* Companies must pay subscription costs on an annual basis to the MedDRA MSSO. Core subscription costs vary with the size of the company and with the level of services. Estimates of costs range from $5,000 to $40,000 for drug and biologics firms. ERG judged that blood facilities would incur only modest annual costs associated with MedDRA subscription and updates because of the limited range of terminology describing medical outcomes. ERG assumed that blood facilities would either work through industry associations to negotiate lower per firm subscription costs or, alternatively, contract with contract research organizations to obtain the necessary MedDRA codes.

V.D.2.b.ii. *MedDRA versions and quarterly updates.* Currently the MSSO intends to provide quarterly updates as well as periodic new versions of MedDRA. Companies did not have a sufficient history with incorporating MedDRA changes to estimate the costs of updates. Cost components would include senior level reviews of each update, communicating the changes to affected personnel, and IT support to upload and reconcile new versions. Costs are estimated to range from $5,700 to $43,000 for drug and biologics firms. No costs were assigned to blood facilities.

V.D.2.b.iii. *Maintenance of existing dictionaries.* Companies reported that they may need to maintain their existing dictionaries for an indeterminate time. Conditions that could influence whether and for how long a company would need to maintain its existing dictionaries are: (1) The company uses different dictionaries for its postmarketing safety and clinical study data bases; (2) the company has products in late-stage clinical trials; and (3) the company has marketed products near the end of their useful life. ERG estimates the maintenance costs for existing dictionaries are expected to range from $4,300 to $136,400 annually for drug manufacturers and from $4,300 to $43,400 annually for biologics manufacturers. No costs were assigned to blood facilities.

Table 18 presents the estimated costs to industry of implementing MedDRA for each cost category.

TABLE 18.—TOTAL COMPLIANCE COSTS OF MEDDRA BY COST CATEGORY

Drugs and biologics	Total cost [1] ($ million)	Percent of total [1]
First-Time Costs:		
Planning and coordination	16.3	9
Purchase or development of auto-encoder	20.5	12
Personnel training	46.0	27
Development of IT structure	14.7	9
Legacy safety data conversion	31.9	18
Revision of SOPs	14.8	9
Total First-time	144.2	83
Recurring Costs:		
Annual MedDRA core subscription	6.6	4
MedDRA versioning	6.9	4
Maintenance of additional medical dictionary	15.0	9
Total recurring	28.5	16
Total first year costs (First-time + recurring)	172.8	100

[1] Totals may not add due to rounding.

V.E. Small Business Analysis

The following analysis along with other sections of this preamble constitute the agency's regulatory flexibility analysis as required under the Regulatory Flexibility Act.

V.E.1. Need for and Objectives of the Rule

A primary objective of this proposed rule is the harmonization of FDA's safety reporting requirements with international initiatives. The proposed rule would also improve the quality of information contained in postmarketing safety reports for marketed human drug and biological products. By providing more complete information for individual case safety reports, the revised reports would enhance the ability of manufacturers, applicants, and the agency to identify, monitor, and communicate the risks and benefits of marketed drug and biological products. Monitoring these risks and benefits is especially critical for recently approved products introduced to large and diverse patient populations following market approval.

V.E.2. Description and Estimate of Small Entities

The proposed rule applies to manufacturers, applicants, and contractors of drug and biological products, and persons involved in blood collection and transfusion. The Small Business Administration (SBA) defines a small business in Standard Industrial Classification (SIC) 2834 (or North American Industry Classification System (NAICS) code 325412) as one employing fewer than 750 employees and in SIC 2836 (or NAICS code 325414) as one employing fewer than 500 employees. According to 1996 U.S. Bureau of the Census statistics, almost 90 percent of the firms under these SIC codes are considered small businesses. A review of 1998 AERS data, which contain postmarketing 15-day and periodic safety reports from manufacturers and applicants of marketed drug and biological products, found that about 200 firms submitted at least one individual case safety report for a trade name product and that the majority of these firms were considered large under the SBA definitions. However, the number of firms submitting reports vary from year to year. Therefore, using the 1998 AERS data, estimates of the percentages of reporting firms by size were distributed to the number of firms in each SIC, suggesting that about 230 drug and 72 biologics firms would be affected by the proposed rule, of which 190, or about 60 percent, would be considered small.

FDA estimates that about 3,200 blood facilities would be affected by the proposed regulation. Approximately 3,000 are hospitals with blood collection and/or compatibility testing operations, classified in SIC 8062 (or NAICS code 62211), and 200 are blood banks or non-hospital blood and plasmapheresis centers, classified in SIC 8099 (or NAICS code 621991). The SBA defines businesses in SIC 8062 and 8099 with annual revenues of $25 million and $7.5 million or less, respectively, as small. ERG estimated the number of small businesses affected in SIC's 8062 and 8099 at 1,786 and 188, respectively. This is approximately 60 and 94 percent of the blood facilities in SICs 8062 and 8099, respectively, that will be implementing the MedDRA requirements.

V.E.3. Projected Reporting, Recordkeeping, and Other Compliance Requirements

V.E.3.a. *Reporting and recordkeeping requirements.* The proposed rule may impose an additional burden on manufacturers of human drug products for which SADRs are reported. In any year, SADRs may be reported for about half of the products marketed in the United States. AERS data from 1998 suggest that small firms manufactured less than 12 percent of the products for which SADRs were reported. Moreover, during this same year, only about 2 percent of the postmarketing 15-day alert reports submitted to the agency were from small firms. Nevertheless, the proposed changes to the postmarketing safety reporting requirements may impose a substantial burden on a significant number of small firms, especially small startup firms with only one product on the market. The extent of the impact will depend on the time that has elapsed since the drug was approved and the number and types of individual case safety reports received in a reporting period.

To illustrate the impact of the safety reporting and recordkeeping requirements of the proposed rule, table 19 shows the hypothetical first-year burden for a drug approved 6 months prior to the effective date of the final rule. Under this scenario, the first-year burden incurred for a newly approved product might be as much as $19,600, assuming 26 expedited and 6 followup reports, two semiannual reports, and two PSURs had been submitted.

TABLE 19.—HYPOTHETICAL FIRST-YEAR REPORTING AND RECORDKEEPING BURDEN FOR NEWLY APPROVED DRUG PRODUCT

	Expedited (serious, unexpected SADR)	Expedited (medication errors)	Expedited (unexpected SADR with unknown outcome)	Always expedited report	30-day follow-up	Individual case safety report—semi-annual submission	PSUR	Total
Per report new burden [1]	$104	$612	$919	$612	$367	$1,042	$1,564	
Number of reports	8	16	1	1	6	2	2	36
Totals [2]	$834	$9,799	$919	$612	$2,202	$2,084	$3,128	$19,578

[1] Only whole dollar values are shown.
[2] Values rounded to the nearest whole number.

V.E.3.b. *Implementing MedDRA.* Implementing MedDRA would impose additional significant one-time and recurring costs on drug and biological product manufacturers. Costs would vary among individual firms depending on circumstances, including the number of products manufactured, the frequency of SADRs, and the extent of legacy data converted. Table 20 displays ERG's estimates per firm of revenues, annualized compliance costs and costs as a percent of revenues. Costs for small entities are 0.15 percent and 0.28 percent of revenues for drug and biological product manufacturers, respectively. Similarly, average compliance costs for small entities are

0.01 percent and 0.03 percent of revenue for SICs 8062 and 8099, respectively.

TABLE 20.—COMPLIANCE COSTS AS A PERCENT OF ESTIMATED REVENUES FOR SMALL ENTITIES

Industry classification	Number of employees	Number of affected firms	Per firm estimated revenues ($000)	Per firm annualized compliance costs ($000)	Compliance cost as a percent of estimated revenues
SIC 2834 Pharmaceutical preparations	< 750	146	44,265	66.9	0.15
SIC 2836 Biological products	< 500	44	15,752	44.4	0.28
SIC 8062 General medical and surgical hospitals	< 500	1,786	13,366	0.6	0.01
SIC 8099 Blood banks (Health and allied services, NEC)	< 500	188	1,320	0.3	0.03

The reporting, coding, and analysis of SADRs are standard procedures that manufacturers routinely conduct under current regulations. No additional professional skills would be necessary to comply with this rule. However, current safety reviewers, analysts, and IT personnel would need training to implement MedDRA.

V.E.4. Alternatives and Steps To Minimize the Impact on Small Entities

The major objectives of this proposed rule are to harmonize FDA's safety reporting requirements with international initiatives and to improve the quality of safety reports. With these objectives in mind, the agency considered alternatives to this proposed rule.

V.E.4.a. *Do nothing.* The agency considered but rejected the option of not proposing this rule. The proposed rule would align FDA's safety report terms, formats and requirements for human drugs and biological products with the recommendations of ICH. With regard to use of a medical dictionary for safety reporting purposes, at the present time, major problems exist with comparing safety data globally because multiple medical dictionaries are being used internationally for coding of SADRs (see section III.F.2 of this document). In this rule, the agency proposes to require the use of MedDRA, the medical dictionary developed by ICH. FDA believes that ''to do nothing'' would be inconsistent with the agency's efforts to harmonize safety reporting with international initiatives.

Another objective of this proposed rule is to improve the quality of safety reports. In this preamble, the agency cited a substantial number of studies that estimate the number of SADRs that have resulted in a hospitalization or that occur in a hospital and the hospital costs related to SADRs. Safety reports that are complete are critical and necessary to reduce SADRs, medication errors, and hospital costs. This proposed rule would improve the agency's ability to monitor the safety of human drugs and biological products. In light of this information, ''to do nothing'' would be inconsistent with the agency's mission of protecting public health.

V.E.4.b. *Do not require a medical dictionary.* The agency considered but rejected the alternative of not requiring the use of MedDRA terms in individual case safety reports. MedDRA is an integral part of the postmarket safety reporting system that was developed jointly with international stakeholders. Requiring MedDRA terms in safety reports will enhance the analysis of drug safety information. Moreover, MedDRA is a medical dictionary designed to translate terms in multiple languages, thus aiding in more expeditious and broader international drug use comparisons and analysis. Not requiring MedDRA would compromise the agency objective of improving drug safety reporting and analysis. In addition, continued use of multiple medical dictionaries to code SADRs will perpetuate the major problems with comparing safety data globally that currently exist.

V.E.4.c. *Do not require medication errors as expedited reports.* The agency considered but rejected the alternative of not requiring medication errors as expedited reports. Requiring expedited reports of medication errors would allow the agency to review critical information and take appropriate and more timely action on SADRs that are preventable. Not requiring expedited reports of medication errors would ignore a key step in reducing medical errors.

V.E.4.d. *Do not require blood establishments to submit reports for all serious SADRs associated with blood collection and transfusion.* The agency considered but rejected the alternative of not requiring blood establishments to submit reports for all serious SADRs associated with blood collection and transfusion, in addition to the current requirement to submit reports of fatalities. Because these establishments are currently required to conduct investigations and prepare and maintain reports of serious SADRs, this proposal would impose minimal costs. However, only some serious SADRs must be reported in a timely manner. The agency believes it is critical that we receive all such reports. This would improve the agency's ability to take appropriate action to protect the blood supply more consistently, to enhance donor safety and to ensure the safety, purity and potency of blood and blood components for administration to patients.

V.E.4.e. *Do not require certain bioavailability and bioequivalence reports as expedited reports.* The agency considered but rejected the alternative of not requiring expedited reports of SADRs for bioavailability and bioequivalence studies not subject to an IND. This requirement would allow the agency quicker access to information and would facilitate appropriate action to protect those enrolled in clinical trials.

V.E.4.f. *Waivers for economic hardship.* The agency recognizes that requiring individual case safety reports to be coded using MedDRA will likely impose significant costs on some small firms (see section III.F.2 of this document). One alternative would be to consider the option of allowing companies to request a waiver from MedDRA coding, based on economic hardship. The agency is seeking comment on ways to reduce economic hardships of implementing MedDRA while maintaining adequate procedures to monitor and assess the safety of products.

V.E.4.g *Small business outreach, training, and assistance.* The agency has received both written and verbal input from interested parties, including small businesses, on the recommendations of ICH regarding safety reporting for human drugs and biological products (*e.g.*, the ICH E2A guidance, the ICH E2C guidance, and ICH M1). These public comments addressed published draft versions of the ICH guidances as well as numerous agency presentations

at public workshops and forums (*e.g.*, sponsored by the Drug Information Association (DIA) or the Pharmaceutical Education and Research Institute (PERI)). The agency has considered these comments in development of this proposed rule.

Once this proposed rule is finalized, the agency will provide the public with an overview of the provisions in the rule at workshops and forums (*e.g.*, DIA meetings, PERI workshops). All firms, including small firms, would have an opportunity to attend these presentations.

Firms can access AERS-related information on the Internet at *http://www.fda.gov/cder/aers/index.htm.* The AERS site includes a ''Reporting Regulations and Guidances'' page that provides a summary of the rulemaking (proposed rules, final rules) and guidances regarding the agency's safety reporting requirements for human drugs and biological products. This site is updated as changes to the safety reporting requirements are made.

V.F. Unfunded Mandates Reform Act of 1995

On the basis of the preceding discussion, under the Unfunded Mandates Reform Act, FDA concludes that if only .85 percent of the estimated SADRs are prevented, then the benefits of this proposed rule will exceed the annualized compliance costs that it imposes on the U.S. economy. In addition, the agency has considered other alternatives as discussed in section V.E.4 of this document and determined that the proposed rule is the best alternative that would meet the objectives of this rule.

V.G. References

The following references have been placed on display in the Dockets Management Branch (address above) and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

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VI. Paperwork Reduction Act of 1995

This proposed rule contains collections of information which 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). ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes agency requests or requirements that members of the public obtain, maintain, retain, or report information to the agency, or disclose information to a third party or to the public. The title, description, and respondent description of the information collection are shown below with an estimate of the annual reporting burden. Included in the estimate is the time for reviewing instructions, gathering and maintaining the data needed, and completing and reviewing the collection of information.

FDA invites comments on: (1) Whether the proposed collection of information is necessary for proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the 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 through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Safety Reporting Requirements for Human Drug and Biological Products

Description: The proposed rule would amend FDA's safety reporting regulations for human drug and biological products to implement definitions, and reporting formats and standards as recommended by the International Conference on Harmonisation of Technical Requirements for Registration of Pharmaceuticals for Human Use (ICH) and by the World Health Organization's Council for International Organizations of Medical Sciences (CIOMS); codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed drugs and licensed biological products; require that certain information, such as domestic reports of medication errors, be submitted to the agency in an expedited manner; clarify certain safety reporting requirements; and make other minor revisions. The proposed rule would also amend FDA's postmarketing annual reports regulations for human drugs and licensed biological products by revising the content for these reports. These changes would further worldwide consistency in the collection of safety information and submission of safety reports, increase the quality of safety reports, expedite FDA's review of critical safety information, and enable the agency to protect and promote public health. The estimates provided in this section are not only attributed to the new proposed requirements in this rulemaking but also include burdens associated with our current safety reporting requirements.

VI.A. Expedited Safety Reporting

Proposed §§ 310.305(c)(2)(i), 314.80(c)(2)(i), and 600.80(c)(2)(i) would require manufacturers and applicants to submit a report to FDA for each SADR, received or otherwise obtained, that is both serious and unexpected, whether foreign or domestic, as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer or applicant of the minimum data set for the serious, unexpected SADR. Based on data concerning the number of expedited reports currently received by the agency, FDA estimates that approximately 350 expedited reports of serious and unexpected SADRs will be submitted annually under proposed § 310.305(c)(2)(i); approximately 50,000 reports will be submitted annually under proposed § 314.80(c)(2)(i); and approximately 3,000 reports will be submitted annually under proposed § 600.80(c)(2)(i). FDA estimates that approximately 14 manufacturers under proposed § 310.305(c)(2)(i) will submit these reports; approximately 282 applicants under proposed § 314.80(c)(2)(i) will submit these reports; and approximately 69 applicants under proposed § 600.80(c)(2)(i) will submit these reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 16 hours for manufacturers and applicants to prepare and submit one of these reports to FDA. Preparation of an expedited report for a serious and unexpected SADR would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(ii), 314.80(c)(2)(ii), and 600.80(c)(2)(ii) would require manufacturers and applicants to submit a report to FDA concerning information, received or otherwise obtained, whether foreign or domestic, that would be sufficient, based upon appropriate medical judgment, to consider product administration changes (*e.g.*, any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an IND, that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a drug or biological product used in treating a life-threatening or serious disease). Manufacturers and applicants would be required to submit this information to FDA as soon as possible, but in no case later than 15 calendar days after determination by the manufacturer or applicant that the information qualifies for expedited reporting. Expedited reports containing information that would be sufficient to consider changes in product administration are a new type of safety report. Based on data concerning voluntary reporting of this type of information to the agency, FDA estimates that approximately 5 expedited reports concerning information sufficient to consider product administration changes will be submitted annually under proposed § 310.305(c)(2)(ii); approximately 300 reports will be submitted annually under proposed § 314.80(c)(2)(ii); and approximately 4 reports will be submitted annually under proposed § 600.80(c)(2)(ii). FDA estimates that approximately 5 manufacturers under proposed § 310.305(c)(2)(ii) will submit these expedited reports; approximately 50 applicants under proposed § 314.80(c)(2)(ii) will submit these expedited reports; and approximately 4 applicants under proposed § 600.80(c)(2)(ii) will submit these expedited reports. Based on the content of the voluntary reports submitted to the agency, FDA estimates that it will take an average of 8 hours for manufacturers and applicants to prepare and submit an expedited report to FDA concerning information sufficient to consider product administration changes. Preparation of these expedited reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(iii), 314.80(c)(2)(iii), and 600.80(c)(2)(iii) would require manufacturers and applicants to submit a report to FDA for each SADR that is unexpected and for which the determination of an outcome is unattainable (*i.e.*, SADR with unknown outcome) within 45 calendar days after initial receipt by the manufacturer or applicant of the minimum data set for an unexpected SADR. Expedited reports of unexpected SADRs with an unknown outcome are a new type of safety report. Based on data concerning the number of unexpected SADR reports with an unknown outcome currently received by the agency, FDA estimates that approximately 46 expedited reports of an unexpected SADR with an unknown outcome will be submitted annually under proposed § 310.305(c)(2)(iii); approximately 912 reports will be submitted annually under proposed § 314.80(c)(2)(iii); and approximately 25 reports will be submitted annually under proposed § 600.80(c)(2)(iii). FDA estimates that approximately 10 manufacturers under proposed § 310.305(c)(2)(iii) will submit these expedited reports; approximately 109 applicants under proposed

§ 314.80(c)(2)(iii) will submit these expedited reports; and approximately 12 applicants under proposed § 600.80(c)(2)(iii) will submit these expedited reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 24 hours for manufacturers and applicants to prepare and submit an expedited report for an unexpected SADR with an unknown outcome to FDA. Preparation of expedited reports for unexpected SADRs with an unknown outcome would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(iv), 314.80(c)(2)(iv), and 600.80(c)(2)(iv) would require manufacturers and applicants to submit to FDA each SADR, received or otherwise obtained, whether foreign or domestic, that is the subject of an always expedited report. Certain medically significant SADRs (*e.g.*, ventricular fibrillation, liver necrosis, confirmed or suspected transmission of an infectious agent by a marketed drug or biological product) which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject would be subject to an always expedited report. These SADRs would be submitted to FDA whether unexpected or expected and whether or not the SADR leads to a serious outcome. Always expedited reports would be submitted to the agency within 15 calendar days after initial receipt by the manufacturer or applicant of the minimum data set for the report. Always expedited reports are a new type of safety report. Based on data concerning the number of safety reports currently received by the agency for the SADRs specified under proposed §§ 310.305(c)(2)(iv), 314.80(c)(2)(iv), and 600.80(c)(2)(iv), FDA estimates that approximately 50 always expedited reports will be submitted annually under proposed § 310.305(c)(2)(iv); approximately 1,500 reports will be submitted annually under proposed § 314.80(c)(2)(iv); and approximately 100 reports will be submitted annually under proposed § 600.80(c)(2)(iv). FDA estimates that approximately 10 manufacturers under proposed § 310.305(c)(2)(iv) will submit these expedited reports; approximately 100 applicants under proposed § 314.80(c)(2)(iv) will submit these expedited reports; and approximately 10 applicants under proposed § 600.80(c)(2)(iv) will submit these expedited reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 16 hours for manufacturers and applicants to prepare and submit an always expedited report to the agency. Preparation of always expedited reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(v), 314.80(c)(2)(v), and 600.80(c)(2)(v) would require manufacturers and applicants to submit all domestic reports of medication errors, whether actual or potential. Expedited reports of medication errors are a new type of safety report. Based on data concerning the number of domestic reports of medication errors voluntarily submitted to the agency, FDA estimates that approximately 1,000 reports of medication errors will be submitted annually under proposed § 310.305(c)(2)(v); approximately 100,000 reports will be submitted annually under proposed § 314.80(c)(2)(v); and approximately 10,000 reports will be submitted annually under proposed § 600.80(c)(2)(v). FDA estimates that approximately 10 manufacturers under proposed § 310.305(c)(2)(v) will submit these expedited reports; approximately 150 applicants under proposed § 314.80(c)(2)(v) will submit these expedited reports; and approximately 30 applicants under proposed § 600.80(c)(2)(v) will submit these expedited reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 16 hours for manufacturers and applicants to prepare and submit an expedited report of a medication error to the agency. Preparation of medication error reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(vi), 314.80(c)(2)(vi), and 600.80(c)(2)(vi) would require manufacturers and applicants to submit a 30-day followup report to FDA for any expedited report under proposed §§ 310.305(c)(2)(i), (c)(2)(iv), (c)(2)(v), 314.80(c)(2)(i), (c)(2)(iv), (c)(2)(v), 600.80(c)(2)(i), (c)(2)(iv), and (c)(2)(v) that does not contain a full data set. These 30-day followup reports would be submitted within 30 calendar days after submission of the expedited report. Thirty-day followup reports are a new type of safety report. Based on data concerning the number of followup reports received by the agency, FDA estimates that approximately 340 30-day followup reports will be submitted annually under proposed § 310.305(c)(2)(vi); approximately 43,000 30-day followup reports will be submitted annually under proposed § 314.80(c)(2)(vi); and approximately 3,000 30-day followup reports will be submitted annually under proposed § 600.80(c)(2)(vi). FDA estimates that approximately 7 manufacturers under proposed § 310.305(c)(2)(vi) will submit 30-day follow up reports; approximately 140 applicants under proposed § 314.80(c)(2)(vi) will submit 30-day follow up reports; and approximately 69 applicants under proposed § 600.80(c)(2)(vi) will submit 30-day followup reports. Based on the agency's familiarity with the content of followup reports for serious and unexpected SADRs, FDA estimates that it will take an average of 8 hours for manufacturers and applicants to prepare and submit a 30-day follow up report to the agency. Preparation of 30-day follow up reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(vii), 314.80(c)(2)(vii), and 600.80(c)(2)(vii) would require manufacturers and applicants to submit a 15-day followup report to FDA concerning any new information, received or otherwise obtained, after any initial expedited report or any followup report, except for

expedited reports which are subject to the 30-day followup reporting requirement under proposed §§ 310.305(c)(2)(vi), 314.80(c)(2)(vi), and 600.80(c)(2)(vi). Proposed §§ 310.305(b)(2), 314.80(b)(2), and 600.80(b)(2) would also require manufacturers and applicants to submit 15-day followup reports to FDA with any new information concerning an individual case safety report forwarded to the manufacturer or applicant by FDA. Proposed §§ 310.305(c)(2)(viii)(A), 314.80(c)(2)(viii)(A), and 600.80(c)(2)(viii)(A) would also require manufacturers and applicants to submit to FDA as 15-day followup reports any documents required under these paragraphs that become available after submission of an expedited report. These 15-day followup reports would be submitted within 15 calendar days of initial receipt of the new information by the manufacturer or applicant. Based on data concerning the number of followup reports currently received by the agency, FDA estimates that approximately 55 15-day followup reports will be submitted annually under proposed § 310.305(b)(2), (c)(2)(vii), and (c)(2)(viii)(A); approximately 10,000 15-day followup reports will be submitted annually under proposed § 314.80(b)(2), (c)(2)(vii), and (c)(2)(viii)(A); and approximately 1,000 15-day followup reports will be submitted annually under proposed § 600.80(b)(2), (c)(2)(vii), and (c)(2)(viii)(A). FDA estimates that approximately 10 manufacturers under proposed § 310.305 will submit 15-day followup reports; approximately 184 applicants under proposed § 314.80 will submit 15-day followup reports; and approximately 69 applicants under proposed § 600.80 will submit 15-day followup reports. Based on the agency's familiarity with the content of followup reports for serious and unexpected SADRs, FDA estimates that it will take an average of 4 hours for manufacturers and applicants to prepare and submit a 15-day followup report to FDA. Preparation of 15-day followup reports would include gathering information (proposed §§ 310.305(b) and (c)(1), 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 310.305(c)(2)(ix) and (c)(2)(x), 314.80(c)(2)(ix), and 600.80(c)(2)(ix)), and formatting information (proposed §§ 310.305(c)(2)(xii), (d), and (e), 314.80(c)(2)(xi), (c)(4), and (e), and 600.80(c)(2)(xi), (c)(4), and (e)).

Proposed §§ 310.305(c)(2)(xi), 314.80(c)(2)(x), and 600.80(c)(2)(x) would require contractors and shared manufacturers to submit safety reports of any SADRs or medication errors for the product to the manufacturer (proposed §§ 310.305(c)(2)(xi)) or applicant (proposed §§ 314.80(c)(2)(x) and 600.80(c)(2)(x)) within 5 calendar days of its receipt by the contractor or shared manufacturer. Based on information included in individual case safety reports currently submitted to the agency, FDA estimates that approximately 10 safety reports will be submitted to manufacturers annually under proposed § 310.305(c)(2)(xi); approximately 11,370 safety reports will be submitted to applicants annually under proposed § 314.80(c)(2)(x); and approximately 250 safety reports will be submitted to applicants annually under proposed § 600.80(c)(2)(x). FDA estimates that approximately 5 contractors under proposed § 310.305 will submit safety reports to the manufacturer; approximately 100 contractors under proposed § 314.80 will submit safety reports to the applicant; and approximately 20 contractors and shared manufacturers under proposed § 600.80 will submit safety reports to the applicant. Based on the agency's familiarity with the content of individual case safety reports, FDA estimates that it will take an average of 2 hours for contractors and shared manufacturers to prepare and submit a safety report to a manufacturer or applicant.

Proposed § 312.32(c)(1)(i) would require sponsors to notify FDA and all participating investigators in a written IND safety report of any SADR, based on the opinion of the investigator or sponsor, that is both serious and unexpected, as soon as possible, but in no case later than 15 calendar days after receipt by the sponsor of the minimum data set for the serious, unexpected SADR. The sponsor would identify all safety reports previously filed with the IND concerning a similar SADR and would analyze the significance of the SADR in light of previous, similar reports. Based on data concerning the number of written IND safety reports currently received by the agency, FDA estimates that approximately 4,860 written IND safety reports of serious and unexpected SADRs will be submitted annually under proposed § 312.32(c)(1)(i) for human drugs, and approximately 2,980 written IND safety reports will be submitted annually under proposed § 312.32(c)(1)(i) for human biological products. FDA estimates that approximately 457 sponsors will submit written IND safety reports for human drugs, and approximately 602 sponsors will submit written IND safety reports for human biological products. Based on the agency's familiarity with the content of written IND safety reports for serious and unexpected SADRs, FDA estimates that it will take an average of 16 hours for sponsors to prepare and submit one of these reports to FDA. Preparation of a written IND safety report for a serious and unexpected SADR would include gathering information (proposed § 312.32(b)) and formatting information (proposed § 312.32(c)(1)(iii)).

Proposed § 312.32(c)(1)(ii) would require sponsors to notify FDA and all participating investigators in a written IND safety report of information, based on appropriate medical judgment, that might materially influence the benefit-risk assessment of an investigational drug, or would be sufficient to consider changes in either product administration or in the overall conduct of a clinical investigation (*e.g.*, any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an IND, that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a drug or biological product used in treating a life-threatening or serious disease). This information would be submitted as soon as possible, but in no case later than 15 calendar days after determination by the sponsor that the information qualifies for expedited reporting. Based on information contained in written IND safety reports that the agency has received in the past, FDA estimates that approximately 300 written IND safety reports concerning information that might materially influence the benefit-risk assessment of an investigational drug, or that would be sufficient to consider changes in either product administration or in the overall conduct of a clinical investigation will be submitted annually under proposed § 312.32(c)(1)(ii) for human drugs, and approximately 300 reports will be submitted annually under proposed § 312.32(c)(1)(ii) for human biological products. FDA estimates that approximately 100 sponsors will submit these written IND safety reports for human drugs, and approximately 100 sponsors will submit these reports for human biological products. Based on the agency's familiarity with the content of written IND safety reports, FDA estimates that it will take an average of 8 hours for sponsors to prepare and submit this type of written IND safety

report to FDA. Preparation of these written IND safety reports would include gathering information (proposed § 312.32(b)) and formatting information (proposed § 312.32(c)(1)(iii)).

Proposed § 312.32(c)(2) would require sponsors to notify FDA by telephone or by facsimile transmission of any unexpected fatal or life-threatening SADR based on the opinion of the investigator or sponsor as soon as possible but in no case later than 7 calendar days after receipt by the sponsor of the minimum data set for an unexpected fatal or life-threatening SADR. Based on data concerning the number of telephone IND safety reports currently received by the agency, FDA estimates that approximately 490 telephone and facsimile IND safety reports will be submitted annually under proposed § 312.32(c)(2) for human drugs, and approximately 290 reports will be submitted annually under proposed § 312.32(c)(2) for human biological products. FDA estimates that approximately 135 sponsors will submit these reports for human drugs, and approximately 180 sponsors will submit these reports for human biological products. Based on the agency's familiarity with telephone and facsimile IND safety reports, FDA estimates that it will take an average of 4 hours for sponsors to prepare and submit one of these reports to FDA. Preparation of a telephone or facsimile IND safety report would include gathering information (proposed § 312.32(b)).

Proposed § 312.64(b) would require an investigator to notify the sponsor of any serious SADR immediately and any other SADR promptly unless the protocol or investigator's brochure specifies a different timetable for reporting the SADR. Based on data concerning the number of sponsors currently conducting clinical investigations under an IND and the number of written IND safety reports currently received by the agency, FDA estimates that approximately 100,000 investigator safety reports will be submitted to sponsors annually under proposed § 312.64(b) for human drugs, and approximately 60,000 investigator safety reports will be submitted to sponsors annually under proposed § 312.64(b) for human biological products. FDA estimates that approximately 10,000 investigators will submit safety reports to sponsors for human drugs, and approximately 6,000 investigators will submit safety reports to sponsors for human biological products. Based on the agency's familiarity with the content of IND safety reports, FDA estimates that it will take an average of 2 hours for an investigator to prepare and submit one of these reports to the sponsor.

Proposed § 320.31(d)(3) would require persons conducting human bioavailability and bioequivalence studies that are not subject to an IND to submit to FDA written safety reports as prescribed under proposed § 312.32(c)(1) and telephone and facsimile safety reports as prescribed under proposed § 312.32(c)(2). These persons would submit these safety reports to all participating investigators and the appropriate FDA division in the Center for Drug Evaluation and Research (*i.e.*, safety reports for the reference listed drug would be forwarded to the new drug review division that has responsibility for that drug; safety reports for the investigational drug product would be forwarded to the Director, Division of Bioequivalence, Office of Generic Drugs). These persons would be required to identify all safety reports previously filed for the bioavailability or bioequivalence study concerning a similar SADR, and analyze the SADR in light of previous similar reports, as required under proposed § 312.32(c)(1)(i). Written, telephone, and facsimile safety reports for bioavailability and bioequivalence studies not subject to an IND are a new type of safety report. Based on data concerning voluntary reporting to the agency of safety information for these bioavailability and bioequivalence studies, FDA estimates that approximately 200 safety reports will be submitted annually under proposed § 320.31(d)(3). FDA estimates that approximately 10 sponsors will submit these safety reports. Based on the agency's familiarity with the content of IND safety reports, FDA estimates that it will take an average of 14 hours for sponsors to prepare and submit a safety report to FDA.

Proposed § 606.170(b) would require blood establishments to notify FDA in a written report of any serious SAR, except a fatality, within 45 calendar days after determination of a serious SAR. These written reports would be submitted to FDA using the reporting format provided in proposed § 600.80(c)(4). Based on data from the scientific literature and reports voluntarily received by the agency, FDA estimates that approximately 7,000 written reports will be submitted annually under proposed § 606.170(b). FDA estimates that approximately 3,062 blood establishments will submit these written reports. Based on the agency's familiarity with the content of expedited reports for serious and unexpected SADRs, FDA estimates that it will take an average of 16 hours to prepare and submit each of these written reports to FDA.

Proposed § 606.170(c) would require blood establishments to notify FDA by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible of an SAR that results in a fatality. Proposed § 606.170(c) would also require these facilities to submit a written report to FDA within 7 calendar days after the fatality. The written reports would be submitted using the reporting format provided in proposed § 600.80(c)(4). Based on data concerning the number of reports for fatalities associated with blood collection and transfusion currently received by the agency, FDA estimates that approximately 75 reports will be submitted annually under proposed § 606.170(c). FDA estimates that approximately 75 blood establishments will submit these reports. Based on the agency's familiarity with the content of written reports for a fatality, FDA estimates that it will take an average of 20 hours to prepare and submit each of these reports to FDA.

VI.B. Periodic Safety Reports

Proposed §§ 314.80(c)(3)(i) and 600.80(c)(3)(i) would require persons holding an application (*i.e.*, NDA, ANDA, BLA) approved before January 1, 1998, to submit a TPSR every 5 years after U.S. approval of the application. These persons would also be required to submit a TPSR at 7.5 and 12.5 years after U.S. approval of the application. Based on data concerning postmarketing periodic safety reports currently received by the agency, FDA estimates that approximately 1,400 TPSRs will be submitted annually under proposed § 314.80(c)(3)(i); approximately 35 TPSRs will be submitted annually under proposed § 600.80(c)(3)(i). FDA estimates that approximately 80 applicants under proposed § 314.80(c)(3)(i) will submit TPSRs, and approximately 20 applicants under proposed § 600.80(c)(3)(i) will submit TPSRs. Based on the agency's familiarity with the content of postmarketing periodic safety reports, FDA estimates that it will take an average of 20 hours for applicants to prepare and submit a TPSR to FDA. Preparation of a TPSR would include gathering information (proposed §§ 314.80(b) and 600.80(b)), and providing attachments (proposed §§ 314.80(c)(3) and 600.80(c)(3)).

Proposed §§ 314.80(c)(3)(ii) and 600.80(c)(3)(ii) would require persons holding an application (*i.e.*, NDA, ANDA, BLA) approved on or after January 1, 1998, to submit a PSUR to

FDA according to the following schedule: Semiannually for 2 years after U.S. approval of the application, annually for the next 3 years, and then every 5 years thereafter. Proposed §§ 314.80(c)(3)(i) and 600.80(c)(3)(i) would permit persons holding an application (*i.e.*, NDA, ANDA, BLA) approved before January 1, 1998, to submit a PSUR, in lieu of a TPSR, every 5 years after U.S. approval of the application. Proposed §§ 314.80(c)(3)(iv) and 600.80(c)(3)(iv) would require persons holding an approved supplement to an approved application for use of the human drug or biological product in the pediatric population to submit a PSUR (even if the supplement or application was approved prior to January 1, 1998) to FDA according to the following schedule: Semiannually for 2 years after U.S. approval of the supplement, annually for the next 3 years, and then every 5 years thereafter. Based on data concerning postmarketing periodic safety reports currently received by the agency, FDA estimates that approximately 2,500 PSURs will be submitted annually under proposed § 314.80(c)(3)(i), (c)(3)(ii), and (c)(3)(iv), and approximately 35 PSURs will be submitted annually under proposed § 600.80(c)(3)(i), (c)(3)(ii), and (c)(3)(iv). FDA estimates that approximately 200 applicants under proposed § 314.80(c)(3) will submit PSURs, and approximately 20 applicants under proposed § 600.80(c)(3) will submit PSURs. Based on the agency's familiarity with the content of PSURs voluntarily submitted to the agency, FDA estimates that it will take an average of 40 hours for applicants to prepare and submit a PSUR to the agency. Preparation of a PSUR would include gathering information (proposed §§ 314.80(b) and 600.80(b)) and providing attachments (proposed §§ 314.80(c)(3) and 600.80(c)(3)).

Proposed §§ 314.80(c)(3)(iii) and 600.80(c)(3)(iii) would require persons holding an application (*i.e.*, NDA, ANDA, BLA) approved on or after January 1, 1998, to submit an IPSR to FDA 7.5 years and 12.5 years after U.S. approval of the application. Proposed §§ 314.80(c)(3)(i) and 600.80(c)(3)(i) would permit persons holding an application (*i.e.*, NDA, ANDA, BLA) approved before January 1, 1998, to submit an IPSR at 7.5 and 12.5 years after U.S. approval of the application. Proposed §§ 314.80(c)(3)(iv) and 600.80(c)(3)(iv) would require persons holding an approved supplement to an approved application for use of the human drug or biological product in the pediatric population to submit an IPSR (even if the supplement or application was approved prior to January 1, 1998) to FDA at 7.5 and 12.5 years after U.S. approval of the supplement. Based on data concerning postmarketing periodic safety reports currently received by the agency, FDA estimates that approximately 350 IPSRs will be submitted annually under proposed § 314.80(c)(3)(i), (c)(3)(iii), and (c)(3)(iv), and approximately 3 IPSRs will be submitted annually under proposed § 600.80(c)(3)(i), (c)(3)(iii), and (c)(3)(iv). FDA estimates that approximately 40 applicants under proposed § 314.80(c)(3) will submit IPSRs, and approximately 3 applicants under proposed § 600.80(c)(3) will submit IPSRs. Based on the agency's familiarity with the content of PSURs voluntarily submitted to the agency, FDA estimates that it will take an average of 30 hours for applicants to prepare and submit an IPSR to FDA. Preparation of an IPSR would include gathering information (proposed §§ 314.80(b) and 600.80(b)) and providing attachments (proposed §§ 314.80(c)(3) and 600.80(c)(3)).

Proposed §§ 314.80(c)(3)(v) and 600.80(c)(3)(v) would require persons holding an application (*i.e.*, NDA, ANDA, BLA) to submit to FDA every 6 months after U.S. approval of the application a report that consists of individual case safety reports (*i.e.*, FDA Form 3500As, VAERS forms for vaccines, CIOMS I forms, if desired, for foreign SADRs) for certain spontaneously reported SADRs for marketed human drug and biological products. Applicants that submit TPSRs to FDA would submit a report consisting of individual case safety reports for each spontaneously reported serious, expected SADR, whether domestic or foreign, and each spontaneously reported nonserious, unexpected SADR occurring in the United States during the reporting period. Reports for vaccines would include a VAERS form for each spontaneously reported nonserious, expected SAR and each expected SAR with unknown outcome occurring in the United States during the reporting period. Applicants that submit PSURs or IPSRs to FDA would submit a report consisting of individual case safety reports for each spontaneously reported serious, listed SADR, whether domestic or foreign, and each spontaneously reported nonserious, unlisted SADR occurring in the United States during the reporting period. Reports for vaccines would include a VAERS form for each spontaneously reported nonserious, listed SAR and each listed SAR with unknown outcome occurring in the United States during the reporting period. If a full data set is not available for a report of a serious SADR, the reason(s) for the lack of such information would be provided. Based on data concerning postmarketing periodic safety reports currently received by the agency, FDA estimates that approximately 4,726 of these reports will be submitted annually under proposed § 314.80(c)(3)(v), and approximately 480 of these reports will be submitted annually under proposed § 600.80(c)(3)(v). FDA estimates that approximately 285 applicants under proposed § 314.80(c)(3) will submit these reports, and approximately 69 applicants under proposed § 600.80(c)(3) will submit reports. Based on the agency's familiarity with the content of postmarketing periodic safety reports, FDA estimates that it will take an average of 120 hours for applicants to prepare and submit a report under proposed §§ 314.80(c)(3)(v) and 600.80(c)(3)(v) to the agency. Preparation of a report under proposed §§ 314.80(c)(3)(v) and 600.80(c)(3)(v) would include gathering information (proposed §§ 314.80(b) and (c)(1), and 600.80(b) and (c)(1)), providing attachments, if applicable (proposed §§ 314.80(c)(2)(ix) and (c)(3), and 600.80(c)(2)(ix) and (c)(3)), and formatting information (proposed §§ 314.80(c)(4) and (e), and 600.80(c)(4) and (e)).

VI.C. Other Reports

Proposed §§ 310.305(f)(1), 314.80(f), and 600.80(f) would require manufacturers, applicants, contractors, and shared manufacturers to submit to FDA, when appropriate, any or all records required to be maintained by these persons. These records would be required to be submitted within 5 calendar days after receipt of the request by the person. Records of all safety information pertaining to the person's product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SADRs or medication errors not submitted to FDA or only provided to FDA in a summary tabulation would be included, as well as records required to be maintained under proposed § 310.305 (§ 310.305(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(xi)(C)), proposed § 314.80 (§ 314.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C)), and proposed § 600.80 (§ 600.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C)). Submission of SADR records to FDA represents a new reporting requirement. Based on the agency's requests for voluntary

submission of safety records, FDA estimates that approximately 2 requests for submission of records will be fulfilled annually under proposed § 310.305(f)(1), approximately 15 requests for submission of records will be fulfilled annually under proposed § 314.80(f), and approximately 4 requests for submission of records will be fulfilled annually under proposed § 600.80(f). FDA estimates that approximately 2 manufacturers and contractors under proposed § 310.305 will submit these records, approximately 15 applicants and contractors under proposed § 314.80 will submit these records, and approximately 4 applicants, contractors and shared manufacturers under proposed § 600.80 will submit these records. Based on the volume of safety information voluntarily submitted to FDA in response to an agency request for such information, FDA estimates that it will take an average of 8 hours for manufacturers, applicants, contractors, and shared manufacturers to fulfill each request for submission of records to the agency.

Proposed § 314.81(b)(2) would require applicants of marketed drug products subject to an NDA to submit an annual report to FDA within 60 days of the anniversary date of U.S. approval of the application. This report would contain summary information; distribution data; chemistry, manufacturing, and controls changes; clinical data; and a status report of any postmarketing studies performed by, or on behalf of, the applicant. Based on data concerning the number of approved NDA annual reports received by the agency, FDA estimates that approximately 2,363 reports will be submitted under proposed § 314.81(b)(2). FDA estimates that approximately 286 applicants will submit these reports. Based on the agency's familiarity with the content of approved NDA annual reports, FDA estimates that it will take an average of 35.5 hours for applicants to prepare and submit one of these annual reports to FDA.

Proposed § 601.28 would require applicants of licensed biological products to submit an annual report of postmarketing pediatric studies to FDA within 60 days of the anniversary date of approval of the application. This report would contain summary information, clinical data in the pediatric population, and a status report of any postmarketing studies in the pediatric population. Based on data concerning the number of approved BLA annual reports received by the agency, FDA estimates that approximately 69 reports will be submitted under proposed § 601.28. FDA estimates that approximately 69 applicants will submit these reports. Based on the agency's familiarity with the content of approved BLA annual reports, FDA estimates that it will take an average of 25 hours for applicants to prepare and submit an annual report to the agency.

VI.D. Recordkeeping

Proposed §§ 310.305(c)(2)(xi)(B), 314.80(c)(2)(x)(B), and 600.80(c)(2)(x)(B) would require that contracts between manufacturers and contractors (proposed § 310.305(c)(2)(xi)(B)) and applicants and contractors (proposed §§ 314.80(c)(2)(x)(B) and 600.80(c)(2)(x)(B)) specify the safety reporting responsibilities of the contractor. For purposes of this section, a record represents a contract. Based on information contained in individual case safety reports submitted to the agency in the past (*i.e.*, report source), FDA estimates that approximately 4 records will be maintained annually under proposed § 310.305(c)(2)(xi)(B), approximately 480 records will be maintained annually under proposed § 314.80(c)(2)(x)(B), and approximately 2 records will be maintained annually under proposed § 600.80(c)(2)(x)(B). FDA estimates that approximately 2 manufacturers under proposed § 310.305 will maintain these records, approximately 160 applicants under proposed § 314.80 will maintain these records, and approximately 2 applicants under proposed § 600.80 will maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 1 hour for manufacturers and applicants to maintain each record annually under proposed §§ 310.305(c)(2)(xi)(B), 314.80(c)(2)(x)(B), and 600.80(c)(2)(x)(B).

Proposed §§ 310.305(f), 314.80(f), and 600.80(f) would require manufacturers, applicants, contractors, and shared manufacturers to maintain for a period of 10 years records of all safety information, received or otherwise obtained, including raw data; any correspondence relating to the safety information; and any reports of SADRs or medication errors not submitted to FDA or only provided to FDA in a summary tabulation. These persons would also be required to retain for a period of 10 years any records required to be maintained under proposed § 310.305 (§ 310.305(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(xi)(C)), proposed § 314.80 (§ 314.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C)), and proposed § 600.80 (§ 600.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C)). For the purposes of this section, a record includes any and all documentation regarding an individual SADR or medication error. Based on data concerning the number of SADRs currently reported to the agency, FDA estimates that approximately 500 records will be maintained annually under proposed § 310.305(f), approximately 220,000 records will be maintained annually under proposed § 314.80(f), and approximately 20,000 records will be maintained annually under proposed § 600.80(f). FDA estimates that approximately 25 manufacturers and contractors under proposed § 310.305 will maintain these records, approximately 700 applicants and contractors under proposed § 314.80 will maintain these records, and approximately 69 applicants, contractors, and shared manufacturers under proposed § 600.80 will maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 5 hours for manufacturers, applicants, contractors, and shared manufacturers to maintain each record annually under proposed §§ 310.305, 314.80, and 600.80.

Proposed §§ 310.305(g), 314.80(g), and 600.80(g) would require manufacturers, applicants, contractors, and shared manufacturers to maintain written procedures for the surveillance, receipt, evaluation, and reporting of safety information to FDA. Based on the number of persons subject to the postmarketing safety reporting regulations, FDA estimates that approximately 25 records will be maintained annually under proposed § 310.305(g), approximately 700 records will be maintained annually under proposed § 314.80(g), and approximately 69 records will be maintained annually under proposed § 600.80(g). FDA estimates that approximately 25 manufacturers and contractors under proposed § 310.305 will maintain these records, approximately 700 applicants and contractors under proposed § 314.80 will maintain these records, and approximately 69 applicants, contractors, and shared manufacturers under proposed § 600.80 will maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 1 hour for manufacturers, applicants, contractors, and shared manufacturers to maintain a record of the written procedures

annually under proposed §§ 310.305(g), 314.80(g), and 600.80(g).

Proposed § 312.32(c) would require sponsors to maintain records for reports of SADRs that do not contain a minimum data set. This would include any information received or otherwise obtained for the SADR along with a record of their efforts to obtain a minimum data set for the report. For the purposes of this section, a record includes any and all documentation regarding an individual SADR. Maintaining records of SADRs that do not contain a minimum data set represents a new recordkeeping requirement. Based on information contained in IND safety reports, FDA estimates that approximately 200 records will be maintained annually under proposed § 312.32(c) for human drugs; approximately 240 records will be maintained annually under proposed § 312.32(c) for human biological products. FDA estimates that approximately 50 sponsors will maintain these records for human drugs and approximately 60 sponsors will maintain these records for human biological products. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 1 hour for sponsors to maintain each record annually under proposed § 312.32(c).

Proposed § 606.170(a) would require blood collection and transfusing facilities to maintain records for complaints of SARs regarding each unit of blood or blood product. These facilities must prepare a written report of the investigation of SARs, including followup and conclusions. Based on data for records currently maintained by blood collection and transfusing facilities, FDA estimates that approximately 4,512 records will be maintained annually under proposed § 606.170(a). FDA estimates that approximately 376 facilities will maintain these records. Based on the agency's familiarity with recordkeeping processes, FDA estimates that it will take an average of 12 hours for facilities to maintain each record annually under proposed § 606.170(a).

Description of Respondents: Business or other for-profit organizations.

In compliance with section 3507(d) of 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 and approval of these information collections. Interested persons are requested to send comments regarding this information collection, including suggestions for reducing this burden, to the Office of Information and Regulatory Affairs, OMB, New Executive Office Bldg., 725 17th St. NW., rm. 10235, Washington, DC 20503, OMB, Attn: Stuart Shapiro, Desk Officer for FDA, FAX: 202–395–6974. Submit written comments on the information collection by April 14, 2003.

TABLE 21.—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
310.305(c)(2)(i) [2]	14	25	350	16	5,600
310.305(c)(2)(ii)	5	1	5	8	40
310.305(c)(2)(iii)	10	4.6	46	24	1,104
310.305(c)(2)(iv)	10	5	50	16	800
310.305(c)(2)(v)	10	100	1,000	16	16,000
310.305(c)(2)(vi)	7	48.6	340	8	2,720
310.305(b)(2), (c)(2)(vii), and (c)(2)(viii)(A)	10	5.5	55	4	220
310.305(c)(2)(xi)	5	2	10	2	20
310.305(f)(1)	2	1	2	8	16
312.32(c)(1)(i) [3]—human drugs	457	10.6	4,860	16	77,760
312.32(c)(1)(ii)—human drugs	100	3	300	8	2,400
312.32(c)(2)—human drugs	135	3.6	490	4	1,960
312.32(c)(1)(i)—human biological products	602	4.9	2,980	16	47,680
312.32(c)(1)(ii)—human biological products	100	3	300	8	2,400
312.32(c)(2)—human biological products	180	1.6	290	4	1,160
312.64(b)—human drugs	10,000	10	100,000	2	200,000
312.64(b)—human biological products	6,000	10	60,000	2	120,000
314.80(c)(2)(i) [4]	282	177.3	50,000	16	800,000
314.80(c)(2)(ii)	50	6	300	8	2,400
314.80(c)(2)(iii)	109	8.4	912	24	21,888
314.80(c)(2)(iv)	100	15	1,500	16	24,000
314.80(c)(2)(v)	150	666.7	100,000	16	1,600,000
314.80(c)(2)(vi)	140	307.1	43,000	8	344,000
314.80(b)(2), (c)(2)(vii), and (c)(2)(viii)(A)	184	54.3	10,000	4	40,000
314.80(c)(2)(x)	100	113.7	11,370	2	22,740
314.80(c)(3)(i)	80	17.5	1,400	20	28,000
314.80(c)(3)(i), (c)(3)(ii), and (c)(3)(iv)	200	12.5	2,500	40	100,000
314.80(c)(3)(i), (c)(3)(iii), and (c)(3)(iv)	40	8.7	350	30	10,500
314.80(c)(3)(v)	285	16.6	4,726	120	567,120
314.80(f)	15	1	15	8	120
314.81(b)(2)	286	8.3	2,363	35.5	83,886
320.31(d)(3)	10	20	200	14	2,800
600.80(c)(2)(i) [5]	69	43.5	3,000	16	48,000
600.80(c)(2)(ii)	4	1	4	8	32
600.80(c)(2)(iii)	12	2.1	25	24	600
600.80(c)(2)(iv)	10	10	100	16	1,600
600.80(c)(2)(v)	30	333.3	10,000	16	160,000
600.80(c)(2)(vi)	69	43.5	3,000	8	24,000
600.80(b)(2), (c)(2)(vii), and (c)(2)(viii)(A)	69	14.5	1,000	4	4,000
600.80(c)(2)(x)	20	12.5	250	2	500
600.80(c)(3)(i)	20	1.8	35	20	700
600.80(c)(3)(i), (c)(3)(ii), and (c)(3)(iv)	20	1.8	35	40	1,400

TABLE 21.—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR section	Number of respondents	Number of responses per respondent	Total annual responses	Hours per response	Total hours
600.80(c)(3)(i), (c)(3)(iii), and (c)(3)(iv)	3	1	3	30	90
600.80(c)(3)(v)	69	6.9	480	120	57,600
600.80(f)	4	1	4	8	32
601.28	69	1	69	25	1,725
606.170(b)	3,062	2.3	7,000	16	112,000
606.170(c)	75	1	75	20	1,500
Total	23,283	2,149.7	424,794	896.5	4,541,113

[1] The estimates provided in this table are not only attributed to the new proposed requirements in this rulemaking but also include burdens associated with our current safety reporting requirements. There are no capital costs or operating and maintainence costs associated with this collection of information.
[2] The paragraphs of § 310.305 cited in the table include burdens associated with gathering information under § 310.305(b) and (c)(1), providing attachments, if applicable, under § 310.305(c)(2)(ix) and (c)(2)(x), and formatting information under § 310.305(c)(2)(xii), (d), and (e).
[3] The paragraphs of § 312.32 cited in the table include burdens associated with gathering information under § 312.32(b) and formatting information under § 312.32(c)(1)(iii).
[4] The paragraphs of § 314.80 cited in the table include burdens associated with gathering information under § 314.80(b) and (c)(1), providing attachments, if applicable, under § 314.80(c)(2)(ix) and (c)(3), and formatting information under § 314.80(c)(2)(xi), (c)(4), and (e).
[5] The paragraphs of § 600.80 cited in the table include burdens associated with gathering information under § 600.80(b) and (c)(1), providing attachments, if applicable, under § 600.80(c)(2)(ix) and (c)(3), and formatting information under § 600.80(c)(2)(xi), (c)(4), and (e).

TABLE 22.—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR section	Number of recordkeepers	Annual frequency of recordkeeping	Total annual records	Hours per record	Total hours
310.305(c)(2)(xi)(B)	2	2	4	1	4
310.305(f) [2]	25	20	500	5	2,500
310.305(g)	25	1	25	1	25
312.32(c)—human drugs	50	4	200	1	200
312.32(c)—human biological products	60	4	240	1	240
314.80(c)(2)(x)(B)	160	3	480	1	480
314.80(f) [3]	700	314.3	220,000	5	1,100,000
314.80(g)	700	1	700	1	700
600.80(c)(2)(x)(B)	2	1	2	1	2
600.80(f) [4]	69	289.8	20,000	5	100,000
600.80(g)	69	1	69	1	69
606.170(a)	376	12	4,512	12	54,144
Total	2,238	653.1	246,732	35	1,258,364

[1] The estimates provided in this table are not only attributed to the new proposed requirements in this rulemaking but also include burdens associated with our current safety reporting requirements. There are no capital costs or operating costs associated with this collection of information. There are maintenance costs of $2,025 annually per recordkeeper ($2,000 annually per recordkeeper for existing recordkeeping requirements (see 67 FR 47821) and $25 annually per recordkeeper for new proposed requirements in this rulemaking).
[2] Includes records required to be maintained under § 310.305(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(xi)(C).
[3] Includes records required to be maintained under § 314.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C).
[4] Includes records required to be maintained under § 600.80(c)(1)(ii), (c)(1)(iii)(A), (c)(2)(ii), (c)(2)(viii)(A), and (c)(2)(x)(C).

VII. Executive Order 13132: Federalism

Executive Order 13132 requires Federal agencies to carefully examine regulatory actions to determine if they would have a significant impact on federalism. Using the criteria and principles set forth in the Executive order, the agency has considered the impact of this proposed rule on the States, on their relationship with the Federal Government, and on the distribution of power and responsibilities among the various levels of government.

FDA is publishing this proposed rule to revise its regulations governing the format, content, and submission of safety reports to the agency for human drugs and biological products. The proposal would revise current regulations to implement definitions and reporting formats and standards recommended by ICH and CIOMS. The proposal would codify the agency's expectations for timely acquisition, evaluation, and submission of relevant safety information for marketed drugs and biological products. The proposal would require that postmarketing individual case safety reports of unexpected SADRs that cannot be classified as either serious or nonserious be submitted to the agency in an expedited manner. The proposal would also require that certain medically significant SADRs always be submitted to FDA in an expedited manner whether the SADR is unexpected or expected. The proposal would also require that all domestic reports of medication errors, whether actual or potential, be submitted to FDA in an expedited manner. The proposal would clarify certain safety reporting requirements and make other minor revisions. The proposal would also amend the agency's postmarketing annual reports regulations for applicants of human drugs and licensed biological products to revise the content for these reports. The proposal would also amend the agency's bioavailability and bioequivalence study regulations for sponsors of human drugs to require expedited safety reports for certain studies which are exempt from submission of an IND. Because enforcement of these safety reporting requirements would be a Federal responsibility, there would be little, if

any, impact on the States from this rule if finalized.

FDA has analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. FDA has determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, the agency has concluded that the rule does not contain policies that have federalism implications as defined in the Executive order and, consequently, a federalism summary impact statement is not required.

List of Subjects

21 CFR Part 310

Administrative practice and procedure, Drugs, Labeling, Medical devices, Reporting and recordkeeping requirements.

21 CFR Part 312

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

21 CFR Part 314

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

21 CFR Part 320

Drugs, Reporting and recordkeeping requirements.

21 CFR Part 600

Biologics, Reporting and recordkeeping requirements.

21 CFR Part 601

Administrative practice and procedure, Biologics, Confidential business information.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act, the Public Health Service Act, and under authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR parts 310, 312, 314, 320, 600, 601, and 606 be amended as follows:

PART 310—NEW DRUGS

1. The authority citation for 21 CFR part 310 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360b–360f, 360j, 361(a), 371, 374, 375, 379e; 42 U.S.C. 216, 241, 242(a), 262, 263b–263n.

2. Section 310.305 is revised to read as follows:

§ 310.305 Safety reporting and recordkeeping for manufacturers of prescription drugs marketed for human use without an approved application.

(a) *Definitions.* The following definitions of terms apply to this section:

Active query means direct verbal contact (*i.e.*, in person or by telephone or other interactive means such as a video conference) with the initial reporter of a suspected adverse drug reaction (SADR) or a medication error by a health care professional (*e.g.*, physician, physician assistant, pharmacist, dentist, nurse, any individual with some form of health care training) representing the manufacturer. For SADRs, active query entails, at a minimum, a focused line of questioning designed to capture clinically relevant information associated with the drug product and the SADR, including, but not limited to, information such as baseline data, patient history, physical exam, diagnostic results, and supportive lab results.

Actual medication error means a medication error that involves an identifiable patient whether the error was prevented prior to administration of the product or, if the product was administered, whether the error results in a serious SADR, nonserious SADR, or no SADR.

Contractor means any person (*e.g.,* packer or distributor whether or not its name appears on the label of the product; licensee; contract research organization) that has entered into a contract with the manufacturer to manufacture, pack, sell, distribute, or develop the drug or to maintain, create, or submit records regarding SADRs or medication errors.

Disability means a substantial disruption of a person's ability to conduct normal life functions.

Full data set means completion of all the applicable elements on FDA Form 3500A (or on a Council for International Organizations of Medical Sciences (CIOMS) I form for reports of foreign SADRs), including a concise medical narrative of the case (*i.e.*, an accurate summary of the relevant data and information pertaining to an SADR or medication error).

Life-threatening SADR means any SADR that, in the view of the initial reporter, places the patient at *immediate* risk of death from the SADR as it occurred. It does not include an SADR that, had it occurred in a more severe form, might have caused death.

Medication error means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: Prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Minimum data set means the report includes an identifiable patient, an identifiable reporter, a suspect drug product, and an SADR.

Nonserious SADR means any SADR that is determined not to be a serious SADR.

Potential medication error means an individual case safety report of information or complaint about product name, labeling, or packaging similarities that does not involve a patient.

SADR with unknown outcome means an SADR that cannot be classified, after active query, as either serious or nonserious.

Serious SADR means any SADR that results in any of the following outcomes: Death, a life-threatening SADR, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious SADR when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Spontaneous report means a communication from an individual (*e.g.*, health care professional, consumer) to a company or regulatory authority that describes an SADR or medication error. It does not include cases identified from information solicited by the manufacturer or contractor, such as individual case safety reports or findings derived from a study, company-sponsored patient support program, disease management program, patient registry, including pregnancy

registries, or any organized data collection scheme. It also does not include information compiled in support of class action lawsuits.

Suspected adverse drug reaction (SADR) means a noxious and unintended response to any dose of a drug product for which there is a reasonable possibility that the product caused the response. In this definition, the phrase ''a reasonable possibility'' means that the relationship cannot be ruled out.

Unexpected SADR means any SADR that is not included in the current U.S. labeling for the drug product. Reactions that may be symptomatically and pathophysiologically related to a reaction included in the U.S. labeling, but differ from the labeled reaction because of greater severity or specificity, would be unexpected. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the U.S. labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the U.S. labeling only included cerebral vascular accidents. ''Unexpected,'' as used in this definition, refers to an SADR that has not been previously observed (*i.e.*, included in the U.S. labeling); it does not refer to an SADR that might be anticipated from the pharmacological properties of the drug product. SADRs that are mentioned in the U.S. labeling as occurring with a class of drugs but not specifically mentioned as occurring with the particular drug are considered unexpected.

