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Briefings on How To Use the Federal Register
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- FOR:** Any person who uses the Federal Register and Code of Federal Regulations.
- WHO:** The Office of the Federal Register.
- WHAT:** Free public briefings (approximately 3 hours) to present:
1. The regulatory process, with a focus on the Federal Register system and the public's role in the development of regulations.
 2. The relationship between the Federal Register and Code of Federal Regulations.
 3. The important elements of typical Federal Register documents.
 4. An introduction to the finding aids of the FR/CFR system.
- WHY:** To provide the public with access to information necessary to research Federal agency regulations which directly affect them. There will be no discussion of specific agency regulations.

WASHINGTON, DC

(two briefings)

- WHEN:** October 19 at 9:00 am and 1:30 pm
- WHERE:** Office of the Federal Register, 7th Floor Conference Room, 800 North Capitol Street NW, Washington, DC (3 blocks north of Union Station Metro)
- RESERVATIONS:** 202-523-4538



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