(b) *Review of safety information.* (1) Each manufacturer of a prescription drug product marketed for human use without an approved application must promptly review all safety information pertaining to its product obtained or otherwise received by the manufacturer from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiology/surveillance studies, animal or in vitro studies, electronic communications with manufacturers via the Internet (*e.g.*, e-mail), reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not been previously reported to the Food and Drug Administration (FDA) by the manufacturer.

(2) Individual case safety reports that are forwarded to the manufacturer by FDA must not be resubmitted to the agency by the manufacturer; however, manufacturers must submit to FDA all followup information for these reports.

(c) *Reporting requirements.* The manufacturer must submit to FDA one copy of each expedited report (described under paragraphs (c)(2)(i) through (c)(2)(vii) of this section) pertaining to its drug product. Upon written notice, FDA may require, when appropriate, that the manufacturer submit reports under this section to FDA at times other than those stated.

(1) *Determination of outcome, minimum data set, and full data set*—(i)(A) *Initial determinations.* Upon initial receipt of an SADR report, the manufacturer must immediately determine, the outcome for the SADR (whether the SADR is serious or nonserious) and at least the minimum data set for the individual case safety report. For reports of actual medication errors that do not result in an SADR and potential medication errors, the manufacturer must immediately determine the minimum information for the individual case safety report (minimum information described under paragraphs (c)(1)(iii)(B) and (c)(1)(iii)(C) of this section). If the manufacturer is not able to immediately determine the information in this paragraph, active query must be used to obtain it as soon as possible.

(B) *Spontaneous reports.* For spontaneous reports, the manufacturer must always assume, for safety reporting purposes under this section, that there is at least a reasonable possibility, in the opinion of the initial reporter, that the drug product caused the spontaneously reported event.

(C) *Clinical trials.* For a clinical trial, the possibility that the drug product caused the SADR or that a medication error has occurred must be assumed if either the investigator or the manufacturer believes that such a reasonable possibility exists.

(ii) *SADRs with unknown outcome.* For an SADR with unknown outcome that cannot be immediately determined, the manufacturer must continue to use active query to attempt to determine the outcome of the SADR within 30 calendar days after initial receipt of the SADR report by the manufacturer. The manufacturer must maintain a record of its efforts to determine the outcome for an SADR with unknown outcome.

(iii)(A) *Minimum data set for SADR reports.* The manufacturer must not submit an individual case safety report for an SADR to FDA if the report does not contain a minimum data set; instead, the manufacturer must maintain records of any information received or otherwise obtained for the SADR along with a record of its efforts to obtain a minimum data set.

(B) *Minimum information for reports of actual medication errors that do not result in an SADR.* For reports of actual medication errors that do not result in an SADR, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an SADR). These reports must contain at least an identifiable patient, an identifiable reporter, and a suspect drug product.

(C) *Minimum information for potential medication error reports.* For reports of potential medication errors, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an identifiable patient or an SADR). These reports must contain at least an identifiable reporter and a suspect drug product.

(iv) *Full data set.* For reports of serious SADRs, always expedited reports (see paragraph (c)(2)(iv) of this section), and medication error reports (see paragraph (c)(2)(v) of this section), the manufacturer must submit a full data set. If a full data set is not available for the report, the manufacturer must use active query to obtain this information. If a full data set is not obtainable, after active query, the manufacturer must:

(A) Submit all safety information, received or otherwise obtained, for the report;

(B) Indicate the reason(s) for its inability to acquire a full data set; and

(C) Document its efforts to obtain a full data set (*i.e.*, description of unsuccessful steps taken to obtain this information).

(v) *Serious SADRs not initially reported by health care professional.* For a serious SADR that was not initially reported to the manufacturer by a health care professional (*e.g.*, report from a consumer), the manufacturer must contact the health care professional associated with the care of the patient using active query to gather further medical perspective on the case and to acquire a full data set for the report. If the manufacturer is unable to contact the health care professional, it must include in the report for the serious SADR:

(A) The reason(s) for its inability to contact the health care professional; and

(B) A description of its efforts to contact the health care professional.

(2) *Postmarketing ''expedited reports''*—(i) *Serious and unexpected SADR.* The manufacturer must report to FDA each SADR, received or otherwise obtained, that is both serious and

unexpected, whether foreign or domestic, as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer of the minimum data set for the serious, unexpected SADR. If a full data set is not available for the serious and unexpected SADR report at the time of initial submission of the report to FDA, the manufacturer must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(ii) *Information sufficient to consider product administration changes.* The manufacturer must also report to FDA information, received or otherwise obtained, whether foreign or domestic, that would be sufficient, based upon appropriate medical judgment, to consider changes in product administration. The manufacturer must submit this information to FDA, as soon as possible, but in no case later than 15 calendar days after determination by the manufacturer that the information qualifies for expedited reporting. Examples of such information include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an investigational new drug application (IND), that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a drug product used in treating a life-threatening or serious disease. The manufacturer must maintain a record of its efforts to determine whether the information required to be reported under this paragraph qualifies for expedited reporting.

(iii) *Unexpected SADR with unknown outcome.* The manufacturer must also report to FDA each SADR that is unexpected and for which the determination of an outcome is unattainable (*i.e.*, SADR with unknown outcome) within 45 calendar days after initial receipt by the manufacturer of the minimum data set for the unexpected SADR. The manufacturer must document in the expedited report the reason(s) for the inability to determine the outcome.

(iv) *Always expedited report.* (A) The manufacturer must also report to FDA each SADR, received or otherwise obtained, whether foreign or domestic, that is the subject of an always expedited report. These reports must be submitted to FDA as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer of the minimum data set for the report. The following medically significant SADRs, which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject, are subject to an always expedited report:

(*1*) Congenital anomalies,
(*2*) Acute respiratory failure,
(*3*) Ventricular fibrillation,
(*4*) Torsades de pointe,
(*5*) Malignant hypertension,
(*6*) Seizure,
(*7*) Agranulocytosis,
(*8*) Aplastic anemia,
(*9*) Toxic epidermal necrolysis,
(*10*) Liver necrosis,
(*11*) Acute liver failure,
(*12*) Anaphylaxis,
(*13*) Acute renal failure,
(*14*) Sclerosing syndromes,
(*15*) Pulmonary hypertension,
(*16*) Pulmonary fibrosis,
(*17*) Confirmed or suspected transmission of an infectious agent by a marketed drug or biological product,
(*18*) Confirmed or suspected endotoxin shock, and
(*19*) Any other medically significant SADR that FDA determines to be the subject of an always expedited report (*i.e.*, may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject).

(B) SADRs that are the subject of an always expedited report must be submitted to FDA whether unexpected or expected and whether or not the SADR leads to a serious outcome. If a full data set is not available for an always expedited report at the time of initial submission of the report to FDA, the manufacturer must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(v) *Medication errors*—(A) *Actual medication error.* The manufacturer must also submit to FDA each domestic report of an actual medication error, received or otherwise obtained, as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer of the minimum data set for a report of an SADR or, if an SADR does not occur, the minimum information described under paragraph (c)(1)(iii)(B) of this section (*i.e.*, identifiable patient, identifiable reporter, and suspect drug product).

(B) *Potential medication error.* The manufacturer must also submit to FDA each domestic report of a potential medication error, received or otherwise obtained, as soon as possible, but in no case later than 15 calendar days after receipt by the manufacturer of the minimum information described under paragraph (c)(1)(iii)(C) of this section (*i.e.*, identifiable reporter and suspect drug product).

(C) *Full data set.* If a full data set is not available for an actual or potential medication error report at the time of initial submission of the report to FDA, the manufacturer must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(vi) *The 30-day followup report.* The manufacturer must use active query to obtain additional information for any expedited report under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that does not contain a full data set and must submit a followup report to FDA within 30 calendar days after initial submission of the expedited report to FDA by the manufacturer. If a full data set is still not obtainable, the 30-day followup report must contain the information required under paragraph (c)(1)(iv) of this section. Any new safety information in the 30-day followup report must be highlighted. Any new information, received or otherwise obtained, after submission of a 30-day followup report must be submitted to FDA as a 15-day followup report under paragraph (c)(2)(vii) of this section.

(vii) *The 15-day followup report.* The manufacturer must report to FDA any new information, received or otherwise obtained, for any expedited or followup report (except for initial expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set) within 15 calendar days of initial receipt of the new information by the manufacturer. Expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set at the time of initial submission of the report to FDA are subject to the 30-day followup reporting requirements under paragraph (c)(2)(vi) of this section rather than the 15-day followup reporting requirements under this paragraph.

(viii) *Supporting documentation.* (A) If the patient dies, the manufacturer must submit a copy of the autopsy report to FDA, if it is available. If an autopsy report is not available, the manufacturer must submit a death certificate to FDA. If an autopsy report becomes available after the manufacturer has submitted a death certificate to the agency, the autopsy report must be submitted to FDA. If the patient was hospitalized, the manufacturer must submit a copy of the hospital discharge summary to FDA, if it is available. If any of these documents is not in English, the document must be

accompanied by an English translation. Manufacturers must use active query to obtain these documents. These documents must be submitted to FDA as 15-day followup reports (see paragraph (c)(2)(vii) in this section) within 15 calendar days of initial receipt of the document by the manufacturer. If these documents are not submitted to FDA in a 15-day followup report within 3 months after submission of the initial expedited report for the death or hospitalization, the agency will assume that active query by the manufacturer has not resulted in access to these documents. In this case, a record of the reason(s) for the lack of such documentation and the effort that was made to obtain the documentation must be maintained by the manufacturer.

(B) Each expedited report must contain in the narrative a list of other relevant documents (*e.g.*, medical records, laboratory results, data from studies) for the report that are maintained by the manufacturer. When appropriate, FDA may require a manufacturer to submit copies of one or more of these documents to the agency within 5 calendar days after receipt of the request.

(ix) *Scientific literature.* An expedited report based on information from the scientific literature applies only to reports found in scientific and medical journals. These expedited reports must be accompanied by a copy of the published article.

(x) *Attachments.* Each expedited report must be accompanied by a copy of the current U.S. labeling for the drug product and a list of current addresses where all safety reports and other safety-related records for the drug product are maintained by manufacturers and contractors.

(xi) *Submission of safety reports by contractors.* (A) Contractors must submit to the manufacturer safety reports of any SADRs or medication errors for the manufacturer's drug product, obtained or otherwise received, within 5 calendar days of initial receipt of the report by the contractor. The contractor must submit a safety report for an SADR to the manufacturer even if the report does not contain a minimum data set. Upon receipt of the safety report from a contractor, the manufacturer must comply with the postmarketing safety reporting requirements of this section.

(B) A contract between the manufacturer and a contractor must specify the postmarketing safety reporting responsibilities of the contractor. The manufacturer is responsible for ensuring that the contractors of its drug products comply with these postmarketing safety reporting responsibilities.

(C) The contractor must maintain a record of each submission to the manufacturer under paragraph (c)(2)(xi)(A) of this section that includes:

(*1*) A copy of each safety report;

(*2*) The date the report was initially received by the contractor;

(*3*) The date the report was submitted to the manufacturer; and

(*4*) The name and address of the manufacturer.

(D) The recordkeeping, written procedures, and disclaimer provisions under paragraphs (f) through (h) of this section apply to contractors.

(xii) *Report identification.* Each expedited report submitted to FDA under paragraphs (c)(2)(i) through (c)(2)(vii) of this section must bear prominent identification as to its contents, *e.g.*, ''expedited report—§ 310.305—serious and unexpected SADR,'' ''expedited report—§ 310.305—30-day followup report.'' Each type of report (*e.g.*, serious and unexpected SADR reports, 30-day followup reports) must be submitted to FDA under separate cover. Reports of medication errors must indicate whether the error is actual or potential and if actual, whether a serious SADR, nonserious SADR, or no SADR occurred, *e.g.*, ''expedited report—§ 310.305—actual medication error—nonserious SADR,'' ''expedited report—§ 310.305—potential medication error.''

(d) *Reporting format.* (1)(i) Except as provided in paragraphs (d)(1)(ii), (d)(1)(iv), and (d)(5) of this section, the manufacturer must complete an FDA Form 3500A for each individual case safety report of an SADR. Reports based on information about individual cases or case series in the scientific literature must be submitted on an FDA Form 3500A(s).

(ii) Foreign SADRs may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form.

(iii) Each domestic report of an actual or potential medication error must be submitted on an FDA Form 3500A.

(iv) Reports of overall findings or data in the aggregate from published and unpublished in vitro, animal, epidemiological, or clinical studies must be submitted in a narrative format.

(2) Each SADR in an individual case safety report must be coded on the FDA Form 3500A or CIOMS I form using the appropriate ''preferred term'' in the latest version of MedDRA (the medical dictionary for regulatory activities) in use at the time the manufacturer becomes aware of the individual case safety report. For individual case safety reports of medication errors, the report must be coded both as a medication error and, if applicable, with the preferred term for any SADRs associated with the medication error.

(3) Each completed FDA Form 3500A or CIOMS I form should refer only to an individual case.

(4) Each completed FDA Form 3500A or CIOMS I form must include the name and telephone number (and fax number and e-mail address, if available) for the licensed physician responsible for the content and medical interpretation of the data contained within the form (*i.e.*, contact person for the company).

(5) Instead of using FDA Form 3500A, the manufacturer may use a computer-generated facsimile of FDA Form 3500A provided that it is readable, includes appropriate identifying information, and contains all the elements (*i.e.*, format, sections, blocks, titles, descriptors within blocks, text for disclaimer) of FDA Form 3500A in the identical enumerated sequence of the form. For individual case safety reports in which no suspect medical device is involved, a one-page FDA Form 3500A is acceptable.

(e) *Patient privacy.* The names and addresses of individual patients should not be included in reports under this section; instead, the manufacturer and its contractors should assign a unique code to each report, preferably not more than eight characters (*i.e.*, numbers/letters) in length. The name of the reporter from whom the information was received should be included. Names of patients, individual reporters, health care professionals, hospitals, and geographic identifiers in safety reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter.

(f) *Recordkeeping.* (1) Each manufacturer must maintain for a period of 10 years records of all safety information pertaining to its drug product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SADRs or medication errors not submitted to FDA. The manufacturer must also retain for a period of 10 years any records required to be maintained under this section. When appropriate, FDA may require a manufacturer to submit any or all of these records to the agency within 5 calendar days after receipt of the request.

(2) Manufacturers and packers may retain the records required in paragraph (f)(1) of this section as part of its complaint files maintained under § 211.198 of this chapter.

(3) Manufacturers must permit any authorized FDA employee, at all

reasonable times, to have access to and copy and verify the records established and maintained under this section.

(g) *Written procedures.* Each manufacturer must develop and maintain written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing safety information to FDA.

(h) *Disclaimer.* A report or information submitted by a manufacturer under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the manufacturer or by FDA, that the report or information constitutes an admission that the drug caused or contributed to an SADR. The manufacturer need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an SADR.

PART 312—INVESTIGATIONAL NEW DRUG APPLICATION

3. The authority citation for 21 CFR part 312 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 371; 42 U.S.C. 262.

4. Section 312.32 is amended by revising paragraphs (a), (b), the introductory text of paragraph (c), paragraphs (c)(1) and (c)(4), and the first sentence of paragraph (c)(2); in paragraph (d)(3) by removing the phrase ''adverse drug experience'' and by adding in its place the abbreviation ''SADR'' and by removing the phrase ''such experience'' and by adding in its place the phrase ''such reaction''; and in paragraph (e) by removing the phrase ''adverse experience'' both times it appears and by adding in its place the abbreviation ''SADR'' to read as follows:

§ 312.32 IND safety reports.

(a) *Definitions.* The following definitions of terms apply to this section:

Disability means a substantial disruption of a person's ability to conduct normal life functions.

Life-threatening suspected adverse drug reaction (SADR) means any SADR that, in the view of the investigator or sponsor, places the patient or subject at immediate risk of death from the SADR as it occurred. It does not include an SADR that, had it occurred in a more severe form, might have caused death.

Minimum data set means the report includes an identifiable patient, an identifiable reporter, a suspect drug product, and an SADR.

Serious SADR means any SADR that results in any of the following outcomes: Death, a life-threatening SADR, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious SADR when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Suspected adverse drug reaction (SADR) means a noxious and unintended response to any dose of a drug product for which there is a reasonable possibility that the product caused the response. In this definition, the phrase ''a reasonable possibility'' means that the relationship cannot be ruled out.

Unexpected SADR means any SADR, the specificity or severity of which is not consistent with the current investigator brochure; or, if an investigator brochure is not required or available, the specificity or severity of which is not consistent with the risk information described in the general investigational plan or elsewhere in the current application, as amended. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the investigator brochure only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the investigator brochure only included cerebral vascular accidents. ''Unexpected,'' as used in this definition, refers to an SADR that has not been previously observed (*e.g.,* included in the investigator brochure); it does not refer to an SADR that might be anticipated from the pharmacological properties of the drug product. SADRs that are mentioned in the investigator's brochure as occurring with a class of drugs but not specifically mentioned as occurring with the particular drug are considered unexpected.

(b) *Review of safety information.* The sponsor must promptly review all information relevant to the safety of the drug obtained or otherwise received by the sponsor from any source, foreign or domestic, including information derived from any clinical or epidemiological investigations, animal or in vitro studies, reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not been previously reported to FDA by the sponsor and reports of foreign commercial marketing experience for drugs that are not marketed in the United States.

(c) *IND safety reports.* The sponsor must not submit an individual case safety report for an SADR to FDA if the report does not contain a minimum data set; instead, the sponsor must maintain records of any information received or otherwise obtained for the SADR along with a record of its efforts to obtain a minimum data set.

(1) *Written reports*—(i) *Serious and unexpected SADR.* The sponsor must notify FDA and all participating investigators in a written IND safety report of any SADR that, based on the opinion of the investigator or sponsor, is both serious and unexpected, as soon as possible, but in no case later than 15 calendar days after receipt by the sponsor of the minimum data set for the serious, unexpected SADR. The sponsor must identify all safety reports previously filed with the IND concerning a similar SADR, and must analyze the significance of the SADR in light of previous, similar reports.

(ii) *Information sufficient to consider product administration changes.* The sponsor must also notify FDA and all participating investigators in a written IND safety report of information that, based upon appropriate medical judgment, might materially influence the benefit-risk assessment of an investigational drug or that would be sufficient to consider changes in either product administration or in the overall conduct of a clinical investigation. The sponsor must submit this information to FDA and all participating investigators as soon as possible, but in no case later than 15 calendar days after the determination by the sponsor that the information qualifies for reporting under this paragraph. Examples of such information include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an IND, that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity or reports of a lack of efficacy with a drug product used in treating a life-threatening or serious disease.

(iii) *Submission of written reports.* Each written report may be submitted on an FDA Form 3500A or in a narrative format. Foreign SADRs may be

submitted either on an FDA Form 3500A or, if preferred, on a Council for International Organizations of Medical Sciences (CIOMS) I form. Reports of overall findings or data in the aggregate from published and unpublished in vitro, animal, epidemiological, or clinical studies must be submitted in a narrative format. Each written notice must bear prominent identification of its contents, *i.e.,* ''IND safety report.'' Each written notification to FDA must be transmitted to the FDA review division that has responsibility for the review of the IND. If FDA determines that additional data are needed, the agency may require further data to be submitted.

(2) *Telephone and facsimile transmission safety reports.* The sponsor must also notify FDA by telephone or by facsimile transmission of any unexpected fatal or life-threatening SADR based on the opinion of the investigator or sponsor as soon as possible but in no case later than 7 calendar days after receipt by the sponsor of the minimum data set for the unexpected fatal or life-threatening SADR. * * *

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(4) *Investigations of marketed drugs.* A sponsor of a clinical study under an IND for a drug marketed in the United States is only required to submit IND safety reports to FDA (review division that has responsibility for the IND) for SADRs from the clinical study itself, whether from domestic or foreign study sites of the IND. The sponsor must also submit to FDA safety information from these clinical studies as prescribed by the postmarketing safety reporting requirements under §§ 310.305, 314.80, and 600.80 of this chapter.

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5. Section 312.64 is amended by revising paragraph (b) to read as follows:

§ 312.64 Investigator reports.

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(b) *Safety reports.* An investigator must report to the sponsor any serious SADR (as defined in § 312.32(a)) immediately and any other SADR (as defined in § 312.32(a)) promptly unless the protocol or investigator's brochure specifies a different timetable for reporting the SADR.

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PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG

6. The authority citation for 21 CFR part 314 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 355a, 356, 356a, 356b, 356c, 371, 374, 379e.

7. Section 314.80 is revised to read as follows:

§ 314.80 Postmarketing safety reporting and recordkeeping.

(a) *Definitions.* The following definitions of terms apply to this section:

Active query means direct verbal contact (*i.e.,* in person or by telephone or other interactive means such as a video conference) with the initial reporter of a suspected adverse drug reaction (SADR) or medication error by a health care professional (*e.g.,* physician, physician assistant, pharmacist, dentist, nurse, any individual with some form of health care training) representing the applicant. For SADRs, active query entails, at a minimum, a focused line of questioning designed to capture clinically relevant information associated with the drug product and the SADR, including, but not limited to, information such as baseline data, patient history, physical exam, diagnostic results, and supportive lab results.

Actual medication error means a medication error that involves an identifiable patient whether the error was prevented prior to administration of the product or, if the product was administered, whether the error results in a serious SADR, nonserious SADR, or no SADR.

Company core data sheet means a document prepared by the applicant containing, in addition to safety information, material relating to indications, dosing, pharmacology, and other information concerning the drug substance. The only purpose of this document is to provide the company core safety information (CCSI) for periodic safety update reports (PSURs), interim periodic safety reports (IPSRs), and certain individual case safety reports—semiannual submissions (*i.e.,* if PSURs are submitted for the product).

Company core safety information (CCSI) means all relevant safety information contained in the company core data sheet that the applicant proposes to include in the approved product labeling in all countries where the applicant markets the drug substance. It is the reference information by which an SADR is determined to be ''listed'' or ''unlisted'' for PSURs, IPSRs, and certain individual case safety reports-semiannual submissions (*i.e.,* if PSURs are submitted for the product).

Contractor means any person (*e.g.,* manufacturer, packer or distributor whether its name appears on the label of the product; licensee; contract research organization) that has entered into a contract with the applicant to manufacture, pack, sell, distribute, or develop the drug or to maintain, create, or submit records regarding SADRs or medication errors.

Data lock point means the date designated as the cut-off date for data to be included in a postmarketing periodic safety report.

Disability means a substantial disruption of a person's ability to conduct normal life functions.

Full data set means completion of all the applicable elements on FDA Form 3500A (or on a Council for International Organizations of Medical Sciences (CIOMS) I form for reports of foreign SADRs), including a concise medical narrative of the case (*i.e.,* an accurate summary of the relevant data and information pertaining to an SADR or medication error).

International birth date means the date the first regulatory authority in the world approved the first marketing application for a human drug product containing the drug substance.

Life-threatening SADR means any SADR that, in the view of the initial reporter, places the patient at immediate risk of death from the SADR as it occurred. It does not include an SADR that, had it occurred in a more severe form, might have caused death.

Listed SADR means an SADR whose nature, specificity, severity, and outcome are consistent with the information in the CCSI.

Medication error means any preventable event that may cause or lead to inappropriate medication use or patient harm, while the medication is in the control of the health care professional, patient or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: Prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Minimum data set means the report includes an identifiable patient, an identifiable reporter, a suspect drug product, and an SADR.

Nonserious SADR means any SADR that is determined not to be a serious SADR.

Potential medication error means an individual case safety report of information or complaint about product name, labeling, or packaging similarities that does not involve a patient.

SADR with unknown outcome means an SADR that cannot be classified, after active query, as either serious or nonserious.

Serious SADR means any SADR that results in any of the following outcomes: Death, a life-threatening SADR, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious SADR when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Spontaneous report means a communication from an individual (*e.g.*, health care professional, consumer) to a company or regulatory authority that describes an SADR or medication error. It does not include cases identified from information solicited by the applicant or contractor, such as individual case safety reports or findings derived from a study, company-sponsored patient support program, disease management program, patient registry, including pregnancy registries, or any organized data collection scheme. It also does not include information compiled in support of class action lawsuits.

Suspected adverse drug reaction (SADR) means a noxious and unintended response to any dose of a drug product for which there is a reasonable possibility that the product caused the response. In this definition, the phrase ''a reasonable possibility'' means that the relationship cannot be ruled out.

Unexpected SADR means any SADR that is not included in the current U.S. labeling for the drug product. Reactions that may be symptomatically and pathophysiologically related to a reaction included in the U.S. labeling, but differ from the labeled reaction because of greater severity or specificity, would be unexpected. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the U.S. labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the U.S. labeling only included cerebral vascular accidents. ''Unexpected,'' as used in this definition, refers to an SADR that has not been previously observed (*i.e.*, included in the U.S. labeling); it does not refer to an SADR that might be anticipated from the pharmacological properties of the drug product. SADRs that are mentioned in the U.S. labeling as occurring with a class of drugs but not specifically mentioned as occurring with the particular drug are considered unexpected.

Unlisted SADR means an SADR whose nature, specificity, severity, or outcome is not consistent with the information included in the CCSI.

(b) *Review of safety information.* (1) Each applicant having an approved application for a drug product under section 505(c) of the act must promptly review all safety information pertaining to its product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiology/surveillance studies, animal or in vitro studies, electronic communications with applicants via the Internet (*e.g.*, e-mail), reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not been previously reported to FDA by the applicant.

(2) Individual case safety reports that are forwarded to the applicant by FDA must not be resubmitted to the agency by the applicant; however, applicants must include information from these individual case safety reports in any comprehensive safety analysis subsequently submitted to FDA. In addition, applicants must submit to FDA all followup information for these individual case safety reports.

(c) *Reporting requirements.* The applicant must submit to FDA two copies of each postmarketing expedited report (described under paragraphs (c)(2)(i) through (c)(2)(vii) of this section) and one copy of each postmarketing periodic safety report of an individual case safety reports—semiannual submission (described under paragraph (c)(3)(v) of this section) pertaining to its drug product. The applicant must also submit to FDA one copy of a PSUR, IPSR, or traditional periodic safety report (TPSR)) along with one copy for each approved application for a human drug product covered by the report. FDA may waive the requirement for multiple copies in appropriate instances. Upon written notice, FDA may require, when appropriate, that the applicant submit reports under this section to FDA at times other than those stated. An applicant that wishes to submit reports under this section at different intervals must submit to FDA a request for a waiver under § 314.90.

(1) *Determination of outcome, minimum data set, and full data set*—(i)(A) *Initial determinations.* Upon initial receipt of an SADR report, the applicant must immediately determine the outcome for the SADR (whether the SADR is serious or nonserious) and at least the minimum data set for the individual case safety report. For reports of actual medication errors that do not result in an SADR and potential medication errors the applicant must immediately determine the minimum information for the individual case safety report (minimum information described under paragraphs (c)(1)(iii)(B) and (c)(1)(iii)(C) of this section). If the applicant is not able to immediately determine the information in this paragraph, active query must be used to obtain it as soon as possible.

(B) *Spontaneous reports.* For spontaneous reports, the applicant must always assume, for safety reporting purposes under this section, that there is at least a reasonable possibility, in the opinion of the initial reporter, that the drug product caused the spontaneously reported event.

(C) *Clinical trials.* For a clinical trial, the possibility that the drug product caused the SADR or that a medication error has occurred must be assumed if either the investigator or the applicant believes that such a reasonable possibility exists.

(ii) *SADRs with unknown outcome.* For an SADR with unknown outcome that cannot be immediately determined, the applicant must continue to use active query to attempt to determine the outcome of the SADR within 30 calendar days after initial receipt of the SADR report by the applicant. The applicant must maintain a record of its efforts to determine the outcome for an SADR with unknown outcome.

(iii)(A) *Minimum data set for SADR reports.* The applicant must not submit an individual case safety report for an SADR to FDA if the report does not contain a minimum data set; instead, the applicant must maintain records of any information received or otherwise obtained for the SADR along with a record of its efforts to obtain a minimum data set.

(B) *Minimum information for reports of actual medication errors that do not result in an SADR.* For reports of actual medication errors that do not result in an SADR, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an SADR). These reports must contain at

least an identifiable patient, an identifiable reporter, and a suspect drug product.

(C) *Minimum information for potential medication error reports.* For reports of potential medication errors, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an identifiable patient or an SADR). These reports must contain at least an identifiable reporter and a suspect drug product.

(iv) *Full data set.* For reports of serious SADRs, always expedited reports (see paragraph (c)(2)(iv) of this section), and medication error reports (see paragraph (c)(2)(v) of this section), the applicant must submit a full data set. If a full data set is not available for the report, the applicant must use active query to obtain this information. If a full data set is not obtainable, after active query, the applicant must:

(A) Submit all safety information, received or otherwise obtained, for the report;

(B) Indicate the reason(s) for its inability to acquire a full data set; and

(C) Document its efforts to obtain a full data set (*i.e.*, description of unsuccessful steps taken to obtain this information).

(v) *Serious SADRs not initially reported by a health care professional.* For a serious SADR that was not initially reported to the applicant by a health care professional (*e.g.*, report from a consumer), the applicant must contact the health care professional associated with the care of the patient using active query to gather further medical perspective on the case and to acquire a full data set for the report. If the applicant is unable to contact the health care professional, it must include in the report for the serious SADR:

(A) The reason(s) for its inability to contact the health care professional; and

(B) A description of its efforts to contact the health care professional.

(vi) *Nonserious SADRs.* For reports of nonserious SADRs with a minimum data set, except for those resulting from a medication error, all safety information received or otherwise obtained by the applicant must be submitted to FDA even though information in addition to the minimum data set is not required to be acquired. Reports of nonserious SADRs resulting from a medication error require a full data set under paragraph (c)(1)(iv) of this section.

(2) *Postmarketing ''expedited reports''*—(i) *Serious and unexpected SADR.* The applicant must report to FDA each SADR, received or otherwise obtained, that is both serious and unexpected, whether foreign or domestic, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for the serious unexpected SADR. If a full data set is not available for the serious and unexpected SADR at the time of initial submission of the expedited report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(ii) *Information sufficient to consider product administration changes.* The applicant must also report to FDA information, received or otherwise obtained, whether foreign or domestic, that would be sufficient, based upon appropriate medical judgment, to consider changes in product administration. The applicant must submit this information to FDA as soon as possible, but in no case later than 15 calendar days after determination by the applicant that the information qualifies for expedited reporting. Examples of such information include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an investigational new drug application (IND), that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a drug product used in treating a life-threatening or serious disease. The applicant must maintain a record of its efforts to determine whether the information required to be reported under this paragraph qualifies for expedited reporting.

(iii) *Unexpected SADR with unknown outcome.* The applicant must also report to FDA each SADR that is unexpected and for which the determination of an outcome is unattainable (*i.e.*, SADR with unknown outcome) within 45 calendar days after initial receipt by the applicant of the minimum data set for the unexpected SADR. The applicant must document in the expedited report the reason(s) for the inability to determine the outcome.

(iv) *Always expedited report.* (A) The applicant must also report to FDA each SADR, received or otherwise obtained, whether foreign or domestic, that is the subject of an always expedited report. These reports must be submitted to FDA as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for the report. The following medically significant SADRs, which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject are subject to an always expedited report:

(*1*) Congenital anomalies,
(*2*) Acute respiratory failure,
(*3*) Ventricular fibrillation,
(*4*) Torsades de pointe,
(*5*) Malignant hypertension,
(*6*) Seizure,
(*7*) Agranulocytosis,
(*8*) Aplastic anemia,
(*9*) Toxic epidermal necrolysis,
(*10*) Liver necrosis,
(*11*) Acute liver failure,
(*12*) Anaphylaxis,
(*13*) Acute renal failure,
(*14*) Sclerosing syndromes,
(*15*) Pulmonary hypertension,
(*16*) Pulmonary fibrosis,
(*17*) Confirmed or suspected transmission of an infectious agent by a marketed drug or biological product,
(*18*) Confirmed or suspected endotoxin shock, and
(*19*) Any other medically significant SADR that FDA determines to be the subject of an always expedited report (*i.e.*, may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject).

(B) SADRs that are the subject of an always expedited report must be submitted to FDA whether unexpected or expected and whether the SADR leads to a serious outcome or not. If a full data set is not available for an always expedited report at the time of initial submission of the report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(v) *Medication errors*—(A) *Actual medication error.* The applicant must also submit to FDA each domestic report of an actual medication error, received or otherwise obtained, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for a report of an SADR or, if an SADR does not occur, the minimum information described under paragraph (c)(1)(iii)(B) of this section (*i.e.*, identifiable patient, identifiable reporter, and suspect drug product).

(B) *Potential medication error.* The applicant must also submit to FDA each domestic report of a potential medication error, received or otherwise obtained, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum information described under paragraph (c)(1)(iii)(C) of this section (*i.e.*, identifiable reporter and suspect drug product).

(C) *Full data set.* If a full data set is not available for an actual or potential medication error report at the time of initial submission of the report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(vi) *The 30-day followup report.* The applicant must use active query to obtain additional information for any expedited report under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that does not contain a full data set and must submit a followup report to FDA within 30 calendar days after initial submission of the expedited report to FDA by the applicant. If a full data set is still not obtainable, the 30-day followup report must contain the information required under paragraph (c)(1)(iv) of this section. Any new safety information in the 30-day followup report must be highlighted. Any new information, received or otherwise obtained, after submission of a 30-day followup report must be submitted to FDA as a 15-day followup report under paragraph (c)(2)(vii) of this section.

(vii) *The 15-day followup report.* The applicant must report to FDA any new information, received or otherwise obtained, for any expedited or followup report (except for initial expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set) within 15 calendar days of initial receipt of the new information by the applicant. Expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set at the time of initial submission of the report to FDA are subject to the 30-day followup reporting requirements under paragraph (c)(2)(vi) of this section rather than the 15-day followup reporting requirements under this paragraph.

(viii) *Supporting documentation.* (A) If the patient dies, the applicant must submit a copy of the autopsy report to FDA, if it is available. If an autopsy report is not available, the applicant must submit a death certificate to FDA. If an autopsy report becomes available after the applicant has submitted a death certificate to the agency, the autopsy report must be submitted to FDA. If the patient was hospitalized, the applicant must submit a copy of the hospital discharge summary to FDA, if it is available. If any of these documents is not in English, the document must be accompanied by an English translation. Applicants must use active query to obtain these documents. These documents must be submitted to FDA as 15-day followup reports (see paragraph (c)(2)(vii) of this section) within 15 calendar days of initial receipt of the document by the applicant. If these documents are not submitted to FDA in a 15-day followup report within 3 months after submission of the initial expedited report for the death or hospitalization, the agency will assume that active query by the applicant has not resulted in access to these documents. In this case, a record of the reason(s) for the lack of such documentation and the effort that was made to obtain the documentation must be maintained by the applicant.

(B) Each expedited report must contain in the narrative a list of other relevant documents (*e.g.*, medical records, laboratory results, data from studies) for the report that are maintained by the applicant. When appropriate, FDA may require an applicant to submit copies of one or more of these documents to the agency within 5 calendar days after receipt of the request.

(ix) *Scientific literature.* An expedited report based on information from the scientific literature applies only to reports found in scientific and medical journals. These expedited reports must be accompanied by a copy of the published article.

(x) *Submission of safety reports by contractors.* (A) Contractors must submit to the applicant safety reports of any SADRs or medication errors for the applicant's drug product, obtained or otherwise received, within 5 calendar days of initial receipt of the report by the contractor. The contractor must submit a safety report for an SADR to the applicant even if the report does not contain a minimum data set. Upon receipt of the safety report from the contractor, the applicant must comply with the postmarketing safety reporting requirements of this section.

(B) A contract between the applicant and a contractor must specify the postmarketing safety reporting responsibilities of the contractor. The applicant is responsible for assuring that the contractors of its drug products comply with these postmarketing safety reporting responsibilities.

(C) The contractor must maintain a record of each submission to the applicant under paragraph (c)(2)(x)(A) of this section that includes:

(*1*) A copy of each safety report;

(*2*) The date the report was initially received by the contractor;

(*3*) The date the report was submitted to the applicant; and

(*4*) The name and address of the applicant.

(D) The recordkeeping, written procedures and disclaimer provisions under paragraphs (f), (g), and (i) of this section apply to contractors.

(xi) *Report identification.* Each expedited report submitted to FDA under paragraphs (c)(2)(i) through (c)(2)(vii) of this section must bear prominent identification as to its contents, *e.g.*, ''expedited report—serious and unexpected SADR,'' ''expedited report—30-day followup.'' Each type of report (*e.g.*, serious and unexpected SADR reports, 30-day followup reports) must be submitted to FDA under separate cover. Reports of medication errors must indicate whether the error is actual or potential and, if actual, whether a serious SADR, nonserious SADR, or no SADR occurred, *e.g.*, ''expedited report—actual medication error—nonserious SADR,'' ''Expedited report—potential medication error.''

(3) *Postmarketing periodic safety reports.* The applicant must submit postmarketing periodic safety reports under this section (*i.e.*, TPSRs, PSURs, IPSRs, individual case safety reports-semiannual submission) to FDA within 60 calendar days after the data lock point for the report. The applicant must include a cover letter containing a list of the new drug application number(s) (*i.e.*, NDA number(s)) for the human drug product(s) covered by the postmarketing periodic safety report. The international birth date for combination products is the international birth date of the human drug product containing the drug substance most recently approved for marketing.

(i) *Traditional periodic safety reports (TPSRs).* An applicant holding an application for a human drug product approved under section 505(c) of the act before January 1, 1998, must submit either a PSUR as prescribed under paragraph (c)(3)(ii) of this section or a TPSR as described under this paragraph every 5 years after U.S. approval of the application. In addition, these applicants must submit either an IPSR as described under paragraph (c)(3)(iii) of this section or a TPSR as described under this paragraph 7.5 years and 12.5 years after U.S. approval of the application. The data lock point for the TPSR, PSUR, or IPSR is the month and day of the international birth date of the drug product or any other month and day agreed on by the applicant and FDA. Each TPSR must contain:

(A) *Summary.* This section of the TPSR includes:

(*1*) A narrative summary and analysis of serious, expected SADRs and nonserious, unexpected SADRs

occurring in the United States that were submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals) (with an index consisting of a line listing of the applicant's manufacturer report number and SADR term(s));

(*2*) An analysis of the expedited reports submitted during the reporting period under paragraphs (c)(2)(i) through (c)(2)(vii) of this section (all expedited reports must be appropriately referenced by the applicant's manufacturer report number, SADR term(s), if appropriate, and date of submission to FDA);

(*3*) A discussion of any increased reporting frequency of serious, expected SADRs, including comments on whether it is believed that the data reflect a meaningful change in SADR occurrence, and an assessment of whether it is believed that the frequency of lack of efficacy reports, obtained or otherwise received during the reporting period, is greater than would be predicted by the premarketing clinical trials for the drug product; and

(*4*) The applicants' conclusion as to what, if any, safety-related actions should be taken based on the analysis of the safety data in the TPSR (*e.g.*, labeling changes, studies initiated);

(B) *Summary tabulations.* This section of the TPSR includes summary tabulations (*i.e.*, lists of all SADR terms and counts of occurrences) presented by body system or by standard organ system classification scheme for:

(*1*) All serious expected SADRs, nonserious unexpected SADRs, nonserious expected SADRs, and expected SADRs with unknown outcome occurring in the United States that are submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals);

(*2*) All serious unexpected SADRs, unexpected SADRs with unknown outcome, and always expedited reports that were previously submitted to FDA in an expedited report under paragraphs (c)(2)(i), (c)(2)(iii), and (c)(2)(iv) of this section (include cumulative data for serious unexpected SADRs, *i.e.*, all cases reported to date);

(*3*) All reports of SADRs not previously submitted to FDA by the applicant (*e.g.*, reports submitted to applicants by FDA, reports obtained from FDA from freedom of information requests at the discretion of the applicant, reports from class action lawsuits); and

(*4*) All domestic reports of medication errors previously submitted to FDA under paragraph (c)(2)(v) of this section. For actual medication errors, provide summary tabulations of serious SADRs, nonserious SADRs, and no SADRs. For potential medication errors, provide the number of reports for specific errors;

(C) *History of safety-related actions taken.* This section of the TPSR includes a history of safety-related actions taken since the last periodic safety report (*e.g.*, labeling changes, studies initiated);

(D) *Location of safety records.* This section of the TPSR includes a list of the current address(es) where all safety reports and other safety-related records for the drug product are maintained; and

(E) *Contact person.* This section of the TPSR includes the name and telephone number for the licensed physician(s) responsible for the content and medical interpretation of the information contained within the TPSR. Include, if available, the fax number and e-mail address for the licensed physician(s).

(ii) *Periodic safety update report (PSUR).* An applicant holding an application for a human drug product approved under section 505(c) of the act on or after January 1, 1998, must submit a PSUR to FDA according to the following schedule: Semiannually (*i.e.*, every 6 months) for 2 years after U.S. approval of the application, annually for the next 3 years and then every 5 years thereafter. The data lock point for the PSUR is the month and day of the international birth date of the drug substance or any other month and day agreed on by the applicant and FDA. Each PSUR must contain:

(A) *Title page, table of contents, and introduction.* (*1*) The title page includes, at a minimum, the following information:

(*i*) Name and international birth date of the drug substance that is the subject of the PSUR,

(*ii*) Various dosage forms and formulations of the drug substance covered by the PSUR,

(*iii*) Name and address of the applicant,

(*iv*) Reporting period covered by the PSUR, and

(*v*) Date of the PSUR.

(*2*) The introduction:

(*i*) Provides a brief description of how the PSUR relates to previous reports and circumstances;

(*ii*) References relevant drug products or substances reported in other periodic safety reports (*e.g.*, a combination product reported in a separate PSUR); and

(*iii*) Indicates any data duplication with other PSURs.

(B) *Worldwide marketing status.* This section of the PSUR contains a table of the chronological history of the worldwide marketing status of the drug product(s) covered by the PSUR from the date the product(s) was first approved (*i.e.*, the international birth date) through its current status (*i.e.*, cumulative information). The table consists of:

(*1*) Dates of drug approval and renewal;

(*2*) Safety-related restrictions on product use;

(*3*) Indications for use and special populations covered by the drug approval;

(*4*) Lack of approval of the drug substance in any dosage form or for any indication for use by any regulatory authority(ies);

(*5*) Withdrawal of a pending marketing application for the drug product by the applicant for safety- or efficacy-related reasons;

(*6*) Dates of market launches; and

(*7*) Trade name(s).

(C) *Actions taken for safety reasons.* (*1*) This section of the PSUR includes details on the following types of regulatory authority-initiated (*e.g.*, by FDA) and/or applicant-initiated actions related to safety that were taken during the period covered by the PSUR and between the data lock point and PSUR submission (*i.e.*, ''late-breaking'' safety concerns):

(*i*) Withdrawal or suspension of drug product approval or indication for use approval;

(*ii*) Failure to obtain a marketing authorization renewal or to obtain an approval for a new indication for use;

(*iii*) Restrictions on distribution (*e.g.*, products recalled for safety reasons);

(*iv*) Clinical trial suspension;

(*v*) Dosage modification;

(*vi*) Changes in target population or indications; and

(*vii*) Formulation changes.

(*2*) This section of the PSUR also contains a narrative identifying the safety-related reasons that led to these actions with relevant documentation appended when appropriate.

(*3*) Any communication with health care professionals (*e.g.*, Dear Healthcare Professional letters) resulting from such actions must also be described with copies appended.

(D) *Changes to CCSI.* This section of the PSUR describes changes to the CCSI (*e.g.*, new contraindications, precautions, warnings, SADRs, or interactions) made during the period covered by the PSUR. A copy of any modified section of the CCSI must be included. The applicant must use the CCSI in effect at the beginning of the reporting period for the PSUR. The revised CCSI is to be used as the reference document for the next reporting period.

(E) *Worldwide patient exposure.* (*1*) This section of the PSUR includes, for the reporting period, an estimate of the worldwide patient exposure to the drug product(s) covered by the PSUR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*2*) When possible, data broken down by gender and age (especially pediatric versus adult) must be provided. For the pediatric population, data must be reported, if possible, by age group (*e.g.*, neonates, infants, children, adolescents). If these data are not available, an explanation must be included.

(*3*) When a pattern of reports indicates a potential problem, details by country (with locally recommended dosage regimens) or other segmentation (*e.g.*, indication, dosage form) must be presented.

(F) *Individual case safety reports.* (*1*) This section of the PSUR includes summary tabulations of individual case safety reports (*e.g.*, serious unlisted SADRs, serious listed SADRs, nonserious unlisted SADRs, nonserious listed SADRs) for the following SADRs obtained or otherwise received during the reporting period:

(*i*) All serious and nonserious SADRs from spontaneous sources that were submitted to applicants by a health care professional;

(*ii*) All serious SADRs from studies, individual patient INDs, or, in foreign countries, from named-patient ''compassionate'' use;

(*iii*) All serious SADRs and nonserious unlisted SADRs from the scientific literature;

(*iv*) All serious SADRs from regulatory authorities; and

(*v*) Serious SADRs from other sources such as reports created by poison control centers and epidemiological data bases.

(*2*) The summary tabulations must be made up of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. For SADRs that are determined to be both serious and unlisted, include cumulative data (*i.e.*, all cases reported to date).

(*3*) The applicant must conclude this section with a brief discussion of the data concerning the individual case safety reports in the PSUR (*e.g.*, discussion of medical significance or mechanism).

(G) *Safety studies.* This section of the PSUR contains a discussion of nonclinical, clinical, and epidemiological studies that contain important safety information, as follows:

(*1*) All applicant-sponsored studies newly analyzed during the reporting period (copies of full reports should be appended only if new safety issues are raised or confirmed; FDA may request copies of other studies, if necessary);

(*2*) New studies specifically planned, initiated, or continuing during the reporting period that examine a safety issue, whether actual or hypothetical; and

(*3*) Published safety studies in the scientific and medical literature, including relevant published abstracts from meetings (provide literature citation).

(H) *Other information.* This section of the PSUR includes:

(*1*) A discussion of medically relevant lack of efficacy reports (*e.g.*, might represent a significant hazard to the treated population) for a product(s) used to treat serious or life-threatening diseases; and

(*2*) Any important new information received after the data lock point (*e.g.*, significant new cases).

(I) *Overall safety evaluation.* This section of the PSUR contains a concise, yet comprehensive, analysis of all of the safety information provided in the PSUR, including new information provided under paragraph (c)(3)(ii)(H)(*2*) of this section. In addition, this section of the PSUR includes an assessment by the applicant of the significance of the data collected during the reporting period, as well as from the perspective of cumulative experience.

(*1*) The applicant must highlight any new information on:

(*i*) Serious, unlisted SADRs;

(*ii*) Increased reporting frequencies of listed SADRs, including comments on whether it is believed that the data reflect a meaningful change in SADR occurrence;

(*iii*) A change in characteristics of listed SADRs (*e.g.*, severity, outcome, target population); and

(*iv*) Nonserious, unlisted SADRs.

(*2*) As part of the overall safety evaluation, the applicant must also explicitly address any new safety issue including but not limited to the following (lack of significant new information for each of the following must be mentioned):

(*i*) Drug interactions;

(*ii*) Experience with overdose, whether deliberate or accidental, and its treatment;

(*iii*) Drug abuse or intentional misuse;

(*iv*) Positive or negative experiences during pregnancy or lactation;

(*v*) Effects with long-term treatment; and

(*vi*) Experience in special patient groups (*e.g.*, pediatric, geriatric, organ impaired). For the pediatric population, data must be evaluated, if possible, by age group (*e.g.*, neonates, infants, children, adolescents).

(J) *Conclusion.* This section of the PSUR:

(*1*) Indicates new safety information that is not in accord with previous cumulative experience and with the CCSI in use at the beginning of the reporting period (*e.g.*, new evidence that strengthens a possible causal relationship between the drug product and an SADR such as positive rechallenge, an epidemiological association, or new laboratory studies); and

(*2*) Specifies and justifies any action recommended or initiated, including changes in the CCSI.

(K) *Appendices.* This section of the PSUR includes:

(*1*) *Company core data sheet.* Provide a copy of the company core data sheet covered by this PSUR (*i.e.*, in effect at the beginning of the period covered by the PSUR) as well as the company core data sheet for the next reporting period. Company core data sheets must be numbered and dated and include the date of last revision.

(*2*) *U.S. labeling.* Provide a copy of the current approved U.S. labeling. Specify any safety information that is included in the CCSI but not in the U.S. labeling and provide an explanation for the discrepancy. Describe any safety-related changes or proposed changes to the U.S. labeling made during the reporting period (include the supplement number(s) and date(s) of submission for the supplement(s)) and any suggested change(s) that should be considered based on the safety analysis in the PSUR.

(*3*) *Spontaneous reports submitted to the applicant by an individual other than a health care professional.* Provide summary tabulations (*e.g.*, serious unlisted SADRs, serious listed SADRs, nonserious unlisted SADRs, nonserious listed SADRs) for all spontaneously reported serious SADRs, whether domestic or foreign, and all spontaneously reported nonserious

SADRs occurring in the United States, obtained or otherwise received during the reporting period by the applicant from an individual other than a health care professional (*e.g.*, reports from consumers). These summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. For those SADRs that are determined to be both serious and unlisted, include cumulative data (*i.e.*, all cases reported to date by individuals other than a health care professional). Include a brief discussion of the impact of the spontaneous reports described in this appendix on the overall safety evaluation.

(*4*) *SADRs with unknown outcome.* Provide summary tabulations for unlisted and listed SADRs with unknown outcome from all spontaneous sources (*i.e.*, health care professionals and other individuals), obtained or otherwise received by the applicant during the reporting period. These summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. Include a brief discussion of the impact of the spontaneous reports described in this appendix on the overall safety evaluation.

(*5*) *Class action lawsuits.* Provide summary tabulations (*e.g.*, serious unlisted SADRs, serious listed SADRs, nonserious unlisted SADRs, nonserious listed SADRs) for all SADRs obtained or otherwise received during the reporting period by the applicant from class action lawsuits. These summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. For those SADRs that are determined to be both serious and unlisted, include cumulative data. Include a brief discussion of the impact of the reports described in this appendix on the overall safety evaluation.

(*6*) *Lack of efficacy reports.* Provide an assessment of whether it is believed that the frequency of lack of efficacy reports, obtained or otherwise received during the reporting period, is greater than would be predicted by the premarketing clinical trials for the drug product.

(*7*) *Information on resistance to antimicrobial drug products.* Provide information, received or otherwise obtained by the applicant, on resistance to antimicrobial drug products intended to treat infectious diseases. Include information on changes in U.S. microbial in vitro susceptibility, the relationship of changes in U.S. microbial in vitro susceptibility and clinical outcomes, therapeutic failure that may possibly be due to resistance to the antimicrobial drug product, and whether the U.S. labeling should be revised because of the information on antimicrobial resistance learned during the period covered by this PSUR.

(*8*) *Medication errors.* Provide summary tabulations of all domestic reports of medication errors submitted during the reporting period under paragraph (c)(2)(v) of this section. For actual medication errors, provide summary tabulations for serious SADRs, nonserious SADRs, and no SADRs (for serious SADRs include cumulative data, *i.e.*, all cases reported to date). For potential medication errors, provide the number of reports for specific errors. If an SADR occurs, the summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SADR terms and counts of occurrences. Include a brief discussion of the impact on the overall safety evaluation of these reports.

(*9*) *U.S. patient exposure.* Provide, for the reporting period, an estimate of the U.S. patient exposure to the drug product(s) covered by the PSUR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*10*) *Location of safety records.* Provide a list of the current address(es) where all safety reports and other safety-related records for the drug product(s) are maintained.

(*11*) *Contact person.* Provide the name and telephone number of the licensed physician(s) responsible for the content and medical interpretation of the data and information contained within the PSUR. Include, if available, the fax number and e-mail address of the licensed physician(s).

(iii) *Interim periodic safety report (IPSR).* An applicant holding an application for a human drug product approved under section 505(c) of the act on or after January 1, 1998, must submit an IPSR to FDA 7.5 years and 12.5 years after U.S. approval of the application. The data lock point for the IPSR is the month and day of the international birth date of the drug substance or any other month and day agreed on by the applicant and FDA. The reporting period for the IPSR covers the period between the last PSUR or TPSR and the data lock point for the IPSR (*e.g.*, between years 5 and 7.5 for an IPSR with a data lock point 7.5 years after U.S. approval of the application). Each IPSR must contain:

(A) *Title page, table of contents, and introduction.* (*1*) The title page includes, at a minimum, the following information:

(*i*) Name and international birth date of the drug substance that is the subject of the IPSR,

(*ii*) Various dosage forms and formulations of the drug substance covered by the IPSR,

(*iii*) Name and address of the applicant,

(*iv*) Reporting period covered by the IPSR, and

(*v*) Date of the IPSR.

(*2*) The introduction:

(*i*) Provides a brief description of how the IPSR relates to previous reports and circumstances,

(*ii*) References relevant drug products or substances reported in other periodic safety reports (*e.g.*, a combination product reported in a separate IPSR), and

(*iii*) Indicates any data duplication with other IPSRs.

(B) *Worldwide marketing status.* This section of the IPSR contains a table of the chronological history of the worldwide marketing status of the drug product(s) covered by the IPSR from the date the product(s) was first approved (*i.e.*, the international birth date) through its current status (*i.e.*, cumulative information). The table consists of:

(*1*) Dates of drug approval and renewal;

(*2*) Safety-related restrictions on product use;

(*3*) Indications for use and special populations covered by the drug approval;

(*4*) Lack of approval of the drug substance in any dosage form or for any indication for use by any regulatory authority(ies);

(*5*) Withdrawal of a pending marketing application for a drug product by the applicant for safety or efficacy related reasons;

(*6*) Dates of market launches; and

(*7*) Trade name(s).

(C) *Actions taken for safety reasons.* (*1*) This section of the IPSR includes details on the following types of regulatory authority-initiated (*e.g.*, by FDA) and/or applicant-initiated actions

related to safety that were taken during the period covered by the IPSR and between the data lock point and IPSR submission (*i.e.*, ''late-breaking'' safety concerns):

(*i*) Withdrawal or suspension of drug product approval or indication for use approval;

(*ii*) Failure to obtain a marketing authorization renewal or to obtain an approval for a new indication for use;

(*iii*) Restrictions on distribution (*e.g.*, products recalled for safety reasons);

(*iv*) Clinical trial suspension;

(*v*) Dosage modification;

(*vi*) Changes in target population or indications; and

(*vii*) Formulation changes.

(*2*) This section of the IPSR also contains a narrative identifying the safety-related reasons that led to these actions with relevant documentation appended when appropriate.

(*3*) Any communication with health care professionals (*e.g.*, Dear Healthcare Professional letters) resulting from such actions must also be described with copies appended.

(D) *Changes to CCSI.* This section of the IPSR describes changes to the CCSI (*e.g.*, new contraindications, precautions, warnings, SADRs, or interactions) made during the period covered by the IPSR. A copy of any modified section of the CCSI must be included. The applicant must use the CCSI in effect at the beginning of the reporting period for the IPSR. The revised CCSI is to be used as the reference document for the next reporting period.

(E) *Worldwide patient exposure.* (*1*) This section of the IPSR includes, for the reporting period, an estimate of the worldwide patient exposure to the drug product(s) covered by the IPSR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*2*) When possible, data broken down by gender and age (especially pediatric versus adult) must be provided. For the pediatric population, data must be reported, if possible, by age group (*e.g.*, neonates, infants, children, adolescents). If these data are not available, an explanation must be included.

(*3*) When a pattern of reports indicates a potential problem, details by country (with locally recommended dosage regimens) or other segmentation (*e.g.*, indication, dosage form) must be presented.

(F) *Safety studies.* This section of the IPSR contains a discussion of nonclinical, clinical, and epidemiological studies that contain important safety information, as follows:

(*1*) All applicant-sponsored studies newly analyzed during the reporting period (copies of full reports should be appended only if new safety issues are raised or confirmed; FDA may request copies of other studies, if necessary);

(*2*) New studies specifically planned, initiated, or continuing during the reporting period that examine a safety issue, whether actual or hypothetical; and

(*3*) Published safety studies in the scientific and medical literature, including relevant published abstracts from meetings (provide literature citation).

(G) *Other information.* This section of the IPSR includes a discussion of medically relevant lack of efficacy reports (*e.g.*, might represent a significant hazard to the treated population) for a product(s) used to treat serious or life-threatening diseases.

(H) *Overall safety evaluation.* This section of the IPSR contains a concise, yet comprehensive, analysis of all of the safety information provided in the IPSR. In addition, this section of the IPSR must include an assessment by the applicant of the significance of the data collected during the reporting period, as well as from the perspective of cumulative experience.

(*1*) The applicant must highlight any new information on:

(*i*) Serious, unlisted SADRs;

(*ii*) Increased reporting frequencies of listed SADRs, including comments on whether it is believed that the data reflect a meaningful change in SADR occurrence;

(*iii*) A change in characteristics of listed SADRs (*e.g.*, severity, outcome, target population); and

(*iv*) Nonserious, unlisted SADRs.

(*2*) As part of the overall safety evaluation, the applicant must also explicitly address any new safety issue including but not limited to the following (lack of significant new information for each of the following must be mentioned):

(*i*) Drug interactions;

(*ii*) Experience with overdose, whether deliberate or accidental, and its treatment;

(*iii*) Drug abuse or intentional misuse;

(*iv*) Positive or negative experiences during pregnancy or lactation;

(*v*) Effects with long-term treatment; and

(*vi*) Experience in special patient groups (*e.g.*, pediatric, geriatric, organ impaired). For the pediatric population, data must be evaluated, if possible, by age group (*e.g.*, neonates, infants, children, adolescents).

(I) *Conclusion.* This section of the IPSR:

(*1*) Indicates new safety information that is not in accord with previous cumulative experience and with the CCSI in use at the beginning of the reporting period (*e.g.*, new evidence that strengthens a possible causal relationship between the drug product and an SADR such as positive rechallenge, an epidemiological association or new laboratory studies); and

(*2*) Specifies and justifies any action recommended or initiated, including changes in the CCSI.

(J) *Appendices.* This section of the IPSR includes:

(*1*) *Company core data sheet.* Provide a copy of the company core data sheet covered by this IPSR (*i.e.*, in effect at the beginning of the period covered by the IPSR), as well as the company core data sheet for the next reporting period. Company core data sheets must be numbered and dated and include the date of last revision.

(*2*) *U.S. labeling.* Provide a copy of the current approved U.S. labeling. Specify any safety information that is included in the CCSI but not in the U.S. labeling and provide an explanation for the discrepancy. Describe any safety-related changes or proposed changes to the U.S. labeling made during the reporting period (include the supplement number(s) and date(s) of submission for the supplement(s)) and any suggested change(s) that should be considered based on the safety analysis in this IPSR.

(*3*) *Spontaneous reports submitted to the applicant by an individual other than a health care professional.* Provide a brief discussion of the impact on the overall safety evaluation of any spontaneously reported serious SADRs, whether domestic or foreign, and any spontaneously reported nonserious SADRs occurring in the United States, obtained or otherwise received during the reporting period by the applicant from an individual other than a health care professional (*e.g.*, reports from consumers).

(*4*) *SADRs with unknown outcome.* Provide a brief discussion of the impact on the overall safety evaluation of any spontaneously reported unlisted and listed SADRs with unknown outcome obtained or otherwise received during the reporting period by the applicant from health care professionals and other individuals.

(*5*) *Class action lawsuits.* Provide a brief discussion of the impact on the overall safety evaluation of any safety information obtained or otherwise received during the reporting period by the applicant from class action lawsuits.

(*6*) *Lack of efficacy reports.* Provide an assessment of whether it is believed that the frequency of any lack of efficacy reports, obtained or otherwise received during the reporting period, is greater than would be predicted by the premarketing clinical trials for the drug product.

(*7*) *Information on resistance to antimicrobial drug products.* Provide information, received or otherwise obtained by the applicant, on resistance to antimicrobial drug products intended to treat infectious diseases. Include information on changes in U.S. microbial in vitro susceptibility, the relationship of changes in U.S. microbial in vitro susceptibility and clinical outcomes, therapeutic failure that may possibly be due to resistance to the antimicrobial drug product, and whether the U.S. labeling should be revised because of the information on antimicrobial resistance learned during the period covered by this IPSR.

(*8*) *Medication errors.* Provide a brief discussion of the impact on the overall safety evaluation of all domestic reports of medication errors submitted during the reporting period under paragraph (c)(2)(v) of this section.

(*9*) *U.S. patient exposure.* Provide, for the reporting period, an estimate of the U.S. patient exposure to the drug product(s) covered by the IPSR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*10*) *Location of safety records.* Provide a list of the current address(es) where all safety reports and other safety-related records for the drug product are maintained.

(*11*) *Contact person.* Provide the name and telephone number for the licensed physician(s) responsible for the content and medical interpretation of the information contained within the IPSR. Include, if available, the fax number and e-mail address for the licensed physician(s).

(iv) *Pediatric use supplements.* After approval of a pediatric use supplement to an approved application (*i.e.*, a supplement for use of the human drug product in the pediatric population), the applicant must submit PSURs to FDA as prescribed under paragraph (c)(3)(ii) of this section according to the following schedule: Semiannually for 2 years after U.S. approval of the supplement, annually for the next 3 years, and then every 5 years thereafter. These applicants must also submit IPSRs to FDA as prescribed under paragraph (c)(3)(iii) of this section at 7.5 years and 12.5 years after U.S. approval of the supplement. The data lock point for the PSUR and IPSR is the month and day of the international birth date of the drug substance or any other month and day agreed on by the applicant and FDA.

(v) *Semiannual submission of individual case safety reports.* (A) An applicant holding an application for a human drug product approved under section 505(c) of the act must submit to FDA semiannually (*i.e.*, every 6 months) after U.S. approval of the application a separate report that consists of individual case safety reports for certain spontaneously reported SADRs for the human drug product. The individual case safety reports must be submitted to FDA on the form designated by the agency under paragraph (c)(4) of this section. The data lock point for the report is the month and day of the international birth date of the drug product or any other month and day agreed on by the applicant and FDA. This report must be identified as ''individual case safety reports—semiannual submission.''

(B) Applicants that submit TPSRs to FDA for the drug product must submit an individual case safety report for each serious, expected SADR, whether domestic or foreign, and each nonserious, unexpected SADR occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals). Applicants that submit PSURs to FDA for the drug product must submit an individual case safety report for each serious, listed SADR, whether domestic or foreign, and each nonserious, unlisted SADR occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources. If a full data set is not available for a serious SADR, the applicant must submit the information required under paragraph (c)(1)(iv) of this section.

(C) Followup information on SADRs submitted in an individual case safety report—semiannual submission may be submitted in the next individual case safety report—semiannual submission unless such information changes the classification of the SADR to a serious, unexpected SADR. In these cases, the followup information must be submitted to FDA as a 15-day followup report (see paragraph (c)(2)(vii) of this section).

(4) *Reporting format.* (i)(A) Except as provided in paragraphs (c)(4)(i)(B), (c)(4)(i)(D), and (c)(4)(v) of this section, the applicant must complete an FDA Form 3500A for each individual case safety report of an SADR. Reports based on information about individual cases or case series in the scientific literature must be submitted on an FDA Form 3500A(s).

(B) Foreign SADRs may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form.

(C) Each domestic report of an actual or potential medication error must be submitted on an FDA Form 3500A.

(D) Reports of overall findings or data in the aggregate from published and unpublished in vitro, animal, epidemiological, or clinical studies must be submitted in a narrative format.

(ii) Each SADR in an individual case safety report must be coded on the FDA Form 3500A or CIOMS I form using the appropriate ''preferred term'' in the latest version of MedDRA (the medical dictionary for regulatory activities) in use at the time the applicant becomes aware of the individual case safety report. For individual case safety reports of medication errors, the report must be coded both as a medication error and, if applicable, with the preferred term for any SADRs associated with the medication error.

(iii) Each completed FDA Form 3500A or CIOMS I form should refer only to an individual case.

(iv) Each completed FDA Form 3500A or CIOMS I form must include the name and telephone number (and fax number and e-mail address, if available) for the licensed physician responsible for the content and medical interpretation of the data contained within the form (*i.e.*, contact person for the company).

(v) Instead of using FDA Form 3500A, the applicant may use a computer-generated facsimile of FDA Form 3500A provided that it is readable, includes

appropriate identifying information, and contains all the elements (*i.e.*, format, sections, blocks, titles, descriptors within blocks, text for disclaimer) of FDA Form 3500A in the identical enumerated sequence of the form. For individual case safety reports in which no suspect medical device is involved, a one-page FDA Form 3500A is acceptable.

(d) *Multiple reports.* An applicant should not include in reports under this section any SADRs that occurred in clinical trials if they were previously submitted as part of the approved application. If a report applies to a drug for which an applicant holds more than one approved application, the applicant should submit the report to the application that was first approved. If a report refers to more than one drug marketed by an applicant, the applicant should submit the report to the application for the drug listed first in the report.

(e) *Patient privacy.* The names and addresses of individual patients should not be included in reports under this section; instead, the applicant and its contractors should assign a unique code to each report, preferably not more than eight characters (*i.e.*, numbers and/or letters) in length. The name of the reporter from whom the information was received should be included. Names of patients, individual reporters, health care professionals, hospitals, and geographic identifiers in safety reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter.

(f) *Recordkeeping.* Each applicant must maintain for a period of 10 years records of all safety information pertaining to its drug product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SADRs or medication errors not submitted to FDA or only provided to FDA in a summary tabulation. Each applicant must also retain for a period of 10 years any records required to be maintained under this section. When appropriate, FDA may require an applicant to submit any or all of these records to the agency within 5 calendar days after receipt of the request.

(g) *Written procedures.* Each applicant must develop and maintain written procedures for the surveillance, receipt, evaluation, and reporting of postmarketing safety information to FDA.

(h) *Withdrawal of approval.* If an applicant fails to establish and maintain records and make reports required under this section, FDA may withdraw approval of the application and, thus, prohibit continued marketing of the drug product that is the subject of the application.

(i) *Disclaimer.* A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the drug caused or contributed to an SADR. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the drug caused or contributed to an SADR.

8. Section 314.81 is amended by removing paragraph (b)(2)(v), by redesignating paragraphs (b)(2)(vi) through (b)(2)(ix) as paragraphs (b)(2)(v) through (b)(2)(viii), respectively, and by revising paragraph (b)(2)(i) and newly redesignated paragraph (b)(2)(v) to read as follows:

§ 314.81 Other postmarketing reports.

* * * * *

(b) * * *

(2) * * *

(i) *Summary.* A brief summary of significant new information from the previous year that might affect the effectiveness of the drug product or the sections of the drug product labeling that are not related to safety. The report must also contain a brief description of actions the applicant has taken or intends to take as a result of this new information, for example, submit an efficacy labeling supplement or initiate a new study. The summary must briefly state whether supplements for pediatric use have been submitted and whether new studies in the pediatric population to support appropriate labeling for the pediatric population have been initiated.

* * * * *

(v) *Clinical data.* (A) Published clinical trials of the drug (or abstracts of them), including clinical trials on effectiveness; clinical trials on new uses; and biopharmaceutic, pharmacokinetic, and clinical pharmacology studies conducted by or otherwise obtained by the applicant. Review articles, papers describing safety related information or the use of the drug product in medical practice, papers and abstracts in which the drug is used as a research tool, promotional articles, press clippings, and papers that do not contain tabulations or summaries of original data should not be reported.

(B) Summaries of completed unpublished clinical trials, or prepublication manuscripts if available, conducted by, or otherwise obtained by, the applicant. Supporting information should not be reported. (A study is considered completed 1 year after it is concluded.)

(C) Analysis of available efficacy data in the pediatric population and changes proposed in the labeling based on this information. An assessment of data needed to ensure appropriate labeling for the pediatric population must be included.

* * * * *

9. Section 314.98 is amended in paragraph (a) by adding the abbreviation ''(ANDA)'' after the phrase ''abbreviated new drug application'', by removing the citation ''§ 314.94'' and by adding in its place the phrase ''section 505(j) of the Act'', by removing the phrase ''adverse drug experiences'' and by adding in its place the phrase ''suspected adverse drug reactions'', and by adding two sentences to the end of the paragraph; and in paragraph (b) by removing the phrase ''Division of Epidemiology and Surveillance (HFD–730), Center for Drug Evaluation and Research, Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857'' and by adding in its place the word ''FDA'' to read as follows:

§ 314.98 Postmarketing reports.

(a) * * * For purposes of postmarketing periodic safety reporting, applicants must determine the data lock point (*i.e.*, month and day of the international birth date or any other month and day agreed by the applicant and FDA) for their periodic safety reports based on the data lock point of postmarketing periodic safety reports for other drug products containing the same drug substance (*i.e.*, innovator new drug application (NDA) product that is the same drug product as the ANDA product, or other ANDA products with the same drug substance if the innovator NDA product is no longer on the market). Applicants must determine the type of postmarketing periodic safety report required to be submitted to FDA (*i.e.*, traditional periodic safety report (TPSR), periodic safety update report (PSUR) or interim periodic safety report (IPSR)) and the frequency of submission for these reports based on the U.S. approval date of the application for the innovator NDA product.

* * * * *

PART 320—BIOAVAILABILITY AND BIOEQUIVALENCE REQUIREMENTS

10. The authority citation for 21 CFR part 320 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 355, 371.

11. Section 320.31 is amended by revising paragraph (d) to read as follows:

§ 320.31 Applicability of requirements regarding an ''Investigational New Drug Application.''

* * * * *

(d) A bioavailability or bioequivalence study in humans other than one described in paragraphs (a) through (c) of this section is exempt from the requirements of part 312 of this chapter, except for the safety reporting requirements under § 312.32 of this chapter, if the following conditions are satisfied:

(1) If the study is one described under § 320.38(b) or § 320.63, the person conducting the study, including any contract research organization, must retain reserve samples of any test article and reference standard used in the study and release the reserve samples to FDA upon request in accordance with and for the period specified in § 320.38;

(2) An in vivo bioavailability or bioequivalence study in humans must be conducted in compliance with the requirements for institutional review set forth in part 56 of this chapter and informed consent set forth in part 50 of this chapter; and

(3) Safety reports as prescribed under § 312.32 of this chapter must be transmitted to all participating investigators and the appropriate FDA division in the Center for Drug Evaluation and Research (*i.e.*, safety reports for the reference listed drug must be sent to the new drug review division that has responsibility for that drug, safety reports for the investigational drug product must be sent to the Director, Division of Bioequivalence, Office of Generic Drugs). Each written notification under this paragraph must bear prominent identification of its contents, *i.e.*, ''bioavailability/bioequivalence safety report.'' For reporting purposes under this paragraph, an unexpected suspected adverse drug reaction (SADR) is any SADR, the specificity or severity of which is not consistent with the U.S. labeling for the reference listed drug.

PART 600—BIOLOGICAL PRODUCTS: GENERAL

12. The authority citation for 21 CFR part 600 continues to read as follows:

Authority: 21 U.S.C. 321, 351, 352, 353, 355, 360, 360i, 371, 374; 42 U.S.C. 216, 262, 263, 263a, 264, 300aa–25.

13. Section 600.80 is revised to read as follows:

§ 600.80 Postmarketing reporting of suspected adverse reactions.

(a) *Definitions.* The following definitions of terms apply to this section:

Active query means direct verbal contact (*i.e.*, in person or by telephone or other interactive means such as a video conference) with the initial reporter of a suspected adverse reaction (SAR) or medication error by a health care professional (*e.g.*, physician, physician assistant, pharmacist, dentist, nurse, any individual with some form of health care training) representing the applicant. For SARs, active query entails, at a minimum, a focused line of questioning designed to capture clinically relevant information associated with the licensed biological product and the SAR, including, but not limited to, information such as baseline data, patient history, physical exam, diagnostic results, and supportive lab results.

Actual medication error means a medication error that involves an identifiable patient whether the error was prevented prior to administration of the product or, if the product was administered, whether the error results in a serious SAR, nonserious SAR, or no SAR.

Blood component means as defined in § 606.3(c) of this chapter.

Company core data sheet means a document prepared by the applicant containing, in addition to safety information, material relating to indications, dosing, pharmacology, and other information concerning the biological product. The only purpose of this document is to provide the company core safety information (CCSI) for periodic safety update reports (PSURs), interim periodic safety reports (IPSRs), and certain individual case safety reports—semiannual submissions (*i.e.*, if PSURs are submitted for the product).

Company core safety information (CCSI) means all relevant safety information contained in the company core data sheet that the applicant proposes to include in the approved product labeling in all countries where the applicant markets the biological product. It is the reference information by which an SAR is determined to be ''listed'' or ''unlisted'' for PSURs, IPSRs, and certain individual case safety reports—semiannual submissions (*i.e.*, if PSURs are submitted for the product).

Contractor means any person (*e.g.*, manufacturer, joint manufacturer, packer, or distributor whether or not its name appears on the label of the product; licensee; contract research organization) that has entered into a contract with the applicant (includes participants involved in divided manufacturing) to manufacture, pack, sell, distribute, or develop the licensed biological product or to maintain, create, or submit records regarding SARs or medication errors.

Data lock point means the date designated as the cut-off date for data to be included in a postmarketing periodic safety report.

Disability means a substantial disruption of a person's ability to conduct normal life functions.

Full data set means completion of all the applicable elements on FDA Form 3500A or the vaccine adverse event reporting system (VAERS) form (or on a Council for International Organizations of Medical Sciences (CIOMS) I form for reports of foreign SARs), including a concise medical narrative of the case (*i.e.*, an accurate summary of the relevant data and information pertaining to an SAR or medication error).

International birth date means the date the first regulatory authority in the world approved the first marketing application for a human biological product.

Life-threatening SAR means any SAR that, in the view of the initial reporter, places the patient at *immediate* risk of death from the SAR as it occurred. It does not include an SAR that, had it occurred in a more severe form, might have caused death.

Listed SAR means an SAR whose nature, specificity, severity, and outcome are consistent with the information in the CCSI.

Medication error means any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. Such events may be related to professional practice, health care products, procedures, and systems including: Prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use.

Minimum data set means the report includes an identifiable patient, an identifiable reporter, a suspect biological product, and an SAR.

Nonserious SAR means any SAR that is determined not to be a serious SAR.

Potential medication error means an individual case safety report of information or complaint about product name, labeling, or packaging similarities that does not involve a patient.

SAR with unknown outcome means an SAR that cannot be classified, after

active query, as either serious or nonserious.

Serious SAR means any SAR that results in any of the following outcomes: Death, a life-threatening SAR, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious SAR when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition. Examples of such medical events include allergic bronchospasm requiring intensive treatment in an emergency room or at home, blood dyscrasias or convulsions that do not result in inpatient hospitalization, or the development of drug dependency or drug abuse.

Spontaneous report means a communication from an individual (*e.g.*, health care professional, consumer) to a company or regulatory authority that describes an SAR or medication error. It does not include cases identified from information solicited by the applicant, shared manufacturer, or contractor, such as individual case safety reports or findings derived from a study, company-sponsored patient support program, disease management program, patient registry, including pregnancy registries, or any organized data collection scheme. It also does not include information compiled in support of class action lawsuits.

Suspected adverse reaction (SAR) means a noxious and unintended response to any dose of a biological product for which there is a reasonable possibility that the product caused the response. In this definition, the phrase ''a reasonable possibility'' means that the relationship cannot be ruled out.

Unexpected SAR means any SAR that is not included in the current U.S. labeling for the licensed biological product. Reactions that may be symptomatically and pathophysiologically related to a reaction included in the U.S. labeling, but differ from the labeled reaction because of greater severity or specificity, would be unexpected. For example, under this definition, hepatic necrosis would be unexpected (by virtue of greater severity) if the U.S. labeling only referred to elevated hepatic enzymes or hepatitis. Similarly, cerebral thromboembolism and cerebral vasculitis would be unexpected (by virtue of greater specificity) if the U.S. labeling only included cerebral vascular accidents. ''Unexpected,'' as used in this definition, refers to an SAR that has not been previously observed (*i.e.*, included in the U.S. labeling); it does not refer to an SAR that might be anticipated from the pharmacological properties of the licensed biological product. SARs that are mentioned in the U.S. labeling as occurring with a class of products but not specifically mentioned as occurring with the particular product are considered unexpected.

Unlisted SAR means an SAR whose nature, specificity, severity, or outcome is not consistent with the information included in the CCSI.

(b) *Review of safety information.* (1) Any person having a biologics license under § 601.20 of this chapter must promptly review all safety information pertaining to its product obtained or otherwise received by the applicant from any source, foreign or domestic, including information derived from commercial marketing experience, postmarketing clinical investigations, postmarketing epidemiology/surveillance studies, animal or in vitro studies, electronic communications with applicants via the Internet (*e.g.*, e-mail), reports in the scientific literature, and unpublished scientific papers, as well as reports from foreign regulatory authorities that have not been previously reported to the Food and Drug Administration (FDA) by the applicant.

(2) Individual case safety reports that are forwarded to the applicant by FDA must not be resubmitted to the agency by the applicant; however, applicants must include information from these individual case safety reports in any comprehensive safety analysis subsequently submitted to FDA. In addition, applicants must submit to FDA all followup information for these individual case safety reports.

(c) *Reporting requirements.* For nonvaccine biological products, the applicant must submit to FDA two copies of each postmarketing expedited report (described under paragraphs (c)(2)(i) through (c)(2)(vii) of this section) and each postmarketing periodic safety report of an individual case safety reports—semiannual submission (described under paragraph (c)(3)(v) of this section) pertaining to its product. For nonvaccine biological products, the applicant must also submit to FDA one copy of a PSUR, IPSR, or traditional periodic safety report (TPSR) along with one copy for each approved application for a human licensed biological product covered by the report. For vaccines, the applicant must submit to VAERS two copies of each safety report pertaining to its product and required under this section. FDA may waive the requirement for multiple copies in appropriate instances. Upon written notice, FDA may require, when appropriate, that the applicant submit reports under this section to the agency at times other than those stated. An applicant that wishes to submit reports under this section at different intervals must submit to FDA a request for a waiver under § 600.90.

(1) *Determination of outcome, minimum data set, and full data set*—(i)(A) *Initial determinations.* Upon initial receipt of an SAR report, the applicant must immediately determine the outcome for the SAR (whether the SAR is serious or nonserious) and at least the minimum data set for the individual case safety report. For reports of actual medication errors that do not result in an SAR and potential medication errors, the applicant must immediately determine the minimum information for the individual case safety report (minimum information described under paragraphs (c)(1)(iii)(B) and (c)(1)(iii)(C) of this section). If the applicant is not able to immediately determine the information in this paragraph, active query must be used to obtain it as soon as possible.

(B) *Spontaneous reports.* For spontaneous reports, the applicant must always assume, for safety reporting purposes under this section, that there is at least a reasonable possibility, in the opinion of the initial reporter, that the biological product caused the spontaneously reported event.

(C) *Clinical trials.* For a clinical trial, the possibility that the biological product caused the SAR or that a medication error has occurred must be assumed if either the investigator or the applicant believes that such a reasonable possibility exists.

(ii) *SARs with unknown outcome.* For an SAR with unknown outcome that cannot be immediately determined, the applicant must continue to use active query to attempt to determine the outcome of the SAR within 30 calendar days after initial receipt of the SAR report by the applicant. The applicant must maintain a record of its efforts to determine the outcome for an SAR with unknown outcome.

(iii) (A) *Minimum data set for SAR reports.* The applicant must not submit an individual case safety report for an SAR to FDA if the report does not contain a minimum data set; instead, the applicant must maintain records of any information received or otherwise obtained for the SAR along with a record of its efforts to obtain a minimum data set.

(B) *Minimum information for reports of actual medication errors that do not result in an SAR.* For reports of actual medication errors that do not result in an SAR, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an SAR). These reports must contain at least an identifiable patient, an identifiable reporter, and a suspect biological product.

(C) *Minimum information for potential medication error reports.* For reports of potential medication errors, an individual case safety report must be submitted to FDA even though the report does not contain a minimum data set (*i.e.*, does not have an identifiable patient or an SAR). These reports must contain at least an identifiable reporter and a suspect biological product.

(iv) *Full data set.* For reports of serious SARs, always expedited reports (see paragraph (c)(2)(iv) of this section), and medication error reports (see paragraph (c)(2)(v) of this section), the applicant must submit a full data set. If a full data set is not available for the report, the applicant must use active query to obtain this information. If a full data set is not obtainable after active query, the applicant must:

(A) Submit all safety information, received or otherwise obtained, for the report;

(B) Indicate the reason(s) for its inability to acquire a full data set; and

(C) Document its efforts to obtain a full data set (*i.e.*, description of unsuccessful steps taken to obtain this information).

(v) *Serious SARs not initially reported by a health care professional.* For a serious SAR that was not initially reported to the applicant by a health care professional (*e.g.*, report from a consumer), the applicant must contact the health care professional associated with the care of the patient using active query to gather further medical perspective on the case and to acquire a full data set for the report. If the applicant is unable to contact the health care professional, it must include in the report for the serious SADR:

(A) The reason(s) for its inability to contact the health care professional; and

(B) A description of its efforts to contact the health care professional.

(vi) *Nonserious SARs.* For reports of nonserious SARs with a minimum data set, except for those resulting from a medication error, all safety information received or otherwise obtained by the applicant must be submitted to FDA even though information in addition to the minimum data set is not required to be acquired. Reports of nonserious SARs resulting from a medication error require a full data set under paragraph (c)(1)(iv) of this section.

(2) *Postmarketing ''expedited reports''*—(i) *Serious and unexpected SAR.* The applicant must report to FDA each SAR, received or otherwise obtained, that is both serious and unexpected, whether foreign or domestic, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for the serious, unexpected SAR. If a full data set is not available for the serious and unexpected SAR report at the time of initial submission of the report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(ii) *Information sufficient to consider product administration changes.* The applicant must also report to FDA information, received or otherwise obtained, whether foreign or domestic, that would be sufficient, based upon appropriate medical judgment, to consider changes in product administration. The applicant must submit this information to FDA as soon as possible, but in no case later than 15 calendar days after determination by the applicant that the information qualifies for expedited reporting. Examples of such information include any significant unanticipated safety finding or data in the aggregate from an in vitro, animal, epidemiological, or clinical study, whether or not conducted under an investigational new drug application (IND), that suggests a significant human risk, such as reports of mutagenicity, teratogenicity, or carcinogenicity, or reports of a lack of efficacy with a biological product used in treating a life-threatening or serious disease. The applicant must maintain a record of its efforts to determine whether the information required to be reported under this paragraph qualifies for expedited reporting.

(iii) *Unexpected SAR with unknown outcome.* The applicant must also report to FDA each SAR that is unexpected and for which the determination of an outcome is unattainable (*i.e.*, SAR with unknown outcome) within 45 calendar days after initial receipt by the applicant of the minimum data set for the unexpected SAR. The applicant must document in the expedited report the reason(s) for the inability to determine the outcome.

(iv) *Always expedited report.* (A) The applicant must also report to FDA each SAR, received or otherwise obtained, whether foreign or domestic, that is the subject of an always expedited report. These reports must be submitted to FDA as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for the report. The following medically significant SARs, which may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject, are subject to an always expedited report:

(*1*) Congenital anomalies,
(*2*) Acute respiratory failure,
(*3*) Ventricular fibrillation,
(*4*) Torsades de pointe,
(*5*) Malignant hypertension,
(*6*) Seizure,
(*7*) Agranulocytosis,
(*8*) Aplastic anemia,
(*9*) Toxic epidermal necrolysis,
(*10*) Liver necrosis,
(*11*) Acute liver failure,
(*12*) Anaphylaxis,
(*13*) Acute renal failure,
(*14*) Sclerosing syndromes,
(*15*) Pulmonary hypertension,
(*16*) Pulmonary fibrosis,
(*17*) Confirmed or suspected transmission of an infectious agent by a marketed drug or biological product,
(*18*) Confirmed or suspected endotoxin shock, and
(*19*) Any other medically significant SAR that FDA determines to be the subject of an always expedited report (*i.e.*, may jeopardize the patient or subject and/or require medical or surgical intervention to treat the patient or subject).

(B) SARs that are the subject of an always expedited report must be submitted to FDA whether unexpected or expected and whether or not the SAR leads to a serious outcome. If a full data set is not available for an always expedited report at the time of initial submission of the report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(v) *Medication error*—(A) *Actual medication error.* The applicant must also submit to FDA each domestic report of an actual medication error, received or otherwise obtained, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum data set for a report of an SAR or, if an SAR does not occur, the minimum information described under paragraph (c)(1)(iii)(B) of this section (*i.e.*, identifiable patient, identifiable reporter, and suspect biological product).

(B) *Potential medication error.* The applicant must also submit to FDA each domestic report of a potential

medication error, received or otherwise obtained, as soon as possible, but in no case later than 15 calendar days after receipt by the applicant of the minimum information described under paragraph (c)(1)(iii)(C) of this section (*i.e.*, identifiable reporter and suspect biological product).

(C) *Full data set.* If a full data set is not available for an actual or potential medication error report at the time of initial submission of the report to FDA, the applicant must submit the information required under paragraph (c)(1)(iv) of this section and also submit a 30-day followup report as required by paragraph (c)(2)(vi) of this section.

(vi) *The 30-day followup report.* The applicant must use active query to obtain additional information for any expedited report under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that does not contain a full data set and must submit a followup report to FDA within 30 calendar days after initial submission of the expedited report to FDA by the applicant. If a full data set is still not obtainable, the 30-day followup report must contain the information required under paragraph (c)(1)(iv) of this section. Any new safety information in the 30-day followup report must be highlighted. Any new information received or otherwise obtained after submission of a 30-day followup report must be submitted to FDA as a 15-day followup report under paragraph (c)(2)(vii) of this section.

(vii) *The 15-day followup report.* The applicant must report to FDA any new information, received or otherwise obtained, for any expedited or followup report (except for initial expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set) within 15 calendar days of initial receipt of the new information by the applicant. Expedited reports under paragraphs (c)(2)(i), (c)(2)(iv), and (c)(2)(v) of this section that do not contain a full data set at the time of initial submission of the report to FDA are subject to the 30-day followup reporting requirements under paragraph (c)(2)(vi) of this section rather than the 15-day followup reporting requirements under this paragraph.

(viii) *Supporting documentation.* (A) If the patient dies, the applicant must submit a copy of the autopsy report to FDA, if it is available. If an autopsy report is not available, the applicant must submit a death certificate to FDA. If an autopsy report becomes available after the applicant has submitted a death certificate to the agency, the autopsy report must be submitted to FDA. If the patient was hospitalized, the applicant must submit a copy of the hospital discharge summary to FDA, if it is available. If any of these documents is not in English, the document must be accompanied by an English translation. Applicants must use active query to obtain these documents. These documents must be submitted to FDA as 15-day followup reports (see paragraph (c)(2)(vii) of this section) within 15 calendar days of initial receipt of the document by the applicant. If these documents are not submitted to FDA in a 15-day followup report within 3 months after submission of the initial expedited report for the death or hospitalization, the agency will assume that active query by the applicant has not resulted in access to these documents. In this case, a record of the reason(s) for the lack of such documentation and the effort that was made to obtain the documentation must be maintained by the applicant.

(B) Each expedited report must contain in the narrative a list of other relevant documents (*e.g.*, medical records, laboratory results, data from studies) for the report that are maintained by the applicant. When appropriate, FDA may require an applicant to submit copies of one or more of these documents to the agency within 5 calendar days after receipt of the request.

(ix) *Scientific literature.* An expedited report based on information from the scientific literature applies only to reports found in scientific and medical journals. These expedited reports must be accompanied by a copy of the published article.

(x) *Submission of safety reports by contractors and shared manufacturers.* (A) Contractors and shared manufacturers must submit to the applicant (includes participants involved in divided manufacturing) safety reports of any SARs or medication errors for the applicant's biological product, obtained or otherwise received, within 5 calendar days of initial receipt of the report by the contractor or shared manufacturer. The contractor and shared manufacturer must submit a safety report for an SAR to the applicant even if the report does not contain a minimum data set. Upon receipt of the safety report from a contractor or shared manufacturer, the applicant must comply with the postmarketing safety reporting requirements of this section.

(B) A contract between the applicant and a contractor must specify the postmarketing safety reporting responsibilities of the contractor. The applicant is responsible for ensuring that the contractors and shared manufacturers of its licensed biological products comply with these postmarketing safety reporting responsibilities.

(C) The contractor and shared manufacturer must maintain a record of each submission to the applicant under paragraph (c)(2)(x)(A) of this section that includes:

(*1*) A copy of each safety report;

(*2*) The date the report was initially received by the contractor or shared manufacturer;

(*3*) The date the report was submitted to the applicant; and

(*4*) The name and address of the applicant.

(D) The recordkeeping, written procedures, and disclaimer provisions under paragraphs (f), (g), and (j) of this section apply to contractors and shared manufacturers.

(xi) *Report identification.* Each expedited report submitted to FDA under paragraphs (c)(2)(i) through (c)(2)(vii) of this section must bear prominent identification as to its contents, *e.g.*, ''expedited report—serious and unexpected SAR,'' ''expedited report—30-day followup report.'' Each type of report (*e.g.*, serious and unexpected SAR reports, 30-day followup reports) must be submitted to FDA under separate cover. Reports of medication errors must indicate whether the error is actual or potential and if actual, whether a serious SAR, nonserious SAR, or no SAR occurred, *e.g.*, ''expedited report—actual medication error—nonserious SAR,'' ''expedited report—potential medication error.''

(3) *Postmarketing periodic safety reports.* The applicant must submit postmarketing periodic safety reports under this section (*i.e.*, TPSRs, PSURs, IPSRs, individual case safety reports—semiannual submission) to FDA within 60 calendar days after the data lock point for the report. The applicant must include a cover letter containing a list of the biologics license application number(s) (*i.e.*, BLA number(s)) for the human biological product(s) covered by the postmarketing periodic safety report. The international birth date for combination products is the international birth date of the human licensed biological product most recently approved for marketing.

(i) *Traditional periodic safety reports (TPSRs).* Each applicant holding a biologics license under § 601.20 of this chapter for a human biological product approved before January 1, 1998, must submit either a PSUR as prescribed under paragraph (c)(3)(ii) of this section or a TPSR as described under this paragraph every 5 years after U.S.

approval of the application. In addition, these applicants must submit either an IPSR as described under paragraph (c)(3)(iii) of this section or a TPSR as described under this paragraph 7.5 years and 12.5 years after U.S. approval of the application. The data lock point for the TPSR, PSUR, or IPSR is the month and day of the international birth date of the licensed biological product or any other month and day agreed on by the applicant and FDA. Each TPSR must contain:

(A) *Summary.* This section of the TPSR includes:

(*1*) A narrative summary and analysis of serious, expected SARs and nonserious, unexpected SARs occurring in the United States that were submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals) (with an index consisting of a line listing of the applicant's manufacturer report number and SAR term(s));

(*2*) An analysis of the expedited reports submitted during the reporting period under paragraphs (c)(2)(i) through (c)(2)(vii) of this section (all expedited reports must be appropriately referenced by the applicant's manufacturer report number, SAR term(s), if appropriate, and date of submission to FDA);

(*3*) A discussion of any increased reporting frequency of serious, expected SARs, including comments on whether it is believed that the data reflect a meaningful change in SAR occurrence, and an assessment of whether it is believed that the frequency of lack of efficacy reports is greater than would be predicted by the premarketing clinical trials for the biological product; and

(*4*) The applicant's conclusion as to what, if any, safety-related actions should be taken based on the analysis of the safety data in the TPSR (*e.g.*, labeling changes, studies initiated).

(B) *Summary tabulations.* This section of the TPSR includes summary tabulations (*i.e.*, lists of all SAR terms and counts of occurrences) presented by body system or by standard organ system classification scheme for:

(*1*) All serious expected SARs, nonserious unexpected SARs, nonserious expected SARs, and expected SARs with unknown outcome occurring in the United States that are submitted to the applicant during the reporting period from all spontaneous sources (*i.e.*, health care professionals and other individuals);

(*2*) All serious unexpected SARs, unexpected SARs with unknown outcome, and always expedited reports that were previously submitted to FDA in an expedited report under paragraphs (c)(2)(i), (c)(2)(iii), and (c)(2)(iv) of this section (include cumulative data for serious unexpected SARs, *i.e.*, all cases reported to date);

(*3*) All reports of SARs not previously submitted to FDA by the applicant (*e.g.*, reports submitted to applicants by FDA, reports obtained from FDA from freedom of information requests at the discretion of the applicant, reports from class action lawsuits); and

(*4*) All domestic reports of medication errors previously submitted to FDA under paragraph (c)(2)(v) of this section. For actual medication errors, provide summary tabulations of serious SARs, nonserious SARs, and no SARs. For potential medication errors, provide the number of reports for specific errors;

(C) *History of safety-related actions taken.* This section of the TPSR includes a history of safety-related actions taken since the last periodic safety report (*e.g.*, labeling changes, studies initiated);

(D) *Location of safety records.* This section of the TPSR includes a list of the current address(es) where all safety reports and other safety-related records for the licensed biological product(s) are maintained; and

(E) *Contact person.* This section of the TPSR includes the name and telephone number for the licensed physician(s) responsible for the content and medical interpretation of the information contained within the TPSR. Include, if available, the fax number and e-mail address for the licensed physician(s).

(ii) *Periodic safety update report (PSUR).* An applicant holding a biologics license under § 601.20 of this chapter for a human biological product approved on or after January 1, 1998, must submit a PSUR to FDA according to the following schedule: Semiannually (*i.e.*, every 6 months) for 2 years after U.S. approval of the application, annually for the next 3 years, and then every 5 years thereafter. The data lock point for the PSUR is the month and day of the international birth date of the licensed biological product or any other month and day agreed on by the applicant and FDA. Each PSUR must contain:

(A) *Title page, table of contents, and introduction.* (*1*) The title page includes, at a minimum, the following information:

(*i*) Name and international birth date of the licensed biological product(s) that is the subject of the PSUR,

(*ii*) Various dosage forms and formulations of the biological product(s) covered by the PSUR,

(*iii*) Name and address of the applicant,

(*iv*) Reporting period covered by the PSUR, and

(*v*) Date of the PSUR.

(*2*) The introduction:

(*i*) Provides a brief description of how the PSUR relates to previous reports and circumstances;

(*ii*) References relevant biological products reported in other periodic safety reports (*e.g.*, a combination product reported in a separate PSUR); and

(*iii*) Indicates any data duplication with other PSURs.

(B) *Worldwide marketing status.* This section of the PSUR contains a table of the chronological history of the worldwide marketing status of the biological product(s) covered by the PSUR from the date the product(s) was first approved (*i.e.*, the international birth date) through its current status (*i.e.*, cumulative information). This table consists of:

(*1*) Dates of biological product approval and renewal;

(*2*) Safety-related restrictions on product use;

(*3*) Indications for use and special populations covered by the biological product approval;

(*4*) Lack of approval of the biological product in any dosage form or for any indication for use by any regulatory authority(ies);

(*5*) Withdrawal of a pending marketing application for the biological product by the applicant for safety- or efficacy-related reasons;

(*6*) Dates of market launches; and

(*7*) Trade name(s).

(C) *Actions taken for safety reasons.* (*1*) This section of the PSUR includes details on the following types of regulatory authority-initiated (*e.g.*, by FDA) and/or applicant-initiated actions related to safety that were taken during the period covered by the PSUR and between the data lock point and PSUR submission (*i.e.*, ''late-breaking'' safety concerns):

(*i*) Withdrawal or suspension of biological product approval or indication for use approval;

(*ii*) Failure to obtain a marketing authorization renewal or to obtain an approval for a new indication for use;

(*iii*) Restrictions on distribution (products recalled for safety reasons);

(*iv*) Clinical trial suspension;

(*v*) Dosage modification;

(*vi*) Changes in target population or indications; and

(*vii*) Formulation changes.

(*2*) This section of the PSUR also contains a narrative identifying the safety-related reasons that led to these actions with relevant documentation appended when appropriate.

(*3*) Any communication with health care professionals (*e.g.*, Dear Healthcare Professional letters) resulting from such actions must also be described with copies appended.

(D) *Changes to CCSI.* This section of the PSUR describes changes to the CCSI (*e.g.*, new contraindications, precautions, warnings, SARs, or interactions) made during the period covered by the PSUR. A copy of any modified section of the CCSI must be included. The applicant must use the CCSI in effect at the beginning of the reporting period for the PSUR. The revised CCSI is to be used as the reference document for the next reporting period.

(E) *Worldwide patient exposure.* (*1*) This section of the PSUR includes, for the reporting period, an estimate of the worldwide patient exposure to the biological product(s) covered by the PSUR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*2*) When possible, data broken down by gender and age (especially pediatric versus adult) must be provided. For the pediatric population, data must be reported, if possible, by age group (*e.g.*, neonates, infants, children, adolescents). If these data are not available, an explanation must be included.

(*3*) When a pattern of reports indicates a potential problem, details by country (with locally recommended dosage regimens) or other segmentation (*e.g.*, indication, dosage form) must be presented.

(F) *Individual case safety reports.* (*1*) This section of the PSUR includes summary tabulations of individual case safety reports (*e.g.*, serious unlisted SARs, serious listed SARs, nonserious unlisted SARs, nonserious listed SARs) for the following SARs obtained or otherwise received during the reporting period:

(*i*) All serious and nonserious SARs from spontaneous sources that were submitted to applicants by a health care professional,

(*ii*) All serious SARs from studies, individual patient INDs, or, in foreign countries, from named-patient ''compassionate'' use,

(*iii*) All serious SARs and nonserious unlisted SARs from the scientific literature,

(*iv*) All serious SARs from regulatory authorities, and

(*v*) Serious SARs from other sources such as reports created by poison control centers and epidemiological data bases.

(*2*) The summary tabulations must be made up of lists by body system or by standard organ system classification scheme of all SAR terms and counts of occurrences. For SARs that are determined to be both serious and unlisted, include cumulative data (*i.e.*, all cases reported to date).

(*3*) The applicant must conclude this section with a brief discussion of the data concerning the individual case safety reports in the PSUR (*e.g.*, discussion of medical significance or mechanism).

(G) *Safety studies.* This section of the PSUR contains a discussion of nonclinical, clinical, and epidemiological studies that contain important safety information, as follows:

(*1*) All applicant-sponsored studies newly analyzed during the reporting period (copies of full reports should be appended only if new safety issues are raised or confirmed; FDA may request copies of other studies, if necessary);

(*2*) New studies specifically planned, initiated, or continuing during the reporting period that examine a safety issue, whether actual or hypothetical; and

(*3*) Published safety studies in the scientific and medical literature, including relevant published abstracts from meetings (provide literature citation).

(H) *Other information.* This section of the PSUR includes:

(*1*) A discussion of medically relevant lack of efficacy reports (*e.g.*, might represent a significant hazard to the treated population) for a product(s) used to treat serious or life-threatening diseases; and

(*2*) Any important new information received after the data lock point (*e.g.*, significant new cases).

(I) *Overall safety evaluation.* This section of the PSUR contains a concise, yet comprehensive, analysis of all of the safety information provided in the PSUR, including new information provided under paragraph (c)(3)(ii)(H)(*2*) of this section. In addition, this section of the PSUR includes an assessment by the applicant of the significance of the data collected during the reporting period, as well as from the perspective of cumulative experience.

(*1*) The applicant must highlight any new information on:

(*i*) Serious, unlisted SARs;

(*ii*) Increased reporting frequencies of listed SARs, including comments on whether it is believed that the data reflect a meaningful change in SAR occurrence;

(*iii*) A change in characteristics of listed SARs (*e.g.*, severity, outcome, target population); and

(*iv*) Nonserious, unlisted SARs.

(*2*) As part of the overall safety evaluation, the applicant must also explicitly address any new safety issue including but not limited to the following (lack of significant new information for each of the following must be mentioned):

(*i*) Drug interactions;

(*ii*) Experience with overdose, whether deliberate or accidental, and its treatment;

(*iii*) Drug abuse or intentional misuse;

(*iv*) Positive or negative experiences during pregnancy or lactation;

(*v*) Effects with long-term treatment; and

(*vi*) Experience in special patient groups (*e.g.*, pediatric, geriatric, organ impaired). For the pediatric population, data must be evaluated, if possible, by age group (*e.g.*, neonates, infants, children, adolescents).

(J) *Conclusion.* This section of the PSUR:

(*1*) Indicates new safety information that is not in accord with previous cumulative experience and with the CCSI in use at the beginning of the reporting period (*e.g.*, new evidence that strengthens a possible causal relationship between the biological product and an SAR, such as positive rechallenge, an epidemiological association, or new laboratory studies); and

(*2*) Specifies and justifies any action recommended or initiated, including changes in the CCSI.

(K) *Appendices.* This section of the PSUR includes:

(*1*) *Company core data sheet.* Provide a copy of the company core data sheet covered by this PSUR (*i.e.*, in effect at the beginning of the period covered by the PSUR), as well as the company core data sheet for the next reporting period. Company core data sheets must be numbered and dated and include the date of last revision.

(*2*) *U.S. labeling.* Provide a copy of the current approved U.S. labeling. Specify any safety information that is included in the CCSI but not in the U.S. labeling, and provide an explanation for the

discrepancy. Describe any safety-related changes or proposed changes to the U.S. labeling made during the reporting period (include the supplement number(s) and date(s) of submission for the supplement(s)) and any suggested change(s) that should be considered based on the safety analysis in this PSUR.

(*3*) *Spontaneous reports submitted to the applicant by an individual other than a health care professional.* Provide summary tabulations (*e.g.*, serious unlisted SARs, serious listed SARs, nonserious unlisted SARs, nonserious listed SARs) for all spontaneously reported serious SARs, whether domestic or foreign, and all spontaneously reported nonserious SARs occurring in the United States, obtained or otherwise received during the reporting period by the applicant from an individual other than a health care professional (*e.g.*, reports from consumers). These summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SAR terms and counts of occurrences. For those SARs that are determined to be both serious and unlisted, include cumulative data (*i.e.*, all cases reported to date by individuals other than a health care professional). Include a brief discussion of the impact of the spontaneous reports described in this appendix on the overall safety evaluation.

(*4*) *SARs with unknown outcome.* Provide summary tabulations for unlisted and listed SARs with unknown outcome from all spontaneous sources (*i.e.*, health care professionals and other individuals), obtained or otherwise received by the applicant during the reporting period. These summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SAR terms and counts of occurrences. Include a brief discussion of the impact of the spontaneous reports described in this appendix on the overall safety evaluation.

(*5*) *Class action lawsuits.* Provide summary tabulations (*e.g.*, serious unlisted SARs, serious listed SARs, nonserious unlisted SARs, nonserious listed SARs) for all SARs obtained or otherwise received during the reporting period by the applicant from class action lawsuits. These summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SAR terms and counts of occurrences. For those SARs that are determined to be both serious and unlisted, include cumulative data. Include a brief discussion of the impact of the reports described in this appendix on the overall safety evaluation.

(*6*) *Lack of efficacy reports.* Provide an assessment of whether it is believed that the frequency of lack of efficacy reports, obtained or otherwise received during the reporting period, is greater than would be predicted by the premarketing clinical trials for the biological product.

(*7*) *Medication errors.* Provide summary tabulations of all domestic reports of medication errors submitted during the reporting period under paragraph (c)(2)(v) of this section. For actual medication errors, provide summary tabulations of serious SARs, nonserious SARs, and no SARs (for serious SARs, include cumulative data, *i.e.*, all cases reported to date). For potential medication errors, provide the number of reports for specific errors. If an SAR occurs, the summary tabulations must consist of lists by body system or by standard organ system classification scheme of all SAR terms and counts of occurrences. Include a brief discussion of the impact on the overall safety evaluation of these reports.

(*8*) *U.S. patient exposure.* Provide, for the reporting period, an estimate of the U.S. patient exposure to the biological product(s) covered by the PSUR (*i.e.*, number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*9*) *Location of safety records.* Provide a list of the current address(es) where all safety reports and other safety-related records for the licensed biological product(s) are maintained.

(*10*) *Contact person.* Provide the name and telephone number for the licensed physician(s) responsible for the content and medical interpretation of the data and information contained within the PSUR. Include, if available, the fax number and e-mail address for the licensed physician(s).

(iii) *Interim periodic safety report (IPSR).* An applicant holding a biologics license under § 601.20 of this chapter for a human biological product approved on or after January 1, 1998, must submit an IPSR to FDA 7.5 years and 12.5 years after U.S. approval of the application. The data lock point for the IPSR is the month and day of the international birth date of the licensed biological product or any other month and day agreed on by the applicant and FDA. The reporting period for the IPSR covers the period between the last PSUR or TPSR and the data lock point for the IPSR (*e.g.*, between years 5 and 7.5 for an IPSR with a data lock point 7.5 years after U.S. approval of the application). Each IPSR must contain:

(A) *Title page, table of contents, and introduction.* (*1*) The title page includes, at a minimum, the following information:

(*i*) Name and international birth date of the licensed biological product(s) that is the subject of the IPSR,

(*ii*) Various dosage forms and formulations of the biological product(s) covered by the IPSR,

(*iii*) Name and address of the applicant,

(*iv*) Reporting period covered by the IPSR, and

(*v*) Date of the IPSR.

(*2*) The introduction: (*i*) Provides a brief description of how the IPSR relates to previous reports and circumstances,

(*ii*) References relevant biological products reported in other periodic safety reports (*e.g.*, a combination product reported in a separate IPSR), and

(*iii*) Indicates any data duplication with other IPSRs.

(B) *Worldwide marketing status.* This section of the IPSR contains a table of the chronological history of the worldwide marketing status of the biological product(s) covered by the IPSR from the date the product(s) was first approved (*i.e.*, the international birth date) through its current status (*i.e.*, cumulative information). This table consists of:

(*1*) Dates of biological product approval and renewal;

(*2*) Safety-related restrictions on product use;

(*3*) Indications for use and special populations covered by the biological approval;

(*4*) Lack of approval of the biological product in any dosage form or for any indication for use by any regulatory authority(ies);

(*5*) Withdrawal of a pending marketing application for the biological product by the applicant for safety- or efficacy-related reasons;

(*6*) Dates of market launches; and

(*7*) Trade name(s).

(C) *Actions taken for safety reasons.* (*1*) This section of the IPSR includes details on the following types of regulatory authority-initiated (*e.g.*, by FDA) and/or applicant-initiated actions

related to safety that were taken during the period covered by the IPSR and between the data lock point and IPSR submission (*i.e.*, ''late-breaking'' safety concerns):

(i) Withdrawal or suspension of biological product approval or indication for use approval;

(*ii*) Failure to obtain a marketing authorization renewal or to obtain an approval for a new indication for use;

(*iii*) Restrictions on distribution (products recalled for safety reasons);

(*iv*) Clinical trial suspension;

(*v*) Dosage modification;

(*vi*) Changes in target population or indications; and

(*vii*) Formulation changes.

(*2*) This section of the IPSR also contains a narrative identifying the safety-related reasons that led to these actions with relevant documentation appended when appropriate.

(*3*) Any communication with health care professionals (*e.g.*, Dear Healthcare Professional letters) resulting from such actions must also be described with copies appended.

(D) *Changes to CCSI.* This section of the IPSR describes changes to the CCSI (*e.g.,* new contraindications, precautions, warnings, SARs, or interactions) made during the period covered by the IPSR. A copy of any modified section of the CCSI must be included. The applicant must use the CCSI in effect at the beginning of the reporting period for the IPSR. The revised CCSI is to be used as the reference document for the next reporting period.

(E) *Worldwide patient exposure.* (*1*) This section of the IPSR includes, for the reporting period, an estimate of the worldwide patient exposure to the biological product(s) covered by the IPSR (*i.e.,* number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*2*) When possible, data broken down by gender and age (especially pediatric versus adult) must be provided. For the pediatric population, data must be reported, if possible, by age group (*e.g.,* neonates, infants, children, adolescents). If these data are not available, an explanation must be included.

(*3*) When a pattern of reports indicates a potential problem, details by country (with locally recommended dosage regimens) or other segmentation (*e.g.,* indication, dosage form) must be presented.

(F) *Safety studies.* This section of the IPSR contains a discussion of nonclinical, clinical, and epidemiological studies that contain important safety information, as follows:

(*1*) All applicant-sponsored studies newly analyzed during the reporting period (copies of full reports should be appended only if new safety issues are raised or confirmed; FDA may request copies of other studies, if necessary);

(*2*) New studies specifically planned, initiated, or continuing during the reporting period that examine a safety issue, whether actual or hypothetical; and

(*3*) Published safety studies in the scientific and medical literature, including relevant published abstracts from meetings (provide literature citation).

(G) *Other information.* This section of the IPSR includes a discussion of medically relevant lack of efficacy reports (*e.g.,* might represent a significant hazard to the treated population) for a product(s) used to treat serious or life-threatening diseases.

(H) *Overall safety evaluation.* This section of the IPSR contains a concise, yet comprehensive, analysis of all of the safety information provided in the IPSR. In addition, this section of the IPSR includes an assessment by the applicant of the significance of the data collected during the reporting period, as well as from the perspective of cumulative experience.

(*1*) The applicant must highlight any new information on:

(*i*) Serious, unlisted SARs;

(*ii*) Increased reporting frequencies of listed SARs, including comments on whether it is believed that the data reflect a meaningful change in SAR occurrence;

(*iii*) A change in characteristics of listed SARs (*e.g.,* severity, outcome, target population); and

(*iv*) Nonserious, unlisted SARs.

(*2*) As part of the overall safety evaluation, the applicant must also explicitly address any new safety issue including but not limited to the following (lack of significant new information for each of the following must be mentioned):

(*i*) Drug interactions;

(*ii*) Experience with overdose, whether deliberate or accidental, and its treatment;

(*iii*) Drug abuse or intentional misuse;

(*iv*) Positive or negative experiences during pregnancy or lactation;

(*v*) Effects with long-term treatment; and

(*vi*) Experience in special patient groups (*e.g.,* pediatric, geriatric, organ impaired). For the pediatric population, data must be evaluated, if possible, by age group (*e.g.,* neonates, infants, children, adolescents).

(I) *Conclusion.* This section of the IPSR:

(*1*) Indicates new safety information that is not in accord with previous cumulative experience and with the CCSI in use at the beginning of the reporting period (*e.g.,* new evidence that strengthens a possible causal relationship between the biological product and an SAR, such as positive rechallenge, an epidemiological association or new laboratory studies); and

(*2*) Specifies and justifies any action recommended or initiated, including changes in the CCSI.

(J) *Appendices.* This section of the IPSR includes:

(*1*) *Company core data sheet.* Provide a copy of the company core data sheet covered by this IPSR (*i.e.,* in effect at the beginning of the period covered by the IPSR), as well as the company core data sheet for the next reporting period. Company core data sheets must be numbered and dated and include the date of last revision.

(*2*) *U.S. labeling.* Provide a copy of the current approved U.S. labeling. Specify any safety information that is included in the CCSI but not in the U.S. labeling and provide an explanation for the discrepancy. Describe any safety-related changes or proposed changes to the U.S. labeling made during the reporting period (include the supplement number(s) and date(s) of submission for the supplement(s)) and any suggested change(s) that should be considered based on the safety analysis in this IPSR.

(*3*) *Spontaneous reports submitted to the applicant by an individual other than a health care professional.* Provide a brief discussion of the impact on the overall safety evaluation of any spontaneously reported serious SARs, whether domestic or foreign, and any spontaneously reported nonserious SARs occurring in the United States, obtained or otherwise received during the reporting period by the applicant from an individual other than a health care professional (*e.g.,* reports from consumers).

(*4*) *SARs with unknown outcome.* Provide a brief discussion of the impact on the overall safety evaluation of any spontaneously reported unlisted and listed SARs with unknown outcome obtained or otherwise received during the reporting period by the applicant from health care professionals and other individuals.

(*5*) *Class action lawsuits.* Provide a brief discussion of the impact on the overall safety evaluation of any safety information obtained or otherwise received during the reporting period by the applicant from class action lawsuits.

(*6*) *Lack of efficacy reports.* Provide an assessment of whether it is believed that the frequency of any lack of efficacy reports, obtained or otherwise received during the reporting period, is greater than would be predicted by the premarketing clinical trials for the biological product.

(*7*) *Medication errors.* Provide a brief discussion of the impact on the overall safety evaluation of all domestic reports of medication errors submitted during the reporting period under paragraph (c)(2)(v) of this section.

(*8*) *U.S. patient exposure.* Provide, for the reporting period, an estimate of the U.S. patient exposure to the biological product(s) covered by the IPSR (*i.e.,* number of patients, average or median dose received, and average or median length of treatment). The method used to estimate patient exposure must always be described. If the patient exposure is impossible to estimate or is meaningless, an explanation of and justification for such conclusions must be provided. If patient exposure is impossible to estimate, other measures of exposure, such as patient-days, number of prescriptions, or number of dosage units, may be used. If these or other more precise measures are not available and an adequate explanation for the lack of such information is provided, bulk sales may be used.

(*9*) *Location of safety records.* Provide a list of the current address(es) where all safety reports and other safety-related records for the licensed biological product(s) are maintained.

(*10*) *Contact person.* Provide the name and telephone number for the licensed physician(s) responsible for the content and medical interpretation of the information contained within the IPSR. Include, if available, the fax number and e-mail address for the licensed physician(s).

(iv) *Pediatric use supplements.* After approval of a pediatric use supplement to an approved application (*i.e.,* a supplement for use of the human biological product in the pediatric population), the applicant must submit PSURs to FDA as prescribed under paragraph (c)(3)(ii) of this section according to the following schedule: Semiannually for 2 years after U.S. approval of the supplement, annually for the next 3 years, and then every 5 years thereafter. These applicants must also submit IPSRs to FDA as prescribed under paragraph (c)(3)(iii) of this section at 7.5 years and 12.5 years after U.S. approval of the supplement. The data lock point for the PSUR and IPSR is the month and day of the international birth date of the licensed biological product or any other month and day agreed on by the applicant and FDA.

(v) *Semiannual submission of individual case safety reports.* (A) An applicant holding a biologics license under § 601.20 of this chapter for a human biological product must submit to FDA semiannually (*i.e.,* every 6 months) after U.S. approval of the application a separate report that consists of individual case safety reports for certain spontaneously reported SARs for the biological product. The individual case safety reports must be submitted on the form designated by the agency under paragraph (c)(4) of this section. The data lock point for the report is the month and day of the international birth date of the licensed biological product or any other month and day agreed on by the applicant and FDA. This report must be identified as ''individual case safety reports—semiannual submission.''

(B) Applicants that submit TPSRs to FDA for the licensed biological product must submit an individual case safety report for each serious, expected SAR, whether domestic or foreign, and each nonserious, unexpected SAR occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources (*i.e.,* health care professionals and other individuals). Reports for vaccines must include an individual case safety report for each nonserious, expected SAR and each expected SAR with unknown outcome occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources. Applicants that submit PSURs to FDA for the licensed biological product must submit an individual case safety report for each serious, listed SAR, whether domestic or foreign, and each nonserious, unlisted SAR occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources. Reports for vaccines must include an individual case safety report for each nonserious, listed SAR and each listed SAR with unknown outcome occurring in the United States that is submitted to the applicant during the reporting period from all spontaneous sources. If a full data set is not available for a report of a serious SAR, the applicant must submit the information required under paragraph (c)(1)(iv) of this section.

(C) Followup information to SARs submitted in an individual case safety report—semiannual submission may be submitted in the next individual case safety report—semiannual submission unless such information changes the classification of the SAR to a serious, unexpected SAR. In these cases, the followup information must be submitted to FDA as a 15-day followup report (see paragraph (c)(2)(vii) of this section).

(4) *Reporting format.* (i)(A) Except as provided in paragraphs (c)(4)(i)(B), (c)(4)(i)(D), and (c)(4)(v) of this section, the applicant must complete the reporting form designated by FDA for each individual case safety report of an SAR (FDA Form 3500A or, for vaccines, a VAERS form). Reports based on information about individual cases or case series in the scientific literature must be submitted on an FDA Form 3500A(s) or, for vaccines, on a VAERS form(s).

(B) Foreign SARs may be submitted either on an FDA Form 3500A or, if preferred, on a CIOMS I form; foreign SARs for vaccines may be submitted either on a VAERS form or, if preferred, on a CIOMS I form.

(C) Each domestic report of an actual or potential medication error must be submitted on an FDA Form 3500A, or, for vaccines, on a VAERS form.

(D) Reports of overall findings or data in the aggregate from published and unpublished in vitro, animal, epidemiological, or clinical studies must be submitted in a narrative format.

(ii) Each SAR in an individual case safety report must be coded on the FDA Form 3500A, VAERS form, or CIOMS I form using the appropriate ''preferred term'' in the latest version of MedDRA (the medical dictionary for regulatory activities) in use at the time the applicant becomes aware of the individual case safety report. For individual case safety reports of medication errors, the report must be coded both as a medication error and, if applicable, with the preferred term for any SARs associated with the medication error.

(iii) Each completed FDA Form 3500A, VAERS form, or CIOMS I form should refer only to an individual case.

(iv) Each completed FDA Form 3500A, VAERS form or CIOMS I form must include the name and telephone number (and fax number and e-mail address, if available) for the licensed

physician responsible for the content and medical interpretation of the data contained within the form (*i.e.,* contact person for the company).

(v) Instead of using FDA Form 3500A (or a VAERS form for vaccines), the applicant may use a computer-generated facsimile of FDA Form 3500A (or the VAERS form for vaccines) provided that it is readable, includes appropriate identifying information, and contains all the elements (*i.e.,* format, sections, blocks, titles, descriptors within blocks, text for disclaimer) of FDA Form 3500A (or the VAERS form for vaccines) in the identical enumerated sequence of the form. For individual case safety reports in which no suspect medical device is involved, a one-page FDA Form 3500A is acceptable.

(d) *Multiple reports.* An applicant should not include in reports under this section any SARs that occurred in clinical trials if they were previously submitted as part of the license application. If a report refers to more than one biological product marketed by an applicant, the applicant should submit the report to the license for the product listed first in the report.

(e) *Patient privacy.* For nonvaccine biological products, the names and addresses of individual patients should not be included in reports under this section; instead, the applicant, shared manufacturer and contractors should assign a unique code to each report, preferably not more than eight characters (*i.e.,* numbers and/or letters) in length. The name of the reporter from whom the information was received should be included. Names of patients, individual reporters, health care professionals, hospitals, and geographic identifiers in safety reports are not releasable to the public under FDA's public information regulations in part 20 of this chapter. For vaccine SAR reports, these data will become part of the CDC Privacy Act System 09–20–0136, ''Epidemiologic Studies and Surveillance of Disease Problems.'' Information identifying the person who received the vaccine or that person's legal representative will not be made available to the public, but may be available to the vaccinee or legal representative.

(f) *Recordkeeping.* Each applicant must maintain for a period of 10 years records of all safety information pertaining to its product, received or otherwise obtained, including raw data, any correspondence relating to the safety information, and any reports of SARs or medication errors not submitted to FDA or only provided to FDA in a summary tabulation. Each applicant must also retain for a period of 10 years any records required to be maintained under this section. When appropriate, FDA may require an applicant to submit any or all of these records to the agency within 5 calendar days after receipt of the request.

(g) *Written procedures.* Each applicant must develop and maintain written procedures for the surveillance, receipt, evaluation, and reporting of safety information to FDA.

(h) *Revocation of license.* If an applicant fails to establish and maintain records and make reports required under this section with respect to a licensed biological product, FDA may revoke the license for such a product in accordance with the procedures of § 601.5 of this chapter.

(i) *Exemptions.* Manufacturers of the following listed products are not required to submit safety reports under this section:

(1) Whole blood or components of whole blood. These products are subject to the reporting requirements for blood and blood components in § 606.170 of this chapter.

(2) In vitro diagnostic products, including assay systems for the detection of antibodies or antigens to retroviruses. These products are subject to the reporting requirements for devices.

(j) *Disclaimer.* A report or information submitted by an applicant under this section (and any release by FDA of that report or information) does not necessarily reflect a conclusion by the applicant or FDA that the report or information constitutes an admission that the biological product caused or contributed to an SAR. An applicant need not admit, and may deny, that the report or information submitted under this section constitutes an admission that the biological product caused or contributed to an SAR.

PART 601—LICENSING

14. The authority citation for 21 CFR part 601 continues to read as follows:

Authority: 15 U.S.C. 1451–1561; 21 U.S.C. 321, 351, 352, 353, 355, 356b, 360, 360c–360f, 360h–360j, 371, 374, 379e, 381; 42 U.S.C. 216, 241, 262, 263, 264; sec. 122, Pub. L. 105–115, 111 Stat. 2322 (21 U.S.C. 355 note).

§ 601.28 [AMENDED]

15. Section 601.28 *Annual reports of postmarketing pediatric studies* is amended by removing the second sentence in paragraph (a) and the phrase ''safety and'' in the first sentence in paragraph (b).

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

16. The authority citation for 21 CFR part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

17. Section 606.170 is revised to read as follows:

§ 606.170 Suspected adverse reaction investigation and reporting.

(a) Any reports of complaints of suspected adverse reactions (SARs), as defined in § 600.80(a) of this chapter, regarding each unit of blood or blood product arising as a result of blood collection or transfusion must be investigated promptly and thoroughly. Records of the complaint and investigation must be maintained. The collection or transfusing facility must prepare and maintain a written report of the investigation of SARs, including followup and conclusions, as part of the record for that lot or unit of final product. If it is determined that there was an SAR related to transfusion or possibly related to the collection procedure, then copies of all such reports must be forwarded to and maintained by the manufacturer or collection facility.

(b) For any serious SAR, as defined in § 600.80(a) of this chapter, except for a fatality, the facility performing the compatibility testing (if the SAR is related to transfusion) or the collecting facility (if the SAR is related to the blood collection procedure), must submit a written report to the Center for Biologics Evaluation and Research (CBER), at FDA within 45 calendar days after determination of the serious SAR. The written report must be submitted using the reporting format provided in § 600.80(c)(4) of this chapter.

(c) For an SAR that results in a fatality, the Director, Office of Compliance and Biologics Quality, at CBER must be notified by telephone, facsimile, express mail, or electronically transmitted mail as soon as possible. Within 7 calendar days after the fatality, the collection facility (if the fatality is related to blood collection) or the facility performing the compatibility tests (if the fatality is related to transfusion) must submit a written report to CBER, FDA, using the reporting format provided in § 600.80(c)(4) of this chapter.

(Information collection requirements approved by the Office of Management and Budget under control number 0910–0116)

Dated: December 13, 2002.

Mark B. McClellan,

Commissioner of Food and Drugs.

Dated: January 29, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 03–5204 Filed 3–13–03; 8:45 am]

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Federal Register

Friday,
March 14, 2003

Part III

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 201, 606, and 610

Bar Code Label for Human Drug Products and Blood; Proposed Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 201, 606, and 610

[Docket No. 02N–0204]

RIN 0910–AC26

Bar Code Label Requirement For Human Drug Products and Blood

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing a new rule that would require certain human drug product labels and biological product labels to have bar codes. The bar code for human drug products and biological products (other than blood and blood components) would contain the National Drug Code (NDC) number in a linear bar code. The proposed rule would help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time. The proposed rule would also require the use of machine-readable information on blood and blood component container labels to help reduce medication errors.

DATES: Submit written or electronic comments on this proposed rule by June 12, 2003. Submit written comments on the information collection requirements by April 14, 2003.

ADDRESSES: Fax written comments to the Dockets Management Branch (HFA–305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852. Fax electronic comments to http://www.fda.gov/dockets/ecomments. Submit written comments on the information collection provisions to the Office of Information and Regulatory Affairs, Office of Management and Budget (OMB), Attn: Stuart Shapiro, Fax: (202) 395–6974.

FOR FURTHER INFORMATION CONTACT: Philip L. Chao, Office of Policy, Planning, and Legislation (HF–23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–827–3380.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. Introduction
A. What Actions Led to This Rulemaking?
B. What Are Medication Errors?
C. How Frequently Do Medication Errors Occur? What Is Their Impact?
D. How Would Bar Coding Help Prevent Medical Errors?
E. Can Bar Code Use Reduce the Incidence of Medication Errors?
F. Is There Support for Putting Bar Codes on Drug Products?
II. Description of the Proposed Rule
A. Who Would Be Subject to the Bar Code Requirement? (Proposed § 201.25(a))
B. What Products Would Have to Have a Bar Code? (Proposed § 201.25(b))
C. What Would the Bar Code Contain? (Proposed § 201.25(c)(1))
D. Would the Rule Require a Specific Type of Bar Code? (Proposed § 201.25(c)(1))
E. Where on the Label Would the Bar Code Appear? (Proposed § 201.25(c)(2))
F. What Would Happen if a Bar Code Could Not Be Put on a Product?
G. What Is the Proposed Implementation Plan?
H. How Does This Rule Apply to Blood and Blood Components? (Proposed § 606.121(c)(13))
I. What Bar Code Requirement Would Apply to Biological Products? (Proposed § 610.67)
III. Legal Authority
IV. Environmental Impact
V. Paperwork Reduction Act of 1995
VI. Executive Order 13132: Federalism
VII. Analysis of Impacts
A. Introduction
B. Objective of the Proposed Rule
C. Estimate of Risk/Risk Assessment
D. The Proposed Rule
E. Description of Affected Sectors
F. Regulatory Costs of the Proposed Rule
G. Other Anticipated Expenditures
H. Reduction in Preventable Adverse Drug Events
I. Value of Avoided ADEs
J. Aggregate Benefit of Avoiding ADEs
K. Other Benefits of Bar Code Technology
L. Distributional Effects of Bar Code Technology
M. Comparison of Costs, Expenditures, and Benefits
N. Uncertainty and Sensitivity
O. Small Business Analysis and Discussion of Alternatives
P. Conclusion
VIII. Request For Comments
IX. References
Appendix—Additional Information on Various Studies Identifying Different Types of Medication Errors

I. Introduction

A. What Actions Led to This Rulemaking?

In 1999, the Institute of Medicine (IOM) issued a report entitled ''To Err Is Human: Building a Safer Health System'' (Ref. 1). (The IOM is a private, nonprofit organization that provides health policy advice under a congressional charter granted to the National Academy of Sciences.) The IOM report cited studies and articles to estimate that between 44,000 and 98,000 Americans may die each year due to a range of medical mistakes made by health care professionals. The IOM report estimated that, in 1993 alone, an estimated 7,000 deaths were attributable to medication errors (Ref. 1 at p. 27) and that:

• Medication errors account for 1 out of every 131 outpatient deaths, and 1 out of every 854 inpatient deaths (Ref. 1 at p. 27); and

• The death rate attributable to medication errors may be increasing. The IOM report cited a study that examined death certificates from 1983 to 1993. The study found that, in 1983, 2,876 deaths were due to medication errors (which the authors defined as accidental poisoning by drugs, medicaments, and biological products resulting from acknowledged errors by patients or health care professionals) (Ref. 1 at p. 32, Ref. A–14 of the Appendix to this document). In 1993, 7,391 deaths were attributed to medication errors, a 2.57-fold increase in the death rate (Ref. 1 at p. 32). Moreover, a comparison of outpatient death rates suggested nearly an 8-fold increase in medication error death rates (Ref. 1 at pp. 32 and 33).

The IOM report stated that deaths due to medication errors are often preventable and cited bar codes as one way to prevent them (Ref. 1 at pp. 37, 175, 188, 189, 195–196).

The IOM report generated considerable controversy. Some felt that the IOM's figures were exaggerated (Ref. 2), while others felt the figures might have been too low (Ref. 3). Some felt that the term ''medical errors'' was, itself, misleading (Ref. 4). Others, including FDA, suggested that the IOM report's basic message—that medical errors are a serious public health problem—should not be lost regardless of whether the annual mortality was 10,000 or 100,000 (Ref. 5)

The IOM report led to new efforts to improve patient safety. For example:

• In December 1999, President Clinton directed the HealthCare Quality Task Force to analyze the IOM report and to report back on recommendations to

protect patients and to promote safety. In February, 2000, he announced a plan to reduce preventable medical errors by 50 percent within 5 years.

• In February 2000, the Quality Interagency Coordination (QuIC) Task Force (a group composed of the Department of Health and Human Services (DHHS) and other Federal agencies) issued an action plan that highlighted steps for Federal agencies to take to reduce medical errors and to improve patient care.

• In March 2001, the Agency for HealthCare Research and Quality (AHRQ) issued a report entitled ''Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs.'' The report stated that more than 770,000 people are injured or die each year in hospitals from adverse drug events and that studies had suggested that 28 to 95 percent of adverse drug events could be prevented by reducing medication errors through the use of computerized monitoring systems, especially computerized medication ordering systems (Ref. 6).

• In April 2001, the Secretary of Health and Human Services, Tommy G. Thompson (Secretary Thompson), announced the establishment of a new Patient Safety Task Force within DHHS. Secretary Thompson named FDA as one of the Federal agencies leading this new effort (Ref. 7).

Congress also focused its attention on patient safety by holding hearings in 2000 and 2001 on patient safety and medical errors. On May 24, 2001, Secretary Thompson appeared before the Senate Committee on Health, Education, Labor, and Pensions' Subcommittee on Patient Health and stated that new technology, such as bar coding, could help save lives and money. Secretary Thompson noted that other industries used bar coding and that the same technology could be used to track drug dispensing and use and to prevent medication errors (Ref. 8).

Shortly thereafter, the American Society for Health-System Pharmacists (ASHP) wrote to Secretary Thompson to urge that FDA ''develop regulations that mandate that drug manufacturers provide a standardized machine-readable code (bar coding) on all drug product containers, including single unit containers, which are essential for hospital unit dose drug distribution systems'' (Ref. 9). ASHP mentioned a June 26, 2001, recommendation by the National Coordinating Council for Medication Error Reporting and Prevention (NCCMERP) urging FDA and the United States Pharmacopeia (USP) to establish and implement a uniform bar coding program for drugs (Ref. 9 at pp. 1 and 2). Secretary Thompson later asked FDA to begin working on a bar coding proposal, thereby putting in motion the events that led to this proposed rule.

B. What Are Medication Errors?

NCCMERP [1] defines a medication error as:

> * * * any preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the healthcare professional, patient, or consumer. Such events may be related to professional practice; healthcare products, procedures, and systems, including prescribing; order communication; product labeling, packaging, and nomenclature; compounding; dispensing; distribution; administration; education; monitoring; and use. (Ref. 10)

For purposes of this preamble, we will adopt the same definition of ''medication error.''

Medication errors are a part of the overall ''medical errors'' problem because medical errors include surgical errors, device failures, and medication errors. Medication errors can occur at several points from the time the physician selects the drug to prescribe to a patient to the time when the patient receives the drug. For example, the physician may write a prescription for the right drug, but in the wrong dose. The pharmacist might misread the prescription and provide the wrong drug, or read the prescription correctly and dispense the wrong drug. The health care professional administering the drug might give it to the wrong patient or give it to the right patient, but at the wrong time or in the wrong dose.

Articles discussing medication errors can be found dating back several decades, and refer to such errors under various names, including ''preventable adverse events,'' ''drug misadventuring,'' and ''iatrogenic illness'' or ''iatrogenic injury.'' (The word ''iatrogenic'' refers to ''any adverse condition in a patient occurring as the result of treatment by a physician or surgeon'' (see *Dorland's Illustrated Medical Dictionary*, 26th ed., at p. 647).) The articles often identify the following types of medication errors:

• Administering the wrong dose,

• Administering a drug to a patient who is known to be allergic,

• Administering the wrong drug to a patient or administering a drug to the wrong patient,

• Administering the drug incorrectly,

• Administering the drug at the wrong time or missing doses.

(See the Appendix elsewhere in this document for a description of various studies identifying different types of medication errors.)

C. How Frequently Do Medication Errors Occur? What Is Their Impact?

Studies differ as to how frequently medication errors occur. Some studies suggest that the medication error rate is under 7 percent, whereas others suggest a medication error rate at or above 20 percent. The differences may be due, in part, to different definitions of ''medication error'' or different research methodology that focused on fatalities, injuries, or medication orders. (See the appendix for a summary of medication error rates reported in several studies.)

Although most medication errors do not result in harm to patients, medication errors can result and have resulted in serious injury or death (Ref. 11).

Medication errors also represent a significant economic cost to the United States. In an article published in 1995, Johnson and Bootman estimated the direct cost of preventable drug-related mortality and morbidity to be $76.6 billion annually, with drug-related hospital admissions accounting for much of the cost (Ref. 12). The authors suggested that indirect costs, such as those relating to lost productivity, might be two to three times greater than the direct costs, making the total cost of all preventable, drug-related mortality and morbidity range from $138 to $182 billion. A study by Ernst and Grizzle published in 2001 used updated figures and revised the direct cost estimate to $177.4 billion (Ref. 13). Another article estimated the cost of preventable adverse drug events in hospitalized patients to be $5,857 for each adverse drug event and the estimated annual costs for preventable adverse drug events for a 700–bed hospital to be $2.8 million (Ref. 14).

D. How Would Bar Coding Help Prevent Medication Errors?

Bar codes would be part of a system, along with bar code scanners and computerized databases, that would enable health care professionals to check whether they are giving the right drug via the right dose and right route of administration to the right patient at the right time. Under this model, the system could work as follows:

• A patient would have his or her drug regimen information entered into a computerized database.

[1] NCCMERP is composed of over 20 national organizations (including FDA) whose objectives are to increase the reporting, understanding, and prevention of medication errors and to recommend strategies relative to systems modifications, practice standards, and guidelines, and changes in packaging, labeling, and product identity.

• Each drug would have a bar code. The bar code would provide unique, identifying information about the drug that is to be dispensed to the patient.

• In hospitals, health-care professionals, such as pharmacists and nurses, would use bar code scanners (also called bar code readers) to read the bar code on the drug before dispensing the drug to the patient and use bar code scanners to read a bar coded wrist band on the patient before giving the drug to the patient. In an outpatient setting, the health care professional (such as a pharmacist) could scan the bar code on the drug and compare the scanned information against the patient's electronic prescription information before giving the drug to the patient.

• The bar code scanner's information would go to the computer where it would be compared against the patient's drug regimen information to check whether the right patient is receiving the right drug (including the right dose of that drug in the right route of administration). The system could also be designed to check whether the patient is receiving the drug at the right time.

• If the identity of the health care professional administering the drug was desired, each health care professional could also have a bar code. The health care professional would scan his or her own bar code before giving the drug to the patient.

Bar codes could also complement other efforts to reduce medication errors.

• In computer physician order entry (CPOE) systems, a physician enters orders into a computer instead of writing them on paper. The order can be checked against the patient's records for possible drug interactions, overdoses, and patient allergies (Ref. 26).

• The retail pharmacy community is beginning to use a bar-coded NDC number to verify that a consumer's prescription is being dispensed with the correct drug. These pharmacy-based systems compare a bar code that the pharmacy's computer prints on the consumer's prescription against the bar code on the drug's label. If the computer detects an error, the computer alerts the pharmacist to the problem.

In addition, bar codes could make it easier to enter medication order entries into a patient's electronic medical records, help in inventory control and billing, and help conserve hospital or health care staff resources or free those resources so that they can be devoted to patient care.

E. Can Bar Code Use Reduce the Incidence of Medication Errors?

Published articles and other information submitted to FDA suggest that bar coding can reduce medication error rates significantly.

• One New Hampshire hospital reduced its medication error rate by 80 percent after it adopted a bar coding program (Ref. 15).

• A medical center in Colorado lowered its medication error rate by 71 percent between 1992 and 1994 (Ref. 16).

• A Department of Veterans Affairs (VA) hospital in Kansas had no medication errors when its computerized, bar coding system was used properly; the hospital estimated that the system prevented over 378,000 medication errors in a 5-year period (Ref. 17).

• Other published articles have discussed how bar coding can reduce medication errors, including missed doses, or increase drug dispensing accuracy (Refs. 18 through 23).

At a public meeting that we (FDA) held on July 26, 2002 (67 FR 41360, June 18, 2002), the VA gave a presentation on its use of bar codes at the VA Medical Center in Topeka, Kansas. The VA stated that a comparison of medication error data from 1993, the last year before the VA implemented the bar code system, to data for 2001 showed that the Topeka medical center reduced its reported medication error rate by 86.2 percent (Ref. 24). The improvements included:

• 75.5 percent improvement in errors caused by the wrong medication being administered to a patient;

• 93.5 percent improvement in errors caused by the incorrect dose being administered to a patient;

• 87.4 percent improvement in wrong patient errors; and

• 70.3 percent improvement in errors caused when medications scheduled for administration were not given. (Ref. 24 at p. 14).

One comment submitted in response to the public meeting indicated that a bar code scanning system, in conjunction with a robotic system for pharmaceutical distribution, reduced dispensing errors at the University of Wisconsin from 1.43 percent to 0.13 percent and that the university realized a return on its investment in 2 years (Ref. 25). The comment also stated that there was an 89 percent reduction in medication administration errors due to point-of-care bar code scanning (Ref. 25 at p. 6).

We discuss the public meeting in greater detail in section II of this document.

F. Is There Support for Putting Bar Codes on Drug Products?

In recent years, many organizations have either commented favorably on or recommended the adoption of bar coding to reduce medication errors. These organizations include the QuIC Task Force, NCCMERP, ASHP, and Premier, Inc., an alliance of not-for-profit hospital and health care systems (Refs. 27 through 29).

We also saw considerable support for bar coding at the July 26, 2002, public meeting we held to discuss a possible rule to require bar code labeling. Nearly 400 individuals attended the meeting, and they represented a broad range of interests, including:

• Nurses, including the American Academy of Nursing;

• Pharmacists, including the American Society of Health-System Pharmacists;

• Physicians, including the American Medical Association;

• Hospitals, including the American Hospital Association, the VA, which already has a bar code program in place for drugs used in VA hospitals, and the Hospital Corporation of America, Inc., which intends to have bar coding technology in place in its hospitals by the end of 2005;

• Pharmaceutical manufacturers, including the Pharmaceutical Research and Manufacturers of America (PhRMA) and the Generic Pharmaceutical Association (GPhA);

• Over-the-counter (OTC) drug manufacturers, including the Consumer HealthCare Products Association (CHPA);

• Medical device manufacturers, including the Advanced Medical Technology Association (also known as AdvaMed);

• Blood centers and blood organizations, including the American Association of Blood Banks, America's Blood Centers, and the American Red Cross;

• The Vaccine Identification Standards Initiative (VISI), a collaborative effort between public health agencies and private organizations involved in immunization practices and whose purpose is to establish voluntary, uniform guidelines for vaccine packaging and labeling and recording identifying information;

• Bar coding and other ''automatic identifier'' interests, including the Uniform Code Council and the Health Industry Business Communications Council (two standards development organizations that have established bar code standards);

• Health or medical product distributors, including McKesson

Corporation, the HealthCare Distribution Management Association, and Cardinal Health; and

• The USP.

In addition, in response to requests to discuss bar code issues in greater detail, we met separately with PhRMA on August 19, 2002, with CHPA, GPhA, and others on September 17, 2002, and with the National Alliance for Health Information Technology on October 9, 2002.

In general, almost all individuals, companies, and organizations attending or commenting on the public meeting strongly supported the use of bar codes on human drug products to help reduce medication errors, but differed in their opinions as to the information that should go into the bar code and whether certain products, such as over-the-counter (OTC) drugs and medical devices, should have a bar code. We discuss various aspects of the public meeting throughout the remainder of this preamble to show how information from the public meeting helped shape this proposal.

II. Description of the Proposed Rule

The proposal would create a new § 201.25 entitled ''Bar Code Label Requirements.'' The proposal would address:

• Who is subject to these bar code requirements?

• What drugs are subject to these bar code requirements?

• What does the bar code look like?

• Where does the bar code go?

The proposed bar code requirement would also apply to biological products (other than blood and blood components). We cross-reference this requirement in the biologics regulations at new § 610.67.

For blood and blood components, the proposal would amend part 606 (21 CFR part 606) in § 606.121(c)(13) which currently allows, but does not require, the use of machine-readable symbols, approved by the Director of the Center for Biologics Evaluation and Research (CBER), on blood and blood component container labels. The proposal would require the use of encoded, machine-readable information approved by the CBER Director on blood and blood component labels.

A. Who Would Be Subject to the Bar Code Requirement? (Proposed § 201.25(a))

In brief, under proposed § 201.25(a), manufacturers, repackers, relabelers, and private label distributors of human prescription drug products and OTC drug products regulated under the Federal Food, Drug, and Cosmetic Act (the act) or the Public Health Service Act would be subject to the bar code requirement unless they are exempt from the establishment registration and drug listing requirements in section 510 of the act (21 U.S.C. 360(g)(1)). In practice, this means that pharmacies which are exempt under section 510(g) of the act are not required to put bar codes on drugs they are dispensing. (The requirements in proposed § 201.25 would apply to biological products (other than blood and blood components) and would include a cross-reference at proposed § 610.67. For convenience, this preamble will refer only to proposed § 201.25 alone without repeated cross-references to proposed § 610.67 (see section II.I of this document).) For purposes of this proposal:

• ''Manufacturer'' means a person or persons who owns or operates an establishment engaged in the manufacture, preparation, propagation, compounding, or processing of a drug by chemical, physical, biological, or other manipulations of the drug. These activities include repackaging or otherwise changing the container, wrapper, or labeling of any drug package in furtherance of the drug's distribution from the original place of manufacture to the person who makes final delivery or sale to the ultimate consumer or user.

• ''Repacker'' means a person or persons who owns or operates an establishment that repackages and relabels a drug and does not engage in any other activities performed by a manufacturer.

• ''Relabeler'' means a person or persons who owns or operates an establishment that affixes or changes labels on a drug and does not engage in any other activities performed by a manufacturer.

• ''Private label distributor'' means a person or persons who owns or operates an establishment that commercially distributes, under its own label or trade name, any drug manufactured, prepared, propagated, compounded, or processed by a manufacturer, repacker, or relabeler.

For example, if you make a prescription drug product, you would be subject to the bar coding requirement. However, if you are a pharmacy operating in conformance with applicable local laws regulating the practice of pharmacy and are regularly engaged in dispensing prescription drugs upon prescriptions of practitioners licensed to administer such drugs to patients, and do not manufacture, prepare, propagate, compound, or process drugs for sale other than in the regular course of business of dispensing such drugs at retail, you would not be subject to the bar code requirements. Your pharmacy would be exempt because section 510(g)(1) of the act does not require you to comply with the establishment registration and listing requirements.

We recognize that some hospitals themselves place bar codes on drugs and have reduced their medication error rates significantly. Requiring persons who manufacture, repackage, or relabel human drug products to bar code their own products should be more efficient and result in better quality bar codes. Manufacturers, repackers, and relabelers generally have sophisticated manufacturing processes and labeling machinery, and quality control systems that hospitals cannot afford. Bar coding by third parties (such as hospitals) would be more costly for the facility and would not achieve the economies of scale that larger entities could realize. Having many small entities affix bar codes could increase the possibility of a label error through the attachment of the wrong bar code and could lead to inconsistent bar code quality. For example, one comment from the public meeting stated that an institution administering 2.5 million doses per year, even if operating at 99.9 percent effectiveness at applying its own bar codes, would introduce seven new errors per day from repackaging. Another comment, submitted by an entity familiar with ''automatic identification'' methods, stated that ''on demand'' bar code printing, as used in hospitals and clinics, will have a higher error rate compared to bar code printing by manufacturers and that the ''use and maintenance of this type of bar code printing is historically haphazard at best.'' Another comment from a bar code standards organization estimated the error rate in hospital labeling to be approximately 17 percent nationwide.

More importantly, requiring persons who manufacture, repackage, or relabel human drug products and private label distributors to bar code their own products and to use the same bar coding standard should result in a more uniform bar coding system that can be used regardless of a patient's or hospital's location in the United States (Ref. 15). Uniformity should also make it easier for health care professionals to train themselves on bar coding procedures and technique and make it easier and less expensive for hospitals to buy bar coding equipment. Uniformity should also make it easier for manufacturers, repackers, relabelers, and private label distributors to put bar codes on products, because they would not have to customize their symbols or

bar codes to meet individual needs. (We discuss issues relating to the choice of a bar code symbology, standard, or other machine-readable format, and the potential impact on innovation, in detail in section II.D of this document.)

B. What Products Would Have to Have a Bar Code? (Proposed § 201.25(b))

1. What Did We Hear at the Public Meeting?

In the June 18, 2002, **Federal Register** notice (67 FR 41360 at 41361) announcing the public meeting on bar coding, we asked which medical products should have a bar code. We specifically invited comment on whether all prescription and OTC drugs should be bar coded, and we asked about blood products, vaccines, and medical devices (id.). We wanted our request for comments to help us decide which products should be covered by the proposal. For example, we sought information about OTC drugs because we did not know the costs and benefits of requiring all OTC drugs to have a bar code. For blood, we knew that an international bar coding standard (ISBT 128) existed, but did not know whether a rule requiring blood to have a bar code was necessary given that international standard. For vaccines, we were concerned that bar coding costs could have an adverse impact on vaccine manufacturers and vaccine supplies. For devices, our request for information was prompted by several letters to Secretary of DHHS Thompson, asking him to include devices in any bar coding rule (Refs. 31, 32, and 33).

The public comments we received reflected a variety of different positions. For example, almost all comments agreed that prescription drugs should have a bar code and that the bar code should extend to products at the unit dose level. However, comments from the pharmaceutical industry indicated that some products, such as samples, should not fall within a bar code regulation or that we should allow for exemptions. The USP also supported an exemption for certain containers, such as ampules or vials under 5 milliliters (mL).

For OTC drugs, many health care professionals supported bar codes on all OTC drugs, but other comments, including a comment from a trade association representing the OTC drug industry, disagreed, stating most OTC drugs are used in consumer settings where bar codes would not add value. The trade association also stated that all OTC drug products intended for retail sale have the universal product code (UPC) on the outer container and that there could be ''significant potential negative impact'' if we modified the UPC bar code system on OTC drug products. In contrast, one manufacturer of OTC drugs supported requiring bar codes on the outer container, but did not favor requiring bar codes for certain categories of products that carry little or no risk of causing adverse drug events in an institutional setting. CHPA and other companies repeated their concerns about bar codes for OTC drug products during a meeting with FDA on September 17, 2002, and emphasized the potential adverse impact on retailers if we required the UPC code to contain the NDC number. Some comments supported bar codes on OTC drugs used in hospitals or in ''institutional settings'' or OTC drugs packaged and sold for use in institutions.

A split between health care professionals and industry also existed for vaccines. For example, the Centers for Disease Control and Prevention, which coordinates the VISI program, recommended that vaccines have bar codes so that information on vaccines could be readily captured into medical records and other forms, thereby enhancing the monitoring of immunization programs and surveillance of adverse effects. Vaccine manufacturers, including VISI members, expressed a different view, stating that even small bar codes may be difficult to place on vaccines. One industry comment added that requiring bar codes on vaccines would ''increase the potential for disrupting vaccine production lines, particularly if there is a need for in-line printing'' and that ''[g]iven the fragile nature of vaccine supply and recent shortages of a number of vaccines, there is concern that any additional disruptions could exacerbate this situation.''

For blood, the comments generally agreed that we should require bar codes. Most comments acknowledged that an internationally standardized bar code symbology (ISBT 128) for blood exists and that the bar codes describe the blood's identification number, blood group and Rh type, product number, expiration date and time, and special testing results. However, while some comments recommended that we require blood containers to have bar codes using the ISBT 128 symbology, one comment, representing thousands of blood collection centers, blood banks, and transfusion services, opposed requiring the use of ISBT 128 through a regulation. Instead, the comment wanted us to require adoption of a United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components or ''focus on requiring electronic data interchange and the definition and use of standard data structures.''

For devices, the comments suggested another split between health care professionals and the regulated industry. Many health care professionals and hospital groups supported requiring bar codes on devices, although some would defer action on medical devices so that progress on a rule to require bar codes on drugs would not be slowed down. Others would defer action on medical devices because different device classes present different levels of risk. Device manufacturers generally opposed the inclusion of medical devices in a bar coding proposal. The device industry noted, as we did in our June 18, 2002, **Federal Register** notice (67 FR 41360) announcing the public meeting, that medical devices present different issues compared to drugs, biological products, and blood. For example, there are different classes of medical devices, and each class represents a different degree of risk, so, for a low-risk device (such as a bandage), a bar code might not have an impact on patient safety (67 FR 41360 at 41361). As another example, some medical devices may be reconditioned by parties other than the original manufacturer; in such situations, the original manufacturer might want to ensure that its bar code is removed or eliminated if the device is reconditioned, because the device no longer comes directly from the original manufacturer. Comments from device industry interests recommended further study and a separate rulemaking for devices or the voluntary use of ''automatic identifiers.'' However, one device manufacturer indicated that it already uses bar codes on its devices, but it uses the bar code for reimbursement purposes and for logistical reasons rather than for safety concerns. The manufacturer also recommended that, if we wanted bar codes on devices, we should issue guidelines instead of a rule.

2. What Products Would the Rule Cover?

After careful consideration of the comments, we propose to require the following products to carry a bar code:

- All prescription drug products, including biological products (including vaccines), but excluding physician samples; and
- Over-the-counter (OTC) drugs that are dispensed pursuant to an order and are commonly used in hospitals; and

For blood and blood components, the proposal would require the use of machine-readable information.

a. *Why Cover Prescription Drug Products, Including Vaccines, But Not Physician Samples*? The comments from the public meeting agreed that prescription drug products should have a bar code, although a small number of comments suggested that only prescription drug products used in institutions should be subject to a bar code requirement and that prescription drug samples should not be included.

We decided to cover all prescription drug products, rather than limit the rule to prescription drug products used in institutions, because we are unaware of any prescription drug products that are not used in hospitals. Our primary focus is to help reduce the number of medication errors occurring in hospitals, and, as we consider ''prescription drugs used in institutions'' as being the same as ''prescription drugs'' generally, the proposal refers to ''prescription drugs.''

However, with regard to prescription drug samples, we decided to omit prescription drug samples from a proposed bar code requirement because most samples are given to patients at physicians' offices, and we do not believe that physicians or patients would have or be inclined to buy bar code scanners for their own use in the immediate future. We recognize that an argument could be made for including samples. We know that some samples are donated to charitable organizations, such as free clinics, for distribution to patients without charge (Ref. 34). These samples could be subject to the same medication errors as marketed prescription drugs, and those medication errors could be prevented through the use of bar codes. In addition, Congress and FDA have been concerned about illegal sales of prescription drug samples, the potential diversion of samples to illegal drug trafficking, and the entry of counterfeit drugs into the wholesale distribution system. Requiring bar codes on samples could help identify diverted or counterfeit drug products that enter distribution through illegal channels, and this could result in benefits that are not directly related to the prevention of medication errors.

We recognize that the vast majority of prescription drug samples are usually given to patients at physicians' offices and are not administered in hospitals. Because we have no evidence to suggest that physicians' offices are likely to be equipped with bar code scanners in the immediate future, the benefits associated with preventing medication errors through bar codes on prescription drug samples are unlikely to be realized in this health care setting. We also recognize that it is unlikely that charitable institutions, such as free clinics, would have the resources to buy bar code scanners to prevent medication errors. As a result, we have decided to omit prescription drug samples from the rule at this time. We do, however, invite comment on whether to require bar codes on prescription drug samples. Comments should address the costs and benefits associated with requiring bar codes on prescription drug samples.

The proposal would apply to vaccines. The National Childhood Vaccine Injury Act of 1986 (Public Law 99–660) (42 U.S.C. 300aa–25(a)) requires each health care provider who administers a vaccine set forth in the Vaccine Injury Table to any person to record, in that person's permanent medical record or in a permanent office log or file, the date of administration of the vaccine, the vaccine manufacturer, the vaccine's lot number, and other information. A bar code on vaccines could help ensure the accuracy of those records insofar as identification of the vaccine, its manufacturer, and date of administration are concerned, and, for those vaccines administered in health care facilities, help ensure that the right vaccine is administered to the right patient at the right time. However, we are sensitive to the vaccine manufacturers' concerns, particularly as they relate to possible adverse impacts on vaccine production or availability, and we invite comment on the risks and benefits of including vaccines in a bar code rule.

As for those comments that suggested an exemption for certain products or small containers, we decline to create an exemption mechanism and explain our reasons in section II.F of this document.

b. *Why Cover OTC Drugs That Are Dispensed Under an Order and Commonly Used in Hospitals*? The public meeting notice asked whether we should require bar codes on all OTC drugs. After reviewing the comments, we decided against requiring all OTC drugs to carry a bar code because it is unlikely that putting bar codes on all OTC drugs would have a significant impact on reducing medication errors and offset the large costs associated with requiring bar codes on all OTC drugs. Most OTC drugs are used outside hospitals and other health care facilities and are used by consumers who purchase the OTC drugs at retail. At this point, it is unlikely that individual consumers would buy, use, or have access to bar code scanners or use such scanners before taking an OTC drug.

We recognize, however, that some OTC drugs are administered to patients in hospitals and that bar codes would enable health care professionals to check whether they are giving the right OTC drug in the right dose and right route of administration to the right patient at the right time. In addition, we recognize that OTC drugs could interact with prescription drugs administered at that hospital or affect another drug's performance. Thus, we propose to require bar codes on OTC drugs that are dispensed pursuant to an order and are commonly used in health care facilities. For example, the bar code on an OTC drug dispensed pursuant to an order and commonly used in a hospital may allow a hospital's database to identify any potential interactions between the OTC drug and any prescription drugs prescribed for the patient, or may alert a health care professional to the patient's allergies relative to the OTC drug's ingredients. The proposal would apply to any manufacturer, repacker, relabeler, or private label distributor who sells a specific package of an OTC drug product to hospitals. It would not apply to all packages of a specific OTC drug product. An example of a specific package of an OTC drug product sold to hospitals would be an individual product, such as an aspirin tablet, packaged in a unit-of-use container.

We would interpret ''commonly used in hospitals'' to include OTC drugs that are sold to hospitals, packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals through drug purchasing contracts or catalogues. For example, if an OTC drug product manufacturer sends its catalogues to hospitals to solicit orders from them, the OTC drug products described in the catalogue would be ''commonly used in hospitals'' because the manufacturer is marketing its OTC drugs to hospitals. If a distributor relabeled an OTC drug ''for institutional use,'' then that OTC drug would be ''commonly used in hospitals'' because it is intended for hospital use.

We expect that manufacturers, repackers, relabelers, and private label distributors would know which of their products meet the definition of OTC drug products commonly used in hospitals. For example, we believe that when manufacturers, repackers, relabelers, and private label distributors label or package their OTC drugs for institutional use, they know that the products will likely be sold to hospitals. Manufacturers also know that their OTC drug products will be sold to hospitals when they market or promote those OTC drugs to hospital staff through detailing the products or other means, enter into hospital purchasing contracts, or sell to hospitals through catalogues.

We recognize that it is possible for a manufacturer to sell an OTC drug to a wholesaler or retailer who then re-sells the product, without making any changes to the product, directly to a hospital without the manufacturer's knowledge. We believe that, in most cases, the manufacturer would know that the product may be sold to a hospital (e.g., because of the product's labeling, packaging). However, there may be rare instances when the manufacturer may not have had reason to believe that its product would be sold to a hospital. Therefore, if the OTC drug is not packaged, labeled, marketed, promoted, or sold to a hospital as described above, we would not expect the OTC drug's manufacturer to comply with the bar code requirement.

Proposed § 201.25(b) would also include the phrase ''dispensed pursuant to an order'' with regard to OTC drugs. Some products in hospitals that are traditional types of OTC drugs, such as aspirin or acetominophen, are dispensed pursuant to a physician's order. Other products that are regulated as OTC drugs are not dispensed pursuant to a physician's order. For example, a hospital might provide fluoride toothpaste or mouth rinses to a patient without a physician's order. Because these products are not likely to contribute to medication errors, the proposal would focus only on those OTC drugs used in hospitals that are dispensed pursuant to an order.

We recognize that there may be other ways to describe the types of OTC drugs that should have a bar code. For example, we considered requiring bar codes for OTC drugs ''sold directly to hospitals.'' If the proposal pertained to OTC drugs sold directly to hospitals, most manufacturers, repackers, relabelers, and private label distributors who sold their products directly to hospitals would be subject to the rule, but the bar code requirement could be avoided by selling the OTC drugs to distributors or other third parties for re-sale to hospitals. We considered applying the bar code requirement to OTC drugs that are labeled for use in an institutional setting. This alternative is equally difficult to administer because it is easily circumvented by relabeling the drug. We considered requiring bar codes on OTC drugs commonly used in health care facilities (rather than hospitals), but could not determine whether clinics, nursing homes, and other facilities would invest in bar code scanning equipment.

We specifically invite comment on the terms we should use to describe OTC drugs that should be subject to the bar code requirement. Comments should also consider the following issues:

• Who should be required to apply the bar code on the OTC drugs that are subject to a bar code requirement? If the proposal refers to OTC drugs ''commonly used in hospitals,'' will manufacturers, repackers, and relabelers know which products require a bar code?

• Do the terms ''dispensed pursuant to an order'' sufficiently distinguish between those OTC drugs that are likely to be involved in medication errors from those that are not?

c. *Which Blood Products Are Covered*? Current FDA regulations state that the container label on blood and blood products ''may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research'' (see 21 CFR 606.121(c)(13)), but they do not require the use of such symbols nor do they specify a particular symbol. Correct identification of blood is essential because transfusion errors or use of contaminated blood can have serious adverse health consequences for a patient. For example, one comment submitted in response to the public meeting stated that transfusion errors cause as many as two dozen patient deaths annually and that the number may be under reported. Consequently, we propose to require that blood and blood component container labels bear ''encoded information that is machine-readable'' and approved for use by the Director of CBER. We address this specific requirement at proposed § 606.121(c)(13), which we discuss more fully in section II.H of this document.

d. *Why Did We Omit Medical Devices From the Rule*? At this time, we are omitting medical devices from this rulemaking. We recognize that different issues arise for devices than for drugs, so further consideration is needed regarding the need for putting bar codes on medical devices. We will continue to study whether to develop a proposed rule to require bar codes on medical devices to prevent or reduce medication errors.

C. What Would the Bar Code Contain? (Proposed § 201.25(c)(1))

1. What Is the National Drug Code Number, and Why Would It Be Helpful?

Proposed § 201.25(c)(1) would require the bar code to contain, at a minimum, the drug's NDC number. The NDC number identifies each drug product that is listed under section 510 of the act. Most persons attending the public meeting agreed that a bar code should, at a minimum, contain the drug's NDC number.

To complement this proposed requirement, we intend to revise our drug establishment registration and listing regulations to redefine the NDC number and to make the NDC number unique and more useful to informational databases, whether those databases are created for purposes of preventing medication errors, obtaining the latest information about a specific drug, or tracking drug use or distribution. We hope to publish a proposed drug establishment registration and listing rule in the **Federal Register** soon.

Please note that proposed § 201.25(c)(1) would require the bar code to contain, at a minimum, the NDC number. Several comments submitted in response to the public meeting indicated that some drug manufacturers already place bar codes on their products, but that the bar code contains a numerical identifier that contains, but is not identical to, the NDC number. For example, some comments suggested that the bar code contain the International Article Number (EAN) or the Global Trade Item Number (GTIN). We are aware that some drug companies already use a bar code containing the:

• Universal Product Code number (UPC). The UPC is usually a 12-digit number that may or may not contain the NDC number within it. For example, if the drug's NDC number were 1234567890, the UPC number might be 312345678906, where the first digit (3) signifies that the product is a drug, and the last digit is a ''check digit'' that helps confirm that the bar code was read correctly. However, some drugs, particularly OTC drugs, may have a UPC number that does not contain the NDC number;

• International Article Number (EAN). The EAN is a 13-digit number and also contains the NDC number within it; or

• Global Trade Item Number (GTIN). The GTIN is a 14-digit number that contains the NDC number in conjunction with a code that identifies the product's packing level. In the GTIN, the first digit signifies the packaging level.

Thus, under the proposal, the bar code could contain the NDC number alone or the UPC number, EAN number, or GTIN number, as long as the NDC number is present. By making the NDC number the minimum bar code information requirement, firms could continue using various numbering systems (such as the UPC, if the UPC number contains the NDC number, EAN, or GTIN numbers) in their bar codes, thus minimizing or eliminating the need for companies to redesign or generate new bar codes and

minimizing any disruptions to the companies' international markets.

We recognize that some comments supported the use of a unique identifying number rather than the NDC number. One comment explained that the UPC code that goes on the product label does not always use the NDC number, so if we required the bar code to contain the NDC number, important label changes could go unnoticed if health care professionals relied on the bar codes instead of product labels. The comment suggested that if distributors establish the unique identifying codes and revise those codes when they make label changes, the revised code could then trigger a need for a health care professional administering the drug to read the label and to update its database accordingly. Another comment described the NDC number as a ''dumb number'' in OTC drugs and suggested following UCC/EAN guidelines instead to identify the product. Another comment stated that OTC drugs should use the UPC number instead of the NDC number because changing UPC bar codes to include the NDC number would result in great expense without a discernable benefit. Additionally, during a meeting with CHPA and others, the industry representatives stated that UPC codes do not always contain NDC numbers, and retailers rely on the UPC codes, so requiring the use of NDC numbers would be disruptive to the industry and retailers. The industry representatives suggested using a unique identifier other than the NDC number.

We decline to require the use of unique identifying numbers other than the NDC number. Through the proposed drug establishment registration and listing rule, the NDC number would become a unique identifying number for listed drugs and correspond to a particular listed drug. If we allowed distributors to assign unique identifying numbers and did not coordinate the assignment of such numbers to drugs, the result could be extremely confusing as distributors could use different identification schemes (such as a mixture of letters, numbers, or other characters). Moreover, creating and maintaining databases on drug products for medication error purposes would become more difficult because identifying information would have to come from multiple sources. For example, the Federal Government might be the source for NDC number information, but firms who created unique, non-NDC identifying numbers would have to provide information on those numbers to the databases themselves if the databases are to be complete and useful. Multiple information sources would increase the likelihood that some information and databases might not be updated as frequently as others, that some information might be unavailable, or that the information would be presented in different or incompatible ways. While we understand the OTC drug industry's reservations about changing UPC codes to include NDC numbers because of a possible impact on retailers, proposed § 201.25(b) would only require bar codes on OTC drugs that are dispensed pursuant to an order and are commonly used in hospitals, so most OTC drugs should not be affected.

2. Would the Bar Code Be Required to Contain the Lot Number and Expiration Date?

Many organizations and individuals have recommended that the bar code contain information regarding the drug's lot number and expiration date, and others have recommended phasing-in a requirement to have the bar code contain the lot number and expiration date.

We decline to require lot number and expiration date information in the bar code at this time. In general, while lot number and expiration date information would make it easier to identify drugs that had been recalled or were expired, we neither found nor received data to show that the benefits of bar coding lot number and expiration date information would exceed the costs of putting that information in the bar code. There is, however, limited information on the extent to which patient safety is affected by and medication errors occur as a result of taking expired or recalled drugs. We reviewed data from our adverse event reporting system (containing 71,546 cases) and found 90 cases where patients received an expired drug and 21 cases where patients received a recalled drug. Expired drugs may become subpotent and might not have the intended therapeutic effect. They also may contain degradation products associated with aging. Products may be recalled for a variety of reasons including no active ingredient present in the product or contamination of the product that could lead to infection.

We also tabulated data from the Office of Compliance, Center for Drug Evaluation and Research, on the reasons for and the extent to which drug products have been recalled from the market. From fiscal year 1997 through fiscal year 2002, there were 1,230 recalls, of which 97 were Class I (reasonable probability that the use or exposure to the violative product will cause serious adverse health consequences or death) and 1,133 were Class II (use or exposure of the violative product may cause temporary or medically reversible adverse health consequences or where the probability of serious adverse health consequences is remote). Despite this number of recalls for safety and health reasons, we received few reports of adverse events associated with the administration of a recalled drug, and we do not have reliable data that show how often these products were administered to patients.

Thus, based on the data available to us, we cannot determine the magnitude of the public health problem associated with administering expired or recalled products, and we cannot quantify the patient safety benefit associated with requiring lot number and expiration date information in a bar code.

Some comments suggested that requiring lot number and expiration date information in a bar code could have benefits outside the medication error context by making it easier to track or trace products and to identify counterfeit products.

We agree that bar codes may be useful outside the medication error context, but our rule focuses on the use of bar codes to prevent medication errors.

Industry comments indicated that adding lot number and expiration date information to the bar code would adversely affect production line speed. One comment from a drug company predicted that encoding lot number and expiration date information would reduce packaging line speed by 40 percent and cost more than $4.8 million for its product lines. Another drug industry comment indicated that a requirement to encode lot number and expiration date information could cause companies to reconsider their packaging choices, or require companies to alter their printing methods.

We also note that inclusion of lot number and expiration date information might require the use of a different machine-readable format, such as a two-dimensional symbology, in addition to or as a substitute for a linear bar code, and that could affect a hospital's equipment purchasing decision. Use of nonlinear bar code formats could require the purchase of a different scanning or reading device and also increase a hospital's equipment costs.

Based on the evidence we had and our obligation under Executive Order 12866 to choose regulatory approaches that maximize net benefits, the potential burden of encoding lot number and expiration date information appeared to outweigh the potential benefit at this time. Consequently, the proposed rule

would not require lot number and expiration date information in the bar code. We will continue to study the issue and invite comments and, more importantly, data on costs and benefits associated with requiring lot number and expiration date information in the bar code. If comments provide information and data to support requiring lot number and expiration date information, we may consider requiring that information with the bar coded NDC number as part of a final rule.

Although the proposed rule would not require the drug's lot number and expiration date to appear in the bar code, the proposed rule would not prohibit the inclusion of such information. In other words, FDA will not object if a manufacturer, repacker, relabeler, or private label distributor were to add the lot number and expiration date to its bar code or add such information in a machine-readable format provided that the lot number and expiration date information is accurate. In a meeting with PhRMA on August 19, 2002, the industry representatives suggested to us that they might add machine-readable lot number and expiration date information if a demand existed for it. (We have placed a memorandum of this meeting in the docket for this rule, along with memoranda of meeting for other meetings we attended.) We do not know how much more such drugs would cost (compared to drugs that only had the NDC number encoded in the bar code) or whether hospitals and other health care facilities would be willing to pay more for drugs that have the NDC number, lot number, and expiration date in a bar code or machine-readable code, but the meeting raises the possibility that market forces could lead to the inclusion of lot numbers and expiration dates in bar codes or other machine-readable formats.

D. Would the Rule Require a Specific Type of Bar Code? (Proposed § 201.25(c)(1))

1. What Did We Hear from the Public Meeting?

In the public meeting notice, we asked whether we should require the use of a specific bar code symbology, such as reduced space symbology (RSS), adopt one symbology over another, or allow for ''machine readable'' formats (67 FR 41360 at 41361). We also asked for the ''pros and cons'' of each approach (id.). We had identified RSS as a possible symbology because we knew about industry-conducted pilot studies that used RSS bar codes on small vials (Ref. 35). Our reasoning was that if RSS symbology could be used on small containers, it could be used on larger containers, too.

The comments we received reflected an array of differing opinions, ranging from the adoption of a specific, non-bar code technology to prescribing no specific symbology or standard at all in order to promote innovation. Two principal, yet contradictory, themes emerged. One view advocated requiring a specific symbology or standard to promote uniformity and to create the conditions whereby hospitals could invest confidently in bar code scanning equipment, without having to buy different pieces of equipment to read different bar codes or other machine readable formats or without having to fear that any equipment purchases would soon become obsolete. Another comment declared that the bar code symbology adopted by FDA should be compatible with current scanning devices used by health care organizations. However, if the rule adopted a single symbology or standard, the rule could affect future innovation in this field, and we would have to engage in new rulemaking to adopt any newer symbology or standard.

The other view stated that we should not select any specific symbology or even require linear bar codes at all; instead, these comments said the rule should require the use of machine-readable or automatic identifier technology, thus creating the conditions under which newer, and perhaps better, technologies could be used in the future. However, the comments and our own analysis suggested that if the rule allowed for multiple symbol types or technologies, hospitals might be confronted with incompatible technologies and decide against buying multiple pieces of equipment. For example, if one drug used an RSS bar code, another used a radio frequency identification format, and a third used a unique, patented, automatic identification technology, a hospital would have to decide whether to buy a bar code scanner, a device to detect the radio frequency information, and a device to detect the patented identifier, or some combination of the three devices. If those costs were too great, the hospital could decide against making any equipment investments altogether, and the benefits from bar coding would not be realized.

Other comments suggested that we require the use of machine-readable codes capable of being read by ''machines currently deployed'' and ''economically available'' or use symbology that is ''compatible'' with ''current scanners.''

Some comments suggested that we conduct research to develop time lines for adopting specific bar code symbologies, that we have USP provide bar code standards, or adopt a standard or family of symbologies. Other comments said we should form a group involving various interests to study issues further or create an ''automatic identification coordinating council'' to ensure that minimum information requirements are met and that the best technology is used.

Deciding whether to require a specific symbology, standard, or an unspecified ''machine-readable'' symbol was a very difficult decision because of the comments' competing and sometimes incompatible positions. For guidance, we examined how another Federal agency reached a decision when confronted with an analogous problem of whether to require a particular action to accomplish a specific goal or to let market forces decide the outcome. We examined how the Federal Communications Commission (FCC) decided to adopt an order to require all television receivers to include digital television (DTV) reception capability in order to move towards a 2006 target date for a transition to digital television. Congress had imposed a December 31, 2006, target date for the return of the spectrum used by broadcasters for analog channels unless 85 percent of homes in a market could not receive local digital broadcast television signals. The FCC faced a problem; the public was reluctant to buy DTV receivers until there were DTV stations offering attractive DTV programs, but broadcasters lacked the incentive to provide such DTV programming in the absence of an audience that would attract advertisers (Ref. 36 at p. 13). Moreover, because analog televisions were still being sold, each sale of an analog television set put the FCC farther from reaching the 85 percent DTV reception goal (Refs. 37 and 38). The FCC ultimately decided to adopt a plan to require DTV tuners on almost all new television sets by 2007 and established a 5-year rollout schedule to minimize costs to television manufacturers and consumers. It recognized that requiring the manufacture of DTV receivers would address ''the root cause of the problem, namely the lack of television receivers capable of receiving DTV signals'' (Ref. 36 at p. 13). The FCC also recognized that, without its intervention, the transition to DTV might remain stalled. The FCC's decision to require all television receivers to include digital television (DTV) reception capability is

even more noteworthy because some FCC Commissioners did not favor significant regulatory intervention in the market (Ref. 38 at p. 1).

Our case is similar to the FCC's in the sense that we have an objective (reduction of medication errors) that can be achieved through bar codes, but hospitals are reluctant to invest in equipment because of the lack of bar coded products, and manufacturers, repackers, relabelers, and private label distributors are reluctant to invest in such bar codes or other technologies in the absence of a demand by hospitals or a requirement for such bar codes. If we fail to specify a particular measure, such as a symbology or standard, progress towards medication error reduction through bar codes could remain stalled; hospitals might still be reluctant to invest in equipment because of uncertainties in the marks, symbols, or technologies used on the drug or a limited amount of resources to buy different types of equipment to read the various marks, symbols, or other technologies. Likewise, manufacturers, repackers, relabelers, and private label distributors might not invest in bar codes or other technologies because no demand would exist or because their investments in such bar codes would be wasted if hospitals declined to buy the necessary equipment to take advantage of those bar codes or other technologies.

Consequently, proposed § 201.25(c)(1) would require the bar code for drugs and biological products (other than blood and blood products) to be any linear bar code in the UCC/EAN standard. This means that the bar code can be any linear bar code symbology, such as UCC/EAN–128, RSS, or UPC (if the UPC contains the NDC number), within the UCC/EAN standard. Adopting a linear bar code in the UCC/EAN standard, as opposed to a specific bar code symbology, should give firms some flexibility in selecting the bar code symbology that best fits their needs and should also give the rule some flexibility as linear bar code symbologies change, are added, or are phased out. For example, we know that the UCC has announced a ''sunrise'' date of 2005 for a new EAN–13 code because the commonly-used UPC code is running out of new company prefixes for that 12-digit code (Ref. 39). So, as new linear bar codes are added to the UCC/EAN standard, those new codes would be acceptable under the proposed rule as long as those new codes include the NDC number.

The UCC/EAN standard also has the advantage of being a widely used global standard. One comment submitted on behalf of the International Working Group on Barcoding of Pharmaceuticals advocated the use of the UCC/EAN standard because it represents a ''validated, testable global standard.'' The comment also suggested that regulatory authorities from Europe, Japan, and Canada are actively pursuing a bar code standard for pharmaceuticals and ''are watching to see what the FDA decides.'' Comments from the UCC, EAN, and some pharmaceutical interests also mentioned the global applicability of the UCC/EAN standard.

We recognize that other bar code standards exist, notably those advanced by the Health Industry Business Communication Council (HIBCC). HIBCC bar code symbologies include code 39 and code 128. (The UCC/EAN system also has a UCC/EAN–128 symbology that is similar, but not identical, to the HIBCC code 128.) HIBCC also has the Universal Product Number (UPN) system which is used for medical and surgical products. Comments from drug and biological product companies, however, usually referred to UCC/EAN standards if they identified any standard at all, so we presume that the use of UCC/EAN standards would be less disruptive to those industries compared to requiring the use of a different bar code standard. However, a comment from HIBCC suggested that some drugs may use HIBCC bar codes, that medical devices, in particular, are ''uniquely identified by the UPN number,'' and that the Department of Defense, Veterans Administration, and other organizations use the UPN numbering system. Therefore, we cannot preclude the possibility that some drug firms and organizations may use or prefer to use HIBCC bar codes, so we invite comment as to whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards.

Our position presumes that, by the time any final bar code rule becomes effective (assuming that we do issue a final rule), bar code scanners will be able to read different UCC/EAN linear bar code symbologies reliably and efficiently. This is a critical consideration because the proposed rule's benefits are realized only if hospitals invest in bar code scanners, and we reiterate that their willingness to make that investment may depend on the number of different bar code symbologies that will be used and the ability of bar code scanners (particularly those scanners already in use at the hospitals) to read different symbologies. Comments from the public meeting disagreed on what capabilities different bar code scanning technology had to read different symbologies. Some comments suggested that new bar code scanners can read different linear bar code symbologies, particularly those in the UCC/EAN standard. In contrast, others suggested that bar code scanners may be unable to read newer bar code symbologies or that older scanners cannot read new symbologies or composite codes. Our understanding is that scanner capability depends on how the scanner is programmed (because scanners are programmed to read individual symbologies) and whether scanners can be upgraded or modified to read new symbologies. For example, some bar code scanners might be programmed to read the most commonly used linear bar codes and might not be able to read the RSS symbology. Some scanner manufacturers may be able to upgrade or modify an existing scanner to read newer symbologies, while other scanners, due to their age or the manner in which they were made, might not be capable of being upgraded. We invite further comment on this point.

As for non-bar code technologies, we know that other technologies exist or are under development, but we decline to specify the use of DataMatrix or other nonlinear bar code formats or technologies, such as radio frequency identification (RFID). We realize that other technologies may be able to encode more data or be more versatile compared to linear bar codes. For example, in a meeting with the National Alliance for Health Information Technology, we heard how RFID could be used to facilitate inventory control and to track individual items because each RFID tag would have its own unique ''electronic product code'' (EPC) consisting of a header code, an ''EPC manager'' that would probably identify the product's manufacturer, an ''object class'' that would refer to the product type, and a ''serial identifier'' that would be unique to each individual item. RFID's ability to track individual items could help drug companies and public health agencies identify and eliminate counterfeit drug products. However, the costs associated with RFID tags and readers could be significant; literature provided by the Auto-ID Center conceded that current RFID tags are ''fairly expensive'' and that a firm might have to purchase more than one reader if multiple RFID frequencies exist (Ref. 40). A representative from the Auto-ID Center stated that the ''target cost'' is five cents per RFID tag, so the technology could become more available and less expensive in the future.

Nevertheless, we find that linear bar codes are sufficient for encoding NDC

numbers, and hospitals that already have or intend to buy linear bar code scanners might not have to upgrade those scanners or purchase new devices if the proposed rule would require the use of linear bar codes only. In contrast, if we were to allow for other technologies such as RFID or even two-dimensional symbols such as DataMatrix, hospitals might have to buy RFID readers, optical scanning equipment, or other equipment because linear bar code scanners may be incapable of reading other technologies and, depending on the particular scanner, may be incapable of being upgraded. However, we invite comment on whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology), and recommend that any comments advocating the use of a different model consider and discuss the following issues:

• What other symbol, standard, or technology should we consider, either in place of a linear bar code or in addition to it? How accepted is that symbol, standard, or technology among firms that would have to affix or use that symbol, standard, or technology? For example, we know that RFID technology has great potential for encoding a lot of data and for identifying individual products, but the technology is not yet widely accepted in the pharmaceutical industry due to its novelty and costs.

• Will hospitals be able to read or use the symbol, standard, or technology, either with existing equipment or equipment under development? We reiterate that hospitals might not have the financial resources to buy multiple pieces of equipment to read multiple, incompatible formats, so hospitals must be able to make equipment purchasing decisions confidently, knowing that they will recapture their investment costs.

Insofar as drug products are concerned, we also decline to have the proposal refer to the use of machine-readable codes or symbologies that can be read by machines ''currently'' used. Although a reference to ''machine-readable'' symbols or to ''current'' technology might seem to make a rule more accommodating to future technological developments, words such as ''machine-readable'' and ''current,'' when used in a regulation, can create several practical difficulties. For example, in the absence of an accepted standard or process, disputes could arise as to how we or any other person or group determines what is ''current.'' A manufacturer who wants to use a novel bar code or symbol could get different answers depending on whom it consulted; a hospital using linear bar code readers might find the novel code incapable of being read by its ''current'' scanners, whereas the firm marketing a new machine to read the novel code would argue that the novel code is ''machine-readable'' by ''current'' machines. Similarly, if only a fraction of the machines used in hospitals can read a new code, a hospital might argue that the new code cannot be read by ''current'' machines, yet, if machines were or could be upgraded or modified, a firm that marketed the machines or upgrade service might argue that the new code can, indeed, be read by current machines, provided that upgrades or modifications are made. These and other potential problems associated with a reference to ''current'' machines or ''machine-readable'' technology lead us to avoid using such terms in this proposal. (Different considerations apply for blood and blood products, and we discuss the proposed requirement for machine-readable symbols for blood and blood product containers at section II. H of this document.)

Furthermore, we decline to establish committees or other bodies to study the issue further or to decide technological issues. Given the comments we have received thus far, we have no assurance that a committee or other body would arrive at a consensus.

Nevertheless, if a group comprised of the affected industries and persons who would use the bar code could agree on a standard, symbology, or technology, we would be interested in learning about such standard, symbology, or technology and its costs and benefits. We would carefully review the information and consider the information when drafting a final rule.

2. Are There Any Specific Requirements for the Bar Code?

Proposed § 201.25(c)(1)(i) and (c)(1)(ii) would require the bar code to be surrounded by sufficient blank space so that the bar code can be scanned correctly and to remain intact under normal conditions of use. These requirements would help ensure that the bar code can be read easily and accurately so that its safety benefits may be realized. We note that today some manufacturers have bar codes at locations where the bar codes are destroyed, damaged, or otherwise rendered useless. For example, some manufacturers have put bar codes on individual foil-wrapped packets, but the bar code overlaps the folds or perforations that separate the foil-wrapped packets. When one packet is separated from the others, the bar code is split into pieces, and the resulting bar code fragments can provide misleading or nonsensical information to the bar code scanner or might not be read at all by the scanner. So, the proposed rule would require the bar code to be placed in a manner so that it remains intact during normal conditions of use. For the foil-wrapped packet example, this would mean that the bar code would be placed away from folds or perforations so that each packet, when separated from the others, has its own intact and easily scanned bar code.

Note, too, that the proposal would include the phrase ''under normal conditions of use.'' Depending on the packaging and container used, the ''normal conditions of use'' may or may not require the bar code to remain intact at all times. For example, assume that you have a tablet in a blister package and that the bar code is printed on the flat side of the blister package. If the bar code is scanned before the tablet is pushed through the flat side, the bar code would not remain ''intact'' after the tablet has been dispensed, and this would be acceptable because, under ''normal conditions of use,'' the bar code would have already served its purpose by being scanned before the drug was dispensed. In contrast, assume that you have a bottle that contains multiple tablets. The bar code on the bottle, under proposed § 201.25(c)(1)(ii), would have to remain intact throughout the bottle's use so that the bar code could be scanned each time a tablet is dispensed from that bottle.

One comment said we should audit bar code quality, help industry build a bar code information infrastructure, publish our results, and support mandatory testing and verification of bar codes.

We decline to adopt the comment's suggestions. The bar code would be part of the drug's label, so issues concerning its quality and verification would be subject to current good manufacturing practices (GMP's). In general, persons who would be subject to the bar code requirement would be responsible for having written procedures for the receipt, identification, storage, handling, sampling, examination, and/or testing of labeling and packaging materials, for exercising control over labeling materials and label operations, and for ensuring that correct labels are used (see 21 CFR 211.122, 211.125, 211.130). Failure to meet GMP's will cause a drug to be considered adulterated under section 502(a)(2)(B) of the act.

We also note that there are various standards relating to bar codes already. For example, the American Society for

Testing and Materials has a standard procedure for bar code verification (Ref. 41). The International Organization for Standardization has various standards for automatic identification and data capture techniques, and several deal with bar code quality and symbologies. The UCC has guidelines on bar code placement and other documents on specific symbologies or quality matters. Given these standards and other documents, as well as the comparatively greater expertise of standards organizations in this area, we do not intend to develop our own guidance documents regarding bar code details such as quality, verification, or testing.

The bar code can also be used to access the medication information found in the professional labeling of a specific drug product. We are currently working on a collaborative initiative with the National Library of Medicine and the Department of Veterans Affairs to create a collection of up to date, computer readable electronic labels for marketed drug products called the ''DailyMed.'' By linking the NDC to the appropriate label in the DailyMed, people will be able to use computer systems to access important medication information simply by scanning the bar code found on the drug package. This could help locate proper dosage instructions, identify drug interactions, and find other information necessary for the safe use of medications.

E. Where on the Label Would the Bar Code Appear? (Proposed § 201.25(c)(2))

In the public meeting notice, we asked where the bar code should be placed. We asked if there were benefits to placing bar codes on immediate containers and if there was a way to distinguish whether certain containers with a bar code would have a more significant effect on preventing medication errors than other containers (67 FR 41360 at 41361).

Some comments suggested that the bar code go on every package level down to the unit-of-use or unit dose. Other comments recommended placing the bar code on the ''immediate container'' or unit dose or unit-of-use package only.

In contrast, one comment expressed surprise that we would even consider putting bar codes on unit dose or unit-of-use packages because of the potential impact on manufacturers.

Several comments also disagreed as to whether we should specify where a bar code should appear on a particular package. For example, one comment recommended that we draft guidelines for bar code placement; the guidelines would consider ergonomics, scanner types, symbologies, and packaging. Another comment would require the bar code to be placed where ''the typical user of the scanning device can reliably and consistently scan it.''

In contrast, other comments stated that we should not restrict the bar code's placement on a package because differences relating to package size, shape, and material demand flexibility as to the bar code's placement.

Proposed § 201.25(c)(2) would require the bar code to appear on the drug's label. Section 201(k) of the act defines ''label'' as ''a display of written, printed, or graphic matter upon the immediate container of any article; and a requirement made by or under authority of this act that any word, statement, or other information appear on the label shall not be considered to be complied with unless such word, statement, or other information also appears on the outside container or wrapper, if any there be, of the retail package of such article, or is easily legible through the outside container or wrapper.'' Thus, by requiring the bar code to be on the drug's label, proposed § 201.25(c)(2) would result in bar codes on the drug's immediate container label as well as the outside container or wrapper, unless the bar code is easily legible and machine-readable through the outside container or wrapper.

We decline to adopt the comments' positions to require bar codes on all packages or only on immediate containers because that would either result in too many products being bar coded or too few. For example, if we required every package to bear a bar code, then arguably a shipping container of drugs would have a bar code, even though no hospital would dispense a drug directly from a shipping container to a patient, and a bar code on the shipping container would have no impact on medication errors. (The bar code could help with inventory control and tracking, but such matters are outside the scope of this proposed rule.) If we required only the immediate container (which is the container that is in direct contact with the drug at all times) to have a bar code, then patients receiving multiple-unit containers (such as a box holding blister packed tablets) would be vulnerable to medication errors because the multiple-unit container would not have a bar code.

As the previous paragraph suggests, there may be more than one bar code on a product depending on the package and whether it has a unique NDC number. For example, assume that you make drug tablets that are individually packaged in a plastic blister pack and then boxed in a cardboard container. If the individually packaged tablets have a unique NDC number, then each individual blister pack would have a bar code. The cardboard container holding the blister pack would have to have a bar code, too, because the cardboard container would be an ''outer container'' within the statutory definition of ''label.''

Although proposed § 201.25(c)(2) would not require the bar code to appear at a specific location on a product, proposed § 201.25(c)(1)(ii) would require the bar code to remain intact under normal conditions of use. The latter requirement may influence the bar code's location.

F. What Would Happen if a Bar Code Could Not Be Put on a Product?

The proposed rule would not contain an exemption provision. We are aware of industry-conducted pilot studies that have placed RSS bar codes on small vials (Ref. 35). These pilot studies suggest that almost all products are capable of bearing a bar code. However, some comments from the public meeting suggested that small products might not be capable of bearing a bar code and recommended that we allow for exemptions.

We decline to create an exemption provision because we believe that almost all products are capable of bearing a bar code. In addition, exemption provisions sometimes create unintended administrative problems and consume agency resources as some individuals or firms may be tempted to submit exemption requests notwithstanding their ability to comply with a particular regulatory requirement. For example, if we were to create a general exemption provision, a firm whose drug product was packaged in a small vial might seek an exemption even though it could use a RSS linear bar code on that vial. If we tried to impose a limitation on the exemption, such as allowing for possible exemptions if it would not be technologically feasible to affix a bar code on the label, a firm might argue over whether economic or other considerations determined whether a bar code was technologically feasible. In the end, we could be obliged to devote resources to reviewing, deciding, and perhaps re-examining exemption requests, and we can avoid that potential drain on FDA resources by not creating an exemption provision. We invite comment as to whether any specific product or class of products should be exempt from a bar code requirement and the reasons why such an exemption is considered to be necessary. We also invite comment on

how we might create a waiver provision that would minimize the potential for misuse of the waiver. We will consider whether to incorporate specific exemptions into the rule.

G. What Is the Proposed Implementation Plan?

If we issue a final rule to require bar coding, we would require bar codes on human prescription drugs and OTC drugs dispensed under an order and commonly used in hospitals within three years after we publish the final rule in the **Federal Register**. The 3-year period would give affected parties time to obtain NDC numbers, if necessary, exhaust supplies of existing labels, and make new labels that contain the bar code or machine-readable information.

Additionally, because the bar code's addition to a label would be a ministerial act that would not require us to exercise any judgment as to the information being presented, we intend to have firms whose drug products are already approved or marketed notify us about the addition of the bar code to their product labels through an annual report (see § 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii) and 601.12(d)). For marketed OTC drugs, there is no comparable, routine reporting requirement if the drug is not the subject of an approved new drug application, and we do not intend to impose any reporting obligation relating to bar codes on OTC drugs.

We recognize that the bar codes' ability to prevent medication errors depends on many external factors outside this rule, such as the availability of bar code scanners, computer software that can process the bar code information and compare it against patient information, training health care professionals to use scanning equipment, and the willingness of hospitals to invest in bar code scanning equipment. However, requiring bar coding on human drugs is a necessary ''first step'' for promoting the use of technology to combat medication errors (Ref. 42).

We also acknowledge the various comments from the public meeting suggested different implementation periods for this rule. In general, some comments suggested short implementation dates measured in months whereas other comments suggested implementation dates measured in years. A few comments suggested different implementation dates for different products or would have the implementation date depend on the product's potential for harm. Several comments recommended requiring bar codes to contain the NDC number first, and require the lot number and expiration date at some future date.

We decided on the 3-year implementation date to give affected firms time to redesign their labels and exhaust pre-existing label stocks and to give hospitals time to decide which scanning devices or systems to develop or purchase. Additionally, as we suggested earlier, we want to give hospitals more time to decide whether they would be willing to work with pharmaceutical firms to have other information (such as lot number and expiration date) encoded. While we believe the 3-year implementation date is appropriate, we invite comment on whether the implementation period can and should be shortened.

We decline to create a ''phased-in'' implementation system whereby we would require the NDC number first, and then require inclusion of lot numbers and expiration dates at a future time. As we explained earlier in section II.C.2 of this document, we lack data that would support requiring lot numbers and expiration dates on bar codes at this time. While we will not object if firms volunteer to encode such information (assuming that they encode the correct information), we will not require or specify any implementation period for the encoding of lot number and expiration date information.

H. How Does This Rule Apply to Blood and Blood Components? (Proposed § 606.121(c)(13))

Like medication errors, errors involving blood transfusions can result in serious injury or death. For example, one study examined reported transfusion errors occurring between January 1, 1990, and December 31, 1999, from approximately 256 transfusion services in New York (Ref. 43). The study focused on reports involving the administration of a unit of blood to someone other than the intended patient or the issuance of incorrect blood because of a blood bank or phlebotomy error. During the study period, nine million red blood cell and whole-blood units were transfused, and 659 cases of erroneous administration were observed, for a frequency of 1 error per 14,000 transfusions. Five cases resulted in fatalities, at a rate of 1 per 1,800,000 units. In cases where the patient received an incompatible unit, nearly half (47 percent) suffered no ill effects, but 41 percent of the cases resulted in an acute hemolytic reaction, and 2 percent resulted in fatalities (id.) The most common error outside blood banks was administering properly labeled blood to a patient other than the one for whom the unit was intended (37 percent). In blood banks, the study identified issuance of the wrong unit (4 percent) and testing errors (7 percent) as some common errors (id.).

Current FDA regulations, at 21 CFR 606.121(c)(13), state that the container label for blood and blood components ''may bear encoded information in the form of machine-readable symbols approved for use by the Director, Center for Biologics Evaluation and Research.'' The reference to ''machine-readable symbols'' in § 606.121(c)(13) was intended to be flexible and accommodate changes in machine-readable technologies. For example, FDA recognized the use of Codabar (a specific bar code symbology) in 1985, and, in 2000, approved the use of ISBT 128, version 1.2.0 (Ref. 44).

Unlike the situation for other prescription drugs, there is already substantial use of bar codes for blood and blood products. Most blood establishments currently use machine-readable symbols or ''ABC Codabar'' on their blood and blood component labels. In August, 1989, the International Society for Blood Transfusion (ISBT), an organization established to promote and maintain a high level of ethical, medical, and scientific standards in blood transfusion medicine and science throughout the world, recognized that ABC Codabar, the first bar coding system adopted by the health care industry, was becoming outdated and initiated the design of a new system using the bar code symbology which eventually became known as ISBT 128.

In December, 1996, the International Council for Commonality in Blood Bank Automation (ICCBBA) held an ISBT 128 Consensus Conference in Washington, DC, to provide an opportunity for dialogue among the affected industry groups and FDA. Although there was a consensus for use of ISBT 128, some participants expressed concerns regarding implementation time frames and costs of implementation to hospital transfusion services. However, ISBT 128 has numerous advantages over the ABC Codabar. For example, ISBT 128 is more secure, allows more flexibility in coding highly variable information, uses double-density coding to allow more information to be encoded in a limited space, and can be interpreted by the same bar code readers used with ABC Codabar.

The ISBT 128 bar code system established by ISBT is similar, but not identical to, Code 128. ISBT 128 is a copyrighted symbology. The ability to read, store, interpret, transfer, print, or otherwise manipulate ISBT 128 data structures requires registration with the ICCBBA and payment of an annual

licensing fee, and the ICCBBA uses the fees to revise, enhance, extend, and maintain the ISBT 128 system and associated databases (Ref. 45). The ISBT Council accepted an application specification for ISBT 128 in July, 1994, and approved a resolution that all bar coded blood products collected after July 4, 1998, be labeled using ISBT 128. However, the use of ISBT 128 in the United States has been slow, and the ISBT 128 system has not been implemented in accordance with the ISBT Council's resolution.

Despite the international convention and guidance document, comments submitted in response to the public meeting suggest that § 606.121(c)(13) has not resulted in a uniform, international bar coding system for blood in the United States. While some comments described ISBT 128 in favorable terms, stating, for example, that it allows more information to be encoded or is more accurate than Codabar or that ISBT 128 represents an internationally-accepted standard for blood, at least one comment indicated that licensing fees associated with ISBT 128 may deter hospitals from using the ICCBBA system. Comments were also divided as to whether to require the use of ISBT 128 or simply require the use of ''machine readable'' symbols.

We considered whether the proposal should specify the use of ABC Codabar, ISBT 128, a different symbology or standard, or simply require the use of ''machine-readable information'' approved by the CBER Director. Each approach has its advantages and disadvantages. For example, requiring the use of ISBT 128 would help ensure a uniform bar coding standard for blood and blood components and be consistent with the international standard, but requiring ISBT 128 would mean that we would have to institute new rulemaking if a new symbology, standard, or technology was adopted. Requiring ''machine-readable'' information approved by the Director of CBER would allow CBER to consider new technologies in the future, but could result in some blood establishments adopting one system and others using a different system, thereby defeating the goal of creating a uniform system for identifying blood and blood components. Therefore, we invite comment as to whether we should require the use of ISBT 128, require the use of a symbology consistent with that required for drugs in proposed § 201.25, or require ''machine-readable information'' as approved by the Director of CBER or some other standard or symbology.

In developing this proposal, we recognize that the blood industry currently uses a machine-readable code that does not meet UCC/EAN standards. Some comments at the public meeting stated that the scanners are capable of reading multiple systems (e.g., UCC/EAN and ISBT). Based on our understanding of the state of the industry and the ability of scanners to read more than one symbology, we decided to propose a rule that would permit the existing coding to continue. We invite comments on whether this proposal is feasible or whether we should require the use of UCC/EAN standards for blood and blood components.

The proposal would require that the machine-readable information meet certain minimum requirements and be approved by the Director of CBER. These minimum requirements would move us closer to the goal of increasing patient safety. We anticipate that the industry will standardize encoded machine-readable information and readers, using our minimum requirements to minimize, to the greatest extent possible, the need for ''country-specific'' software and the high cost associated with software development and maintenance.

Thus, we propose to amend § 606.121(c)(13) to require the use of ''machine-readable information'' approved by the Director of CBER. The Director will review the machine-readable information technology to ensure that the minimum requirements are met regarding the accuracy of the required labeling information, spacing, and conditions of use.

Proposed § 606.121(c)(13) also would:

- Explain that all blood establishments that manufacture, process, repackage, or relabel blood or blood components intended for transfusion and regulated under the act or the Public Health Service Act are subject to the machine-readable information requirement. This would be consistent with the pre-existing requirement at § 606.121(a) and (b).
- State that blood and blood components intended for transfusion are subject to the machine-readable information requirement. This would be consistent with the pre-existing requirement at § 606.121(a) that describes the purpose behind container label requirements.
- Describe the minimum contents of the machine-readable information as a unique facility identifier, lot number relating to the donor, product code, and the donor's ABO blood group and Rh type. This would reflect the pre-existing requirement at § 606.121(c)(1), (c)(2), (c)(3), (c)(10), and (c)(12).
- Specify that the machine-readable information must be unique to the blood or blood component, be surrounded by sufficient blank space so that the machine-readable information can be read correctly, and remain intact under normal conditions of use. This would be consistent with the pre-existing requirement at § 606.120(c) that requires labeling to be clear and legible.
- State that the machine-readable information must appear on the label of the blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient. The proposal would not specify where the machine-readable information must appear on the label. To illustrate how this would work, the proposal's reference to any blood or blood component would include a unit of whole blood, packed red blood cells, plasma, platelets, and cryoprecipitate AHF. The unit of blood or blood component label would contain the machine-readable information if the blood or blood component has any possibility of being transfused to a patient, whether or not the unit is actually transfused. Additionally, the phrase, ''from which the blood or blood component can be taken and transfused to a patient'' would include the circumstance where blood or a blood component is extracted or aspirated with a syringe from the container of blood or blood component in order to transfuse to a patient. This technique might be used when transfusing neonates or under other medically necessitated circumstances. In this case, the blood or blood component from which the aspirate is taken must have affixed to it a label containing the required machine-readable information. This would be consistent with the pre-existing requirement at § 606.121(c)(8)(iii) that requires specific statements if a product is intended for transfusion.

We also invite comment on how the proposed rule might affect hospitals where patients receive blood or blood components. Specifically, we want to hear how the proposal might affect a hospital's decision to purchase a machine reader (e.g., scanner) that properly identifies the intended recipient of the blood or blood component. To prevent medical errors, this machine reader would need to be compatible with the machine readable information encoded on the blood or blood component label, yet a hospital's purchasing decision might also be influenced by the bar codes appearing

on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital.

We intend to make a machine-readable information requirement effective for blood and blood components 3 years after we publish a final rule in the **Federal Register**. Changes to existing blood and blood component labels would require the submission of an annual report as described in 21 CFR 601.12(f)(3).

I. What Bar Code Requirement Would Apply to Biological Products? (Proposed § 610.67)

The proposal would create a new § 610.67 that describes a new labeling requirement for biological products (other than blood and blood products, which would be covered by proposed § 606.121(c)(13)). Proposed § 610.67 would simply state that biological products must be labeled in accordance with the bar code requirements at § 201.25. In addition to the separate authority provided by section 351(j) of the Public Health Service Act, the Federal Food, Drug, and Cosmetic Act also applies to a biological product that is regulated under section 351 of the Public Health Service Act.

The proposal would not apply to biological products that are regulated as devices for the reasons we stated earlier in section II.B.2.d of this document.

III. Legal Authority

We believe we have the authority to impose a bar coding requirement for the efficient enforcement of various sections of the act. These include sections 201(n), 201(p), 501, 502, 503, 505, and 701(a)) (21 U.S.C. 321(n), 321(p), 351, 352, 353, 355, and 371(a)) of the act, and sections 351 and 361 of the Public Health Services Act.

A bar coding requirement for drugs would permit the efficient enforcement of the misbranding provisions in section 502(a) and (f) of the act, as well as the safety and effectiveness provisions of sections 201(p) and 505 of the act. Bar coding is expected to significantly advance: (1) The provision of adequate directions for use to persons prescribing, dispensing, and administering the drug; (2) the provision of adequate warnings against use by patients where a drug's use may be dangerous to health; and (3) the prevention of unsafe use of prescription drugs.

Section 502(a) of the act prohibits false or misleading labeling of drugs. This prohibition includes, under section 201(n) of the act, failure to reveal material facts relating to potential consequences under customary conditions of use. Information in a database that could be readily accessed through the use of a bar code, such as the drug strength, dosage form, route of administration, and active ingredient and drug interactions is material with respect to consequences which might result from use of the drug under such conditions of use. Because all the drugs (prescription drugs and the subset of covered OTC drugs) covered by this proposal may be used in the hospital setting, such use in hospitals can be considered the ''conditions of use as are customary or usual.'' As is made clear in section I of this document, bar coding can be expected to reduce the incidence of the following types of medication errors:

- Administering the wrong dose to a patient;
- Administering a drug to a patient who is known to be allergic;
- Administering the wrong drug to a patient or administering a drug to the wrong patient;
- Administering the drug incorrectly;
- Administering the drug at the wrong time; and
- Missing or duplicating doses.

Because information accessed through use of the bar code will reveal material facts relating to potential consequences under customary conditions of use, the bar code requirements are justified under section 502(a) of the act.

Section 502(f) of the act requires drug labeling to have adequate directions for use, adequate warnings against use by patients where its use may be dangerous to health, as well as adequate warnings against unsafe dosage or methods or duration of administration, in such manner and form, as necessary to protect users. The bar code would make it easier for the person administering the drug to have full access to all of the drug's labeling information, including directions for use, warnings and contraindications. Moreover, because the bar code's information would go to the computer where it could be compared against the patient's drug regimen and medical record, the person administering the drug will be able to determine whether the right patient is receiving the right drug (including the right dose of that drug in the right route of administration) at the right time. The person administering the drug will also be able to avoid giving products to a patient who might be allergic to, or otherwise unable to take, a particular drug. Because the bar code will facilitate access to information including adequate directions for use and adequate warnings, the bar code requirements are justified under section 502(f) of the act.

In addition to the misbranding provisions, the premarket approval provisions of the act authorize FDA to require that prescription drug labeling provide the practitioner with adequate information to permit safe and effective use of the drug product. Under section 505 of the act, we will approve a new drug application (NDA) only if the drug is shown to be safe and effective for its intended use under the conditions set forth in the drug's labeling. Bar coding will ensure the safe and effective use of drugs by reducing the number of medication errors in hospitals and other health care settings. Such coding would allow health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is given to the right patient at the right time.

Section 505(b)(1)(D) of the act requires a new drug application to contain a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and packing of such drug. The same requirement exists for abbreviated new drug applications (see section 505(j)(2)(A)(vi) of the act) and for biological products (see section 351(a)(2)(B)(i)(II) of the Public Health Service Act). Information in the bar code would reflect the facilities and controls used to manufacture the product. As described in section II.C.1 of this document, the NDC number would identify the manufacturer, product, and package.

A bar coding requirement also would permit the efficient enforcement of the adulteration provisions of the act. A regulation requiring the bar coding of products should avert unintentional mix up and mislabeling of drugs during labeling, packaging, relabeling, and repackaging. A bar coding requirement therefore prevents adulteration under section 501(a)(2)(B) of the act. It is a manufacturing method or control necessary to ensure that a drug product has the identity and strength its labeling represents it to have, and meets the quality and purity characteristics which the drug purports or is represented to possess.

Requiring that the bar code be surrounded by sufficient blank space, and remain intact under normal conditions of use, would also further the efficient enforcement of section 502(c) of the act. Section 502(c) of the act provides that a drug product is misbranded if: Any word, statement, or other information required by or under authority of this Act to appear on the label or labeling is not prominently placed thereon with such conspicuousness (as compared with

other labeling) and in such terms as to render it likely to be read and understood by the ordinary individual under customary conditions of purchase and use. The requirement that the bar code be surrounded by sufficient blank space and remain intact under normal conditions of use would help ensure that the bar code can be read easily and accurately so that its safety benefits may be realized.

Because biological products, including blood, are also prescription drug products, the sections of the act discussed elsewhere in this legal authority section provide ample legal authority for promulgating a regulation requiring bar coding for such biological products. There is, however, additional legal authority for the rule's requirements as to biological products. Section 351 of the Public Health Service Act authorizes the imposition of restrictions through regulations ''designed to insure the continued safety, purity, and potency'' (including effectiveness) of the products. Biological product licenses are to be ''issued, suspended, and revoked as prescribed by regulations'' (42 U.S.C. 262(d)(1); see §§ 601.4 through 601.6). The bar code requirement for biological drugs, and the machine-readable information requirement for blood and blood products, is designed to insure the continued safe and effective use of licensed biological products. Therefore, if this rule were finalized, we may refuse to approve biologics license applications (BLAs), or may revoke already approved licenses, for biological drug products that do not have such codes.

Additionally, section 361 of the Public Health Service Act authorizes regulations necessary to prevent the introduction, transmission, or spread of communicable diseases. With specific regard to blood and blood products, the requirement for machine readable information will aid in the recall, quarantine and retrieval of units that are at risk of spreading communicable diseases.

After the effective date of any final rule, if a product required by the final rule to bear a bar code does not have such a bar code, the product may be considered adulterated or misbranded under the act and would be subject to regulatory action. Our enforcement actions under the act include seizure, injunction, and prosecution, and violation may result in withdrawal of an NDA or BLA.

IV. Environmental Impact

We have determined under 21 CFR 25.30(h) and 25.30(k) 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.

V. Paperwork Reduction Act of 1995

This proposed rule contains information collection requirements that are subject to public comment and review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). We describe the provisions in this section of the document with an estimate of the annual reporting burden. Our estimate includes 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 collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the 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 through the use of automated collection techniques, when appropriate, and other forms of information technology.

Title: Bar Code Label Requirement for Human Drug Products and Blood.

Description: We are proposing a new rule that would require human drug product and biological product labels to have bar codes. The proposed rule would require bar codes on human prescription drug products and OTC drug products that are dispensed pursuant to an order and commonly used in hospitals and would require machine-readable information on blood and blood components. For human prescription drug products and OTC drug products that are dispensed pursuant to an order and commonly used in hospitals, the bar code would contain the National Drug Code for the product. For blood and blood components, the proposed rule would specify the minimum contents of the machine-readable information approved by the Director of the Center for Biologics Evaluation and Research as blood centers have generally agreed upon the information to be encoded on the label. The proposed rule would help reduce the number of medication errors in hospitals and other health care settings by allowing health care professionals to use bar code scanning equipment to verify that the right drug (in the right dose and right route of administration) is being given to the right patient at the right time.

Because the Center for Drug Evaluation and Research would have bar code information for drugs subject to a new drug application or abbreviated new drug application to be reported through an annual report, this proposed rule affects the reporting burden associated with § 314.81(b)(2)(iii) (21 CFR 314.81(b)(2)(iii)). Section 314.81(b)(2)(iii) requires the submission of an annual report containing a representative sample of package labels and a summary of labeling changes (or, if no changes have been made, a statement to that effect) since the previous report. Here, the bar code would result in a labeling change. We have previously estimated the reporting burden for submitting labels as currently required under § 314.81(b)(2)(iii), and OMB has approved the collection of information until March 31, 2005 under OMB control number 0910–0001. We are not re-estimating these approved burdens in this rulemaking; we are only estimating the additional reporting burdens associated with the submission of label changes under § 314.81(b)(2)(iii).

Minor label changes for blood and blood products may be reported as part of an annual report, as described in 21 CFR 601.12(f)(3), and we would consider the machine-readable information on blood and blood product labels to be a minor change. We have previously estimated the reporting burden for submitting labels as currently required under § 601.12(f)(3), and OMB has approved the collection of information until August 31, 2005 under OMB control number 0910–3338. We are not re-estimating these approved burdens in this rulemaking; we are only estimating the additional reporting burdens associated with the submission of label changes under § 601.12(f)(3).

Description of Respondents: Persons who manufacture, repackage, or relabel prescription drug products or OTC drugs that are dispensed pursuant to an order and commonly used in hospitals, and blood establishments.

We estimate the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN[1]

21 CFR Section	No. of Respondents	Frequency of Responses	Total Annual Responses	Hours per Response	Total Hours
§ 201.25, § 610.67	1,447	31.1	45,000	24 hrs.	1,080,000
§ 314.81(b)(2)(iii)	1,447	5.9	8,576	10.5 min.	1,497
§ 601.12(f)(3)	211	1	211	1 min.	3.5
§ 606.121(c)(13)	981	42,507.7	41.7 million	1 min.	695,000
Total					1,776,590.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimates are based on the following assumptions.

• For prescription drugs (including prescription biologics and vaccines) and OTC drugs subject to the bar code requirement, information from our own records indicates that there are 1,447 establishments that would be affected by a bar code requirement, and there are approximately 89,800 separate, identifiable product packages subject to this proposed rule. We expect that half of the packages (45,000) would need redesigned labels to comply with a bar code requirement because they do not currently use coded NDC numbers. This means that the annual frequency of reports, under proposed § 201.25 (and proposed § 610.67 for biological products not regulated as devices), would be 31.1 (45,000 package labels requiring a bar code/1,447 establishments = 31.09 packages per establishment, which we have rounded up to 31.1). Consultations with industry sources suggest that the number of hours per response to redesign a package label to include bar coded information to comply with this regulation is approximately 24 hours. Therefore, the total burden hours for proposed § 201.25 and § 610.67 would be 1,080,000 hours (45,000 packages x 24 hours per package label = 1,080,000 hours).

• For prescription drugs whose label changes would be reported in an annual report under § 314.81 or under § 601.12(f)(3) for biological products), there are approximately 1,447 registered establishments that would be reporting. Information on listed drugs indicates there are 89,800 separate, identifiable product packages that will comply with the proposed bar code requirement. These packages account for 8,576 separate and distinct products (each product is marketed in an average of 10.47 packaging variations). This means that the annual frequency of reports would be 5.9 (8,576 products subject to annual reports/1,453 registered establishments = 5.92 products per registered establishment, which we have rounded down to 5.9). Section 314.81(b)(2)(iii) requires firms to submit an annual report that includes a summary of any changes in labeling since the last annual report. Similarly, § 601.12(f)(3)(I)(A) requires manufacturers of biologics to include in their annual reports editorial or similar minor labeling changes. We expect that the addition of a bar code to a label would necessitate a simple statement in the annual report declaring that the bar code has been added, so we have assigned an estimate of one minute for such statements per label. Each product's annual report would include labels for all packaging variations. Thus, the total reporting burden would be 1,496.67 hours ((8,576 reports x 10.47 labels (or one label per packaging variation) per report x 1 minute per report)/60 minutes per hour = 1,496.67 hours), which we have rounded up to 1,497 hours.

• For minor labeling changes for blood and blood components included in an annual report under § 601.12(f)(3)(i)(A), FDA's database indicates there are 211 licensed blood and blood component manufacturers. We expect that the addition of machine-readable information to the label of blood and blood components would necessitate a simple statement in the annual report declaring that the machine-readable information has been added, so we have assigned an estimate of one minute for such statements. Thus, the total reporting burden would be 3.5 hours ((211 reports x 1 minute per report)/60 minutes per hour = 3.516 hours), which we have rounded down to 3.5 hours.

• For the requirement in proposed § 601.121(c)(13) to include machine-readable information on blood and blood components, FDA's registration database indicates there are 981 blood and plasma establishments. The American Association of Blood Banks estimates that approximately 13.9 million blood donations are collected annually. We estimate that each blood donation yields approximately three blood components. This means that the frequency of responses is approximately 41.7 million occurrences (13.9 million blood donations x three blood components per donation) divided by 981 establishments or 42,507.645 occurrences per establishment, which we have rounded up to 42,507.7. We estimate that it takes 1 minute to apply a machine-readable code manually; if a blood collection facility uses an on-demand printer, the time would range between 15 to 30 seconds. For purposes of this estimate, we adopt the larger time estimate of 1 minute per machine-readable information for blood, thus resulting in an annual reporting burden of 695,000 hours ((41.7 million reports x one minute per report) /60 minutes per hour = 695,000 hours). However, we reiterate that facilities using on-demand printers would face lower burdens. In addition, blood collection centers are currently allowed and encouraged to apply machine readable information to collections. This burden estimate accounts for requiring an activity that is currently voluntary and does not reflect an additional activity.

In compliance with the Paperwork Reduction Act of 1995 (44 U.S.C. 3507(d)), we have submitted the information collection requirements of this rule to OMB for review. Interested persons are requested to fax comments regarding information collection by April 14, 2003, to the Office of Information and Regulatory Affairs, OMB (see **ADDRESSES**).

VI. Executive Order 13132: Federalism

We have analyzed this proposed rule in accordance with the principles set forth in Executive Order 13132. We have determined that the rule does not contain policies that have substantial direct effects on the States, on the relationship between National Government and the States, or on the distribution of power and responsibilities among the various levels of government. Accordingly, we have concluded that the rule does not contain policies that have federalism implications as defined in the order and, consequently, a federalism summary impact statement is not required.

VII. Analysis of Impacts

A. Introduction

We have examined the proposed rule under Executive Order 12866, the Regulatory Flexibility Act as amended by the Small Business Regulatory Enforcement Fairness Act, the Unfunded Mandates Reform Act, and the Congressional Review Act. 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, distributive impacts and equity). Under the Regulatory Flexibility Act (as amended by the Small Business Regulatory Enforcement Fairness Act), if a regulation has a significant economic impact on a substantial number of small entities, we must analyze regulatory options that would minimize the impact on small entities. Section 202(a) of the Unfunded Mandates Reform Act requires that agencies prepare a written statement of anticipated costs and benefits before proposing any regulation that may result in expenditure by State, local, and tribal governments, or by the private sector of $100 million in any one year (adjusted annually for inflation). Currently, such a statement is required if costs exceed about $110 million for any one year. The Congressional Review Act requires that regulations determined to be major must be submitted to Congress before taking effect.

The proposed rule is consistent with the principles set forth in Executive Order 12866 and the three statutes. We have identified the proposed rule as an economically significant regulatory action, as defined in Executive Order 12866. We believe the proposed rule is unlikely to have a significant impact on a substantial number of small entities. The expected cost of this proposed rule is greater than $110 million in a single year and therefore is considered a major regulatory action as defined by the Unfunded Mandates Reform Act. The Office of Information and Regulatory Affairs (OIRA) in the Office of Management and Budget (OMB) has determined this proposed rule to be major under the Congressional Review Act.

We contracted with the Eastern Research Group, Inc. (ERG), to collect data, interview industry experts, and analyze the costs and benefits of the proposed rule. The detailed analyses and references in support of the impacts summarized in Table 2 are included in the docket as Reference 46.

TABLE 2.—ESTIMATED IMPACTS OF THE PROPOSED RULE (IN MILLIONS OF DOLLARS) (OVER 20-YEAR PERIOD AT 7-PERCENT DISCOUNT RATE)

Impacts	Regulatory Costs	Anticipated Hospital Costs[1]	Societal Benefits[2]	Potential Hospital Efficiencies[3]	Net Benefits (benefits minus costs)[4]
Present Value	$53.1	$7,204.3	$41,381.3	$4,783.3–$7,643.0	$34,123.9
Annualized	$5.1	$680.0	$3,906.1	$451.5–$721.5	$3,221.0

[1] Costs due to voluntary accelerated purchase and utilization of bar coding systems.
[2] Benefits to public health due to avoidance of adverse drug events.
[3] Potential efficiencies in reports, records, inventory, and other hospital activities.
[4] Net benefits include only public health benefits of increased patient safety.

Table 2 presents the total expected regulatory costs to manufacturers, repackers, relabelers, retail outlets, and FDA. Most of these costs will occur during the first several years after implementation. Table 2 also shows the estimated opportunity costs of the expected accelerated investment in bar coding systems by the health care sector. These investment expenditures are necessary to achieve the societal benefits expected from the proposed rule. Table 2 also shows our estimated range of possible efficiencies in hospital activities associated with accelerated adoption of technology. Both anticipated hospital costs and societal benefits would occur after hospitals purchase and install the necessary equipment to take advantage of bar codes. The net benefit figure is the societal benefit minus the induced expenditures minus the regulatory costs. This estimate, however, accounts for neither potential hospital efficiencies, nor income transfers to hospitals following fewer awards for medical malpractice.

B. Objective of the Proposed Rule

The objective of the proposed rule is to enable the health care sector to utilize technological solutions to reduce preventable adverse drug events (ADEs)[2] associated with medication errors[3] in hospitals.[4]

C. Estimate of Risk/Risk Assessment

In 1999, the Institute of Medicine (IOM) issued a report that drew public attention to the number of deaths that occur each year in the United States from preventable medication errors in hospitals. A significant proportion of the reported deaths, as well as the additional illnesses and morbidities, were associated with errors involving FDA-regulated products, especially medications. This section briefly describes the agency's efforts to estimate the current number of preventable ADEs.

The public health literature includes many attempts to determine the rate of preventable ADEs in United States hospitals, although these studies typically employed varying methodologies and definitions. Our methodology begins by multiplying estimated hospital admissions by reported rates of ADEs per admission. We combined the resulting number of ADEs per hospital per year with the reported ratio of preventable to total ADEs to estimate the number of preventable ADEs per hospital per year. We first developed these calculations for various hospital size classes and then aggregated the data to present national estimates. We relied on published literature to derive ADE rates for each major stage of the medication process in hospitals.

ERG identified four comparable published studies that reported rates of ADEs per hospital admissions (Bates et al., 1995, Classen et al., 1997, Jha et al.,

[2] For this analysis, an adverse drug event (ADE) is an injury from a medicine (or a lack of an intended medicine). (source: American Society of Hospital Pharmacists, 1998)

[3] For this analysis, a medication error is a preventable event that may cause or lead to inappropriate medication use or patient harm while the medication is in the control of the health care professional, patient, or consumer. (source: NCCMERP, 2002)

[4] For this analysis, a hospital is a facility that provides medical, diagnostic, and treatment services that include physician, nursing, and other health services to inpatients and the specialized accommodation services required by inpatients. (source: NAICS, 2002)

1998, and Senst et al., 2001). The reported incidence rates of hospital admissions with ADEs ranged from 2.4 percent to 6.5 percent with a mean rate of 4.3 percent. According to AHRQ, there were 29.1 million nonobstetric hospital admissions during 2000. We multiplied these admissions by 0.043 and found that approximately 1.25 million ADEs occur annually in United States hospitals. The same four studies reported that between 15 percent and 49 percent of all ADEs are preventable. We used the mean of these studies to estimate that about 372,400 (30 percent) of these ADEs were preventable. Based on published reports (Bates et al., 1998, and Leape et al., 1998), we also estimated that 1,046,000 potential ADEs[5] are either intercepted before reaching the patient or do not cause an injury. According to projected increases in hospital expenditures and population demographics that imply future increases in hospital admissions, the annual number of ADEs could triple within 20 years.

ERG searched the public health literature to identify stages in the hospital medication process in which errors occur and concluded that the medication stages of prescribing, transcribing, dispensing, and administration provide a useful analytic structure. The most common reported ADE symptom was cardiac arrhythmia followed by itching and/or nausea. Relatively few fatalities have been documented as preventable ADEs, but several published studies conclude that as many as 2.8 percent of all preventable ADEs probably result in fatalities. Another study has asserted that as many as 2.7 percent of all ''negligent'' (as defined in the study) ADEs have resulted in permanent disability. We used these estimates in our analysis.

D. The Proposed Rule

We propose to require machine-readable information on all prescription drug and biological products (including vaccines), all OTC drug products dispensed pursuant to an order and commonly used in hospitals, and all human blood products. This information would include the NDC number identifying the dosage, strength, nature, and form of each administered product and would be portrayed in a standardized linear bar code[6] and include product-specific and package-specific NDC numbers. We would maintain a database of all unique NDC numbers and ensure these data are available for use in commercial computerized systems that can provide bedside bar code identification. The bar code requirement would, if finalized, be effective within 3 years after we have published a final rule.

We are proposing this regulation because private markets have failed to establish the standardized bar codes that are needed to motivate hospitals to adopt an important health-saving technology. In particular, we believe that the private market's failure to develop standardized bar codes has impeded the growth of the technological investment necessary to reduce the number of ADEs in the nation's hospitals. We find that a regulatory intervention to establish a standardized system of bar codes is needed to address this market failure.

The proposed rule would increase costs to the manufacturers, marketers, and packagers of the affected products by requiring changes in manufacturing, packaging, and labeling processes. It would also increase costs to some hospitals by requiring a change in some bar code readers associated with these products. The proposed rule would also require FDA resources to ensure industry compliance with the bar coding requirement and additional resources to maintain a computerized database of NDC numbers. Once bar codes are standardized, the proposed rule would enable hospitals to take advantage of the coded information that would permit hospitals to reduce ADEs, while achieving other operational cost efficiencies. The proposed rule would also enable other sectors to use machine-readable technology in ways that would benefit public health (for example, accessing up to date labeling information from home computers).

E. Description of Affected Sectors

1. Current Machine-Readable Technologies

Before developing the proposed rule, we contracted with ERG to examine the current machine-readable technologies available for use by the health care sector and report on trends. The resulting report is included in the docket (Ref. 47) and summarized here.

Bar coding is currently the most widely used machine-readable technology and is also the technology most likely to see increased acceptance in the near future. Healthcare companies have sponsored two organizations that have each developed different bar code symbologies;[7] the Uniform Code Council's Universal Product Code (UPC) and the Health Industry Bar Code Council's Health Industry Bar Code (HIBCC). UPC codes are more widely used in retail stores while HIBCC is specially designed to safeguard against errors. However, although the HIBCC code has been more effectively used by medical device manufacturers, it has not won wide acceptance within the pharmaceutical markets. Within these symbologies, the groups have defined acceptable linear (or one-dimensional) codes, two-dimensional codes, and composite codes (a combination of one- and two-dimensional symbology). The advantage of two-dimensional and composite codes is that they can include additional information in the same area. Potential disadvantages of two-dimensional and composite symbologies are the higher costs for readers and scanners and the additional risk of uncertain data recovery by misinterpreting coded information.

While these organizations' bar codes are widely used, their use for the prevention of ADEs remains limited. Most pharmaceutical and OTC manufacturers use bar codes to move shipping cases through their distribution chain, but relatively few pharmaceuticals are sold with the specific bar codes that would be required by this proposed rule. Some hospitals use computer-controlled technology to add their own bar codes to incoming products.

Bar code systems require printers, scanners, and software to ensure that correct information is communicated. According to discussions with consultants, pharmaceutical manufacturers prefer to label products as late as possible in the manufacturing process in order to maximize their flexibility. Printing technology advancements have allowed more printing options to be available. Manufacturers currently use contract label printers or packagers along with in-house operations. Contract printers are commonly used for preprinted labels that do not carry customized data. Currently, ink jet and thermal printers may be appropriate for production line printing of bar codes, although ink jet printers may cause difficulties in media compatibility, print speed, and resolution. Water-based inks can streak or blur, but nonwater soluble inks produce a shine that reflects to the scanner and affect how the bar code is read. Laser printers are subject to toner

[5] A potential ADE is a medication error that could have caused an ADE, but did not. Potential ADEs include medication errors that were intercepted before reaching the patient. Potential ADEs include any errors that do not involve patients.

[6] A bar code is a graphic representation, in the form of bars and spaces of varying width, of numeric or alphanumeric data.

[7] A symbology refers to a distinct technological, machine-readable language.

flaking, which makes them unreliable for long-term bar code printing. Production line speeds may also create problems for bar code resolution levels.

The complexities of bar code scanners have evolved as the codes have become more data intensive. Most scanners in current use are laser-based systems designed to read linear bar codes. In health care settings, scanners are routinely programmed to discriminate among the symbologies they are likely to encounter. Some laser scanners can also read composite or two-dimensional codes, if properly programmed. These scanners are more costly, and some consultants have cautioned that multiple data systems may introduce potential misreading at hospital bedsides. Moreover, in certain situations, health care scanners may not need to use all of the available information. For example, scanners at bedside point of care may only need to capture limited identifying information while the central dispensing pharmacies may require full database capabilities. At this time, the scanning industry is confident that linear standards[8] will be readily accessible, whereas other standards may require additional market research. We believe that scanners will work in conjunction with hand-held personal digital assistants (PDAs) in wards due to their portability and multi-functional characteristics.

2. Manufacturers and Packagers of Affected Products

Discussions with staff at two large Veteran Health Administration Comprehensive Mail Order Pharmacies indicate that the large majority of exterior pharmaceutical packages include the NDC number in a bar code. The proposed rule, however, would require this bar coded information on both exterior and interior packaging. In addition, some prescription and OTC drug products are sold in blister packs, where individual pills or capsules are enclosed in a bubble. Prescription products are often repackaged into blister cards for more convenient use in hospitals. While some blister cards may now be labeled with bar codes for specified concerns, many are not. OTC drug products rarely include bar coded information on blisters. Moreover, many bar coded exterior packages cannot be read by hospital or retail scanners, because manufacturers use bar codes for sales promotions and other special offers that have separate and distinct NDC numbers that do not appear in all customer databases.

[8] A standard refers to a general description of a system of machine-readable languages.

There are currently approximately 1,218 establishments in the Pharmaceutical and Biologic Preparation industries (NAICS 325412 and 325414). Based on the size distribution of industry establishments, we estimate a total of approximately 3,728 in-house packaging production lines. In addition, an estimated 229 establishments in the Packaging and Labeling Services industry (NAICS 561910) are dedicated to serving the pharmaceutical industry, accounting for an additional 501 packaging lines. Overall, we estimate that 4,229 packaging lines are used in 1,447 establishments for these products.

In addition, we estimate there are 981 blood collection centers in the United States (NAICS 621991). Each of these collection centers acts as a separate packaging line. Consultants have estimated that about 25 percent of these blood collection centers are included in published industry counts. We added blood collection centers to the industry packaging lines for a total of 4,995 affected packaging lines in 2,428 separate establishments.

The number of separate trade and generic named products has increased by over 500 percent since 1990, and now encompasses about 17,000 names. Each of these named products may be marketed in varying strengths or dosage forms. Overall, we estimate there are 78,000 separate prescription unit-of-sale packages, 98,000 OTC drug packages, and 2,000 blood/vaccine packages. Over time, the number of distinct packaging units is expected to continue to increase. The OTC drug industry has suggested that fewer than 10 percent of OTC packages (9,800 packages) are commonly used in hospital settings and would be subject to the proposed rule. For example, OTC analgesics that may be dispensed to a patient pursuant to an order would be subject to the proposed rule, but mouth rinses or toothpastes that may be provided would not. We are collecting data to confirm the proportion of affected OTC drug products. The Consumer Healthcare Products Association (CHPA) estimated that as many as 10 percent of their members' products were regularly dispensed from hospital pharmacies or packaged specifically for sale to hospitals. Other responses include a report from a hospital that only 200 OTC drug products are routinely dispensed. For purposes of this analysis, we have assumed that 10 percent of all OTC drug products would be required to provide bar coded information. We are trying to collect better information for these products. Overall, 89,800 separate unit-of-sale packages are expected to be subject to the proposed rule.

OTC drug manufacturers frequently redesign labels. Based on discussions with manufacturers, we believe that the majority of OTC labels are redesigned within a 6-year cycle for marketing reasons. Many products have redesigned labels every 2 or 3 years. Prescription drug product labels may be redesigned less frequently, but there is evidence that numerous labeling changes occur. While marketing of prescription products may not be as sensitive to labeling graphics and package design as OTC products, there are many other reasons why manufacturers change their labels. Although we examined NDA files and found that changes to prescription product labels occur an average of more than once per year, for this analysis we have nevertheless assumed that the proposed rule would require significant involuntary actions by the affected industry.

3. Retail Outlets

Retail pharmacies currently have the capacity to read linear standardized bar codes at their in-house scanners. However, if we had selected an alternative to the proposed rule that would have required reduced space symbology (RSS), the current stock of scanners may have required upgrades or replacement. These upgrades would not have been directly mandated by the alternative, but would have been necessary for these entities to continue with bar coded activity. The retail sector currently relies on UPC or other symbologies, and a single standard would not require scanner replacements or upgrades. Only OTC drug products dispensed pursuant to an order and commonly used in hospitals would be affected by the proposed rule. Although small vials or bottles may require specific RSS symbology, these items are available to consumers in larger packages that accommodate current standards for retail outlets. According to the National Association of Chain Drug Stores, there are 55,000 community and chain pharmacies (NAICS 446110), and pharmacies in supermarkets and mass merchandisers (NAICS 445110) that utilize over 515,000 scanners. The expected useful life of a retail scanner is 5 years. The proposed rule is not expected to impact this sector, but we have considered alternatives that would affect retail outlets.

4. Hospitals

The proposed rule would not require hospitals to introduce the new automated technologies, but the development of consistent bar codes on

pharmaceutical and blood products would greatly encourage hospitals to implement bar code based systems to reduce ADEs associated with medication errors. Moreover, unit-dose blister packs and other vials and small bottles might necessitate the use of RSS symbology. In order to scan these products properly, hospitals that currently have installed bar code readers may need to upgrade or replace some scanners. According to the most recent census, there are 6,591 hospitals in the United States (NAICS 622) with a total of over 1.25 million beds. Estimates of personnel in these hospitals include 97,500 pharmacists, 75,500 pharmacy assistants, and almost 1.2 million nurses. Overall, a nurse is responsible for 4.5 beds per shift. An average hospital includes 191 beds and employs approximately 15 pharmacists, 11 pharmacy assistants, and 182 nurses.

Hospitals are currently adopting bar code technology to better control the entire medication process and improve the delivery of care to patients. Virtually all hospital pharmacies use bar code scanners for inventory and stock keeping activities, but only approximately one percent of all hospitals have installed bedside, point-of-care systems that use bar coded information. An additional three percent of hospitals use some form of computerized system in the medication process, but not all use bar codes. Overall, an estimated two percent of all hospitals (131 hospitals) currently use bar codes in everyday operations. Even in the absence of the proposed rule, we expect the remaining 6,460 hospitals to gradually implement computerized tracking systems. Discussions with industry consultants and the American Hospital Association (AHA), however, suggest that without standardization, it would take 20 years for all hospitals to adopt and use systems with bar code readers and utilize in-house overpackaging and self-generation of bar code identifiers. ERG discussed with several consultants whether 20 years is a realistic horizon for acceptance of this technology. While they recognized the uncertainty of future projections in this area, these industry experts felt that 20 years was a reasonable expectation. We examined the impact of alternative acceptance streams as a sensitivity analysis.

We requested comments on the potential uses of bar coded information on drug products at a public meeting held on July 26, 2002. These comments indicated that while patient safety reasons were the primary goals for installation of scanning systems, there are other potential uses. Industry groups and individual hospitals noted that installation of scanning systems may lead to more efficient inventory control, purchasing and supply utilization, and other potential risk management activities. Other groups noted that an integrated computerized network would assist billing and laboratory systems as well. The AHA stated that bar codes would improve patient care and safety, increase workforce productivity and satisfaction, streamline payment, billing, and administrative systems, lead to efficient management of assets and resources, and meet consumer expectations for service and access to information. We believe these comments indicate that internal investment decisions concerning the acquisition of computerized systems entail additional returns that are in addition to ADE avoidance. While some of these returns to hospitals (such as reduced liability awards and malpractice liability insurance premiums) may be transfers, we believe additional efficiencies are likely.

5. FDA Oversight and Responsibilities

We would be affected in two areas. For successful bar code use, hospitals need access to the unique NDC numbers that identify specific active ingredients, packages, dosage forms, and units. We would maintain the database containing these unique identifiers and arrange access to it for the private sector.

The second area in which our activities would be impacted by the proposed rule is our use of compliance resources. The proposed rule would require the affected products to have bar coded information. Although the exact impact on our compliance resources is not quantified, we recognize that the creation of new regulatory requirements would require additional resources to ensure compliance.

F. Regulatory Costs of the Proposed Rule

1. Introduction

We estimated costs for a 20-year evaluation period to reflect the time that hospitals are expected to take to invest in bar code technology in the absence of the regulation. This summary describes these costs and presents both the present value (PV) and the annualized value of the cost streams. We analyzed costs in the affected sectors over the entire evaluation period using a seven percent annual discount rate. We assume that costs accrue at the beginning of any period. The detailed calculations and references that support the following analysis are available in Reference 46.

2. Costs to Manufacturers and Packagers of Affected Products

The pharmaceutical industry would face compliance costs from this proposed rule because we would require manufacturers, repackers, relabelers, and private label distributors to include NDC numbers in bar code format, using linear standardized symbology, down to the unit-dose level. The proposed rule would require this information within 3 years of the implementation date of the final regulation. The proposed rule would also affect the production processes of the pharmaceutical and biological product industries. Although manufacturers appear to initiate labeling changes fairly often for internal purposes, the proposed rule would necessitate large-scale production line alterations that could affect a manufacturer's entire product line.

a. *Prescription Drugs*. Based on ERG's analysis, we expect the overall investment costs to the prescription drug industry to total $26.3 million over the first 3 years of the evaluation period. Most costs ($17.6 million) accrue for modifications to unit-dose interior packaging to include a unique NDC number in a linear standardized format for every product. Exterior packaging modifications that include NDC information would cost $4.1 million over the 3-year period. Because the capital equipment installed for these packaging modifications would require upgrading and replacement after an average 10-years of productive life, the industry would invest an additional $3.8 million over the 11th, 12th, and 13th evaluation year for this replacement and upgrade. In addition, the packaging production process would require additional annual operating and maintenance costs reaching $0.4 million by the third evaluation year. In total, we estimate that the PV of the costs incurred by prescription drug manufacturers, repackers, and relabelers to comply with the proposed rule over the 20-year period is $30.4 million and the annualized cost is $2.9 million.

b. *Over-the-Counter Drugs*. The OTC drug industry has estimated that fewer than 10 percent of its products are commonly used in hospitals (CHPA, 2002). We are currently collecting data on the size of this market share. For this analysis, we assume that 10 percent of all OTC drug products would be subject to the regulation and will include bar coded NDC numbers. The industry would either assign internal production processes that allow labeling differentiation for these products, or repackers and relabelers would provide the required labeling. We believe that

the magnitude of packaging changes required to install bar coding equipment would result in manufacturer decisions to bar code entire product lines rather than incremental, specific products. We estimate that the initial investment for OTC drug manufacturers, repackers, and relabelers would total $1.7 million over 3 years, with additional capital investments of $0.1 million during the 11th evaluation year. The estimated annual operating costs to provide bar codes to the affected proportion of the OTC drug market are negligible (less than $0.05 million by the third year). Overall, the PV of these costs over the 20-year evaluation period to the OTC drug industry is $2.1 million and the estimated annualized costs are $0.2 million.

c. *Blood and Blood Products*. Manufacturers of blood and blood products would also be affected by the proposed rule. Although most blood and blood product manufacturers have voluntarily applied bar coded information, this requirement would add to their costs by requiring specific machine-readable information in a consistent format. These costs would equal approximately $0.4 million over the first 3 years, with additional capital expenditures of $0.1 million over the following 20-year evaluation period for replacement or upgrade of equipment installed in response to the proposed rule. The annual operating costs to blood manufacturers of maintaining the equipment would be negligible (less than $0.05 million by the third year). We estimate that the PV of these compliance costs to blood and blood product manufacturers for using machine-readable information in a consistent machine-readable format over the 20-year period is $0.7 million and that the annualized costs are $0.1 million.

d. *Total Cost to Manufacturers, Repackers, and Relabelers*. The estimated PV of regulatory costs to manufacturers, repackers, and relabelers of prescription drug products, OTC drug products, blood, and blood products is $33.2 million. The average annualized costs to these industries are $3.2 million.

3. Costs to Retailers and Distributors

We do not expect increased costs to retailers, wholesalers, and distributors. Currently installed scanners and readers are able to read the linear bar codes described in the proposed rule. However, if we had selected an alternative that would have required RSS symbology, independent community pharmacies, chain pharmacies, and pharmacies in chain merchandisers or supermarkets would have had to upgrade scanners in order to take advantage of the proposed standardized information. Given the widespread reliance on bar code information in the retail sector, the currently installed stock of bar code scanners would not be affected by the proposed rule.

4. Costs to Hospitals

The proposed rule would require NDA numbers in linear bar codes on the immediate containers of affected products and machine-readable information on blood and blood products. However, because manufacturers, repackers, and relabelers are expected to find it necessary to use RSS symbology on small unit-dose packages or vials and bottles, their scanners and readers must have the ability to capture this information in a RSS format. As a result, in order for hospitals that have currently installed bar code reading systems to maintain current operating practice, their scanners may need to be replaced with scanners that are capable of reading RSS symbologies. Replacement of these scanners would not be a voluntary hospital investment, but would be necessary to maintain current operations.

These costs are somewhat mitigated for the approximately 2 percent of all hospitals (131 hospitals) that currently use bar codes in everyday practice by repackaging medications in unit-dose form and applying internally printed and generated bar codes. According to published reports and discussions with industry experts, ERG estimated that such hospitals now incur costs to apply bar codes on nearly 28 percent of dispensed medications. These 131 hospitals would avoid these expenditures under the proposed rule.

The proposed rule would result in the premature replacement of scanners used in hospital pharmacies and treatment wards. ERG has estimated that the PV of the incremental initial cost of accelerated scanner replacement or upgrade to read RSS symbologies, based on the expected remaining useful life of current equipment, is approximately $13.7 million. The average annualized costs to hospitals of early replacement is $1.3 million.

According to reports in the literature, it costs as much as $0.03 per unit-dose to apply a bar code in hospital pharmacies. Avoidance of this activity will reduce costs by approximately $0.7 million per year. The PV of this cost reduction is $7.6 million.

Overall, we estimate the PV of regulatory costs, less the cost savings to hospitals of the proposed rule, to be $6.1 million, and the average annualized costs are $0.6 million.

5. Costs to the Food and Drug Administration

According to a recent study, the number of available pharmaceutical products has increased by 500 percent in 10 years and now totals over 17,000 separate trade and generic names. With the multitude of dose strengths and packages, the total number of unique packaging units is now 178,000 separate identifiable products. Of this total, we expect 89,800 of these packaging units would need bar coded NDC numbers because we estimate that only 10 percent of all OTC drug products will be affected. Even if the recent growth rate in new products were halved (so that the number of available products increased by 500 percent in 20 years), there would be 449,000 new NDC codes over 20 years, or 22,500 per year for the evaluation period.

We expect that the requirement for notification of unique NDC numbers would require the development and maintenance of an accessible agency database. We have assumed 0.5 hours per notification to represent the cost to input and encode a specific NDC number and to maintain an accessible data base containing all NDC numbers. This implies an annual resource requirement of 11,250 hours, or approximately 5.6 full-time equivalents (FTEs). These direct resources require supervision, administration, and support. To account for these indirect resources, we multiplied direct resources by two, resulting in 11.2 annual FTEs. The most recent FDA budget documents have used a value of approximately $120,000 per FTE. Therefore, we expect the annual costs of maintaining a system of unique NDC numbers to be $1.3 million with a PV of $13.8 million. Although additional regulatory requirements, such as requiring readable bar code information on product labels, would increase our compliance burden, we have not quantified that impact at this time.

6. Total Regulatory Costs

The estimated PV of the total direct regulatory costs of the proposed rule over the 20-year period is $53.1 million, which is equivalent to an annualized cost of $5.1 million. Table 3 illustrates the timing of the stream of investments and increased annual operating and maintenance costs expected from the proposed rule.

TABLE 3.—REGULATORY COSTS (IN MILLIONS) BY YEAR

Evaluation Year	Investment During Year	Operating and Maintenance Cost
1	$23.2	$0.9
2	$9.5	$1.0
3	$9.5	$1.1
4	0	$1.1
5	0	$1.1
6	0	$1.1
7	0	$1.1
8	0	$1.1
9	0	$1.1
10	0	$1.1
11	$1.4	$1.1
12	$1.4	$1.1
13	$1.4	$1.1
14	0	$1.1
15	0	$1.1
16	0	$1.1
17	0	$1.1
18	0	$1.1
19	0	$1.1
20	0	$1.1

G. Other Anticipated Expenditures

We anticipate that the proposed rule would affect all facilities defined as hospitals and included in NAICS 622, including general medical and surgical hospitals, psychiatric and substance abuse hospitals, and other specialty hospitals. We did not quantify impacts on nursing and residential care facilities (NAICS 623). The proposed rule would impact hospitals by encouraging them to accelerate the efficient use of bar code reading technology in hospital bedside point of care settings. The expected increased investment would lead to a significant reduction in the number of ADEs among hospital patients. We assume that investments by the health care sector are made at the beginning of each period.

The hospital sector has long considered the application of bar code reading technology for its facilities. According to the AHA, almost half of the hospitals in the United States have explored the possibility of independently installing this technology. A few (about four percent of all hospitals) are currently using some form of computerized systems in their medication processes, and half of them use bar codes in everyday practice. However, because hospitals currently have no standardized bar coded information for all therapeutic products, each hospital must generate and internally affix bar codes that are only applicable within that specific facility. In some cases, hospitals overpackage drug products in order to make current scanning systems usable. This extra effort reduces the expected efficiency of the bar code reading systems and has been a barrier to the general acceptance of readable technology. Standardized universal codes would remove this impediment and encourage health care facilities to invest and use technology to reduce patient ADEs.

Hospital facilities will face significant capital investments and significant process changes in order to implement bar code reading and scanning technology. ERG estimated that the average initial cost to a typical hospital for installation of scanners, readers, software, initial training etc. is $377,000.[9] In addition, although there is considerable uncertainty, ERG contacted hospital industry executives and consultants who agreed that negative productivity effects were likely after installation of a bar code reading system. The contacts noted that using the scanners could result in reductions in patient ward productivity because current scanners and administration procedures would have to be revised to accommodate this technology. Difficulties could arise, for example, when multiple doses of medication are required at the same time for different patients and when current administrative practices, such as pre-preparing certain medication, could not be accommodated with the bar code reading systems. Also, moving the scanner and reader from room to room, not adequately reading the bar code on one swipe, and other procedural changes might result in operational inefficiencies. It is possible (and hopeful) that long-term process changes would moderate or eliminate these potential inefficiencies, but our analysis assumes that hospital ward productivity levels would fall by three percent annually over the evaluation period. The annual opportunity costs of these productivity losses, together with the operation and maintenance expenses, amount to $320,000 per year for the average sized hospital. Some of these expected productivity losses would be mitigated by efficiency gains in other hospital procedures and are discussed later.

Despite these costs, interviews with consultants in the field of health care technology indicate that hospitals are gradually making this commitment. Experts have predicted that in the absence of this proposed rule, the hospital sector would likely install bar code readable technology within 20 years. Therefore, we believe that, while approximately 131 hospitals currently use bar codes in everyday operations, the remaining 6,460 hospitals would ultimately invest in this technology. The experts have also predicted that if standardized bar code information on medications were available to allow scanning systems to capture information without requiring in-facility labeling systems, many hospitals would make these investments much earlier. For example, ERG estimated that if in-hospital pharmacy operations were no longer required to repackage and relabel products because of the proposed rule, the annual operating and maintenance costs of a bar code scanning system would fall from $377,000 to $314.800. Thus, we believe that the proposed rule would effectively prompt facilities to accelerate these investments.

[9] Per hospital expenditures and benefits are based on an average sized hospital based on bed capacity. The average United States hospital has 191 beds (ASHP, 1999).

Based on ERG's discussions with industry consultants, we predict that the rule could double the rate of hospital investment in this technology, thereby achieving the installation of complete systems within 10 years. For example, for those hospitals that now expect to acquire bar code systems within 10 years, we assume the availability of standardized bar codes on medications would accelerate the purchase to within 5 years. The cost to the hospital of this accelerated investment expenditure would be the opportunity cost of the investment capital for 5 years (the difference between making the investment in year 5 as opposed to year 10) as well as the five additional years of maintenance expenses and productivity losses. In addition, industry experts suggest that systems of bar code readers and scanners would require software and equipment upgrades within 10 years of installation. For the example facility, the installed system would require upgrades during the 15th project year under the accelerated investment, whereas upgrades would not occur until the 20th year in the absence of a regulation. We acknowledge that precise estimates of the rate of acceleration of technology acceptance are highly uncertain, but industry experts have indicated that doubling the rate of technology acceptance is a reasonable assumption. Alternative rates of acceptance were analyzed and discussed as a sensitivity exercise. We specifically invite public comment on the feasibility of this assumption.

ERG used a Probit function to estimate the annual rate of acceptance. This function assumes a normal density distribution for the selected period and has been used to describe rates of technology acceptance for other new products. Consequently, over the 20-year period, FDA estimates the PV of the costs of the accelerated investment in bar coding technology by hospitals, including the annual operating expenses and productivity losses, to be $7.2 billion. The estimated annualized cost is $680.0 million. Table 4 shows the expected annual incremental expenditures by year for adopting hospitals under the proposed rule.

TABLE 4.—EXPECTED INCREMENTAL HOSPITAL EXPENDITURES (IN MILLIONS) PER YEAR[1]

Evaluation Year	Incremental Cost to Hospitals Adopting Bar Codes[1]
1	$1.2
2	$18.9
3	$129.8
4	$506.9
5	$1,187.4
6	$1,823.6
7	$2,062.7
8	$1,934.0
9	$1,617.8
10	$1,226.8
11	$834.3
12	$499.2
13	$254.5
14	$102.4
15	($15.3)[2]
16	($29.4)
17	($34.5)
18	($35.6)
19	($36.0)
20	($36.0)

[1] Reflects both negative and direct positive fixed productivity changes. Hospitals expected to install bar code systems without the proposed rule would not achieve productivity gains associated with internal repackaging. Therefore, given the different expected rates of technology adoption with the proposed rule, the hospital sector would have net productivity gains beginning in the 15th evaluation year.

[2] Numbers in parentheses indicate cost reductions from baseline.

H. Reduction in Preventable Adverse Drug Events

The benefits of the proposed rule are focused on the reductions in ADEs that would follow the earlier use of bar code reading technology and bar coded drug products. We have not quantified all of the other institutional benefits of computerized systems and medical informatics, but have estimated a potential range of efficiency gains. Any ADEs avoided during a period are analyzed as if they occur at the end of the period.

ERG determined that, under current conditions, about 1.25 million ADEs occur each year in the United States, of which 372,400 are preventable. As discussed above, the proposed rule would substantially reduce the number of ADEs caused by errors originating in the dispensing and administration of pharmaceutical or blood products in hospitals. Studies of medication errors in hospitals that have installed bedside bar coding and use internally applied labels show error interception rates of from 70 percent to 85 percent (Malcolm et al., 1999; Yang et al., 2001; Brown, 2002; Rough, 2002; and Churchill, 2002). Other industry experts, however, suggest that those published interception rates would not be as high if the technology were widely dispersed, because of the likelihood of events such as lost wristbands, erroneous bar codes, or intentional system bypasses. Therefore, FDA and ERG have assumed that bar code system use would produce no reduction in prescribing and transcribing errors, but that its use would intercept one-half of 45.1 percent of all preventable ADEs that now originate in the dispensing and administration stages of the medication process. Thus, ERG assumed that if all hospitals adopted bar code systems, the number of preventable ADEs would fall by 22.6 percent (45.1 times 0.5), which would prevent about 84,200 ADEs per year (372,400 times 0.226). This equals a reduction of 12.8 preventable ADEs per year for an average hospital. We believe the assumption that bar code readers could intercept one-half of both dispensing and administration errors is reasonable and conservative, but we specifically invite comment on alternative interception rates. This assumption is tested as a sensitivity analysis.

We estimate that the proposed rule, by stimulating earlier hospital investment in bar code scanning systems, would produce a corresponding increase in the number of avoided ADEs. To project the aggregate number of ADEs avoided due to the proposed rule, ERG calculated the number of ADEs per hospital that would be avoided by bar coding systems and multiplied that number by the additional number of hospitals that would use bar coding reading systems during each year of the evaluation period. For example, during the 10th evaluation year, our model predicts that 3,295 more hospitals would have installed bar code reading systems than would have installed them in the absence of the rule. The additional hospitals using bar codes would intercept an estimated 42,182 errors (12.8 ADEs per hospital times 3,295 hospitals) that would otherwise have resulted in ADEs during that year. Over the entire evaluation period, this methodology predicts that the accelerated investment would avoid over 413,000 ADEs.

I. Value of Avoided ADEs

FDA and ERG estimated two values of avoided preventable ADEs. First, ERG estimated the avoided direct hospital

costs needed to cover additional tests, longer patient stays, and other direct expenses. Based on published studies, the estimated average direct cost of an ADE not attributable to prescribing error is $2,257 (Classen et al., 1997; Bates et al., 1997; and Senst et al., 2001). This figure represents a weighted average of direct hospital costs over all degrees of ADE severity and does not include patient pain and suffering or liability. Second, ERG and FDA estimated the monetized value of avoiding decreases in quality-adjusted life years (QALYs) due to ADEs. This latter approach attempts to value a patient's subjective ADE experience, including inconvenience, pain and suffering, foregone earnings, and other out-of-pocket costs.

ERG examined the literature to determine the probability distribution of specific symptoms associated with ADEs. These reported symptoms range from rashes and itching to cardiac arrhythmia, renal failure, and mortality. The duration of each symptom (additional length of hospital stays) ranged from about 0.7 days to 5.5 days (except for mortality). ERG then examined reported preference scores from the Harvard Center for Risk Analysis' (HCRA) Catalog of Preference Scores, which includes a survey of the health economics literature and presents published estimates of preferences for defined symptoms. The preference scores ranged from 0.95 (for significant but not serious ADEs) to 0.00 for death. Typical symptoms encountered with serious ADEs had a preference score of 0.8, while life-threatening ADEs had a derived preference score of 0.6. We note that the reported preference scores vary widely by definition and methodology and must be interpreted with great caution.

ERG calculated the change in QALYs expected from an avoided ADE as one minus the preference score multiplied by the duration of the event. For example, minor drug toxicity (such as a rash) has a derived preference score of 0.95 and a reported duration of 2 days (0.005 years). The change in QALYs expected for such an event is 0.05 (one minus 0.95) times 0.005, or 0.0003 QALYs. There are no precise means of valuing QALYs. One approach is to derive the value from studies that estimate the willingness-to-pay to avoid a statistical death. For example, values derived from occupational wage-premiums to accept measurable work-place risk suggest a figure of about $5 million per statistical death avoided. Apportioning this value over the remaining life expectancy of the average workforce member and adjusting for future disability implies (at a 7-percent discount rate) a value per QALY of about $373,000. Thus, in the example above, the value of the decease in QALYs due to minor drug toxicity would be $102.

ERG examined the literature and found that by combining several published accounts, 36.1 percent of the outcomes associated with preventable ADEs were deemed significant, 41.7 percent were deemed serious, 19.4 percent were deemed life threatening (of which 10 percent (or 1.9 percent of the total) result in permanent conditions), and 2.8 percent resulted in fatalities. Overall, these assumptions indicate that the weighted average preference value for each avoided preventable ADE is $181,600. We note that this value is very sensitive to the number of fatal preventable ADEs.

J. Aggregate Benefit of Avoiding ADEs

FDA and ERG estimated the benefit of avoiding ADEs due to the use of bar code reading systems by multiplying the value of each avoided preventable ADE by the expected number of ADEs avoided. As stated earlier, an average hospital is expected to have 12.8 fewer preventable ADEs each year after installing bar code reading technology. The direct cost savings by avoiding treatment ($2,257 per ADE) and the weighted preference value ($181,600 per ADE) indicate a societal value of $183,900 per average ADE avoided, and a societal benefit of about $2.35 million per facility per year. We multiplied this derived value per hospital by the expected difference in the number of hospitals with installed bar code technology under the proposed rule. For example, during the 10th evaluation year, an estimated 3,245 additional hospitals would have installed bar code reading systems due to the proposed rule. We would expect the increased use of these systems to result in 42,182 fewer ADEs. The estimated PV of avoiding these ADEs is $7.7 billion. The PV of the societal benefits that would result from reductions in ADEs over the entire 20- evaluation period is $41.4 billion. The annualized societal benefit of the reduced number of ADEs is $3.9 billion. Table 5 illustrates the expected reduction in ADEs for the entire evaluation period.

TABLE 5.—EXPECTED REDUCTION IN ADEs BY YEAR WITH BAR CODE (SOCIETAL BENEFITS IN MILLIONS)

Evaluation Year	Additional ADEs Avoided	Societal Benefit of Avoided ADEs
1	38	$7.0
2	627	$113.7
3	4,314	$781.9
4	16,845	$3,053.5
5	39,462	$7,153.4
6	60,634	$10,991.1
7	68,646	$12,443.6
8	64,486	$11,689.5
9	54,144	$9,814.7
10	41,344	$7,494.5
11	28,493	$5,164.9
12	17,523	$3,176.5
13	9,510	$1,724.0
14	4,531	$821.4
15	1,882	$341.1
16	678	$123.0
17	218	$39.4
18	51	$9.3
19	13	$2.3
20	0	0

K. Other Benefits of Bar Code Technology

The availability of standardized bar codes would result in additional benefits to patients and the health care sector. As bar codes are an enabling technology, their adoption for hospital patient care would foster their use in other hospital and nonhospital settings. With automated systems, hospitals would no longer need to repackage and self-generate bar codes. Hospital pharmacies and wards would likewise take advantage of the availability of bar coded products to generate new production efficiencies for activities such as reporting, record keeping, purchasing, and inventory controls. For example, integrated scanning systems may allow for electronic versions of daily Medication Administration Records (MARs) and pharmacy reconciliation reports. According to industry experts, if these activities could be avoided by automatically generating the records, an average sized hospital could save as many as 592 hours of pharmacist resources and 4,233 hours of nursing resources each year. The estimated annual efficiency savings of avoiding these opportunity costs equals $167,000. Moreover, ERG and FDA believe the identified potential gains from electronic MAR and reconciliation reports may account for only between 50 and 80 percent of the potential gains in these areas. If so, the total estimated annual efficiency gains to an average hospital would range from $209,000 to $334,000 from use of bar code scanners in pharmacies and patient care wards. These new operation efficiencies would continue beyond the evaluation period. If such gains were obtainable, the PV of these gains for the sector as a whole would be between $4.8 billion and $7.6 billion. The average annualized gains of these potential efficiencies are between $451.5 million and $721.5 million.

The proposed rule could also increase the use of medical informatics in locations other than hospitals. Other health care facilities, such as physician offices and home health delivery systems, would be more likely to adopt bar coding and scanning systems to safeguard the use of patient medications and achieve additional efficiencies. We could not quantify the value of all of these expected additional uses of bar coding, but note that they are realistic and practical future uses of the technology.

L. Distributional Effects of Bar Code Technology

Bar code usage would likely result in distributional transfers between sectors of society. For example, bar code use could reduce hospital payments due to punitive damage awards from potential lawsuits. According to legal data bases (JVR, 2002), there were approximately 35,000 personal injury and malpractice claims per year between 1995 and 2000 in the health care sector. Approximately half of these claims involved pregnancies with the remainder including surgical claims, misdiagnosis, and medication errors. If these claims are distributed equally by type and sector (inpatient and outpatient), we estimate that approximately 600 legal claims per year are potentially associated with preventable ADEs in hospitals. This implies that only 0.2 percent of all preventable ADEs are likely subject to legal claims (600 divided by 372,400). The average jury award for damages from medication errors was $636,800 in 2000, although only 40 percent of the cases were decided for plaintiffs. Estimated pre-trial settlements for malpractice claims in 2000 averaged $318,400. We do not have data on the proportion of settlements, but have assumed that 80 percent of claims are settled before trial. If so, the average likely award per preventable ADE is $532. Bar code systems are expected to avoid 12.8 ADEs per year in an average hospital. This implies an average reduction in annual legal awards of $6,800 per hospital and $43.9 million for all hospitals. Fewer awards would also result in lower malpractice insurance premiums, which would reduce other hospital expenditures. The General Accounting Office (GAO, 1995) reported hospital malpractice insurance rates ranging between $511 and $7,734 per bed, depending on location. Recent reports have suggested that annual premiums have increased to approximately $1,250 to $18,800 per bed. Although we were unable to quantify average hospital malpractice premiums or precise reductions in hospital liability insurance premiums due to the use of bar codes, the potential exists for industry savings. While reductions in legal settlements or liability insurance premiums represent transfers between hospitals, third-party payers, attorneys, and patients, and are not opportunity gains or losses, such reductions could increase the efficient allocation of resources by sector.

Bar code systems may also increase hospital revenues by improving the ''cost capture rate.'' One published study (Lee et al., 1992) reported the cost capture rate (the ratio of billed uncontrolled pharmaceuticals to all pharmaceuticals used) increased from 63 percent to 97 percent after installation of computerized systems in nursing wards. According to the authors, this would imply an increase in revenues of approximately $65,000 per year for an average hospital. While such accounting improvements are transfers from patients and third-party payers to hospitals rather than reduced opportunity costs, this practice illustrates the potential use of bar code scanning systems in increasing the efficient allocation of resources by sector. Other potential transfers may include avoidance of certain billing errors or increased timeliness of payment.

Although reduced lawsuits and liability insurance and increased cost capture represent transfers, they are also critical in determining whether and at what rate hospitals will adopt bar code technology. Combined with the efficiency gains explained previously, these transfers should allow hospitals to cover a significant portion of their bar code technology investment.

M. Comparison of Costs, Expenditures, and Benefits

The annualized costs of the proposed rule to the manufacturing, packaging, and labeling sectors totals $3.2 million. Hospitals would incur an annualized cost of $0.6 million to continue current operating practices. FDA resource costs to support the regulation equal an estimated $1.3 million per year. Thus, we estimate the annualized regulatory cost of the proposed rule to be $5.1 million. In addition, we expect the proposed rule to spur earlier investment by hospitals in bedside point-of-care systems that read bar coded labels. The annualized opportunity cost of this accelerated investment in technology is $680.0 million for the entire industry. Table 6 presents, by sector, the present value of the estimated regulatory costs, the annual costs expected at the end of the 20-year evaluation period, and the annualized costs over the entire evaluation period. The estimated reduction in hospital operating expenses results from the assumption that hospitals could eliminate in-house labeling operations.

TABLE 6.—COSTS AND OTHER EXPECTED EXPENDITURES OF PROPOSED RULE (IN MILLIONS OF DOLLARS; 20-YEAR EVALUATION PERIOD; 7-PERCENT DISCOUNT RATE)

Industry Sector	Present Value of Costs	Annual Operating Costs at End of Period	Annualized Costs
Prescription Drugs	$30.4	$0.4	$2.9
OTC Drugs	$2.1	[1]	$0.2
Blood Products	$0.7	[1]	$0.1
Sub-Total Manufacturers	$33.2	$0.5	$3.2
Hospital Regulatory	$6.1	(-$0.7)[2]	$0.6
Sub-Total Private Sector Regulatory Costs	$39.8	(-$0.2)	$3.8
FDA Oversight	$13.8	$1.3	$1.3
Total Regulatory Costs	$53.1	$1.1	$5.1
Expected Expenditures From Healthcare Sector	$7,204.3	(-$348.8)[2]	$680.0

[1] Less than $0.05 million
[2] Hospital operating costs decrease due to fewer in-house packaging and bar coding operations.

As discussed above, we estimate the annualized public health benefit to be $3.9 billion. This estimate includes the societal value of the avoided ADEs as well as the reduced hospital stays expected due to the earlier use of bar code reading technology. Other indirect potential benefits, such as efficient inventory control, patient tracking, electronic generation of daily reconciliation and medication reports, or other administrative gains were estimated to contribute an annualized amount of between $451.5 and $721.5 million in efficiency gains to hospitals. The likely distributional effects of revenue enhancement, other cost capture measures, or reduced legal costs are not completely quantified, but are likely.

If all costs and expenditures are combined, the annualized outlays total $685.1 million. The expected annualized public health benefit of over $3.9 billion far outweighs these outlays. Thus, the annual net benefits for the entire evaluation period are greater than $3.2 billion. Moreover, this calculation does not account for the potential efficiency gains as described above.

N. Uncertainty and Sensitivity

We recognize that the expected impacts of the proposed rule are based on a large number of uncertain assumptions. We attempted to account for this uncertainty by examining the key assumptions in the analysis.

1. Voluntary Share of Labeling Costs

The costs attributable to the proposed rule are the incremental costs above what the industry would incur in the normal course of business. As briefly discussed earlier, many drug products change labels, on average, as often as once a year for marketing or design reasons. The ERG estimate, however, assumes that 30 percent of the required labeling costs would be attributable to the regulation, due to the production process changes that would be required to use bar coding equipment. In addition, we believe that market driven label changes are not completely comparable to regulation required changes. We reviewed the sensitivity of this assumption by examining the impact that would occur if no required re-labeling costs were attributable to the regulation, 75 percent were attributable to the regulation, or all re-labeling costs were attributable to the regulation. These scenarios altered the current estimate of $3.2 million in annualized costs for manufacturers, repackers, and relabelers to a range of from $2.7 million (if all costs are considered voluntary) to $4.2 million (if no additional labeling costs are considered voluntary).

2. Packaging Decisions

We are sensitive to industry packaging decisions and asked our contractor to specifically assess the impact of the proposal on the future of unit-dose packaging (e.g. blister packs) trends. The concern was whether bar code printing would reduce the use of unit-dose packaging because it would add more to its cost than to other formats. In general, ERG found that although the overall demand for the product is inelastic, the demand for a particular package type is more elastic in that it is affected by relative prices to a greater degree. Industry contacts, however, noted that this impact is moderated because consumers of some OTC drug product are accustomed to blister packs, and manufacturers could lose market share if they abandon this format. Also, many hospitals require drug purchases to be in unit-dose form.

ERG concluded that although a bar code requirement would increase the relative cost of the unit-dose version of a product, the cost increment would not be great enough to significantly impact the market. In fact, ERG found that the expected reduction in hospital over-packaging could increase market demand for unit-dose products despite the cost difference. Thus, we expect that the proposed rule would not have a significant impact on product packaging choices.

3. Mortality Associated with ADEs

FDA's contractor estimated that 2.8 percent of preventable ADEs are fatal. This was derived by averaging results from several medical studies. These studies relied on relatively small samples and varying methodologies. Due to the uncertainty attached to this estimate and the major impact this assumption has on valuing public health benefits, we tested two additional mortality rates: one percent and 0.1 percent. These rates reduce the expected value of an avoided ADE from $183,900 to $91,500 and $46,400, respectively, by changing the probability distribution of the expected outcomes of ADEs. The impact on the expected annualized benefits of ADE avoidance fall from $3.9 billion to $2.0 billion and $1.0 billion respectively. These estimated benefits continue to exceed the costs.

4. Value per QALY

There is no precise measure of value for quality-adjusted life-year. We have used published estimates of society's implied value of a statistical life (VSL) of $5 million derived from wage premiums required to attract employment to higher risk occupations. The life expectancy of a 35 year-old blue-collar male employee (the typical characteristics of the population for most of the wage premium studies) was adjusted for expected future bed and nonbed disability. When the implied VSL is amortized over the 41.3 years of adjusted life-expectancy, using a 7-percent discount rate, the resulting value ($373,000) may suggest a societal willingness-to-pay for a QALY. Cost-

effectiveness studies in the health economics literature have often relied on lower values, such as $100,000, to represent the monetary value of a QALY. In addition, the $5 million VSL is based on research conducted in the early 1990's and relies on relative risk and relative wages. Other typical estimates of the VSL have ranged from as low as $2 million to as high as $8 million.

We analyzed the societal benefit of the proposed rule using $100,000 as the QALY value for preventing a nonfatal ADE and the low VSL estimate of $2 million as the willingness-to-pay to avoid a fatality. The willingness-to-pay to avoid an average ADE decreased from $183,900 to $70,800 using these parameters. Overall, the estimated annualized benefit of the proposed rule fell from $3.9 billion to $1.5 billion, which would still exceed the estimated annualized costs.

5. Hospital Response Rates

The expected benefits rely on a faster rate of hospital acceptance of bar code technology than the rate expected in the absence of the regulation. The current estimate of public health benefits is based on all hospitals acquiring bar coding systems within 10 years as compared to 20 years without the proposed rule. However, because we are not requiring hospitals to make this investment, we examined the impact of different diffusion rates. ERG examined two additional scenarios: one in which the technology is accepted within 20 years with a rule as compared to 30 years without a rule, and one in which technology is accepted within 15 years, as compared to 20 years with a rule. Both cases decrease costs and benefits. The first case reduced expected net annualized net benefits from $3.2 billion to $2.0 billion. Annualized hospital expenditures declined from $680 million to $408 million, and benefits decreased from $3.9 billion to $1.8 billion. The second case reduced annualized net benefits to $1.5 billion. Annualized hospital expenditures declined from $680 million to $303 million, and benefits decreased from $3.9 billion to $1.8 billion. The public health benefits of the proposed rule would still exceed costs and expenditures with these slower diffusion rates.

6. Hospital Intercept Rates with Machine-Readable Technology

The expected benefit of avoidance of patient ADEs is dependent on the expected rate of error interception. For this analysis, ERG found that about 45 percent of the errors that lead to preventable ADEs originate in the dispensing and administration stages of the medication process and that the use of bar coded information and installed systems would intercept about 50 percent of these errors. Because of the direct relationship between expected interception rates and avoided ADEs, we tested the impact of the assumed rates. Although the literature has implied that interception rates as high as 85 percent are obtainable, ERG assumed a 50 percent rate to account for potential nonoptimal use of technology. If the true increase in interception rates were between 80 percent and 20 percent, the total number of avoided ADEs would be between 660,400 and 165,000. The monetized annualized value of these avoided ADEs would vary from the current estimate of $3.9 billion to the lower and higher values of $1.6 billion (with a 20 percent improvement in interception rates) or $6.2 billion (with an 80 percent improvement in interception rates). From a societal perspective, therefore, the accelerated technology investment appears reasonable even with significantly lower interception rates.

7. Productivity Losses in Hospital Wards

The decision by hospitals to make significant investments in bar code reading technology is highly dependent on expected productivity changes in the delivery of bedside care by nurses. Our current analysis assumes a 3-percent productivity loss of ward nurses due to the use of this new technology. We examined the sensitivity of this estimate and found that if long-term productivity loss approximated only 1 percent of the current workload, the average annualized cost of accelerated hospital investments would decrease from $680.0 million to $246.7 million. However, if the productivity loss of nursing resources was as great as 5 percent, the annualized expenditures by hospitals would increase to $1.2 billion. In order for the productivity losses to outweigh the expected benefits, however, there would have to be an almost 700-percent estimated productivity loss. We recognize the extreme uncertainty of this projection and particularly invite public comment in this area.

8. Minimum Hospital Response

The expected benefits rely on a faster rate of hospital acceptance of bar code technology than the rate expected in the absence of a rule. The current estimate of public health benefits is based on all hospitals acquiring bar code systems within 10 years as compared to 20 years without the proposed rule. However, because we are not requiring hospitals to make this investment, we examined the minimum number of hospitals needed to install systems in order to be confident that benefits exceed costs. The ratio of costs to benefits implies that if only 0.05 percent of all hospitals in the United States (three facilities) make this investment 10 years earlier, the rule would generate sufficient public health benefits to justify costs. This estimate is based on average hospital size. We tested this assumption by assuming that only very small (fewer than 50 bed capacity) hospitals would adopt the technology. In this case, 22 hospitals would be required to adopt the technology (0.3 percent of all hospitals and 1.9 percent of all small capacity hospitals) in order for the expected benefits to exceed the costs.

9. Investments by Hospital Size

The internal decision to acquire and use new bar code reading technology could be affected by the size of the purchasing hospital. Hospitals that have already installed this equipment are, for the most part, fairly large or part of a large network of hospitals. Because the benefits of error interception are dependent on the number of annual admissions, we were concerned about the likelihood of technology adoption by small hospitals.

According to the most recent census, there are 1,117 hospitals in the United States with capacities fewer than 50 beds. These hospitals account for only about 3 percent of the estimated annualized opportunity cost of investment from this proposed rule, because the potential productivity losses are not as great as for larger hospitals. The annualized opportunity costs per facility with fewer than 50 beds is approximately $57,100. However, because of the fewer admissions to hospitals of this size, we estimate that the interception rate of the bar code technology is expected to result in an average of 1.7 avoided ADEs per year per facility. The estimated societal benefit of avoiding 1.7 ADEs is $303,800. If these small hospitals adopt technology at the same accelerated rate as all hospitals, the annualized benefit per hospital is $86,900, or more than the investment.

We are aware that the estimated direct annual hospital cost savings of avoiding ADEs alone ($2,257 per avoided ADE) may not cover the costs of the expected earlier investment pattern. For example, the average facility with fewer than 50 beds would experience direct annual cost savings of $3,837 (1.7 ADEs avoided x $2,257) and annualized costs

of $57,100. As noted, the investment decision to install bar code reading technology is voluntary and would include consideration of patient safety and other cost-savings. We have estimated that potential reductions in resources needed to generate reports and to keep track of records may likely vary between $27,400 and $43,700 per year for a small hospital. Other institutional gains, including transfers such as increased revenue capture rates and reduced malpractice awards, may also affect internal decisions. Many industry representatives have indicated their willingness to invest in this technology. Nonetheless, even if some hospitals choose to delay or not to invest, this rule would still produce substantial societal benefits.

O. Small Business Analysis and Discussion of Alternatives

We believe the proposed rule is unlikely have a significant impact on a substantial number of small entities. Despite this, we have prepared an initial Regulatory Flexibility Analysis (IRFA) and invite comment from affected entities. In addition, the regulation is considered a significant economic impact under UMRA and alternatives are examined and briefly discussed here.

1. Affected Sectors and Nature of Impacts

We described the affected industry sectors earlier in this section. The proposal would directly affect manufacturers of pharmaceutical and biological products (NAICS 325412 and NAICS 325414), packaging services (NAICS 561910), and blood and organ banks (NAICS 621991), and indirectly affect hospitals (NAICS 622). We accessed data on these industries from the 1997 Economic Censuses and estimated revenues per establishment. Although other economic measures, such as profitability, may be preferable alternatives to revenues in estimating the significance of regulatory impacts in some cases, any reasonable estimate of profits would not change the results of this analysis. These revenues were updated to 2000 values by using the Consumer or Producer Price Index as appropriate.

a. *Pharmaceutical Manufacturers (NAICS 325412)*. The Small Business Administration (SBA) has defined as small any entity in this industry with fewer than 750 employees. According to census data, 84 percent of the industry is considered small. The average annual revenue for these small entities is $26.6 million per entity. Small manufacturers of prescription and OTC drug products dispensed under an order and commonly used in hospitals would be required to generate and label products with bar coded information. We estimate the annualized compliance costs for small entities in this industry at $1,800 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

b. *Biological Product Manufacturers (NAICS 325414)*. The SBA has defined as small any entity in this industry with fewer than 500 employees. According to census data, 68 percent of the industry is considered small. The average annual revenue for these small entities is $4.7 million per entity. Small manufacturers of biological products would be required to use standardized bar code information on their products. We estimate the annualized compliance costs for small entities in this industry at $600 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

c. *Packagers (NAICS 5619190)*. The SBA has defined as small any entity in this industry that has less than $6 million in annual revenues. On this basis, almost 75 percent of the industry is considered small. The average annual revenue for small entities is $1.7 million per entity. Small packagers would be required to apply bar coded information to all affected products. This would require printing and process improvements to packaging operations. We estimated the annualized compliance cost for small entities in this industry at $240 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

d. *Blood and Organ Banks (NAICS 621991)*. The SBA has defined as small any entity in this industry with less that $8.5 million in annual revenues. On this basis, 40 percent of the industry is considered small. The average annual revenue for small entities is $1.4 million per entity. Small blood banks and collection centers would be required to apply standardized bar coded information on all blood products. This would require printing and process improvements to blood handling operations. We estimated the annual compliance cost for small entities in this industry at $100 per entity. This is less than 0.1 percent of their annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

e. *Hospitals (NAICS 622)*. The SBA has defined as small any entity in this industry with less than $29.0 million in annual revenues. According to census data, 35 percent of the industry is considered small. The average annual revenue for small entities is $12.6 million per entity. There is no specific regulatory requirement for hospitals to respond to this proposed rule. We anticipate that the rule would make the investment in bar code technology more attractive to hospitals, but the rule would not require such investments. Hospitals that have already installed bar code reading systems and internally affix self-generated information might need to prematurely upgrade or replace currently installed scanners in order to capture bar coded information on small vials or bottles. These hospitals would also achieve productivity gains by avoiding the resources now used to self-generate bar code readable information. The total annual net cost of the proposed rule is estimated at $3,300 per facility, which is equal to less than 0.1 percent of annual revenues. We believe this does not constitute a significant impact on a substantial number of small entities in this industry.

2. Alternatives

We considered several alternatives to the proposed rule. Each is discussed below. We invite comments and suggestions for additional potential alternatives.

a. *Do Nothing*. This alternative would not result in any change in current labeling or packaging practices. We believe that, in the absence of agency action, hospitals would gradually purchase and utilize independent bar code reading systems, but that it would take 20 years before they were installed in all facilities. We rejected this alternative because of the expected positive net benefits of the proposal. Also, we believe that standardizing bar codes would generate additional health and production efficiencies for a variety of different health care sectors.

b. *Requiring Variable Information*. We considered requiring additional information in bar codes, such as expiration dates and lot numbers. The incremental benefit of this data would include improved inventory control and ease of recalls. In addition, we are aware that some firms are voluntarily applying this information. However, we were unable to quantify potential public health benefits for this additional information, and the estimated additional annualized cost of this

alternative was $46.0 million. We did not select this alternative because we could not demonstrate that the added benefits would exceed the added costs.

c. *Covering All OTC Drug Products*. We considered requiring all OTC drug products to include bar coded information. This alternative is currently rejected (although we invite comments on the OTC drugs to be covered) because the additional costs do not appear to be justified by the expected benefits. At this time, most noninstitutional settings are unlikely to have access to bar code reading systems. Therefore, we could not identify any significant reductions in ADEs due to this alternative. Including all OTC drug products would create estimated additional annualized costs to the manufacturing sector of $1.9 million. The expected annualized costs of the regulation therefore would increase from $5.1 million to $7.0 million with no additional quantifiable benefit.

d. *Exemption for Small Entities*. We considered exempting small entities, but rejected the alternative due to the modest projected impact of this initiative on small businesses and the lack of label standardization that would result.

e. *FDA Selecting a Specific Symbology*. We considered requiring bar coded information with a specific symbology. The rationale for considering this option was to minimize uncertainty to hospitals in selecting systems that would be able to confidently read the specific language. We decided, however, that identifying a specific symbology might adversely impact future innovations in other machine-readable technologies. The selected alternative would allow individual facilities and suppliers to devise systems that would maximize their own internal efficiencies, as long as the standardized information could be accessed. The lack of consistent universal standards has been a major impediment to the use of this technology. As long as symbologies could be read within a single standard, however, the identified market failure would be overcome. In addition, the expected costs of this proposal would be much greater than the selected alternative. Annualized costs to manufacturers would increase to $8.3 million and significant costs would occur to the retail sector due to the need for accelerated upgrade or replacement of currently installed scanners. Retail pharmacies would incur annualized costs of $14.4 million. Consequently, we rejected the alternative of identifying a specific symbology.

3. Outreach

We held a public meeting on July 26, 2002 to solicit comments from the affected sectors. Interested parties from the health care sector, manufacturing sector, retail sector, and equipment suppliers provided comment and insight to the agency. In addition, we met with various industry groups in order to ensure viewpoints were appropriately considered. These insights affected the regulatory considerations, and additional outreach is planned during the regulatory process.

P. Conclusion

We have examined the proposed rule and find that the expected benefits outweigh the costs and that the regulation would improve public health. The detailed analysis that provides references and support for the summary that appears in this section is available in the docket as Ref. 46.

VIII. Request for Comments

In addition to requesting general comments on the proposal, and the specific requests on assumptions contained in the economic analysis, we are seeking comment on the following specific issues identified in the description of the proposed rule (presented here for the convenience of the reader):

1. Whether we should require bar codes on prescription drug samples, and the costs and benefits associated with such bar codes (see section II.B.2.a of this document).

2. The risks and benefits of including vaccines in a bar code rule (see section II.B.2.a of this document).

3. What terms we should use to describe OTC drugs that should be subject to the bar code requirement (see section II.B.2.b of this document).

4. Information on the costs and benefits associated with putting lot number and expiration date information in the bar code (see section II.C.2 of this document).

5. Whether the rule should refer instead to linear bar codes without mentioning any particular standard or refer to UCC/EAN and HIBCC standards (see section II.D.1 of this document).

6. Additional information regarding bar code scanning technology and the ability of bar code scanners to read different symbologies (see section II.D.1 of this document).

7. Whether the rule should adopt a different format (whether that format is a symbology, standard, or other technology), considering the following issues:

- What other symbol, standard, or technology should we consider, either in place of a linear bar code or in addition to it?
- How accepted is that symbol, standard, or technology among firms that would have to affix or use that symbol, standard, or technology?
- Will hospitals be able to read or use the symbol, standard, or technology, either with existing equipment or equipment under development? (see section II.D.1 of this document).

8. Whether any specific product or class of products should be exempt from a bar code requirement and the reasons why an exemption is considered to be necessary (see section II.F of this document). In addition, how could we create a waiver provision that would minimize the potential for misusing the waiver?

9. Whether the implementation period for a final rule can and should be shortened from 3 years to some other specific time period (see section II.G of this document).

10. Whether we should require the use of ISBT 128 for blood products, a specific symbology that is consistent with that required for drugs in proposed § 201.25, or ''machine-readable symbols'' as approved by the Director of CBER (see section II.H of this document).

11. How the proposed rule might affect hospitals where patients receive blood or blood components, particularly with respect to a hospital's decision to purchase a machine reader (e.g., scanner) that can properly identify the intended recipient of the blood or blood component, the machine readable information encoded on the blood or blood component label, and perhaps the linear bar codes appearing on drugs and OTC drugs that are dispensed pursuant to an order and commonly used in the hospital (see section II.H of this document).

12. Whether any of the alternatives discussed in the economic analysis have merit (see section VII.O of this document).

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 mailed 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.

IX. References

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 am. and 4 p.m., Monday through Friday.

1. Institute of Medicine, ''To Err Is Human: Building a Safer Health System,'' 1999.
2. McDonald, C. J., M. Winer, and S. L. Hui, ''Deaths Due to Medical Errors Are Exaggerated in Institute of Medicine Report,'' *Journal of the American Medical Association*, 284:93–95, July 5, 2000.
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6. Agency for Healthcare Research and Quality, ''Reducing and Preventing Adverse Drug Events to Decrease Hospital Costs'' at pages 4 to 6.
7. Department of Health and Human Services, ''HHS News: 'Secretary Thompson Announces HHS Patient Safety Task Force','' April 23, 2001.
8. Testimony of Tommy G. Thompson, Secretary of Health and Human Services, before the Senate Committee on Health, Education, Labor, and Pensions' Subcommittee on Patient Health, May 24, 2001.
9. Letter from Henri R. Manasse, Jr., Executive Vice President and Chief Executive Officer, ASHP, to the Honorable Tommy G. Thompson, Secretary of Health and Human Services, dated July 10, 2001, at p. 1.
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15. Bates, D. W., ''Using Information Technology to Reduce Rates of Medication Errors in Hospitals,'' *British Medical Journal*, 320: 788–791, March 18, 2000.
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17. Malcolm, B., R. A. Carlson, C. L. Tucker, and C. Willette, ''Veterans Affairs: Eliminating Medication Errors Through Point-of-Care Devices,'' Technical paper for 2000 Annual HIMSS Conference, November 30, 1999.
18. Hokanson, J. A. et al., ''Potential Use of Bar Codes to Implement Automated Dispensing Quality Assurance Programs,'' *Hospital Pharmacy*, 20: 327–337, May 1985.
19. Dinklage, K. C., S. J. White, J. C. Lenhart, and H. N. Godwin, ''Accuracy and Time Requirements of a Bar-Code Inventory System for Controlled Substances,'' *American Journal of Hospital Pharmacy*, 46: 2304–2307, November 1989.
20. Davis, N. M., ''Detection and Prevention of Ambulatory Care Pharmacy Dispensing Errors,'' *Hospital Pharmacy*, 25: 18–28, January 1990.
21. Meyer, G. E. et al., ''Use of Bar Codes in Inpatient Drug Distribution,'' *American Journal of Hospital Pharmacy*, 48: 953–966, May 1991.
22. Hynniman, C. E., ''Drug Product Distribution Systems and Departmental Operations,'' *American Journal of Hospital Pharmacy*, 48: S22–S35, October 1991 (Supplement 1).
23. Carmenates, J. and M. R. Keith, ''Impact of Automation on Pharmacist Interventions and Medication Errors in a Correctional Health Care System,'' *American Journal of Health System Pharmacy*, 58(9): 779–783, May 1, 2001.
24. Transcript from ''Public Hearing: Bar Coding—A Regulatory Initiative,'' at pages 13–14 (remarks of Kay Willis, Chief of Pharmacy, VA Medical Center, Chicago, IL).
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26. The Leapfrog Group, ''Fact Sheet: Computer Physician Order Entry (CPOE),'' dated November 2000.
27. Quality Interagency Coordination Task Force, ''Doing What Counts for Patient Safety: Federal Actions to Reduce Medical Errors and Their Impact—Report of the Quality Interagency Coordination Task Force (QuIC) to the President,'' at page 74 (February 2000).
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29. American Society of Health-System Pharmacists, House of Delegates Session–2001, Policy Recommendation F, ''Machine-Readable Coding,'' dated June 4 and 6, 2001.
30. Testimony of Albert Patterson, Vice-President for Contracting, Premier, Inc., before the Senate Subcommittee on Science, Technology, and Space, dated July 23, 2001.
31. Letter from Robert A. Hankin, President and CEO, Health Industry Business Communications Council (HIBCC), to the Honorable Tommy G. Thompson, Secretary of Health and Human Services, dated January 3, 2002.
32. Letter from Herb Kuhn, Corporate Vice-President, Premier, Inc., and others, to the Honorable Tommy G. Thompson, Secretary of Health and Human Services, dated January 24, 2002.
33. Letter from Joe Pleasant, Chair of Board, Premier, Inc., and others for the Coalition for Healthcare eStandards, to the Honorable Tommy G. Thompson, Secretary of Health and Human Services, dated March 19, 2002.
34. Food and Drug Administration, ''Guidance for Industry: Prescription Drug Marketing Act Regulations for Donation of Prescription Drug Samples to Free Clinics'' (draft), June, 2002.
35. Uniform Code Council, ''Case Study: Alcon Laboratories, Reduced Space Symbology on Small Healthcare Items from Print to Beside'' (sample GTIN applied using RSS on 3 mL and 5 mL bottles).
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41. ASTM, ''F1851–98: Standard Practice for Bar Code Verification'' (1998).
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43. Linden, J.V. et al., ''Transfusion Errors in New York State: An Analysis of 10 Years' Experience,'' *Transfusion*, 40: 1207–1213 (October 2000).
44. FDA, ''Guidance for Industry: Recognition and Use of a Standard for the Uniform Labeling of Blood and Blood Components,'' June 2000, at page 1.
45. Food and Drug Administration, ''Guidance for Industry: United States Industry Consensus Standard for the Uniform Labeling of Blood and Blood Components Using ISBT 128,'' November 1999, at section 1, page 2.
46. Eastern Research Group, ''Impact of Proposed Barcode Regulations for Drug and Biological Products,'' Contract Number 223–98–8002, Task Order Number 21, December 2, 2002.
47. Eastern Research Group, ''Profile of Machine-Readable Technologies for Medical Applications,'' Contract Number 223–94–8031, In partial fulfillment of Task Order Number 8, December 2, 2002.

Appendix

Additional Information on Various Studies Identifying Different Types of Medication Errors

This appendix includes summaries of several articles that identify different types of medication errors, a table illustrating varied medication error rates among studies, and a list of references cited in the appendix.

I. Types of Medication Errors

Administering the Wrong Dose

Folli et al. examined errant chart orders in two large pediatric hospitals (Ref. A–1). The study defined an errant chart order as a potentially lethal error if certain consequences (such as cardiopulmonary arrest if administered at the dose ordered) resulted. The authors found that incorrect doses and missed doses were the most prevalent errors. Overdoses accounted for 55 percent of the dosing errors, while underdoses led to 26.9 percent of all errors.

In a study of adverse events in hospitalized patients, Leape et al. reviewed 30,195 randomly selected hospital records and identified 1,133 patients whose disabling injuries were caused by medical treatment (Ref. A–2). Errors in dose or method of use accounted for 42 percent of all errors.

In a study of two urban teaching hospitals, Kaushal et al. found dosing errors to be the most frequent medication error (which the authors defined as errors in drug ordering, transcribing, dispensing, administering, or monitoring) and the most frequent preventable adverse drug event (Ref. A–3).

Lesar et al. conducted a study of prescribing errors at a teaching hospital (Ref. A–4). The authors' review of 289,411 medication orders revealed 905 prescribing errors that were detected and averted, and overdoses and underdoses accounted for 28.7 and 17.8 percent of total errors respectively.

McCarthy, Kelly, and Reed studied the medication administration practices of school nurses (Ref. A–5). The authors found that 48.5 percent of school nurses surveyed reported medication errors, and overdoses or double doses were the third most commonly reported error (22.9 percent of medication errors).

Administering a Drug to a Patient Who Is Known to Be Allergic

In the Lesar review of medication orders, 6.7 percent of all medication order errors that were detected and averted involved prescribing a drug to a patient who is allergic to the prescribed drug (Ref. A–4).

In an article by Classen et al. involving a case control study of all patients admitted to a hospital in a 3-year period, medication errors due to known drug allergies represented 1.5 percent of all adverse drug events, and all were preventable (Ref. A–6).

Administering the Wrong Drug to a Patient or Administering a Drug to the Wrong Patient

A study by Thur et al. observed how nurses in two surgical units prepared to administer parenteral admixtures (which the authors defined as including only fluids to which one or more drugs were added directly into a single or primary bottle) (Ref. A–7). The authors defined ''medication error'' as including the administration of the wrong drug or solution, the wrong dosage of a drug or solution volume, an unordered or discontinued drug, or two or more pharmaceutically incompatible drugs in the same admixture. The study involved 100 observations where 331 parenteral admixtures were prepared; unordered drugs accounted for 3 percent of the errors that were observed. In one instance, the drug was administered two times per day for 4 days, even though the order for the drug had been discontinued earlier.

In the Classen et al. article that involved a case control study, of 905 prescribing errors that were detected and averted, 1.1 percent of all errors involved prescribing a drug to the wrong patient (Ref. A–6).

Administering the Drug Incorrectly

In the study by Kaushal et al. that examined 10,778 medication orders at two urban teaching hospitals, errors involving the drug's route of administration were the second most common form of medication error and accounted for 18 percent of the medication errors (Ref. A–3). These medication errors also accounted for the third-most common form (14 percent) of potential adverse drug events, which the authors defined as a medication error having a significant potential for injuring a patient.

Administering the Drug at the Wrong Time or Missing Doses

In a study of two pediatric critical care units by Tisdale, ''wrong time'' errors, which were defined as medications administered 30 minutes before or after the scheduled administration time, were the most prevalent error and accounted for a 16 percent error rate (Ref. A–8).

In McCarthy, Kelly, and Reed's study of school nurses, of the 315 school nurses who reported a medication error, 251 cited missed doses as the most common medication error (Ref. A–5).

In their study of the relationship between medication errors and adverse drug events, Bates, Boyle, et al. found that 53 percent of the medication errors surveyed involved at least one missing dose of medication (Ref. A–9).

A recently published study by Barker et al. examined 36 institutions in Colorado and Georgia and found that 19 percent of the doses administered were in error and that the most prevalent error (at 8 percent of the medication errors) was ''wrong time'' medication errors (Ref. A–10). The authors defined ''wrong time'' as administration of a dose more than 60 minutes before or after the scheduled administration time, or a 30 minute window for medications that were ordered before, with, or after a meal. However, the ''wrong time'' medication error rate ranged between zero percent for some nonaccredited hospitals in Georgia to 26.2 percent for a nonaccredited hospital in Colorado.

II. Frequency of Medication Errors

Table 1 illustrates the variation in medication error rates among several studies. Some studies suggest a medication error rate of under 7 percent, whereas others suggest a rate at or above 20 percent. The differences may be due, in part, to different definitions of medication error or different research methodology that focused on fatalities, injuries, or medication orders.

TABLE 1.—MEDICATION ERROR RATES REPORTED IN VARIOUS STUDIES

Study	Definition of Medication Error Used	Medication Error Rate
Observation of nurses in two surgical units by Thur (Ref. A–7).	''Medication error'' defined as wrong drug or solution; wrong dosage of a drug or solution volume; an unordered or discontinued drug; or two or more pharmaceutically incompatible drugs in the same admixture.	21%.

TABLE 1.—MEDICATION ERROR RATES REPORTED IN VARIOUS STUDIES—Continued

Study	Definition of Medication Error Used	Medication Error Rate
Review of 101,022 medication orders at 2 pediatric hospitals by Folli et al. (Ref. A–1).	''Errant medication order'' considered to be an order that was not in accordance with standard pediatric references, current published literature, or dosing guidelines approved by the hospital's pharmacy and therapeutics committees.	Medication order error rate was between 4.9 and 4.5 errors per 1,000 orders.
Review of 289,411 medication orders written during a 1-year period by Lesar (Ref. A–4).	Not defined.	Prescribing errors were detected at a rate of 3.13 errors per 1,000 orders.
Survey of 26,462 patients in 7 countries; 24 were considered to have died as a result of a drug or group of drugs, by Porter and Jick (Ref. A–11).	''Suspected adverse reactions'' defined as any undesired or unintended effect of a drug.	0.02% fatality rate (6 deaths were considered preventable).

TABLE 1.—MEDICATION ERROR RATES REPORTED IN VARIOUS STUDIES—Continued

Study	Definition of Medication Error Used	Medication Error Rate
Review of 30,195 randomly selected hospital records by Leape et al. (Ref. A–2).	''Adverse event'' defined as an unintended injury caused by medical management and resulted in measurable disability. The reviewers considered an adverse event to be due to ''negligence'' if they felt there was a deviation from accepted norms of treatment and after they considered other factors (such as potential consequences, frequency of risk, degree of emergency, and complexity of the case). The authors defined ''negligence'' as failure to meet the standard of care reasonably expected of an average physician qualified to take care of the patient in question.	Of the adverse events due to drug treatment, 18% resulted from negligence, although the authors also explain that negligence occurs not merely when there is error, but when the degree of error exceeds an accepted norm.

TABLE 1.—MEDICATION ERROR RATES REPORTED IN VARIOUS STUDIES—Continued

Study	Definition of Medication Error Used	Medication Error Rate
Study of 18,262 medication and intravenous fluid orders given in a 3–month period at a children's hospital by West et al. (Ref. A–12).	Not defined.	Medication order error rate ranged between 2.6 to 8.5 per 1,000 orders. Verbal medication orders had the lowest error rate, followed by computer-entered orders (6.3 per 1,000) and handwritten orders.
Study of 4,031 adult admissions of 11 medical and surgical units in 2 hospitals by Bates, Cullen et al. (Ref. A–13).	''Adverse drug event'' defined as an injury resulting from medical intervention related to a drug.	28% of adverse drug events are preventable, and there were 7.3 preventable adverse drug events per every 100 admissions.
Review of 10,070 medication orders to identify medication errors by Bates, Boyle et al. (Ref. A–9).	''Medication error'' defined as errors in the process of ordering or delivering medication, regardless of whether an injury occurred or the potential for injury was present.	5.3%.

TABLE 1.—MEDICATION ERROR RATES REPORTED IN VARIOUS STUDIES—Continued

Study	Definition of Medication Error Used	Medication Error Rate
Matched case-control study of all patients admitted to a hospital in a 3-year period by Classen et al. (Ref. A–6).	''Adverse drug event'' defined as an event that is ''noxious and unintended and occurs at doses used in humans for prophylaxis, diagnosis, therapy, or modification of physiologic functions'' but excludes therapeutic failures, poisonings, and intentional overdoses.	1% of all adverse drug events, but the authors also state that almost 50% of all adverse drug events are potentially preventable.
Review of 10,778 medication orders at 2 urban teaching hospitals by Kaushal et al. (Ref. A–3).	''Medication errors'' defined as errors in drug ordering, transcribing, dispensing, administering, or monitoring.	5.7%, with adult patients cared for in a pediatric setting experiencing the most medication errors.
Prospective cohort study in 36 institutions by Barker et al. (Ref. A–10).	''Medication error'' defined as a dose administered differently than as ordered on the patient's medical records.	19%, or nearly 2 errors every day for a typical patient receiving 10 doses per day, or, for a facility with 300 patients, almost 40 potential adverse drug events in a facility. The percentage of potentially harmful errors was 7% or more than 40 per day per 300 inpatients.
Examination of all U.S. death certificates between 1983 and 1993 by Phillips et al. (Ref. A–14).	''Medication errors are ''accidental poisonings by drugs, medicaments, and biologicals'' and have resulted from ''acknowledged errors, by patients or medical personnel.	Medication error rate rose from 1 out of every 439 outpatient deaths and 1 out of every 1, 622 inpatient deaths in 1983 to 1 out of every 131 outpatient deaths and 1 out of every 854 inpatient deaths in 1993. The authors suggest the increase may be due to an increasing willingness to attribute error deaths that were previously ascribed to natural causes.

III. References in the Appendix

The following references have been placed on display in the Dockets Management Branch (see **ADDRESSES**) and may be seen by interested persons between 9 am. and 4 p.m., Monday through Friday.

A–1. Folli, H. L., R. L. Poole, W. E. Benitz, et al., ''Medication Error Prevention by Clinical Pharmacists in Two Children's Hospitals,'' *Pediatrics*, 79:718–722, 1987.

A–2. Leape, L. L. et al., ''The Nature of Adverse Events in Hospitalized Patients,'' *New England Journal of Medicine*, 324:377–384, 1991.

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A–13. Bates, D. W., D. J. Cullen, N. Laird, et al., ''Incidence of Adverse Drug Events and Potential Adverse Drug Events,'' *Journal of the American Medical Association* 274:29–34, 1995.

A–14. Phillips, D. P., N. Christenfeld, and L. M. Glynn, ''Increase in US Medication-Error Deaths Between 1983 and 1993,'' *Lancet*, 351: 643–644, 1998.

List of Subjects

21 CFR Part 201

Drugs, Labeling, Reporting and recordkeeping requirements.

21 CFR Part 606

Blood, Labeling, Laboratories, Reporting and recordkeeping requirements.

21 CFR Part 610

Biologics, Labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, it is proposed that parts 201, 606, and 610 be amended as follows:

PART 201—LABELING

1. The authority citation for 21 CFR Part 201 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 358, 360, 360b, 360gg–360ss, 371, 374, 379e; 42 U.S.C. 216, 241, 262, 264.

2. Section 201.25 is added to read as follows:

§ 201.25 Bar code label requirements.

(a) Who is subject to these bar code requirements? Manufacturers, repackers, relabelers, and private label distributors of a human prescription drug product or an OTC drug product that is regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act are subject to the bar code requirements in this section unless they are exempt from the registration and drug listing requirements in section 510 of the act.

(b) What drugs are subject to these bar code requirements? The following drug products are subject to the bar code label requirements: Prescription drug products (excluding samples), biological products, and over-the-counter drug products that are dispensed under an order and are commonly used in hospitals. For purposes of this section, an over-the-counter drug product is ''commonly used in hospitals'' if it is packaged for institutional use, labeled for institutional use, or marketed, promoted, or sold to hospitals.

(c) What does the bar code look like, and where does the bar code go?

(1) Each drug product described in paragraph (b) in this section must have a bar code that contains, at a minimum, the appropriate National Drug Code (NDC) number in a linear bar code that meets Uniform Code Council (UCC/EAN) standards. Additionally, the bar code must:

(i) Be surrounded by sufficient blank space so that the bar code can be scanned correctly; and

(ii) Remain intact under normal conditions of use.

(2) The bar code must appear on the drug's label as defined by section 201(k) of the act.

PART 606—CURRENT GOOD MANUFACTURING PRACTICE FOR BLOOD AND BLOOD COMPONENTS

3. The authority citation for part 606 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 355, 360, 360j, 371, 374; 42 U.S.C. 216, 262, 263a, 264.

4. Section 606.121 is amended by revising paragraph (c)(13) to read as follows:

§ 606.121 Container label.

* * * * *

(c) * * *

(13) The container label must bear encoded information that is machine-readable and approved for use by the Director, Center for Biologics Evaluation and Research.

(i) Who is subject to this machine-readable requirement? All blood establishments that manufacture, process, repackage, or relabel blood or blood components intended for transfusion and regulated under the Federal Food, Drug, and Cosmetic Act or the Public Health Service Act.

(ii) What blood products are subject to this machine-readable requirement? All blood and blood components intended for transfusion are subject to the machine-readable information label requirement in this section.

(iii) What information must be machine-readable? Each label must have machine-readable information that contains, at a minimum:

(A) A unique facility identifier,

(B) Lot number relating to the donor,

(C) Product code, and

(D) ABO and Rh of the donor.

(iv) How must the machine-readable information appear? The machine-readable information must:

(A) Be unique to the blood or blood component;

(B) Be surrounded by sufficient blank space so that the machine-readable information can be scanned correctly; and

(C) Remain intact under normal conditions of use.

(v) Where does the machine-readable information go? The machine-readable information must appear on the label of any blood or blood component which is or can be transfused to a patient or from which the blood or blood component can be taken and transfused to a patient.

* * * * *

PART 610—GENERAL BIOLOGICAL PRODUCTS STANDARDS

5. The authority citation for part 610 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 355, 360, 360c, 360d, 360h, 360i, 371, 372, 374, 381; 42 U.S.C. 216, 262, 263, 263a, 264.

6. Section 610.67 is added to read as follows:

§ 610.67 Bar code label requirements.

Unless it is regulated as a device, a biological product must comply with the bar code requirements at § 201.25 of this chapter.

Dated: January 24, 2003.

Mark B. McClellan,

Commissioner of Food and Drugs.

Dated: February 6, 2003.

Tommy G. Thompson,

Secretary of Health and Human Services.

[FR Doc. 03–5205 Filed 3–13–03; 8:45 am]

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Federal Register

Friday,
March 14, 2003

Part IV

Department of Education

Office of Innovation and Improvement—Public Charter Schools Program (PCSP); Notice Inviting Applications for New Awards for Fiscal Year (FY) 2003; Notice

DEPARTMENT OF EDUCATION

[CFDA Nos.: 84.282A, 84.282B, and 84.282C]

Office of Innovation and Improvement—Public Charter Schools Program (PCSP); Notice Inviting Applications for New Awards for Fiscal Year (FY) 2003

Purpose of Program: The purpose of the PCSP is to increase national understanding of the charter school model and to expand the number of high-quality charter schools available to students across the Nation by providing financial assistance for the planning, program design, and initial implementation of charter schools and evaluating the effects of charter schools, including the effects on students, student academic achievement, staff, and parents.

Eligible Applicants: (a) State educational agencies (SEAs) in States with a specific State statute authorizing the establishment of charter schools may apply for funding. The Secretary awards grants to SEAs to enable them to conduct charter school programs in their States. SEAs use their PCSP funds to award subgrants to ''eligible applicants,'' as defined in this notice, for planning, program design, and initial implementation of a charter school; and to support the dissemination of information about, including successful practices in, charter schools. A charter school may apply to an SEA for funds to carry out dissemination activities, whether or not the charter school has applied for or received funds under the PCSP for planning or implementation, if the charter school has been in operation for at least three consecutive years and has demonstrated overall success, including—

(1) Substantial progress in improving student achievement;

(2) High levels of parent satisfaction; and

(3) The management and leadership necessary to overcome initial start-up problems and establish a thriving, financially viable charter school.

(b) Non-SEA eligible applicants may apply for funding directly from the U.S. Department of Education (Department) if the SEA in the State elects not to participate in the PCSP or does not have an application approved under the program. An ''eligible applicant'' is defined as a developer that has applied to an authorized public chartering authority to operate a charter school and has provided to that authority adequate and timely notice, and a copy, of its PCSP application, except that the Secretary or the SEA may waive these requirements in the case of a pre-charter planning grant. If an SEA's application is approved in this competition, applications received from non-SEA eligible applicants in that State will be returned to the applicants. In such a case, the non-SEA eligible applicant should contact the SEA for information related to the State's subgrant competition.

Note: The following States currently have approved applications under this program: Arkansas, California, Colorado, Connecticut, Delaware, District of Columbia, Florida, Georgia, Hawaii, Idaho, Illinois, Indiana, Louisiana, Massachusetts, Michigan, Minnesota, Missouri, Nevada, New Jersey, New York, North Carolina, Ohio, Oklahoma, Oregon, Rhode Island, Tennessee, Texas, Utah and Wisconsin. In these States, only the SEA is eligible to receive an award under this competition. Eligible applicants in these States should contact their respective SEAs for information about participation in the State's charter school subgrant program. Non-SEA eligible applicants in States that are not listed must apply directly to the Department on or before the deadline for transmittal of applications in order to be considered for funding in this competition.

Applications Available: March 14, 2003.

Deadline for Transmittal of Applications: April 28, 2003.

Deadline for Intergovernmental Review: June 27, 2003.

Estimated Available Funds: $24,750,000.

Estimated Range of Awards: State educational agencies: $500,000–$8,000,000 per year. Other eligible applicants: $10,000–$150,000 per year.

Estimated Average Size of Awards: State educational agencies: $3,000,000 per year. Other eligible applicants: $150,000 per year.

Estimated Number of Awards: State educational agencies: 4–6. Other eligible applicants: 50–75.

Note: The Department is not bound by any estimates in this notice.

Project Period: Up to 36 months.

Note: Planning and implementation grants or subgrants awarded by the Secretary or an SEA directly to non-SEA eligible applicants will be awarded for a period of up to 36 months, no more than 18 months of which may be used for planning and program design; and no more than two years of which may be used for the initial implementation of a charter school. Dissemination grants are awarded for a period of up to two years.

Applicable Regulations and Statute: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75 (except § 75.210), 76, 77, 79, 80, 81, 82, 85, 86, 97, and 99; and (b) Title V, Part B, Subpart 1 (formerly Title X, Part C) of the Elementary and Secondary Education Act of 1965 (ESEA), as amended by the No Child Left Behind Act of 2001 (NCLB), 20 U.S.C. 7221–7221j.

SUPPLEMENTARY INFORMATION: As part of wider education reform efforts to improve student achievement, the development of charter schools is an innovative approach to improving public education and expanding parental options in education. While charter school laws vary by State, public charter schools are granted greater flexibility in exchange for accountability for results. They are also public schools of choice in that all students, parents, and faculty associate with charter schools voluntarily. They are intended to stimulate the creativity and commitment of teachers, parents, students, and citizens to improve student academic achievement.

Congress reauthorized the PCSP in January 2002, in amendments to the ESEA that were included in NCLB. Under the new legislation, a non-SEA eligible applicant for PCSP funds must submit an application for a charter to an authorized public chartering authority and provide adequate and timely notice, and a copy, of its PCSP application to that agency. The SEA or the Secretary, as appropriate, may waive these requirements in cases where the eligible applicant is applying for a pre-charter planning grant or subgrant.

The new legislation also added a specific provision prohibiting local educational agencies (LEAs) from deducting funds for administrative fees or expenses from a subgrant awarded to an eligible applicant, unless the eligible applicant voluntarily enters into a mutually agreed upon arrangement for administrative services with the LEA.

When developing their proposals, applicants should be aware of Department regulations governing conflicts of interest. PCSP grantees must avoid apparent and actual conflicts of interest when administering grants and entering into contracts for equipment or services. Among other things, Federal grant recipients must develop written procurement procedures and conduct all procurement transactions in a manner that provides open and free competition. Department regulations also prohibit a person from participating in an administrative decision regarding a project if (a) the decision is likely to benefit that person or his or her immediate family member; and (b) the person has a family or business relationship with the grantee. The Department's conflict of interest regulations can be found generally at 34 CFR 74.40–74.48 and 75.524–75.525. Additional information about the PCSP,

including an application checklist, assurances, certifications, ED forms, waivers, and instructions for transmittal, is provided in the application package for this program.

The Department will hold three (3) separate competitions under this program. All SEA applicants must apply for grant funds under CFDA No. 84.282A. Non-SEA eligible applicants that propose to use grant funds for planning, program design, and implementation must apply under CFDA No. 84.282B; and Non-SEA eligible applicants that are requesting funds for dissemination activities must submit their applications under CFDA No. 84.282C.

Application Requirements and Selection Criteria for the PCSP: All SEA and Non-SEA applicants applying for PCSP grant funds must address both the application requirements and selection criteria. All SEA and Non-SEA applicants applying for PCSP grant funds may choose to respond to the application requirements in the context of their response to the selection criteria.

(1) *SEAs (CFDA No. 84.282A).*

(A) *Application Requirements (CFDA No. 84.282A).* (1) Describe the objectives of the SEA's charter school grant program and describe how these objectives will be fulfilled, including steps taken by the SEA to inform teachers, parents, and communities of the SEA's charter school grant program;

(2) Describe how the SEA will inform each charter school in the State about Federal funds that the charter school is eligible to receive and Federal programs in which the charter school may participate;

(3) Describe how the SEA will ensure that each charter school in the State receives the school's commensurate share of Federal education funds that are allocated by formula each year, including during the first year of operation of the school;

(4) Describe how the SEA will disseminate best or promising practices of charter schools to each local educational agency in the State;

(5) If an SEA elects to reserve part of its grant funds (no more than 10 percent) for the establishment of a revolving loan fund, describe how the revolving loan fund would operate;

(6) If an SEA desires the Secretary to consider waivers under the authority of the PCSP, include a request and justification for any waiver of statutory or regulatory provisions that the SEA believes is necessary for the successful operation of a charter school; and

(7) Describe how charter schools that are considered to be LEAs under State law and LEAs in which a charter school is located will comply with sections 613(a)(5) and 613(e)(1)(B) of the Individuals with Disabilities Education Act.

(B) *Selection Criteria (CFDA No. 84.282A).* SEAs that propose to use a portion of their grant funds for dissemination activities must address each selection criterion (1) through (8) individually and title each accordingly. SEAs that do not propose to use a portion of their grant funds for dissemination activities must address selection criteria (1) through (7) only, and need not address selection criterion (8).

The maximum possible score is 130 points for SEAs that do not propose to use grant funds to support dissemination activities, and 150 points for SEAs that propose to use grant funds to support dissemination activities.

The maximum possible score for each criterion is indicated in parentheses following the criterion.

To ensure fairness, if an SEA is not proposing to use grant funds to support dissemination activities, the Secretary will not consider points awarded under criterion (8) in determining whether to approve an application for funding.

In evaluating an application from an SEA, the Secretary considers the following criteria:

(1) The contribution the charter school grant program will make in assisting educationally disadvantaged and other students to achieve State academic content standards and State student academic achievement standards (25 points).

(2) The degree of flexibility afforded by the SEA to charter schools under the State's charter school law (20 points).

(3) The ambitiousness of the objectives for the State charter school grant program (15 points).

(4) The quality of the SEA's strategy for assessing achievement of those objectives (15 points).

(5) The likelihood that the charter school grant program will meet those objectives and improve educational results for students (15 points).

(6) The number of high-quality charter schools to be created in the State (20 points).

(7) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (20 points).

(8) In the case of SEAs that propose to use grant funds to support dissemination activities under section 5204(f)(6) of the ESEA, the quality of the dissemination activities and the likelihood that those activities will improve student achievement (20 points).

(2) *Non-SEA Applicants (CFDA No. 84.282B and 84.282C).* The application requirements for *all* non-SEA applicants are listed in paragraph A in this section.

The selection criteria for non-SEA applicants for *Planning, Program Design, and Implementation Grants (CFDA No. 82.282B)* are listed in paragraph B in this section.

The selection criteria for non-SEA applicants for *Dissemination Grants (CFDA No. 84.282C)* are listed in paragraph C in this section.

(A) *Application Requirements (CFDA Nos. 84.282B and 84.282C).* (1) Describe the educational program to be implemented by the proposed charter school, including how the program will enable all students to meet challenging State student performance standards, the grade levels or ages of students to be served, and the curriculum and instructional practices to be used;

(2) Describe how the charter school will be managed;

(3) Describe the objectives of the charter school and the methods by which the charter school will determine its progress toward achieving those objectives;

(4) Describe the administrative relationship between the charter school and the authorized public chartering agency;

(5) Describe how parents and other members of the community will be involved in the planning, program design and implementation of the charter school;

(6) Describe how the authorized public chartering agency will provide for continued operation of the charter school once the Federal grant has expired, if that agency determines that the charter school has met its objectives;

(7) If the charter school desires the Secretary to consider waivers under the authority of the PCSP, include a request and justification for waivers of any Federal statutory or regulatory provisions that the applicant believes are necessary for the successful operation of the charter school, and a description of any State or local rules, generally applicable to public schools, that will be waived for, or otherwise not apply to, the school;

(8) Describe how the grant funds will be used, including how these funds will be used in conjunction with other Federal programs administered by the Secretary;

(9) Describe how students in the community will be informed about the charter school and be given an equal

opportunity to attend the charter school; and

(10) Describe the extent of community support for the application.

(B) *Selection Criteria (CFDA No. 84.282B).* Non-SEA Planning, Program Design, and Initial Implementation Grant applicants must address each selection criterion (1) through (9) individually and title each accordingly.

The maximum possible score for all of the criteria in this section is 145 points.

The maximum possible score for each criterion is indicated in parentheses following the criterion.

In evaluating an application from a non-SEA eligible applicant for Planning, Program Design, and Implementation, the Secretary considers the following criteria:

(1) The quality of the proposed curriculum and instructional practices (25 points).

(2) The degree of flexibility afforded by the SEA and, if applicable, the (LEA) to the charter school (10 points).

(3) The extent of community support for the application (10 points).

(4) The ambitiousness of the objectives for the charter school (15 points).

(5) The quality of the strategy for assessing achievement of those objectives (20 points).

(6) The likelihood that the charter school will meet those objectives and improve educational results for students during and after the period of Federal financial assistance (20 points).

(7) The extent to which the proposed project encourages parental involvement (10 points).

(8) The qualifications, including relevant training and experience, of the project director; and the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (10 points).

(9) The contribution the charter school will make in assisting educationally disadvantaged and other students to achieve to State academic content standards and State student academic achievement standards (25 points).

(C) *Selection Criteria (CFDA No. 84.282C).* Non-SEA applicants for Dissemination Grants must address each selection criterion (1) through (5) individually and title each accordingly.

The maximum possible score for all of the criteria in this section is 125 points.

The maximum possible score for each criterion is indicated in parentheses following the criterion.

In evaluating an application from a non-SEA eligible applicant for a dissemination grant, the Secretary considers the following criteria:

(1) The quality of the proposed dissemination activities and the likelihood that those activities will improve student achievement (30 points).

(2) The extent to which the school has demonstrated overall success, including—

(a) Substantial progress in improving student achievement (25 points);

(b) High levels of parent satisfaction (10 points); and

(c) The management and leadership necessary to overcome initial start-up problems and establish a thriving, financially viable charter school (10 points).

(3) The extent to which the results of the proposed project will be disseminated in a manner that will enable others to use the information or strategies (20 points).

(4) The qualifications, including relevant training and experience, of the project director; and the extent to which the applicant encourages applications for employment from persons who are members of groups that have traditionally been underrepresented based on race, color, national origin, gender, age, or disability (10 points).

(5) The adequacy of the management plan to achieve the objectives of the proposed project on time and within budget, including clearly defined responsibilities, timelines, and milestones for accomplishing project tasks (20 points).

Priorities

Invitational Priority. The Secretary invites applications that propose to increase the capacity of charter schools to offer public school choice in those communities with the greatest need for public school choice by addressing the following factors:

(a) The extent to which the applicant would plan, design, and implement one or more high-quality charter schools in geographic areas, including urban and rural areas, in which a large proportion or number of public schools have been identified for improvement, corrective action, or restructuring under Title I, Part A of the ESEA; and

(b) The extent to which the applicant will plan, design, and implement one or more high-quality charter schools in geographic areas in which a large proportion of students have difficulty meeting State academic content and student achievement standards.

Under 34 CFR 75.105(c)(1), the Department does not give an application that meets this invitational priority a competitive or absolute preference over other applications.

Competitive Preference. In accordance with 34 CFR 75.105(c)(2)(i) and section 5202(e) of the ESEA, in awarding grants to SEAs under this competition, the Secretary gives priority to States to the extent that the State meets the statutory criterion described in paragraph (a) of this section, *and* one or more of the statutory criteria described in paragraphs (b) through (d) of this section.

An SEA that meets priority (a) but does not meet one or more of the other priorities will not receive any priority points.

An SEA that does not meet priority (a) but meets one or more of the other priorities will not receive any priority points.

In order to receive preference, an applicant must identify the priorities that it meets and provide documentation supporting its claims.

The maximum number of priority points for all of the priorities in this section is 40 points.

(a) *Periodic Review and Evaluation.* The State provides for periodic review and evaluation by the authorized public chartering agency of each charter school at least once every 5 years to determine whether the charter school is meeting the terms of the school's charter, and is meeting or exceeding the academic performance requirements and goals for charter schools as provided under State law or the school's charter (10 points).

(b) *Number of High-Quality Charter Schools.* The State has demonstrated progress in increasing the number of high-quality charter schools that are held accountable in the terms of the school's charters for meeting clear and measurable objectives for the educational progress of the students attending the schools, in the period prior to the period for which an SEA or eligible applicant applies for a grant under this competition (10 points).

(c) *One Authorized Public Chartering Agency Other than an LEA, or an Appeals Process.* The State—

(1) Provides for one authorized public chartering agency that is not an LEA, such as a State chartering board, for each individual or entity seeking to operate a charter school pursuant to State law; or

(2) In the case of a State in which LEAs are the only authorized public chartering agencies, allows for an appeals process for the denial of an application for a charter school (10 points).

(d) *High Degree of Autonomy.* The State ensures that each charter school has a high degree of autonomy over the

charter school's budgets and expenditures (10 points).

Other Statutory Provisions: The following definitions, amount criteria, allowable activities, and authorized uses of funds for dissemination activities are taken from the PCSP authorizing statute, in Title V, Part B, Subpart 1 of the ESEA. They are repeated in this application notice for the convenience of the applicant. Other statutory requirements also apply to this program.

Definitions. The following definitions apply to this program:

(a) *Charter school* means a public school that—

(1) In accordance with a specific State statute authorizing the granting of charters to schools, is exempted from significant State or local rules that inhibit the flexible operation and management of public schools, but not from any rules relating to the other requirements of this definition;

(2) Is created by a developer as a public school, or is adapted by a developer from an existing public school, and is operated under public supervision and direction;

(3) Operates in pursuit of a specific set of educational objectives determined by the school's developer and agreed to by the authorized public chartering agency;

(4) Provides a program of elementary or secondary education, or both;

(5) Is nonsectarian in its programs, admissions policies, employment practices, and all other operations, and is not affiliated with a sectarian school or religious institution;

(6) Does not charge tuition;

(7) Complies with the Age Discrimination Act of 1975, title VI of the Civil Rights Act of 1964, title IX of the Education Amendments of 1972, section 504 of the Rehabilitation Act of 1973, as amended, and part B of the Individuals With Disabilities Education Act;

(8) Is a school to which parents choose to send their children, and that admits students on the basis of a lottery, if more students apply for admission than can be accommodated;

(9) Agrees to comply with the same Federal and State audit requirements as do other elementary and secondary schools in the State, unless the requirements are specifically waived for the purposes of this program;

(10) Meets all applicable Federal, State, and local health and safety requirements;

(11) Operates in accordance with State law; and

(12) Has a written performance contract with the authorized public chartering agency in the State that includes a description of how student performance will be measured in charter schools pursuant to State assessments that are required of other schools and pursuant to any other assessments mutually agreeable to the authorized public chartering agency and the charter school.

(b) *Developer* means an individual or group of individuals (including a public or private nonprofit organization), which may include teachers, administrators and other school staff, parents, or other members of the local community in which a charter school project will be carried out.

(c) *Eligible applicant* means a developer that has—

(1) applied to an authorized public chartering authority to operate a charter school; and

(2) provided adequate and timely notice to that authority under section 5203(d)(3) of the ESEA.

Note: Section 5203(d)(3) requires the eligible Non-SEA applicant to provide the authority with timely notice, and a copy, of its application for PCSP funds. The Secretary or SEA may waive these requirements in the case of an application for a precharter planning grant or subgrant.

(d) *Authorized public chartering agency* means an SEA, LEA, or other public entity that has the authority under State law and is approved by the Secretary to authorize or approve a charter school.

Amount Criteria. In determining the amount of a grant to be awarded under this competition to an SEA, the Secretary shall take into consideration the number of charter schools that are operating or approved to open in the State.

Allowable Activities. An eligible applicant receiving a grant or subgrant under this program may use the grant or subgrant funds only for—

(a) Post-award planning and design of the educational program, which may include—

(1) Refinement of the desired educational results and of the methods for measuring progress toward achieving those results; and

(2) Professional development of teachers and other staff who will work in the charter school; and

(b) Initial implementation of the charter school, which may include—

(1) Informing the community about the school;

(2) Acquiring necessary equipment and educational materials and supplies;

(3) Acquiring or developing curriculum materials; and

(4) Other initial operating costs that cannot be met from State or local sources.

Use of Funds for Dissemination Activities. An SEA may reserve not more than 10 percent of the grant funds to support dissemination activities. A charter school may use those funds to assist other schools in adapting the charter school's program (or certain aspects of the charter school's program), or to disseminate information about the charter school through activities such as—

(a) Assisting other individuals with the planning and start-up of one or more new public schools, including charter schools, that are independent of the assisting charter school and the assisting charter school's developers, and that agree to be held to at least as high a level of accountability as the assisting charter school;

(b) Developing partnerships with other public schools, including charter schools, designed to improve student performance in each of the schools participating in the partnership;

(c) Developing curriculum materials, assessments, and other materials that promote increased student achievement and are based on successful practices within the assisting charter school; and

(d) Conducting evaluations and developing materials that document the successful practices of the assisting charter school and that are designed to improve student achievement.

For Applications and Further Information Contact: Dean Kern, U.S. Department of Education, 400 Maryland Avenue, SW., room 3E116, Washington, DC 20202–6140. Telephone (202) 260–1882 or via Internet: *dean.kern@ed.gov.*

If you use a telecommunications device for the deaf (TDD), you may call the Federal Information Relay Service (FIRS) at 1–800–877–8339.

Individuals with disabilities may obtain this document in an alternative format (*e.g.*, Braille, large print, audiotape, or computer diskette) on request to the program contact person listed under *For Applications and Further Information Contact.*

Individuals with disabilities may obtain a copy of the application package in an alternative format by contacting that person. However, the Department is not able to reproduce in an alternative format the standard forms included in the application package.

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Program Authority: 20 U.S.C. 7221–7221j.

Dated: March 10, 2003.

Nina S. Rees,

Deputy Under Secretary for Innovation and Improvement.

[FR Doc. 03–6160 Filed 3–13–03; 8:45 am]

BILLING CODE 4000–01–P

Federal Register

Friday,
March 14, 2003

Part V

Department of Transportation

Federal Aviation Administration

14 CFR Parts 91, 121, 135, and 145
Repair Stations; Final Rule

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Parts 91, 121, 135, and 145

[Docket No.:FAA–1999–5836]

RIN 2120–AC38

Repair Stations

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule; delay of effective date.

SUMMARY: FAA is delaying the effective date of a final rule that amends the regulations for aeronautical repair stations. This action is necessary to give repair station certificate holders more time to develop required manuals using FAA guidance material, which has yet to be issued, before submitting the manuals to FAA for acceptance. Also this action will allow repair station certificate holders to follow FAA guidance material for requesting FAA approval of contract maintenance functions.

DATES: The effective date of the final rule amending 14 CFR parts 91, 121, 135, and 145 published on August 6, 2001, at 66 FR 41088 is delayed until October 6, 2003, with the following exception: § 145.163 is delayed until October 6, 2005.

FOR FURTHER INFORMATION CONTACT: Diana Frohn, Flight Standards Service, Aircraft Maintenance Division, General Aviation and Repair Station Branch, AFS–340, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267–7027; e-mail *diana.frohn@faa.gov.*

SUPPLEMENTARY INFORMATION:

The Final Rule

On July 30, 2001, FAA issued Repair Stations; Final Rule with Request for Comments and Direct Final Rule with Request for Comments (66 FR 41088; August 6, 2001). That final rule, which becomes effective April 6, 2003, updates and revises part 145 of title 14, Code of Federal Regulations, which prescribes the regulations for aeronautical repair stations. In that rulemaking action, FAA established a new requirement that each repair station must maintain and use a current repair station manual and a quality control manual. FAA also prescribed the contents of these manuals.

In the preamble to the final rule FAA stated, ''This final rule will become effective 20 months after it is published in the **Federal Register**. This time period is needed to develop advisory circulars and internal FAA guidance, and to train FAA personnel. Additionally, repair stations will need adequate time to comply with the new requirements.'' On November 7, 2002, a notice was published in the **Federal Register** (67 FR 67891) announcing the availability of Proposed Advisory Circular (AC) 145–MAN, Guide for Developing and Evaluating Repair Station and Quality Control Manuals. In response to commenter requests, FAA extended the close of the comment period for AC 145–MAN from November 22, 2002, to February 5, 2003, (67 FR 70291; November 21, 2002).

On October 21, 2002, Mr. Jason Dickstein, Counsel, sent a petition to FAA for the Aircraft Electronics Association, the Aerospace Industries Association, the Aviation Suppliers Association, and the National Air Transportation Association.

The petitioners request that FAA—

1. ''Postpone the implementation date of the changes to part 145 that were published at 66 FR 41088–41124 (August 6, 2001) until no earlier than 180 days after the FAA publishes a notice in the **Federal Register** of the availability of the advisory circular that describes how to comply with the repair station manual and quality control manual provisions of new sections 145.207 through 145.211.''

2. ''Publish notice of implementation postponement in the **Federal Register**.''

3. ''Publish a transition rule that permits early compliance with the new rule.''

The petitioners contend that FAA has not yet published advisory material and guidance explaining how to produce a manual that is acceptable to FAA. Further, the petitioners assert that without advisory material, FAA cannot adequately train its personnel.

FAA has reviewed the petition and agrees with the petitioners that additional time is necessary to allow each repair station to prepare a repair station manual and a quality control manual following the guidance to be provided in AC 145–MAN. Since the guidance has not yet been issued, FAA finds that an extension is in the public interest.

Although the petitioners request that FAA allow for early compliance with the new rule, FAA finds it appropriate to extend the effective date of the entire final rule. FAA has determined that it would not be in the public interest to have both the current rule and the final rule in effect at the same time. Although this would allow some repair stations to comply with the final rule while repair stations operating under the current rule prepare their manuals, FAA finds this administratively complex.

The vast majority of repair station principal inspectors have oversight responsibility for several repair stations of varying complexity. Concurrent oversight and enforcement of two separate rules with different regulatory requirements would cause confusion and adversely impact the standardized application of repair station regulations. Additionally, FAA has determined that this would not be an efficient use of its inspector resources.

Further, the petitioners request an extension of 180 days from **Federal Register** publication of the notice of availability of a final AC. Since FAA intends to publish a final AC in the near future, the agency finds that an extension of 180 days from the April 6, 2003, effective date of the rule is sufficient.

Finally, the delay in the effective date of the final rule does not impose any new requirements or any additional burden on the regulated public. FAA, therefore, finds there are no additional costs or benefits associated with this action. However, the 180-day extension will delay realization of some cost savings provided by the rule.

Good Cause for Immediate Adoption

In accordance with 5 U.S.C. 553(b)(3)(B), FAA finds good cause for issuing this rule without prior notice and comment. Seeking public comment is impracticable, unnecessary, and contrary to the public interest. This delay of effective date will give repair stations sufficient time to use FAA guidance material in preparing to operate under the amended regulations for repair stations. Given the imminence of the effective date, seeking prior public comments on this temporary delay would have been impracticable, as well as contrary to the public interest in the orderly promulgation and implementation of this rule.

In consideration of the foregoing, FAA is amending parts 91, 121, 135, and 145 to delay the effective date of the final rule by 180 days.

Issued in Washington, DC, on March 4, 2003.

Marion C. Blakey,

Administrator.

[FR Doc. 03–6181 Filed 3–12–03; 8:45 am]

BILLING CODE 4910–13–P

Federal Register

Friday,
March 14, 2003

Part VI

Department of Homeland Security

Federal Emergency Management Agency

Assistance to Firefighters Grant Program; Final Rule and Notice

DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

44 CFR Part 152

RIN 3067–AD21

Assistance to Firefighters Grant Program

AGENCY: U.S. Fire Administration (USFA), FEMA, Emergency Preparedness and Response, Homeland Security.

ACTION: Final rule.

SUMMARY: FEMA is publishing this final rule to establish guidance on our program to make grants directly to fire departments of a State for the purpose of enhancing their ability to protect the health and safety of the public as well as that of firefighting personnel facing fire and fire-related hazards. These grants are awarded on a competitive basis to eligible applicants that most closely address the program's priorities and then demonstrate financial need and maximize the benefit to be derived from the grant funds. The program's priorities will be stated in the Notice of Funds Availability (NOFA) that we will publish pursuant to the program's annual appropriation.

DATES: *Effective Date:* This final rule is effective on March 14, 2003.

ADDRESSES: Please send any comments to the Rules Docket Clerk, Office of the General Counsel, Federal Emergency Management Agency, 500 C Street, SW., room 840, Washington, DC 20472. Comments may also be transmitted via fax to (202) 646–4536 or e-mail to *rules@fema.gov.* Please reference ''Assistance to Firefighters Grant Program'' in the subject line of your e-mail or comment letter.

FOR FURTHER INFORMATION CONTACT: Brian Cowan, Director, Grants Program Office, U.S. Fire Administration (USFA), Federal Emergency Management Agency, 500 C Street, SW., room 304, Washington, DC 20472, or call 1–866–274–0960, or e-mail *USFAGRANTS@fema.gov.*

SUPPLEMENTARY INFORMATION: This final rule establishes guidance on the administration of grants made under the authority of the Federal Fire Prevention and Control Act of 1974 (15 U.S.C. 2201 *et seq.*).

The purpose of the program is to award grants directly to fire departments of a State to enhance their ability to protect the health and safety of the public, as well as that of firefighting personnel, facing fire and fire-related hazards.

We will award the grants on a competitive basis to the applicants that (1) most closely address the program's priorities, and (2) demonstrate financial need; maximum benefit derived from the grant funds with their projects; and effective and efficient project plans and procurements. For the purpose of this program, ''State'' is defined as the fifty States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Eligible applicants for the Assistance to Firefighters Grant Program are limited to fire departments of a State as defined herein. A ''fire department of a State'' is defined as an agency or organization that has a formally recognized arrangement with a State, local or tribal authority (city, county, parish, fire district, township, town or other governing body) to provide fire suppression to a population within a fixed geographical area. A fire department can apply for assistance for its emergency medical services (EMS) unit provided the unit falls organizationally under the auspices of the fire department. A municipality or fire district may submit an application on behalf of a fire department when the fire department lacks the legal status to do so, *e.g.*, where the fire department falls within the auspices of the municipality. When a municipality or fire district submits an application on behalf of a fire department, the fire department is precluded from submitting an additional application.

Fire departments that are Federal fire departments are not eligible for this grant program. Fire departments that are contracted by the Federal government and are solely responsible for suppression of fires on Federal installations are not eligible for this grant program. Fire stations that are not independent fire departments but are part of, or controlled by a larger fire department or agency are typically not eligible. Fire departments that are for-profit departments (*i.e.*, do not have specific non-profit status and/or are not municipally based) are not eligible to apply for assistance under this program. Also not eligible for this program are ambulance services, rescue squads, auxiliaries, dive teams, urban search and rescue teams, fire service organizations or associations, and State/local agencies such as a forest service, fire marshal, hospitals, and/or training offices.

Congress included in the legislation a list of fourteen activities eligible for funding under this program. Those activities are as follows: (a) To hire additional firefighting personnel; (b) to train firefighting personnel in firefighting, emergency response (including response to a terrorism incident or use of a weapon of mass destruction), arson prevention and detection, or the handling of hazardous materials, or to train firefighting personnel to provide any of the training described above; (c) to fund the creation of rapid intervention teams to protect firefighting personnel at scenes of fires and other emergencies; (d) to certify fire inspectors; (e) to establish wellness and fitness programs for firefighting personnel to ensure that the firefighting personnel can carry out their duties; (f) to fund emergency medical services provided by fire departments; (g) to acquire additional firefighting vehicles, including fire trucks; (h) to acquire additional firefighting equipment, including equipment for communications, monitoring, and response to a terrorism incident or use of a weapon of mass destruction; (i) to acquire personal protective equipment required for firefighting personnel by the Occupational Safety and Health Administration (OSHA), and other personal protective equipment for firefighting personnel, including protective equipment to respond to a terrorism incident or the use of a weapon of mass destruction; (j) to modify fire stations, fire training facilities, and other facilities to protect the health and safety of firefighting personnel; (k) to enforce fire codes; (l) to fund fire prevention programs; (m) to educate the public about arson prevention and detection; and, (n) to provide incentives for the recruitment and retention of volunteer firefighting personnel for volunteer firefighting departments and other firefighting departments and other firefighting departments that utilize volunteers.

The specific activities that will be eligible for funding will be announced in the NOFA that we will publish pursuant to the program's annual appropriation.

Eligible applicants can apply for this program on-line via FEMA's electronic grant (e-grant) application process. (While we encourage all applicants to apply on-line, we will provide and accept paper applications. Details about how to request a paper application and how to submit a paper application can be found later in this section of this final rule or on the U.S. Fire Administration's Web site: *www.usfa.fema.gov*). The e-grant application consists of electronic versions of FEMA's grant forms. The

application will include questions that are designed to provide general, generic information about the applicant. The application will also include activity-specific questions for each activity that the department plans to implement with the grant funds. The activity-specific questions will also be used by us to determine if your application addresses the program's priorities and merits further review.

In connection with the activity-specific questions, the applicants will be asked to provide details concerning the various budget items necessary to accomplish their proposed projects. Lastly, the application will include a project narrative in which the applicant provides a detailed description of their planned activity or activities, the applicant's financial need, and the benefits to be derived from the costs of the activity.

In selecting applications for award, we will first evaluate each application independently based on established applicant eligibility criteria and with respect to program priorities. Then we will evaluate the applications of those with the best score for their project descriptions, the financial needs of the applicant and an analysis of the benefits that would result from the grant award. In the first screening, every application will be evaluated based on the answers to the activity-specific questions. The applications that most closely address the Assistance to Firefighters Grant Program's established priorities will be deemed to be in the ''competitive range'' and subject to a second level of review. This second level of review is conducted using technical review panels (made up of individuals from the fire service and fire service organizations) that assess the application's merits with respect to the detail provided in the narrative about the project, the applicant's financial need, and the project's benefit to be derived from the cost. At least three technical evaluation panelists will independently score each application and then discuss the merits/shortcomings of the application in order to reconcile any major discrepancies. A consensus on the score is not required. The scores of the panelists will be added together, and then divided by the number of panelists to arrive at the final score of the application. The highest scoring applications will then be considered for award.

The law requires a certain distribution of grant funds between career departments and combination/volunteer fire departments. Specifically, we must ensure that fire departments that have either all-volunteer forces of firefighting personnel or combined forces of volunteer and career firefighting personnel receive a portion of the total grant funding that is not less than the proportion of the United States population that those departments protect. The specific proportions will be gleaned from the most recent survey conducted by the National Fire Protection Association and announced in the NOFA that we will publish pursuant to the program's annual appropriation.

To fulfill our obligations under the law which requires us to make grants to a variety of fire departments, we may deviate from our primary decision factor of rank order and use department type (career, combination, or volunteer) and/or the type of community the fire department serves (urban, suburban, or rural) and/or the geographic location of the department as alternate decision factors when selecting departments for award. In these instances in which we are making decisions based on geographic location, we will use States as the basic geographic unit. We are also required under the law to make grants for fire prevention programs that total no less than five (5) percent of the funds appropriated for the grant program. We are also limited in the amount of funds that may be awarded for firefighting vehicles, specifically, no more than twenty-five (25) percent of the funds appropriated for the grants shall be used to assist grant recipients to purchase firefighting vehicles.

For each year the grant program is appropriated, we will issue a NOFA and announce the application requirements as well as other pertinent information regarding the application. The application will be available on FEMA's e-grant system and accessible from the FEMA and USFA Internet homepages. Although we do not encourage the use of paper applications, paper applications will be available for applicants that do not have access to the Internet.

Complete application packages must be submitted electronically or otherwise received by us on or before the close of business (5 p.m. EST) on the closing date as announced in the Notice of Availability of Funds. We will not accept late or incomplete applications. The automated grant application system has features built into it that will guarantee that the application is complete when submitted.

Eligible applicants can access an electronic version of the application form at the FEMA/USFA Web site (*www.usfa.fema.gov*). If an applicant does not have access over the Internet to the FEMA/USFA Web sites, the applicant may contact us directly to request a copy via mail. Those applicants interested in receiving an application in the mail can (1) submit their request to USFA Grant Program Technical Assistance Center, 16825 South Seton Avenue, Emmitsburg, Maryland, 21727–8998, (2) phone 866–274–0960, or (3) e-mail us at *USFAGRANTS@fema.gov.* Applicants not using the automated e-grant system should complete and submit their signed original application to us at USFA Grant Program Technical Assistance Center, 16825 South Seton Avenue, Emmitsburg, Maryland, 21727–8998. In order for us to receive paper applications by the closing date, paper applications must be postmarked three business days prior to the closing date, or transmitted via next-day courier service one full business day prior to the closing date. Faxed applications will not be considered.

We solicited comments on the proposed rule in our previously published interim final rule. The interim final rule appeared in the **Federal Register** on February 22, 2002. We received thirteen (13) responses that contained seventeen (17) individual comments. Five comments were unrelated to the rule (*e.g.*, dealing with the application deadline or advertising the availability of excess Federal property). Three comments were specific to the eligibility of certain items and five were specific to the eligibility of certain types of applicants. All concerns over expense eligibility have been addressed in this final rule. The five comments regarding applicant eligibility were all focused on the eligibility of non-fire based organizations; four were related to the exclusion of non-fire based EMS providers into the program. We are bound by our statutory authority, which only allows us to make grants to fire departments, and therefore we made no changes to the final rule with respect to applicant eligibility. One comment indicated that the program's emphasis should be based on basic operational needs rather than basing it on the industry's standards that often incorporate a certain amount of ''expensive technology.'' We made no adjustments to our rule as a result of this comment because our program already places a higher priority on basic firefighting needs. We received one comment that concerned the inclusion of combination departments with volunteer departments rather than with career departments. This policy is a direct reflection of the authorizing legislation. Therefore, we did not make

any changes. We also received a comment regarding the non-funding of firefighting personnel. The hiring of firefighting personnel is one of the fourteen activities delineated by Congress as an eligible activity under this program. We have been very deliberate in our expansion of the program to include all of these activities, but the policy not to fund the hiring of firefighting personnel for 2002 was derived from the program's appropriation language. Each year that the program is appropriated, we will announce specific details concerning the activities that will be available for funding in a Notice of Funds Availability.

The final comment concerned the inability of many departments to meet the required cost-share. This concern has been supported by several applicants that have had to decline their award due to lack of funds and by several of our grantees that reported their difficulties in funding their match. Unfortunately, the authorizing legislation requires that the applicants participate in the cost of the grant projects by providing ''funds'' as a cost-share. As such, no changes were made to the requirement for a cash match.

In any year that the Assistance to Firefighters Grant Program is authorized and appropriated, we may elect to set aside a portion of the funds available under this program to make grants to, or enter into contracts or cooperative agreements with, national, State, local or community organizations or agencies, including fire departments, for the purpose of carrying out fire prevention and injury prevention programs.

In accordance with statutory requirement, our support for these fire prevention and safety activities will concentrate on organizations that focus on the prevention of injuries to children from fire. In addition to this priority, we are also placing an emphasis on funding projects that focus on protecting the U.S. Fire Administration (USFA)-identified high-risk populations, *i.e.*, children under fourteen, seniors over sixty-five, and firefighters. Since the victims of burns experience both short- and long-term physical and psychological effects, we are also placing a priority on programs that focus on reducing the immediate and long-range effects of fire and burn injuries, primarily those affecting children.

The specific details concerning this fire prevention and safety program will be announced in the NOFA that we will publish pursuant to the program's annual appropriation.

Administrative Procedures Act Determination

We are publishing this final rule having incorporated all appropriate public comment received under the Administrative Procedures Act (APA), 5 U.S.C. 553.

National Environmental Policy Act

The National Environmental Policy Act requires that any major Federal action be reviewed for its potential impact on the environment. This rule, a major Federal action, has been reviewed as to its potential to impact the environment. It was found that the types of activities proposed to be eligible by this rule would fall under at least one of the categorical exclusions defined by 44 CFR 10.8(d)(2). Therefore, this rule, which addresses those actions, is categorically excluded from the preparation of an environmental assessment or environmental impact statement according to 44 CFR 10.8(d)(2)(ii).

E.O. 12898, Environmental Justice

Under Executive Order 12898, ''Federal Actions to Address Environmental Justice in Minority Populations and Low-Income Populations,'' 59 FR 7629, February 16, 1994, agencies must undertake to incorporate environmental justice into their policies and programs. The Executive Order requires each Federal agency to identify and address, as appropriate, disproportionately high and adverse human health or environmental effects of its programs, policies, and activities on minority and low-income populations. In addition, each Federal agency must conduct its programs, policies, and activities that substantially affect human health or the environment, in a manner that ensures that those programs, policies, and activities do not have the effect of excluding persons from participation in, denying persons the benefits of, or subjecting persons to discrimination in those programs, policies, and activities because of their race, color, or national origin. No action that we can anticipate under this final rule will have a disproportionately high and adverse human health and environmental effect on any segment of the population. In addition, the final rule does not impose substantial direct compliance costs on those communities nor does it discriminate by excluding persons or denying benefits because of race, color, or national origin. Accordingly, this final rule is in compliance with the requirements of Executive Order 12898.

E.O. 12866, Regulatory Planning and Review

Under Executive Order 12866, 58 FR 51735, October 4, 1993, we are required to examine whether this rule is a ''significant regulatory action'' as defined in the rule. A significant regulatory action is subject to review by the Office of Management and Budget (OMB) and the requirements of the Executive Order. The Executive 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.

This final rule sets out our administrative procedures for making grants under the Assistance to Firefighters Grant Program. This program has been authorized and appropriated at levels that exceed the $100,000,000 threshold and when the applicant's cost-share is considered we must conclude this rule to be a significant action. We have, therefore, determined that this rule is a ''significant regulatory action'' under the terms of Executive Order 12866. In light of this finding, we set forth the following regulatory impact analysis.

The final rule would facilitate the issuance of grants to local fire departments in the following programmatic areas: Fire operations and firefighter safety, fire prevention, emergency medical services, and firefighting vehicles. Although we have not undertaken quantitative studies to measure the envisaged effects of the program, we have determined that the funding distributed under this program will have an immediate, lasting, and positive effect on the safety of the communities served by the recipient fire departments, as well as on the safety of the firefighters themselves.

We highlight the fact that the final rule does not relate to a new or discretionary program of a regulatory nature. Instead, through this final rule, we are implementing a Congressionally mandated initiative aimed at protecting

the health and safety of the public and firefighting personnel against fire and fire-related hazards. See 15 U.S.C. 2229.

The Office of Management and Budget has reviewed the final rule under Executive Order 12866.

Paperwork Reduction Act

This final rule contains a collection of information that is subject to the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The Office of Management and Budget (OMB) has approved our use of the collection of information titled ''Assistance to Firefighters Grant Program—Grant Application Supplemental Information'' to implement the program and assigned it OMB control number 1660–0054, which expires December 31, 2005. Under the provisions of the Act, we may not conduct or sponsor, and a person is not required to respond to or may not be penalized for failing to comply with, a collection of information unless it displays a currently valid OMB control number. The information provided by grant applicants is required by us to provide them Federal grant assistance under the Assistance to Firefighters Grant Program under the authority of the Federal Fire Prevention and Control Act of 1947 (15 U.S.C. 2201 *et seq.*).

We use the information included in grant application packages to evaluate the eligibility and merits of each request for funding. The supplementary information augments the screening and referral forms used by the grants administration program to determine if applicants meet basic eligibility requirements.

The information collected will be used to evaluate each of the 20,000 to 25,000 anticipated applications objectively to verify eligibility and to determine which of the proposed projects most closely address the established program priorities and which applicants have the greatest needs. The information will also be used to determine which projects offer the highest benefits for the costs incurred and the information will be used to ensure that FEMA's responsibilities mandated in the legislation are fulfilled accurately and efficiently. FEMA will also use the information to ensure that funds are distributed to volunteer and career departments; and to urban, suburban, and rural fire departments, as mandated by Congress. We also will use the information to assure an equitable distribution geographically, using States as the geographic unit.

Executive Order 13132, Federalism

This Executive Order sets forth principles and criteria that agencies must adhere to in formulating and implementing policies that have federalism implications, that is, regulations that have substantial direct effects on the States, or on the distribution of power and responsibilities among the various levels of government. Federal agencies must closely examine the statutory authority supporting any action that would limit the policymaking discretion of the States, and to the extent practicable, must consult with State and local officials before implementing any such action.

We have reviewed this final rule under the threshold criteria of Executive Order 13132, Federalism. We have determined that the rule does not have federalism implications as defined by the Executive Order. The rule sets out our administrative procedures for making grants available for fire departments to enhance their ability to protect the health and safety of the public and that of their firefighting personnel facing fire and fire-related hazards. The rule does not significantly affect the rights, roles, and responsibilities of States, and involves no preemption of State law, nor does it limit State policymaking discretion.

The Office of Management and Budget has reviewed the final rule under Executive Order 13132.

Congressional Review of Agency Rulemaking

We have sent this final rule to the Congress and to the General Accounting Office under the Congressional Review of Agency Rulemaking Act, 5 U.S.C. 801 *et seq.* The rule is a ''major rule'' within the meaning of that Act. It will result in an annual effect on the economy of $100,000,000 or more. The rule sets out our administrative procedures for making grants available for eligible applicants, *i.e.,* fire departments, to enhance their ability to protect the health and safety of the public as well as that of the firefighting personnel facing fire and fire-related hazards.

In compliance with section 808(2) of the Congressional Review of Agency Rulemaking Act, 5 U.S.C. 808(2), for good cause we find that notice and public procedure on this final rule are impractical, unnecessary, or contrary to the public interest.

Unfunded Mandates Reform Act

The rule is not an unfunded Federal mandate within the meaning of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1501 *et seq.*, and any enforceable duties that we impose are a condition of Federal assistance or a duty arising from participation in a voluntary Federal program.

List of Subjects in 44 CFR Part 152

Fire prevention, Grant programs—firefighters assitance.

Accordingly, we revise Part 152 of 44 CFR, Chapter I, to read as follows:

PART 152—ASSISTANCE TO FIREFIGHTERS GRANT PROGRAM

Sec.
152.1 Purpose and eligible uses of grant funds.
152.2 Definitions.
152.3 Availability of funds.
152.4 Roles and responsibilities.
152.5 Review process and evaluation criteria.
152.6 Application review and award process.
152.7 Grant payment, reporting and other requirements.
152.8 Application submission and deadline.
152.9 Reconsideration.

Authority: Federal Fire Protection and Control Act, 15 U.S.C. 2201 *et seq.*

§ 152.1 Purpose and eligible uses of grant funds.

(a) This competitive grant program will provide funding directly to fire departments of a State for the purpose of enhancing departments abilities to protect the health and safety of the public, as well as that of firefighting personnel, facing fire and fire-related hazards. Eligible applicants can submit only one application per application period. Departments that submit multiple applications in one application period will have each of their applications deemed ineligible.

(b) Eligible applicants are fire departments or fire departments of a State which is defined as an agency or organization that has a ''formally recognized arrangement'' with a State, local or tribal authority (city, county, parish, fire district, township, town, or other non-Federal governing body) to provide fire suppression services within a fixed geographical area. A fire department can apply for assistance for its emergency medical services unit provided the unit falls organizationally under the auspices of the fire department. A municipality or fire district may submit an application on behalf of a fire department when the fire department lacks the legal status to do so, *e.g.*, where the fire department falls within the auspices of the municipality. When a municipality or fire district submits an application on behalf of a fire department, the fire department is

precluded from submitting an additional application. Non-Federal airport and/or port authority fire departments are eligible, but only if they have a formally recognized arrangement with the local jurisdiction to provide fire suppression, on a first-due basis, outside the confines of the airport or port facilities. Airport or port authority fire departments whose sole responsibility is suppression of fires on the airport grounds or port facilities are not eligible for this grant program. Fire departments that are Federal or contracted by the Federal government and whose sole responsibility is suppression of fires on Federal installations are not eligible for this grant program. Fire stations that are not independent but are part of, or controlled by a larger fire department or agency, are typically not eligible. Fire departments that are for-profit departments (*i.e.*, do not have specific non-profit status or are not municipally based) are not eligible to apply for assistance under this program. Also not eligible for this program are ambulance services, rescue squads, auxiliaries, dive teams, urban search and rescue teams, fire service organizations or associations, and State/local agencies such as a forest service, fire marshal, hospitals, and training offices.

(c) Congress included in the legislation a list of fourteen activities eligible for funding under this program. Those activities are as follows:

(1) To hire additional firefighting personnel;

(2) To train firefighting personnel in firefighting, emergency response (including response to a terrorism incident or use of a weapon of mass destruction), arson prevention and detection, or the handling of hazardous materials, or to train firefighting personnel to provide any of the training in this paragraph (c);

(3) To fund the creation of rapid intervention teams to protect firefighting personnel at scenes of fires and other emergencies;

(4) To certify fire inspectors;

(5) To establish wellness and fitness programs for firefighting personnel to ensure that the firefighting personnel can carry out their duties;

(6) To fund emergency medical services provided by fire departments;

(7) To acquire additional firefighting vehicles, including fire trucks;

(8) To acquire additional firefighting equipment, including equipment for communications, monitoring, and response to a terrorism incident or use of a weapon of mass destruction;

(9) To acquire personal protective equipment required for firefighting personnel by the Occupational Safety and Health Administration, and other personal protective equipment for firefighting personnel, including protective equipment to respond to a terrorism incident or the use of a weapon of mass destruction;

(10) To modify fire stations, fire training facilities, and other facilities to protect the health and safety of firefighting personnel;

(11) To enforce fire codes;

(12) To fund fire prevention programs;

(13) To educate the public about arson prevention and detection; and

(14) To provide incentives for the recruitment and retention of volunteer firefighting personnel for volunteer firefighting departments and other firefighting departments that utilize volunteers.

(d) The specific activities that will be eligible for funding will be announced in the Notice of Funding Availability (NOFA) that we will publish pursuant to the program's annual appropriation.

§ 152.2 Definitions.

Active firefighter is a member of a fire department or organization in good standing that is qualified to respond to and extinguish fires or perform other fire department emergency services and has actively participated in such activities during the past year.

Bay is the part or compartment of a building that provides parking for one or more pieces of firefighting apparatus.

Career department is a fire suppression agency or organization in which all active firefighters are considered full-time employees, are assigned regular duty shifts, and receive financial compensation for their services rendered on behalf of the department. Departments with active firefighters that are paid stipends on a per-call basis are not career departments. See the definition of combination department in this section.

Combination department is a fire suppression agency or organization in which at least one active firefighter receives financial compensation for his/her services rendered on behalf of the department and at least one active firefighter does not receive financial compensation for his/her services rendered on behalf of the department other than life/health insurance, workmen's compensation insurance, length of service awards, pay per-call or per-hour, or similar token compensation.

Construction is the creation of a new structure or any modification of the footprint or profile of an existing structure. Changes or renovations to an existing structure that do not change the footprint or profile of the structure but exceed either $10,000 or 50 percent of the value of the structure, are also considered construction for the purposes of this grant program. Changes that are less than $10,000 and/or 50 percent of the value of the structure are considered renovations, for the purposes of this grant program.

Direct delivery of training is training conducted within a training organization's own jurisdiction using the organization's own resources (trainers, facilities, equipment, etc.).

Fire boat is a vessel designed primarily for firefighting operations, however, may also be capable of water rescue and hazardous materials spills mitigation, etc. These vessels may also have the capability to pump a large volume of water from a drafting operation.

Fire department or fire department of a State is an agency or organization that has a ''formally recognized arrangement'' with a State, local or tribal authority (city, county, parish, fire district, township, town, or other non-Federal governing body) to provide fire suppression services within a fixed geographical area. A fire department can apply for assistance for its emergency medical services unit provided the unit falls organizationally under the auspices of the fire department. A municipality or fire district may submit an application on behalf of a fire department when the fire department lacks the legal status to do so, *e.g.,* where the fire department falls within the auspices of the municipality. When a municipality or fire district submits an application on behalf of a fire department, the fire department is precluded from submitting an additional application. Non-Federal airport and/or port authority fire departments are eligible, but only if they have a formally recognized arrangement with the local jurisdiction to provide fire suppression services, on a first-due basis, outside the confines of the airport or port facilities. Airport or port authority fire departments whose sole responsibility is suppression of fires on the airport grounds or port facilities are not eligible for this grant program. Fire departments that are Federal or contracted by the Federal government and whose sole responsibility is suppression of fires on Federal installations are not eligible for this grant program. Fire departments or fire stations that are not independent but are part of, or controlled by a larger fire department or agency, are typically not eligible. Fire departments that are for-profit departments (*i.e.*, do not have specific non-profit status or are not

municipally based) are not eligible to apply for assistance under this program. Also not eligible for this program are ambulance services, rescue squads, auxiliaries, dive teams, urban search and rescue teams, fire service organizations or associations, and State/local agencies such as a forest service, fire marshal, hospitals, and training offices.

Firefighter see the definition of *Active Firefighter* in this section.

First-due response area is a geographical area in proximity to a fire or rescue facility and normally served by the personnel and apparatus from that facility in the event of a fire or other emergency.

Formally recognized arrangement is an agreement between the fire department and a local jurisdiction such that the jurisdiction has publicly or otherwise formally deemed that the fire department has the first-due response responsibilities within a fixed geographical area of the jurisdiction. Often this agreement is recognized or reported to the appropriate State entity with cognizance over fire departments, such as registration with the State Fire Marshal's office, or the agreement is specifically contained in the fire department's or jurisdiction's charter.

Integrated communication systems and devices are equipment or systems for dispatch centers or communication infrastructure. Examples of these include 911 systems, computer-aided dispatch systems, global positioning systems, fixed repeaters, etc. Towers are an integral part of any communication system, but they are not eligible to be included in any award under this program.

New mission is a first-responder function that a department has never delivered in the past or that was once delivered but has since been abandoned by the department due to the lack of funding or community support. Examples include technical search and rescue, emergency medical services, hazardous materials response, etc. A new mission does not include services already provided from existing facilities. Opening additional stations to provide similar services would be considered an expansion of existing services.

Population means permanent residents in the first-due response area or jurisdiction served by the applicant. It would include students but does not include seasonal population or any population in area that the fire department responds to under mutual/automatic aid agreements.

Prop is something that can be held up in a classroom or moved from site to site in order to facilitate or enhance the training experience. A training tower (pre-fabricated or constructed) is not a prop.

Renovation is changes or alterations or modifications to an existing structure that do not exceed either $10,000 and/or 50 percent of the market value of the structure and do not involve a change in the footprint or profile of the structure.

Rural community is a community that has low population density, zoned agricultural or parkland, and whose fire department has a relatively low volume of fire calls.

State means any of the fifty States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

Suburban community is a community that has a medium density population with a portion of their jurisdiction being zoned for industrial and/or commercial uses, and whose fire department has a high call volume relative to a rural community.

Supplies means any expendable property that typically has a one-time use limit and an expectation of being replaced within one year.

The United States Fire Administrator's (USFA) operational and performance objectives are to reduce losses of life and reduce economic losses due to fire and related emergencies. Specific target groups are children under 14 years old, seniors over 65 years old, and firefighters.

Urban community is a community with a high density population with a major proportion of its jurisdiction zoned for commercial and/or industrial use and a significant call volume.

Vehicle is a mechanized device used for carrying passengers, goods, or equipment. Examples of vehicles include, but are not limited to: pumpers, brush trucks, tankers, tenders, attack pumpers, rescue (transport and non-transport), ambulances, foam units, quints, aerials, ladders, hazmat vehicles, squads, crash rescue (ARFF), boats, hovercraft, planes, and helicopters. Details concerning vehicle eligibility will be provided in the NOFA that will be published pursuant to this program's annual appropriation.

Volunteer department is a fire suppression agency or organization in which no active firefighters are considered full-time employees, and which no members receive financial compensation for their services rendered on behalf of the department other than life/health insurance, workers' compensation insurance, length of service awards, pay per-call or per-hour, or similar token compensation.

Watercraft is a small boat (less than 13 feet in length) or other watercraft designed and equipped for water and/or ice rescue, rather than basic firefighting operations. Generally, these vessels will be equipped with water rescue equipment, flotation devices, and other basic medical and rescue equipment and their primary function will be rescue activities.

§ 152.3 Availability of funds.

(a) Fire departments that have received funding under the Assistance to Firefighter Grant Program in previous years are eligible to apply for funding in the current year. However, due to our responsibilities under this program to assure adequate distribution of awards amongst certain types of departments (career, combination and volunteer) and certain types of communities (urban, suburban or rural) as well as a equitable geographic distribution, we reserve the right to fund or not to fund previous recipients of grants under this program in order for us to fulfill these responsibilities.

(b) No applicant can receive more than $750,000 in Federal grant funds under this program in any fiscal year.

(c) No applicant can submit more than one application per fiscal year. Applicants that submit multiple applications will have each of their applications deemed ineligible.

(d) The scoring of the applications will determine the distribution of the funding across the eligible programs. Notwithstanding anything in this part, no more than twenty-five (25) percent of the funds appropriated for grants shall be used to assist grant recipients to purchase firefighting vehicles and not less than five (5) percent of the funds shall be used for fire prevention programs.

(e) We will not provide assistance under this part for activities for which another Federal agency has more specific or primary authority to provide assistance for the same purpose. We may disallow or recoup amounts that fall within other Federal agency's authority.

§ 152.4 Roles and responsibilities.

(a) Applicants must:

(1) Complete the application and certify to the accuracy of all the information contained therein;

(2) Certify that they are an eligible applicant, *i.e.*, a fire department, as defined in this part;

(3) Certify that the person submitting the application is duly authorized to do so, and

(b) Recipients (Grantees) must agree to:

(1) Share in the costs of the projects funded under this grant program. Fire departments in areas serving populations over 50,000 must agree to match the Federal grant funds with an amount of non-Federal funds equal to thirty (30) percent of the total project cost. Fire departments serving areas with a population of 50,000 or less will have to match the Federal grant funds with an amount of non-Federal funds equal to ten (10) percent of the total project cost. No waivers of this requirement will be granted except for fire departments of Insular Areas as provided for in 48 U.S.C. 1469a.

(2) Maintain operating expenditures during the grant's period of performance in the areas funded by a grant at a level equal to or greater than the average of their operating expenditures in the two years preceding the year in which this assistance is received.

(3) Obtain the appropriate Federal, State, or local permits necessary to fulfill the grant's scope of work including historical and/or environmental clearances as required.

(4) Retain grant files and supporting documentation for three years after the official closeout of the grant.

(5) Report to FEMA on the progress made on the grant and financial status of the grant. The award documents will detail the specific period of performance for each grantee and provide instructions on the frequency and timing of the required performance reports.

(6) Maintain documentation to support the expenditure of grant funds as well as pertinent grant decisions.

(7) Make their grant files and other books and records related to the grant, available if requested for an audit to ensure compliance with any requirement of the grant program.

(8) Agree to provide information to the U.S. Fire Administration's National Fire Incident Reporting System (NFIRS) for the period covered by the grant. If a grantee does not currently participate in the incident reporting system and does not have the capacity to report at the time of the award, that grantee must agree to provide information to the system for a twelve-month period commencing as soon as they develop the capacity to report. Capacity to report to the NFIRS must be established prior to the termination of the one-year performance period. [NFIRS is under review for approval by the Office of Management and Budget under OMB control number 3067–0161.]

(c) FEMA activities:

(1) We will ensure that the funds are awarded based on the priorities and expected benefits articulated in the statute, this part, USFA's strategic plan, and the Notice of Funds Availability.

(2) We will ensure that not more than twenty-five (25) percent of the appropriated funding will be used to purchase firefighting vehicles.

(3) We will ensure that not less than five (5) percent of the funds are made available to national, State, local, or community organizations, including fire departments, for the purpose of carrying out fire prevention programs.

(4) We will ensure that fire departments with volunteer staff, or staff comprised of a combination of career fire fighters and volunteers, receive a proportion of the total grant funding that is not less than the proportion of the United States population that those firefighting departments protect.

(5) We will ensure that grants are made to fire departments located in urban, suburban, and rural communities.

(6) We will strive to ensure geographic diversity of awards as stipulated in § 152.6.

(7) We will strive to ensure that activities funded under this grant program are consistent with the programs goals and intent, and generally in the government's best interest.

(8) We will provide the chief executives of the States with information concerning the total number and dollar amount of awards made to fire departments in their States; the program areas and activities supported by these grants; and other information about specific awards when generated and available.

§ 152.5 Review process and evaluation criteria.

(a) Every application will be evaluated based on the answers to the activity-specific questions during our initial screening. The applications that are determined to best address the Assistance to Firefighters Grant Program's established priorities during this initial screening will be in the ''competitive range'' and subject to a second level of review. We will use the narratives/supplemental information provided by the applicants in their grant applications to evaluate, on a competitive basis, the merits and benefits of each request for funding. In selecting applications for award, we will evaluate each application for assistance independently based on established eligibility criteria and the program priorities. Eligible applicants that best address the priorities will advance to a second level of review. The second level of review involves an assessment of the financial needs of the applicant, and an analysis of the benefits that would result from the grant award.

(b) In order to be successful at this second level of the evaluation, an applicant must complete the narrative section of the application package. The narrative should include a detailed description of the planned program, uses for the grant funds including details of each budget line item. For example, if personnel costs are included in the budget, please provide a break down of what those costs are for. The narrative should explain why the grant funds are needed and why the department has not been able to obtain funding for the planned activities on its own. A discussion of financial need should include a discussion of any Federal funding received for similar activities. Finally, the applicant's narrative should detail the benefits the department or community will realize as a result of the grant award.

(c) This second level of review will be conducted using a panel of technical evaluation panelists. These panelists are largely made up of non-Federal experts with a fire service background. The panelists will assess the application's merits with respect to the clarity and detail provided in the narrative about the project, the applicant's financial need, and the project's purported benefit to be derived from the cost. Technical evaluation panelists will independently score each application before them and then discuss the merits/shortcomings of the application in an effort to reconcile any major discrepancies. A consensus on the score is not required. The highest scoring applications resulting from this second level of review will then be considered for award. We seek to maximize the benefits derived from the funding by crediting applicants with the greatest financial need and whose proposed activities provide the greatest benefit versus the cost.

(d) In addition to the project narrative, the applicant must provide an itemized budget detailing the use of the grant funds. If an applicant is seeking funds in more than one eligible activity within a program, separate budgets will have to be generated for each activity and then an overall or summary budget will have to be generated. For those applicants applying on line, the summary budget will be automatically generated by the e-grants system.

(e) Specific rating criteria for each of the eligible programs will be published in a Notice of Funding Availability that we will publish pursuant to the program's annual appropriation.

§ 152.6 Application review and award process.

(a) As stated in §152.5, we will evaluate each application in the preliminary screening process to determine which applications best address the program's established priorities. The best applications as determined in this preliminary step will be deemed to be in the ''competitive range.'' All applications in the competitive range will advance to a second level review by a technical evaluation panel. Using the evaluation criteria detailed in the Program Guidance and in the NOFA (both of which are published pursuant to this program's annual appropriation), the panelists will score each application they evaluate. The assigned score will reflect the degree to which the applicant: clearly relates their proposed project; demonstrates financial need; and, details a high benefit to cost value of the proposed activities. We will provide the panelists the complete application content for their evaluation. We will also provide them with reference materials for national standards or regulations and guidelines with respect to typical costs for proposed apparatus and equipment purchases.

(b) Our award decisions will be based on the stated priorities of the grant program first, then on the demonstrated need of the applicant and the benefits to be derived from the proposed projects. We will make awards on a competitive basis, *i.e.*, we will fund the highest scored applications before considering lower scored applications.

(c) In a few cases, to fulfill our obligations under the law to make grants to a variety of departments, we may also make funding decisions using rank order as the preliminary basis, and then analyze the type of fire department (paid, volunteer, or combination fire departments), the size and character of the community it serves (urban, suburban, or rural), and/or the geographic location of the fire department. In these instances where we are making decisions based on geographic location, we will use States as the basic geographic unit. We may also base our funding decisions on previous grant awards funded by this program and/or grantees' performance on previous grants and a technical evaluation of reasonable costs for labor, services, materials or equipment.

§ 152.7 Grant payment, reporting and other requirements.

(a) Grantees will have twelve months to incur obligations and complete the scope of work to fulfill their responsibilities under this grant program. The performance period of each grant will be detailed in the Articles of Agreement that we provide each grantee. Grantees may request funds from FEMA as reimbursement for expenditures made under the grant program or they may request funds for immediate cash needs under FEMA regulations (44 CFR 13.21). Advances of funds may also be approved to meet immediate cash needs.

(b) Generally, fire departments cannot use grant funds to pay for products and services contracted for, or purchased prior to the effective date of the grant. However, we will consider requests for reimbursement for these on an exception basis. Expenses incurred after the application deadline but prior to award may be eligible for reimbursement if the expenses were justified, unavoidable (i.e., urgent and compelling), consistent with the scope of work, and specifically approved by the Assistance Officer. Expenses, obligations, commitments or contracts incurred or entered into prior to the application deadline are not eligible to be included as an expense.

(c) All grantees must follow their own established procurement process when buying anything with Federal grant funds (as provided in 44 CFR 13.26). If the grantee does not have an established procurement process, they must seek a minimum of two bids for any acquisition.

(d) When requesting funding, grantees can only request an amount that is necessary to satisfy their immediate cash needs directly related to the grant, i.e., an amount equal to the total eligible grant expenses due within 30 days. Grantees can request payments of up to one hundred (100) percent of the federal share of the award amount but only if delivery of the ordered products and/or services is imminent (approximately 30 days) and the resulting payment will require the entire amount of funds.

(e) A grantee may request sufficient funding for a down payment if required to do so by the seller, such as in grants involving some purchases of firefighting vehicles. The grantee may request as much as fifty (50) percent of the federal share of the award amount at the time of the order placement to pay the down payment. The grantee may request the balance of the federal share upon delivery of the ordered equipment or vehicle.

(f) The recipients of funding under this program must report to us on how the grant funding was used and the benefits that resulted. This will be accomplished via submission of performance reports. Details regarding the reporting requirements will be provided in the Articles of Agreement provided to each grantee.

(g) Fire departments that receive funding under this program must agree to provide information to the National Fire Incident Reporting System (NFIRS) for the period covered by the assistance. If a grantee does not currently participate in the incident reporting system and does not have the capacity to report at the time of the award, that grantee must agree to provide information to the system for a twelve-month period commencing as soon as possible after they develop the capacity to report. Capacity to report to the NFIRS must be established prior to the termination of the one-year performance period. [NFIRS is under review for approval by the Office of Management and Budget under OMB control number 3067–0161.]

§ 152.8 Application submission and deadline.

In each year that this program is authorized and receives an appropriation, we will announce the grants availability via Notice of Funds Availability. That Notice will contain all pertinent information concerning the eligible funding activities, funding priorities, funding levels, application period, timelines, and deadlines.

§ 152.9 Reconsideration.

(a) *Reconsideration of initial grant award decisions.* We will review our decision with respect to an initial grant award decision only when the applicant asserts that we have made a material technical or procedural error in the processing of the application and can substantiate such assertions. As grants are awarded on a competitive basis, in accordance with the findings of an independent panel of experts, we cannot consider requests for reconsideration based upon the merits of an original application. Similarly, we will not consider new information provided after the submission of the original application. In the case of new information, we encourage applicants to incorporate their changed circumstances into their applications for future grant cycles.

(b) *Reconsideration of other decisions.* We will consider requests for reconsideration of decisions other than those related to the initial grant award on their merits.

(c) We must receive a request for reconsideration under this section within 60 days of the date of the notice of the decision for which reconsideration is requested.

(d) Requests for reconsideration should be directed to: Director, Grants Program Office, U.S. Fire Administration, FEMA, 500 C Street, SW., Room 330, Washington, DC 20472.

Dated: March 7, 2003.

Michael D. Brown,

Acting Under Secretary, Emergency Preparedness and Response Directorate.

[FR Doc. 03–6171 Filed 3–13–03; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Federal Emergency Management Agency

Assistance to Firefighters Grant Program

AGENCY: U.S. Fire Administration (USFA), FEMA, Emergency Preparedness and Response, Homeland Security.

ACTION: Notice of funds availability.

SUMMARY: We, USFA, are publishing this Notice to announce the availability of grant funding for the Assistance to Firefighters Grant Program (AFGP) for fiscal year 2003 and to provide the details and guidance regarding the 2003 program year.

The program is intended to make grants directly to fire departments of a State for the purpose of enhancing the departments' ability to protect the health and safety of the public as well as that of firefighting personnel facing fire and fire-related hazards. A portion of this year's grants will be awarded on a competitive basis to the applicants that best address the program's priorities as described in this Notice of Funds Availability (NOFA), then demonstrate financial need and maximize the benefits to be derived from the grant funds.

DATES: This notice is effective March 14, 2003.

FOR FURTHER INFORMATION CONTACT: Brian A. Cowan, Director, Grants Program Office, USFA, DHS, 500 C Street, SW., Room 330, Washington, DC 20472.

SUPPLEMENTARY INFORMATION:

Authority: Federal Fire Prevention and Control Act of 1974, 15 U.S.C. 2201 *et seq.*, and the Consolidated Appropriations Resolution, 2003, Pub. L. 108–7.

Appropriations

For fiscal year 2003, Congress appropriated $750,000,000 to carry out the activities of the Assistance to Firefighters Grant Program (AFGP). From this amount $4,875,000 was rescinded leaving $745,125,000 to carry out the AFGP. We are also authorized to spend up to $37,500,000 for administration of the AFGP (five percent of the appropriated amount). In addition, we may set aside as much as $27,500,000 of the funds available under the Assistance to Firefighter Grant Program in order for us to make grants to, or enter into contracts or cooperative agreements with, national, State, local or community organizations or agencies, including fire departments, for the purpose of carrying out fire prevention and injury prevention programs. This leaves approximately $680,000,000 for competitive grants to fire departments. We have until September 30, 2004, to obligate the appropriated funds.

Background

The purpose of the AFGP is to award grants directly to fire departments of a State to enhance their ability to protect the health and safety of the public, as well as that of firefighting personnel, with respect to fire and fire related hazards. We will award the grants on a competitive basis to the applicants that first address the AFGP's priorities then demonstrate financial need and adequately demonstrate the benefit to be derived from their projects.

For the purpose of the AFGP, ''State'' is defined as the fifty States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands. We will provide the chief executives of the States with information concerning the total number and dollar amount of awards made to fire departments in their States.

Applicants may apply for any number of activities within one grant proposal that address all of their needs within a programmatic or functional area. The programs, and associated activities are as follows:

(a) *Fire Operations and Firefighter Safety Program.* Eligible activities under this function are Training, Wellness and Fitness, Firefighting Equipment, Personal Protective Equipment, and Modification to Fire Stations and Facilities.

(b) *Fire Prevention Program.* Eligible activities under this function include, but are not limited to Public Education and Awareness, Enforcing Fire Codes, Inspector Certification, Purchase and Install Smoke Alarms, and Arson Prevention and Detection.

(c) *Emergency Medical Services Program.* Eligible activities under this function are Equipment Acquisition, Training, and Wellness and Fitness Activities. Vehicles are not eligible in this programmatic area.

(d) *Firefighting Vehicle Acquisition Program.* Eligible apparatus under this program include, but are not limited to, pumpers, brush trucks, tankers, rescue, ambulances, quints, aerials, foam units, and fireboats.

Applicants seeking funding from this grant program in fiscal year 2003 may apply for assistance in only one of the four programmatic areas listed above. Within the selected programmatic area, applicants may develop a comprehensive program and include in their application as many of the eligible activities as necessary to address their needs. For example, if a fire department determines that it has needs in the area of fire operations, that fire department could apply for any one of the activities, or any combination of activities, or all of the activities listed within that program. If a department wants a vehicle, it would apply under the vehicle program.

We anticipate 20,000 to 25,000 fire departments will apply for assistance. Of these, we anticipate awarding approximately 7,000 grants. However, due to the length of time that it will take us to make these awards, we anticipate that approximately half of these awards will be made before September 30, 2003. We anticipate the balance of the awards will be made before June 30, 2004.

The law requires a certain distribution of grant funds between career departments and combination/volunteer fire departments. Specifically, we must ensure that fire departments that have either all-volunteer forces of firefighting personnel or combined forces of volunteer and career firefighting personnel receive a portion of the total grant funding that is not less than the proportion of the United States population that those departments protect. According to a 2001 survey by the National Fire Protection Association (NFPA), volunteer and combination departments protect 56 percent of the population of the United States and career departments protect 44 percent of the population. Therefore, we will ensure that no less than 56 percent of the funding available for grants will be awarded to volunteer and combination departments.

In order to fulfill our obligations under the law, we will make funding decisions using rank order after the panel evaluation as the preliminary basis. We may deviate from rank order and make funding decisions based on the type of department (career, combination, or volunteer), size and character of the community the applicant serves (urban, suburban, or rural), and/or the geographic location of the fire department. In these instances where we are making decisions based on geographic location, we will use States as the basic geographic unit. Geographic location of an applicant may be used primarily as a final discriminator, *i.e.*, in cases where applicants have similar qualifications, we may use the geographic location of the applicants to maximize the diversity of the awardees.

Fire Prevention and Safety Grants

In addition to the grants available to fire departments in fiscal year 2003 through the competitive grant program, we will set aside as much as $27,500,000 of the funds available under the Assistance to Firefighter Grant Program in order for us to make grants to, or enter into contracts or cooperative agreements with, national, State, local or community organizations or agencies, including fire departments, for the purpose of carrying out fire prevention and injury prevention programs.

In accordance with statutory requirement to fund fire prevention activities, our support to Fire Prevention and Safety Grant activities will concentrate on organizations that focus on the prevention of injuries to children from fire. In addition to this priority, we are also placing an emphasis on funding innovative projects that focus on protecting the USFA-identified high-risk populations, *i.e.*, children under fourteen, seniors over sixty-five, and firefighters. Since the victims of burns experience both short- and long-term physical and psychological effects, we are also placing a priority on programs that focus on reducing the immediate and long-range effects of fire and burn injuries, and primarily those affecting children.

A separate Notice of Funds Availability will be issued to announce the pertinent details of the Fire Prevention and Safety Grant portion of this program.

Applicant Eligibility

Eligible applicants for the Assistance to Firefighters Grant Program are limited to fire departments of a State. Under the existing interim final rule, a ''fire department of a State'' is defined as an agency or organization that has a formally recognized arrangement with a State, local or tribal authority (city, county, parish, fire district, township, town or other governing body) to provide fire suppression services to a population within a fixed geographical area. For the purpose of this program, ''State'' is defined as the fifty States, the District of Columbia, Puerto Rico, the U.S. Virgin Islands, Guam, American Samoa, and the Commonwealth of the Northern Mariana Islands.

A fire department can apply for assistance for its emergency medical services unit provided the unit falls organizationally under the auspices of the fire department. Airport fire departments and port authority fire departments are eligible, but only if they have a formally recognized arrangement with the local jurisdiction to provide fire suppression services, on a first-due basis, outside the confines of the airport or port facilities. Airport fire departments and port authority fire departments whose sole responsibility is suppression of fires on the airport grounds or port are not eligible for this grant program.

Fire departments that are Federal, or contracted by the Federal government, and which are solely responsible under their formally recognized arrangement for suppression of fires on Federal installations, are not eligible for this grant program. Fire departments or fire stations that are not independent but are part of, or controlled by a larger fire department or agency are typically not eligible to apply on their own, but may be included in the larger agency's application. Fire departments that are for-profit departments (*i.e.*, do not have specific non-profit status or are not municipally based) are not eligible to apply for assistance under this program. Also not eligible for this program are non-fire based EMS companies, ambulance services, rescue squads, auxiliaries, dive teams, urban search and rescue teams, fire service organizations or associations, and State/local agencies such as a forest service, fire marshal, hospitals, and training offices.

Application Process

Eligible applicants will be able to access the application on USFA's e-grant system. This system is accessible from the USFA Internet homepages. The application will only be available during the application period. Although we do not encourage the use of paper applications, paper applications will be available for applicants that do not have access to the Internet. If an applicant does not have access over the Internet to the USFA Web site, the applicant may contact us directly to request a copy via mail. Although we do not recommend it due to inherent delays and relatively short application period, those fire departments interested in receiving an application in the mail must call our toll-free hotline at 866–274–0960.

Applicants applying via paper application rather than the automated e-grant system should complete and submit their applications to us at Grant Program Technical Assistance Center, 16825 South Seton Avenue, Emmitsburg, Maryland, 21727–8998. Faxed applications will not be considered. We will not be responsible for applications sent to any other address.

The application period for the 2003 Assistance to Firefighters Grant Program is Monday, March 10, 2003, to Friday, April 11, 2003. Complete application packages must be submitted electronically or otherwise received by us on or before the close of business (5 p.m. EST) on Friday, April 11, 2003. Applications submitted by mail must be post-marked by April 8, 2003, or received by us on or before close of business (5 p.m. EST) on April 11, 2003. We will not accept late, faxed, or emailed applications.

The automated grant application system has features built into it that will guarantee that the application is complete when submitted. We will not accept incomplete applications submitted by mail. We will not be responsible for any application that is not mailed to the address specified above.

We will evaluate each application in the preliminary screening process to determine which applications best address the program's established priorities. This preliminary screening is based on the applicants' answers to the activity-specific questions. Each activity within an application will be scored and applications that have multiple activities will have the scores prorated based on the amount of funding requested for each activity.

The best applications as determined in this preliminary step will be deemed to be in the ''competitive range.'' All applications in the competitive range will be subject to a second level review by a technical evaluation panel. The panelists will assess the application's merits with respect to the clarity and detail provided in the narrative about the project, the applicant's financial need, and the project's purported benefit to be derived from the cost.

Using the evaluation criteria included herein, the panelists will independently score each application before them and then discuss the merits/shortcomings of the application in an effort to reconcile any major discrepancies. A consensus on the score is not required. The assigned score will reflect the degree to which the applicant: clearly relates their proposed project; demonstrates financial need; and, details a high benefit to cost value of the proposed activities. The highest scoring applications resulting from this second level of review will then be considered for award.

In order to be successful in the panel evaluation, the narrative should include a detailed description of the planned activities, uses for the grant funds including details of each budget line item. For example, if personnel costs are

included in the budget, please provide a break down of what those costs are for. The narrative should also explain why the grant funds are needed and why the department has not been able to obtain funding for the planned activities on its own. A discussion of financial need should include an explanation of any Federal funding received for similar activities. Finally, the applicant's narrative should detail the benefits the department or community will realize as a result of the grant award. In addition to describing the cost effectiveness of the grant request, an applicant can demonstrate cost benefit by describing, *as applicable,* how the grant award will (1) Fit in with a regional approach, *i.e.*, is consistent with current capabilities and requests of neighboring fire departments or otherwise benefits other fire departments in the region, (2) promote interoperability of equipment/technology with other fire departments and local, state and Federal first responders, and (3) allow the fire department to respond to all hazards. In addition to fire prevention/suppression, all hazards includes incidents involving seismic (earthquake), atmospheric (tornados, hurricanes), technological (hazardous materials, nuclear, etc.), and terrorism.

In addition to the project narrative, the applicant must provide an itemized budget detailing the use of the grant funds. If an applicant is seeking funds in more than one eligible activity within a program, separate budgets will have to be generated for each activity and then an overall or summary budget would have to be generated. For those applicants applying on line, the summary budget will be automatically generated by the e-grant system.

Applicants that need assistance in formulating the justification or narrative statement required by this program may contact us for technical assistance. We will also be conducting grant workshops in each State. We will place the information regarding the workshops on the USFA Web site. Our Technical Assistance Center's toll free number is 866–274–0960, our email address is *USFAGRANTS@fema.gov,* and our Web site addresses are *www.fema.gov* and *www.usfa.fema.gov,* respectively.

Eligible Activities

Specific activities that are eligible for consideration for each program area are provided below under the descriptions of this year's eligible programs. Each department may only submit one application per application period. Applicants may only apply for one program area per application but they may seek funding in as many activities within the program area as they need. The specific activities eligible for each program area are delineated below. Applicants that submit multiple applications within one application period or more than one program will have each of their applications deemed ineligible. Applications submitted under this NOFA does not preclude applications submitted under subsequent NOFAs, though multiple awards in one Federal fiscal year may be limited.

Fire Operations and Firefighter Safety Program.

Appropriate activities under this program area include: Training, Wellness and Fitness, Firefighting Equipment, Personal Protective Equipment, and Modifications to Fire Stations and Facilities. You can apply for as many eligible activities under this function as necessary to meet your operational needs. There are no bonuses or penalties for applying for only one activity or for multiple activities. The purchase of any equipment (communications systems and equipment or personal protective equipment or firefighting equipment) under this program should have the intent and/or goal of solving your interoperability problems, as applicable. Any applicant seeking funding for equipment herein should provide details in the narrative section of their application regarding their local plan to enable interoperability for their jurisdiction.

(a) *Training activities*: USFA may make grants for the purpose of training firefighting personnel. Examples of training activities include, but are not limited to firefighting I and II, driver/operator, fire officer, hazardous materials response, incident command, supervision and safety, arson prevention and detection, handling of hazardous materials, or training firefighting personnel to provide training in any of these areas.

Eligible uses of training funds include but are not limited to purchase of training curricula, training equipment (including trailers), training props, training services, attendance at formal training forums, etc. Tow vehicles or other means of transport may be eligible as a transportation expense under this activity if adequately justified in your grant proposal, but we will limit transportation expenses to $6,000 per year. Compensation to volunteer firefighters for wages lost as a result of attending training under this program is an eligible expense if justified in your grant proposal. Overtime expenses paid to career firefighters to attend training, or overtime expenses paid to firefighters to cover for their colleagues while their colleagues are in training, is an eligible expense if justified in your grant proposal. Even though compensation is an eligible expense, proposals that contain such compensation expenses may be less favorable than similar proposals without compensation expenses due to the benefit/cost element in the evaluation process.

Activities that are not eligible in this area include construction of facilities such as classrooms, buildings, towers, etc. Renovations to an existing facility necessary to accomplish training activities are allowable if the renovations are minor and comply with the definition in the final rule and published in the **Federal Register** (*i.e.*, limited to minor interior alterations costing less than $10,000).

(b) *Wellness and fitness activities*: USFA may make grants for the purpose of establishing or expanding wellness and fitness initiatives for firefighting personnel. Applicants will not be eligible for funding under the wellness and fitness activity unless they currently provide entry level physical examinations, immunization programs, and periodic health screenings, or intend to use grant funds to provide these three benefits to all their active firefighting personnel including EMS staff.

Eligible expenses in a wellness and fitness activity for firefighting personnel may include the procurement of medical services to ensure that the firefighting personnel are physically able to carry out their duties (purchase of medical equipment is not eligible under this category). Expenses to carry out wellness and fitness activities may include costs such as personnel (*i.e.*, health-care consultants, trainers, and nutritionists), physicals, equipment (including shipping), supplies, and other related contract services that are directly associated with the implementation of the proposed activity are eligible.

Transportation expenses and fitness club memberships for the firefighters or their families are not eligible under the wellness and fitness activity. Other expenses that are not eligible in this area include construction of facilities to house a fitness program such as exercise or fitness rooms, showers, etc. Renovations to an existing facility necessary to accomplish wellness and fitness activities are allowable if the renovations are minor and comply with the definition in the final rule and published in the **Federal Register** (*i.e.*,

limited to minor interior alterations costing less than $10,000).

(c) *Firefighting equipment acquisition*: USFA may make grants for the purpose of acquiring additional firefighting equipment, including equipment needed directly for fire suppression or to enhance the safety or effectiveness of firefighting or rescue activities.

Eligible expenses include those expenses necessary to acquire additional firefighting equipment, including equipment for individual communications and monitoring equipment. Compressor systems, cascade systems, or similar SCBA refill systems are eligible expenditures in this area. Small boats (under 13 feet in length), jet-skis, and all-terrain vehicles (ATVs) may be considered firefighting or rescue equipment if properly justified in the narrative section of the application.

Renovations to an existing facility necessary to accommodate new firefighting equipment are allowable if the renovations are minor and comply with the definition in the final rule and published in the **Federal Register** (*i.e.*, limited to minor interior alterations costing less than $10,000).

Thermal imaging cameras are eligible, but the number of cameras that can be applied for and/or purchased with grant funds will be limited based on the population served by the department applying for assistance. Departments that serve communities of less than 20,000 can purchase one thermal imaging camera with grant funds if awarded a grant; departments serving communities between 20,000 and 50,000 can purchase two cameras with grant funds if awarded a grant; and departments serving communities of over 50,000 can purchase three cameras with grant funds if awarded a grant.

Activities that are not eligible in this area include construction of facilities such as buildings, towers, etc. Vehicles, as defined in the final rule and published in the **Federal Register**, are not eligible under this activity. Signage and outdoor warning sirens or systems are also not eligible. Personal protective equipment, including clothing for structural and/or wildland fire suppression such as ''Turnout Gear'' or ''Bunker Gear'' (including boots, pants, coats, gloves, hoods, goggles, vests, helmets, coveralls, and fire shelters), self-contained breathing apparatus, spare cylinders, and personal alert safety systems, is not eligible under this activity, but is eligible under the Personal Protective Equipment Acquisition activity.

Integrated communications systems (or parts thereof), such as computer-aided dispatch, base stations, repeaters, etc., are eligible under this activity. Portable radios and/or mobile communications equipment (including mobile repeaters) are also eligible. Personal accountability systems are eligible as well. The cost of shipping equipment purchased under this program is also an eligible expense.

The purchase of any equipment under this program must have the intent and/or goal of satisfying local problems with interoperable systems. Any applicant seeking funding for communications systems and/or equipment must provide details regarding their local plan to enable interoperability for their jurisdiction in the narrative section of their application.

(d) *Personal protective equipment acquisition*: USFA may make grants for the purpose of acquiring personal protective equipment required for active firefighting personnel by the Occupational Safety and Health Administration, and other personal protective equipment for firefighting personnel.

Eligible personal protective equipment includes clothing for structural and wildland fire suppression such as ''Turnout Gear'' or ''Bunker Gear'' (including boots, pants, coats, gloves, hoods, goggles, vests, helmets, coveralls, and fire shelters), self-contained breathing apparatus, spare cylinders, and personal alert safety systems. Protective clothing for response to hazardous materials incidents and other specialized incidents are also eligible under this activity.

The purchase of three-quarter length rubber boots is an ineligible expenditure under this activity since it precludes the effective use of the eligible PPE cited above. Uniforms (formal/parade or station/duty) or uniform items (hats, badges, etc.) are also not eligible expenditures under this activity. Personal communications equipment such as radios and pagers are not eligible under this activity, but eligible under firefighting equipment acquisition activity.

The purchase of any equipment under this program must have the intent and/or goal of satisfying local problems with interoperable systems. Any applicant seeking funding for communications systems and/or equipment must provide details regarding their local plan to enable interoperability for their jurisdiction in the narrative section of their application.

(e) *Modifications to fire stations and facilities activities:* Eligible measures under this activity are limited but focused on promoting fire and life safety in fire stations and facilities. We believe that each of the eligible measures, if incorporated, would make any facility safer for firefighters. Measures that are eligible for funding are the installation of sprinkler systems, installation of vehicle exhaust extraction systems, the installation of smoke and/or fire alarm notification systems, and minor renovations to facilities that are necessary in order to accomplish other activities under this grant. The grant funds are to be used to retrofit existing structures that do not have the eligible safety features or to upgrade facilities whose features are dated. The funds are not to be used to supplement new construction.

There are no monetary limits on the individual initiatives under this activity such as vehicle exhaust systems, sprinkler systems or smoke/fire alarm systems, but no applicant can request more than $100,000 in the modifications per fire station under their jurisdiction.

Fire Prevention Program.

USFA may make grants for the purpose of establishing or enhancing a fire prevention program. Appropriate activities in this program include, but are not limited to the following: public education, public awareness, enforcing fire codes, inspector certification, purchase and installation of smoke alarms and fire suppression systems, and arson prevention and detection activities. Applicants can apply for as many related activities under this function as necessary.

Eligible expenses to carry out these activities would include costs such as a fire education/safety trailer, personnel, transportation, equipment (including appropriate personal protective equipment), supplies, and contracted services which are directly associated with the implementation of the proposed activity. Tow vehicles or other means of transport may be eligible as a transportation expense if adequately justified in the proposal, but transportation expenses will be limited to $6,000 per year.

Construction is not eligible under this program. A safety village that is not transportable would be considered construction, and therefore, not eligible. Firearms are also not eligible.

Emergency Medical Services Program.

USFA may make grants for the purpose of establishing or enhancing a fire department's emergency medical services program. Applicants can apply the training activity, the equipment acquisition activity, or the wellness and fitness activity or all of these activities under this program area.

Eligible expenses for the training activities under this program could include instructional costs (*i.e.*, books, materials, equipment, supplies, and exam fees), certification/re-certification expenses, and continuing education programs. Eligible expenses for equipment acquisition in this program could include defibrillators, basic and advanced life support equipment, universal precaution supplies (*i.e.*, medical PPE) mobile and portable communication equipment, computers, expendable supplies (but not medications), and infectious disease control and decontamination systems.

Integrated communications systems (or parts thereof), such as computer-aided dispatch, base stations, repeaters, etc., are eligible under this activity. Portable radios and/or mobile communications equipment (including mobile repeaters) are also eligible. The purchase of any equipment under this program must have the intent and/or goal of satisfying local problems with interoperable systems. Any applicant seeking funding for equipment must provide details regarding their local plan to enable interoperability for their jurisdiction in the narrative section of their application.

Wellness and fitness activities under the EMS program: USFA may make grants for the purpose of establishing or expanding wellness and fitness initiatives for firefighting and EMS personnel of a fire department. An applicant will not be eligible for funding under this wellness and fitness activity unless the applicant currently provides entry-level physical examinations, immunization programs, and periodic health screenings, or intends to use grant funds to provide these benefits to all firefighting personnel including active EMS staff.

Eligible expenses in a wellness and fitness activity for EMS personnel may include the procurement of medical services to ensure that the EMS personnel are physically able to carry out their duties (purchase of medical equipment is not eligible under this category). Expenses to carry out wellness and fitness activities may include costs such as personnel (*i.e.*, health-care consultants, trainers, and nutritionists), physicals, equipment (including shipping), supplies, and other related contract services that are directly associated with the implementation of the proposed activity are eligible.

Not eligible in this program are medications and vehicles, such as ambulances. Vehicles must be applied for under the Vehicle Acquisition Program detailed below. Transportation expenses and fitness club memberships for the EMS personnel or their families are not eligible under the wellness and fitness activity. Other expenses that are not eligible in this area include construction of communication towers or facilities to house a fitness program such as exercise or fitness rooms, showers, etc. Renovations to an existing facility necessary to accomplish wellness and fitness activities are allowable if the renovations are minor and comply with the definition in the final rule and published in the **Federal Register** (*i.e.*, limited to minor interior alterations costing less than $10,000).

Firefighting Vehicle Acquisition Program

USFA may make grants for the purpose of acquiring new firefighting vehicles, used fire apparatus, or refurbished apparatus. The funds may also be used to refurbish a vehicle that the department currently owns. Applicants may apply for only one vehicle per year under this program. A listing of the eligible vehicles and their relative priority is contained in the Evaluation Criteria section below.

Eligible expenses under this program would include the cost of the vehicle and associated equipment necessary to conform to applicable national standards. New, used or refurbished vehicles are eligible, however any used or refurbished vehicles must conform to national standards that were in effect the year the vehicle was manufactured. Custom vehicles are eligible, but due to benefit/cost considerations during review, they may not be as favorably evaluated as a lower costing standard model commercial vehicle. An allowance for transportation to inspect a vehicle under consideration or during a vehicle's production would be eligible if justified and included in the grant proposal. Also eligible would be the additional costs associated with the purchase and installation of a vehicle-mounted exhaust filtration system for any vehicle purchased with grant funds.

Applicants will not be allowed to modify the scope of work of a vehicle award, *i.e.* change the type of vehicle requested. Aircraft, bulldozers, and construction-related equipment are not eligible.

Other Eligible Costs

Administrative Costs. Administrative costs are allowable under any of the program areas listed above, in accordance with OMB Circular A–87 or OMB Circular A–122, as applicable. Applicants may apply for administrative costs if the costs are directly related to the implementation of the program for which they are applying. Applicants must list their costs under the ''other'' category in their budget and explain what the costs are for in their project narrative. Examples of eligible administrative costs would be shipping, computers, office supplies, etc. We will assess the reasonableness of the administrative costs requested in each application and determine if it is in the best interest of the program to fund all or a portion of the requested expenses.

Indirect Costs. Applicants that have an approved indirect cost rate may charge indirect costs to the grant if they submit the documentation that supports the rate to us. Indirect cost rates must be formally established and approved by the applicant's cognizant Federal agency. We will allow the rate to be applied as long as it is consistent with its established terms. For example, some indirect cost rates may not apply to capital procurements; in this case, indirect cost rates would not apply for a grant to purchase equipment or a vehicle.

Audit Costs. Some applicants with large awards may be required to undergo an audit in accordance with OMB Circular A–133, specifically, recipients of Federal funding that spends in excess of $300,000 of those funds in a year. The costs incurred for such an audit would be an expenditure that is eligible for reimbursement if included in the budget proposal.

Grant Writer Fees. Fees for grant writers may be included as a pre-award expenditure (as provided in section 152.7(b)), but fees payable on a contingency basis are not an eligible expense that can be charged to the grant. For grant writers' fees to be eligible as a pre-award expenditure, the fees must have been paid prior to award. Applicants may be required to provide documentation to support these pre-award expenditures.

Reasonableness of Costs. The panelists will review the applications that make it into the competitive range and judge each application on its own merits. The panelists will consider all expenses budgeted, including administrative and indirect, as part of the cost-benefit determination and may recommend appropriate adjustments. Regardless of eligibility of any costs requested, we reserve the right to reduce any requests for assistance, in whole or in part, that we deem to be excessive or otherwise contrary to the best interests of this program.

Pre-award Costs. Generally, fire departments cannot use grant funds to pay for products and services contracted for, or purchased prior to the effective date of the grant. However, we will

consider requests for reimbursement for these on an exception basis. Expenses incurred after the application deadline but prior to award may be eligible for reimbursement if the expenses were justified, unavoidable (*i.e.*, urgent and compelling), consistent with the scope of work, and specifically approved by the Assistance Officer. Expenses, obligations, commitments or contracts incurred or entered into prior to the application deadline are not eligible to be included as an expense.

Evaluation Criteria

Specific rating criteria for each of the eligible programs and activities follow below. These rating criteria will provide an understanding of the grant program's priorities and the expected cost effectiveness of any proposed projects.

(1) *Fire Operations and Firefighter Safety Program.*

(i) *Training Activities.* We believe that more benefit is derived from the direct delivery of training than from the purchase of training materials, equipment or props. Therefore, applications focused on direct delivery of training will receive a higher competitive rating. We will also accord higher rating to programs achieving benefits from statutorily required training over non-mandatory or strictly voluntary training. We will rate more highly those programs that benefit the highest percentage of targeted personnel within a fire department. Training designated for Rapid Intervention Teams will have a slightly higher competitive advantage. It should be noted that on average the sending of trainees away for training will be less cost effective than delivery of the same training on-site.

Due to the inherent differences between urban, suburban, and rural firefighting characteristics, we have developed different priorities in the training activity for departments that service these different types of communities. For departments serving rural communities, we believe that funding of basic, operational-level firefighting, rescue, and responder training (*i.e.*, training in basic firefighting duties or operating fire apparatus) has greater benefit than funding of officer training, safety officer training, or operations training. Likewise, we feel there is a greater cost-benefit to officer training than for other specialized training such as mass casualty, HAZMAT, WMD awareness, advance rescue, or inspector training. Conversely, for departments that are servicing communities that are suburban or urban, we believe there is a higher benefit to be gained by funding specialized training such as mass casualty, HAZMAT, advance rescue, or inspector training than the funding of officer training, safety officer training, or operations training, which in turn has a higher benefit than basic, operational, or awareness level activities.

(ii) *Wellness and Fitness Activities.* We believe that in order to have an effective wellness/fitness program, fire departments must offer an entry physical examination, an immunization program, and periodic health screenings. Accordingly, applicants seeking funding in this category must currently offer all three benefits, or must propose to initiate any of these benefits not currently offered with these grant funds in order to receive additional consideration for funding this activity. We believe the greatest benefit will be realized by supporting new wellness and fitness programs, and therefore, we will accord higher competitive ratings to those applicants lacking wellness/fitness programs over those applicants that already possess a wellness/fitness program. We believe that programs with annual physicals and general health screening provide high benefits and programs including employee assistance-type offerings, incident rehabilitation, formal fitness regiments, and/or injury prevention components offer significant benefits. Injury rehabilitation is eligible but provide a low cost benefit. Finally, since participation is critical to achieving any benefits from a wellness or fitness program, we will give higher competitive rating to departments whose wellness and fitness programs mandate participation as well as programs that provide incentives for participation.

(iii) *Firefighting Equipment Acquisition.* The stated purpose of this grant program is to protect the health and safety of the public and firefighters from fire and fire related hazards. As such, we believe that this grant program will achieve the greatest benefits if we provide funds to fire departments purchasing basic firefighting equipment before any other type of equipment. We will afford departments buying basic firefighting equipment for the first time (equipment never owned before) a higher competitive rating than departments buying replacement equipment or equipment that will be used to expand the department's capabilities into new mission areas. We believe there is more benefit realized to bring a department up to the applicable minimum standard (*i.e.*, as required by statute, regulation, or professional firefighting guidance), rather than to the department that is replacing equipment or enhancing capabilities. Equipment designated for Rapid Intervention Teams will have a slightly higher competitive advantage.

(iv) *Personal Protective Equipment Acquisition.* A stated purpose of this grant program is to protect the health and safety of firefighters from fire, fire related hazards and other hazardous conditions. The goal is to provide active firefighters with a complete set of equipment, breathing apparatus as well as turnout gear. As such, this grant program will achieve the greatest benefits if we provide funds to fire departments purchasing basic protective equipment for firefighting before other types of protective equipment. In order to achieve the goal and maximize the benefit to the firefighting community, we believe that we must fund those applicants needing to provide personal protective equipment (PPE) to a high percentage of their personnel. Accordingly, we will give a high competitive rating in this category to fire departments in which a large percentage of their active firefighting staff do not have any personal protective equipment and to departments that wish to purchase enough PPE to equip 100 percent of their active firefighting staff. We will also give a higher competitive rating to departments that are purchasing the equipment for the first time as opposed to departments replacing obsolete or substandard equipment (*e.g.*, equipment that does not meet current NFPA and OSHA standards), or purchasing equipment for a new mission. Departments that are replacing used gear that is very old, will be afforded a higher competitive rating than a department whose gear is relatively new. We will provide a higher competitive rating to departments requesting integrated PASS devices than to those departments that are requesting non-integrated PASS devices. We also believe it is more cost beneficial to fund departments that have a high volume of fire related responses per year before funding less active departments. With respect to call volume, departments will be compared to departments with similar characteristics, *i.e.*, urban compared to urban, suburban compared to suburban, and rural compared to rural. Equipment designated for Rapid Intervention Teams will have a slightly higher competitive advantage.

(v) *Modifications to Fire Stations and Facilities.* The stated purposes of this grant program is to protect the health and safety of firefighters, as such, eligible projects under this activity that are designed to directly protect the health and safety of firefighters. We believe that more benefit would be

derived from modifying fire stations than would be realized by modifying fire-training facilities or other fire-related facilities. Facilities that would be open for broad usage and have a high occupancy capacity would receive a higher competitive rating than facilities that have limited use and/or low occupancy capacity. The frequency of use would also have a bearing on the benefits to be derived from grant funds. The frequency and duration of a facility's occupancy have a direct relationship to the benefits to be realized from funding in this activity. As such, facilities that are occupied or otherwise in use 24-hours-per-day/seven-days-a-week would receive a higher competitive rating than facilities used on a part-time or irregular basis.

(2) *Fire Prevention Program.* We believe that the public as a whole will receive the greatest benefit by creating new fire prevention programs. Therefore, our priority is to target these funds to fire departments that do not have an existing fire prevention program as opposed to those departments that already have such a program. Also, we believe the public will benefit greatly from establishing fire prevention programs that will continue beyond the grant year as opposed to limited efforts. Therefore, we will give a higher competitive rating to programs that will be self-sustaining after the grant period.

Because of the benefits to be attained, we will give a higher competitive rating to programs that target one or more of USFA's identified high-risk populations (*i.e.*, children under fourteen years of age, seniors over sixty-five and firefighters), and programs whose impact is/will be periodically evaluated. We believe that the purchase or development and/or implementation of public education programs provides the highest benefits to a community therefore, applications that propose this type of project will receive the highest competitive rating. Programs that develop and enforce fire codes and standards, and arson prevention and detection programs typically provide long-term effect on fire prevention, therefore, they will receive a high competitive rating. We also believe programs that purchase and install residential and public detection and suppression systems provide significant benefits.

Programs that are limited to the purchase of public information materials and presentation aids and equipment achieve the least benefit; therefore, these types of activities will receive a lower competitive rating.

(3) *Emergency Medical Services Program.* Our overall objective in this program is to help fire departments start or expand EMS service delivery by providing training and equipment necessary to achieve their desired level of capacity. Because of the inherent benefits, the primary goal of this program is to train and equip all firefighters to the basic EMS certification level (*i.e.*, first responder and EMT) and work toward an EMT–B level of capacity before assisting departments with established EMS programs in upgrading existing services.

In this program area, we will give the highest competitive rating to fire departments that are planning on acquiring a basic life-support level of service over upgraded or expanded services. We believe that enhancing or expanding an existing service that currently meets basic life-support to an intermediate life-support system would a higher benefit than enhancing existing services to the paramedic level.

Higher priority will be given to departments with a high call volume relative to departments of similar characteristic (*i.e.*, urban, suburban, or rural). Also, departments that strive to comply with a State, Federal, or national standard will be afforded a slightly higher competitive standing.

(1) *Firefighting Vehicle Program.* In recognition of the inherent differences between urban, suburban, and rural firefighting conventions, we have developed different priorities in the vehicle acquisition program for departments that service these different types of communities. The following chart delineates our priorities in this program area for each type of community. Due to the competitive nature of this program and the imposed limits of funding available for this program, it is unlikely that we would fund many vehicles that are not listed as a priority-one or a priority-two this year.

VEHICLE ACQUISITION PROGRAM PRIORITIES

	Urban	Suburban	Rural
Priority One	Pumper Quint Rescue-pumper Aerial Rescue	Pumper Quint Rescue-pumper	Pumper. Tanker. Brush. Rescue-pumper. Pumper-tanker.
Priority Two	HAZMAT Light/Air Rehab	Brush Rescue Aerial HAZMAT	Rescue. Light/Air. Quint.
Priority Three	ARFF Foam Brush Command Fire Boat	Light/Air Tanker Pumper-tanker Rehab Command	HAZMAT. Rehab. Command.
Priority Four	Tanker Pumper-tanker Watercraft Ambulance	ARFF Foam Watercraft Fire Boat Ambulance	ARFF. Foam. Aerials. Watercraft. Fire Boat. Ambulance.

Regardless of the type of community served, we believe that more benefit will be realized by funding fire departments that own few or no firefighting apparatus than by providing funding to a department with numerous vehicles. Therefore, we will give a higher competitive rating in the apparatus category to fire departments that have

few or no firefighting vehicles relative to other departments servicing similar types of communities. We consider vehicles that are on long-term loan or assignment to the applicant to be part of the applicant's fleet.

We will also give higher competitive rating to departments that have not recently purchased a new firefighting vehicle, and departments that wish to replace or relegate an old, high-mileage vehicle. We will also provide a higher competitive rating to departments seeking a vehicle that incur a significant number of responses relative to other departments servicing similar communities.

We believe that more benefit will accrue to a community that needs a new vehicle (*i.e.*, the initial purchase of a new or used vehicle) as its first vehicle or to relegate a non-compliant vehicle to reserve status, *i.e.*, relegate a vehicle that does not conform to applicable standards. Relegating a compliant vehicle has a lower priority than relegating a non-compliant vehicle. But replacing a compliant vehicle has more benefit than purchasing a vehicle to expand the operational capacity of a department into a new mission area.

While no competitive advantage has been assigned to the purchase of commercial vehicles versus custom vehicles, or used vehicles versus new vehicles in the preliminary evaluation of applications, it has been our experience that depending on the type and size of department, the technical evaluation panelists often prefer low-cost vehicles when evaluating the cost/benefit section of the project narratives. Panelists may be provided with guidance for use in their evaluation on the reasonableness of vehicle costs. We may also instill funding limits on requests for vehicles that we deem excessive or otherwise not in the best interest of the program.

Finally, we believe that it would be more beneficial to the nation's fire service if we gave these vehicle awards to as many fire departments as possible, therefore, we will allow each fire department to apply for only one vehicle per year.

Reporting Requirements

The grantees may be required to submit a progress report regarding the financial and performance status of their project after six months of performance and at the closure of the grant. The due dates will vary from grantee to grantee, based on the performance period as indicated in the Articles of Agreement. These performance reports should provide us with a comparison of actual accomplishments to the objectives approved in the grant scope of work. Any issues that may affect a timely close out of the award should be reported at this time.

The mid-term report is due within 30 days of the end of the first six-months. All grantees will be required to submit a final report within 90 days of completion of the grant performance period or the closure of the grant, whichever comes first.

Dated: March 7, 2003.

Michael D. Brown,

Acting Under Secretary, Emergency Preparedness and Response Directorate.

[FR Doc. 03–6172 Filed 3–13–03; 8:45 am]

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Federal Register

Friday,
March 14, 2003

Part VII

The President

Notice of March 12, 2003—Continuation of the National Emergency With Respect to Iran

Federal Register
Vol. 68, No. 50
Friday, March 14, 2003

Presidential Documents

Title 3—

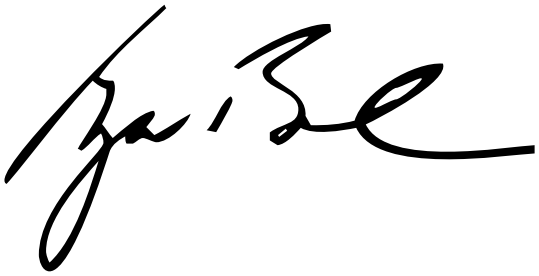
The President

Notice of March 12, 2003

Continuation of the National Emergency With Respect to Iran

On March 15, 1995, by Executive Order 12957, the President declared a national emergency with respect to Iran pursuant to the International Emergency Economic Powers Act (50 U.S.C. 1701–1706) to deal with the unusual and extraordinary threat to the national security, foreign policy, and economy of the United States constituted by the actions and policies of the Government of Iran, including its support for international terrorism, efforts to undermine the Middle East peace process, and acquisition of weapons of mass destruction and the means to deliver them. On May 6, 1995, the President issued Executive Order 12959 imposing more comprehensive sanctions to further respond to this threat, and on August 19, 1997, the President issued Executive Order 13059 consolidating and clarifying the previous orders.

Because the actions and policies of the Government of Iran continue to pose an unusual and extraordinary threat to the national security, foreign policy, and economy of the United States, the national emergency declared on March 15, 1995, must continue in effect beyond March 15, 2003. Therefore, in accordance with section 202(d) of the National Emergencies Act (50 U.S.C. 1622(d)), I am continuing for 1 year the national emergency with respect to Iran. Because the emergency declared by Executive Order 12957 constitutes an emergency separate from that declared on November 14, 1979, by Executive Order 12170, this renewal is distinct from the emergency renewal of November 2002. This notice shall be published in the **Federal Register** and transmitted to the Congress.



THE WHITE HOUSE,
March 12, 2003.

[FR Doc. 03–6421
Filed 3–13–03; 11:08 am]
Billing code 3195–01–P

Federal Register

Friday,
March 14, 2003

Part VIII

The President

Executive Order 13289—Establishing the Global War on Terrorism Medals

Federal Register
Vol. 68, No. 50
Friday, March 14, 2003

Presidential Documents

Title 3—

The President

Executive Order 13289 of March 12, 2003

Establishing the Global War on Terrorism Medals

By the authority vested in me as President by the Constitution and the laws of the United States of America, including my authority as Commander in Chief of the Armed Forces of the United States, it is hereby ordered as follows:

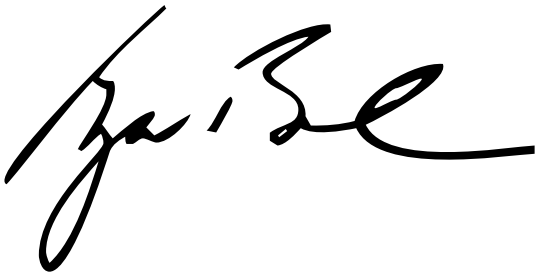
Section 1. Global War on Terrorism Expeditionary Medal. There is hereby established the Global War on Terrorism Expeditionary Medal with suitable appurtenances. Except as limited in section 3 of this order, and under uniform regulations to be prescribed by the Secretaries of the military departments and approved by the Secretary of Defense, or under regulations to be prescribed by the Secretary of Homeland Security with respect to the Coast Guard when it is not operating as a service in the Navy, the Global War on Terrorism Expeditionary Medal shall be awarded to members of the Armed Forces of the United States who serve or have served in military expeditions to combat terrorism, as defined by such regulations, on or after September 11, 2001, and before a terminal date to be prescribed by the Secretary of Defense.

Sec. 2. Global War on Terrorism Service Medal. There is hereby established the Global War on Terrorism Service Medal with suitable appurtenances. Except as limited in section 3 of this order, and under uniform regulations to be prescribed by the Secretaries of the military departments and approved by the Secretary of Defense, or under regulations to be prescribed by the Secretary of Homeland Security with respect to the Coast Guard when it is not operating as a service in the Navy, the Global War on Terrorism Service Medal shall be awarded to members of the Armed Forces of the United States who serve or have served in military operations to combat terrorism, as defined by such regulations, on or after September 11, 2001, and before a terminal date to be prescribed by the Secretary of Defense.

Sec. 3. Relationship to Other Awards. Notwithstanding section 3 of Executive Order 10977 of December 4, 1961, establishing the Armed Forces Expeditionary Medal and section 3 of Executive Order 12985 of January 11, 1996, establishing the Armed Forces Service Medal, any member who qualified for those medals by reason of service in operations to combat terrorism between September 11, 2001, and a terminal date to be determined by the Secretary of Defense, shall remain qualified for those medals. Upon application, any such member may be awarded either the Global War on Terrorism Expeditionary Medal or the Global War on Terrorism Service Medal in lieu of the Armed Forces Expeditionary Medal or the Armed Forces Service Medal, but no person may be awarded more than one of these four medals by reason of service in the same approved Global War on Terrorism expedition or operation to combat terrorism, and no person shall be entitled to more than one award of the Global War on Terrorism Expeditionary Medal or the Global War on Terrorism Service Medal.

Sec. 4. Posthumous Award. The Global War on Terrorism Expeditionary Medal and the Global War on Terrorism Service Medal may be awarded posthumously to any person covered by and under regulations prescribed in accordance with the first or second sections of this order.

Sec. 5. Nothing in this Executive Order shall be construed for any purpose as fixing, or authorizing the fixing of, the dates of initiation or termination of armed hostilities between the United States and terrorists of global reach.



THE WHITE HOUSE,
March 12, 2003.

[FR Doc. 03–6445
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Reader Aids

Federal Register

Vol. 68, No. 50

Friday, March 14, 2003

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Presidential Documents	
Executive orders and proclamations	**741–6000**
The United States Government Manual	**741–6000**
Other Services	
Electronic and on-line services (voice)	**741–6020**
Privacy Act Compilation	**741–6064**
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FEDERAL REGISTER PAGES AND DATE, MARCH

9851–10140 3
10141–10344 4
10345–10650 5
10651–10952 6
10953–11310 7
11311–11462 10
11463–11732 11
11733–11966 12
11967–12282 13
12283–12568 14

CFR PARTS AFFECTED DURING MARCH

At the end of each month, the Office of the Federal Register publishes separately a List of CFR Sections Affected (LSA), which lists parts and sections affected by documents published since the revision date of each title.

3 CFR

Administrative Orders:
Memorandums:
Memorandum of February 12, 2003 10141
Memorandum of March 12, 2003 12281
Presidential Determinations:
No. 2003–15 of February 13, 2003 10651
Notices:
Notice of March 12, 2003 12563

Proclamations:
7648 10641
7649 10643
7650 10645
7651 10647
7652 10649

Executive Orders:
4601 (Amended by: 13286) 10619
10977 12567
10113 (Amended by: 13286) 10619
10163 (Amended by: 13286) 10619
10179 (Amended by: 13286) 10619
10271 (Amended by: 13286) 10619
10448 (Amended by: 13286) 10619
10499 (Amended by: 13286) 10619
10554 (Amended by: 13286) 10619
10631 (Amended by: 13286) 10619
10637 (Amended by: 13286) 10619
10694 (Amended by: 13286) 10619
10789 (Amended by: 13286) 10619
10977 (Amended by: 13286) 10619
11016 (Amended by: 13286) 10619
11046 (Amended by: 13286) 10619
11079 (Amended by: 13286) 10619
11139 (Amended by: 13286) 10619
11190 (Amended by: 13286) 10619
11231 (Amended by: 13286) 10619
11239 (Amended by: 13286) 10619
11366 (Amended by: 13286) 10619
11438 (Amended by: 13286) 10619
11446 (Amended by: 13286) 10619
11448 (Amended by: 13286) 10619
11623 (Amended by: 13286) 10619
11645 (Amended by: 13286) 10619
11800 (Amended by: 13286) 10619
11858 (Amended by: 13286) 10619
11926 (Amended by: 13286) 10619
11965 (Amended by: 13286) 10619
12002 (Amended by: 13286) 10619
12146 (Amended by: 13286) 10619
12148 (Amended by: 13286) 10619
12160 (Amended by: 13286) 10619
12188 (Amended by: 13286) 10619
12208 (Amended by: 13286) 10619
12341 (Amended by: 13286) 10619
12382 (Amended by: 13286) 10619
12472 (Amended by: 13286) 10619
12501 (Amended by: 13286) 10619
12555 (Amended by: 13286) 10619
12580 (Amended by: 13286) 10619
12656 (Amended by: 13286) 10619
12657 (Amended by: 13286) 10619
12699 (Amended by: 13286) 10619
12727 (Amended by: 13286) 10619
12728 (Amended by: 13286) 10619
12733 (Amended by: 13286) 10619
12742 (Amended by: 13286) 10619
12743 (Amended by: 13286) 10619
12777 (Amended by: 13286) 10619
12788 (Amended by:

13286) 10619
12789 (Amended by: 13286) 10619
12793 (Amended by: 13286) 10619
12807 (Amended by: 13286) 10619
12824 (Amended by: 13286) 10619
12830 (Amended by: 13286) 10619
12835 (Amended by: 13286) 10619
12870 (Amended by: 13286) 10619
12906 (Amended by: 13286) 10619
12919 (Amended by: 13286) 10619
12957 12563
12959 12563
12977 (Amended by: 13286) 10619
12978 (Amended by: 13286) 10619
12982 (Amended by: 13286) 10619
12985 (Amended by: 13286) 10619, 12567
12989 (Amended by: 13286) 10619
13011 (Amended by: 13286) 10619
13059 12563
13076 (Amended by: 13286) 10619
13100 (Amended by: 13286) 10619
13112 (Amended by: 13286) 10619
13120 (Amended by: 13286) 10619
13130 (See: 13286) 10619
13133 (Amended by: 13286) 10619
13154 (Amended by: 13286) 10619
13165 (Amended by: 13286) 10619
13212 (Amended by: 13286) 10619
13223 (Amended by: 13286) 10619
13228 (Amended by: 13286) 10619
13231 (Amended by: 13286) 10619
13254 (Amended by: 13286) 10619
13257 (Amended by: 13286) 10619
13260 (Amended by: 13286; Revoked by: 13286, eff. 3/31/03) 10619
13271 (Amended by: 13286) 10619
13274 (Amended by: 13286) 10619
13276 (Amended by: 13286) 10619
13284 (See: 13286) 10619
13286 10619
13287 10619
13288 11457
13289 12567

5 CFR

Ch. XIV 10953
110 10666
2416 10953
2424 10953
2429 10953
2471 10953
2472 10953

6 CFR

9 10912
15 10886
17 10892
21 10904

7 CFR

301 11311
318 11967
319 9851
911 10345
944 10345
959 11463
982 11733
984 10347
Proposed Rules:
340 11337
770 12309
930 9944
932 11340
985 11751
1205 12310
1218 11756
1230 11996
1405 9944
1499 9944

8 CFR

1 10922
2 10922
103 10922
217 10954
235 10143
239 10922
1001 10349
1003 10349
1101 10349
1103 10349
1205 10349
1208 10349
1209 10349
1212 10349
1216 10349
1235 10349
1236 10349
1238 10349
1239 10349
1240 10349
1241 10349
1244 10349
1245 10349
1246 10349
1249 10349
1270 10349
1274a 10349
1292 10349
1337 10349

9 CFR

1 12283
50 10361
92 10667
Proposed Rules:
94 11998
317 11008
327 11008

10 CFR

40 10362
150 10362
430 10957
Proposed Rules
40 10411
150 10411
430 11009
490 10320

12 CFR

Proposed Rules:
203 11010
225 12316

14 CFR

Ch. 1 10145
25 ..... 9854, 10365
39 ..... 10147, 10149, 10152, 10154, 10156, 10583, 10653, 11467, 11469, 11967, 11971, 12285
47 10316
71 ..... 10367, 10369, 10654, 11736, 11738
91 12542
97 ..... 10962, 10963
121 12542
135 12542
145 12542
Proposed Rules:
21 ..... 11475, 11759
39 ..... 9947, 9950, 9951, 9954, 10185, 10188, 10413, 10416, 11014, 11015, 11342, 11476, 11479, 11760, 11762, 11764, 11999, 12318
43 ..... 11475, 11759
145 ..... 11475, 11759

15 CFR

740 10586
743 10586
772 10586
774 10586

16 CFR

304 9856

17 CFR

Proposed Rules:
1 12319
4 12001

18 CFR

375 9857
388 9857

19 CFR

Proposed Rules:
181 12011

20 CFR

625 10932

21 CFR

165 9873
610 10157
1310 11471
Proposed Rules:
1 10668
111 ..... 10418, 12158
112 12158
165 9955
201 12500
310 12406
312 12406
314 12406
320 12406
600 12406
601 12406
606 ..... 12406, 12500
610 12500

22 CFR

Proposed Rules:
211 9944

24 CFR

92 10160
906 11714
Proposed Rules:
203 11730
3285 11448
3286 11452

26 CFR

1 ..... 10161, 10655, 11313, 12287
20 10161
25 10161
31 10161
53 10161
54 10161
56 10161
301 ..... 10161, 11739
602 ..... 10161, 11739, 12287
Proposed Rules:
1 ..... 10190, 12324

27 CFR

4 10076
5 10076
7 10076

28 CFR

540 10656
Proposed Rules:
28 11481

29 CFR

1404 10659
1910 12301
4022 12303
4044 12303

30 CFR

18 10965
948 10178
Proposed Rules:
70 10784
72 10940
75 ..... 10784, 11770
90 10784
950 10193

31 CFR

103 10965
560 11741
575 11741
Proposed Rules:
103 12155

32 CFR

171 11633
199 11973

33 CFR

52 9882
117 9890

165 12304
401 11974

36 CFR

704 11974

Proposed Rules:

7 11019
219 ....10421, 12155

38 CFR

17 11977

40 CFR

52 ....9892, 10966, 10969, 11316, 11977
62 ....10659, 10661, 10663, 11472, 11978
63 11745
70 10969
82 10370
122 11325
180 ....10370, 10377, 10972, 10983, 11330
271 11981
439 12266

Proposed Rules:

Ch. I 10675, 12013
51 12014
52 ....11022, 11023, 12014
62 ....10680, 10681, 11483, 11484, 12015
70 11023
136 ....11770, 11791
228 11488
271 12015
439 12776

42 CFR

50 12306
412 10987

Proposed Rules:

83 11924
412 ....10421, 11234

43 CFR

Proposed Rules:

4100 ....9964, 11345

44 CFR

61 9895
64 9897
152 12544
206 9899

45 CFR

162 11445

47 CFR

0 11747
2 ....10179, 11986
25 11986
73 ....10388, 10664, 10665, 11335, 11993
90 10179
95 9900

Proposed Rules:

15 12015
54 ....10430, 12020
73 ....10681, 10682, 10683, 11345, 12023, 12024

48 CFR

1825 11747

49 CFR

1 10988
107 11748
190 11748
191 11748
192 11748
193 11748
195 11748
198 11748
199 11748
219 10108
225 10108
240 10108
1540 9902

Proposed Rules:

192 9966

50 CFR

17 10388
300 10989
622 ....10180, 11003
648 ....9905, 10181
660 11182
679 ....9902, 9907, 9924, 9942, 11004, 11994

Proposed Rules:

17 ....12326, 12336
229 10195
600 ....9967, 11501, 11793
622 11794
648 ....9968, 11023, 11346

REMINDERS

The items in this list were editorially compiled as an aid to Federal Register users. Inclusion or exclusion from this list has no legal significance.

RULES GOING INTO EFFECT MARCH 14, 2003

ENVIRONMENTAL PROTECTION AGENCY

Superfund program:
- National oil and hazardous substances contingency plan—
  - National priorities list update; published 1-13-03

HEALTH AND HUMAN SERVICES DEPARTMENT

Grants:
- Sterilization of persons in federally assisted family planning projects; published 3-14-03

HOMELAND SECURITY DEPARTMENT

Federal Emergency Management Agency

Emergency Preparedness and Response Directorate:
- Firefighters Assistance Grant Program; published 3-14-03

LABOR DEPARTMENT

Occupational Safety and Health Administration

Safety and health standards:
- Grain handling facilities; published 3-14-03

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:
- Stock dispositions; suspension of losses; published 3-14-03

COMMENTS DUE NEXT WEEK

AGRICULTURE DEPARTMENT

Commodity Credit Corporation

Loan and purchase programs:
- 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

Administrative practice and procedure:
- Civil rights discrimination complaints; adjudication; comments due by 3-17-03; published 2-14-03 [FR 03-03565]

COMMERCE DEPARTMENT

National Oceanic and Atmospheric Administration

Fishery conservation and management:
- Alaska; fisheries of Exclusive Economic Zone—
  - Pacific cod; comments due by 3-20-03; published 2-18-03 [FR 03-03589]
- Atlantic highly migratory species—
  - Atlantic tunas, swordfish, and sharks; comments due by 3-17-03; published 11-15-02 [FR 02-29086]
  - Atlantic tunas, swordfish, and sharks, and Atlantic billfish; exempted fishing activities; comments due by 3-17-03; published 1-10-03 [FR 03-00520]
- Magnuson-Stevens Act provisions—
  - Domestic fisheries; exempted fishing permit applications; comments due by 3-17-03; published 2-28-03 [FR 03-04681]
  - Domestic fisheries; exempted fishing permit applications; comments due by 3-17-03; published 2-28-03 [FR 03-04680]
  - National standard guidelines; revision; comments due by 3-17-03; published 2-14-03 [FR 03-03758]

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 03-03701]

Air quality implementation plans; approval and promulgation; various States:
- California; comments due by 3-17-03; published 2-13-03 [FR 03-03416]
- Rhode Island; comments due by 3-17-03; published 2-14-03 [FR 03-03698]

FEDERAL COMMUNICATIONS COMMISSION

Radio services, special:
- Private land mobile services—
  - Dedicated short-range communication services in 5.850-5.925 GHz band; comments due by 3-17-03; published 1-15-03 [FR 03-00812]

HEALTH AND HUMAN SERVICES DEPARTMENT

Food and Drug Administration

Medical devices:
- General and plastic surgery devices—
  - Eight surgical suture devices; special control designation; comments due by 3-19-03; published 12-19-02 [FR 02-31991]

HOMELAND SECURITY DEPARTMENT

Coast Guard

Ports and waterways safety:
- Chicago Captain of Port Zone, IL; safety zones; comments due by 3-17-03; published 2-14-03 [FR 03-03739]
- St. Thomas, U.S. Virgin Islands; security zone; comments due by 3-21-03; published 2-19-03 [FR 03-03978]

INTERIOR DEPARTMENT

Fish and Wildlife Service

Endangered and threatened species:
- Mountain plover; comments due by 3-21-03; published 2-21-03 [FR 03-04152]

INTERIOR DEPARTMENT

Minerals Management Service

Outer Continental Shelf; oil, gas, and sulfur operations:
- Documents incorporated by reference; comments due by 3-17-03; published 1-14-03 [FR 03-00665]

INTERIOR DEPARTMENT

National Park Service

Special regulations:
- Glen Canyon National Recreation Area, UT and AZ; personal watercraft use; comments due by 3-18-03; published 1-17-03 [FR 03-01157]

JUSTICE DEPARTMENT

Drug Enforcement Administration

Schedules of controlled substances:
- Anabolic steroid products; comments due by 3-17-03; published 1-15-03 [FR 03-00772]

PERSONNEL MANAGEMENT OFFICE

Employee responsibilities and conduct; comments due by 3-17-03; published 1-15-03 [FR 03-00818]

Retirement:
- Retirement coverage and service credit elections for current and former nonappropriated fund employees; comments due by 3-17-03; published 1-16-03 [FR 03-00819]

SECURITIES AND EXCHANGE COMMISSION

Practice and procedure:
- Administrative proceedings; timeliness; comments due by 3-21-03; published 2-19-03 [FR 03-03915]

TRANSPORTATION DEPARTMENT

Computer reservation systems, carrier-owned; expiration date extension; comments due by 3-16-03; published 12-9-02 [FR 02-30951]

Privacy Act; implementation; comments due by 3-17-03; published 1-15-03 [FR 03-00828]

TRANSPORTATION DEPARTMENT

Federal Aviation Administration

Air carrier certification and operations:
- Transponder continuous operation; comments due by 3-17-03; published 1-14-03 [FR 03-00685]

Airworthiness directives:
- Bell; comments due by 3-17-03; published 1-15-03 [FR 03-00328]
- Boeing; comments due by 3-17-03; published 1-29-03 [FR 03-01957]
- Honeywell; comments due by 3-17-03; published 1-15-03 [FR 03-00643]
- McDonnell Douglas; comments due by 3-17-03; published 1-30-03 [FR 03-02095]
- New Piper Aircraft, Inc.; comments due by 3-21-03; published 1-27-03 [FR 03-01679]
- Pilatus Aircraft Ltd.; comments due by 3-21-03; published 2-12-03 [FR 03-03449]

Airworthiness standards:
- Special conditions—
  - Embraer Model 170-100 and 107-200 airplanes;

comments due by 3-20-03; published 2-3-03 [FR 03-02423]

Colored Federal airways; comments due by 3-17-03; published 1-30-03 [FR 03-02189]

VOR and colored Federal airways; comments due by 3-17-03; published 1-30-03 [FR 03-02190]

TRANSPORTATION DEPARTMENT

Research and Special Programs Administration

Hazardous materials:

Miscellaneous amendments; comments due by 3-17-03; published 1-21-03 [FR 03-00580]

TREASURY DEPARTMENT

Alcohol, Tobacco and Firearms Bureau

Alcohol; viticultural area designations:

Red Hill, OR, and Red Hills, CA; comments due by 3-17-03; published 1-16-03 [FR 03-00847]

TREASURY DEPARTMENT

Internal Revenue Service

Income taxes:

Expenditures deduction and capitalization; guidance; public hearing; comments due by 3-19-03; published 12-19-02 [FR 02-31859]

VETERANS AFFAIRS DEPARTMENT

Medical benefits:

Enrollment; hospital and outpatient care provided to veterans subpriorities of priority categories 7 and 8 and annual enrollment decision; comments due by 3-18-03; published 1-17-03 [FR 03-01201]

LIST OF PUBLIC LAWS

This is a continuing list of public bills from the current session of Congress which have become Federal laws. It may be used in conjunction with ''P L U S'' (Public Laws Update Service) on 202–741–6043. This list is also available online at *http://www.nara.gov/fedreg/plawcurr.html*.

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H.R. 395/P.L. 108–10

Do-Not-Call Implementation Act (Mar. 11, 2003; 117 Stat. 557)

Last List March 10, 2003

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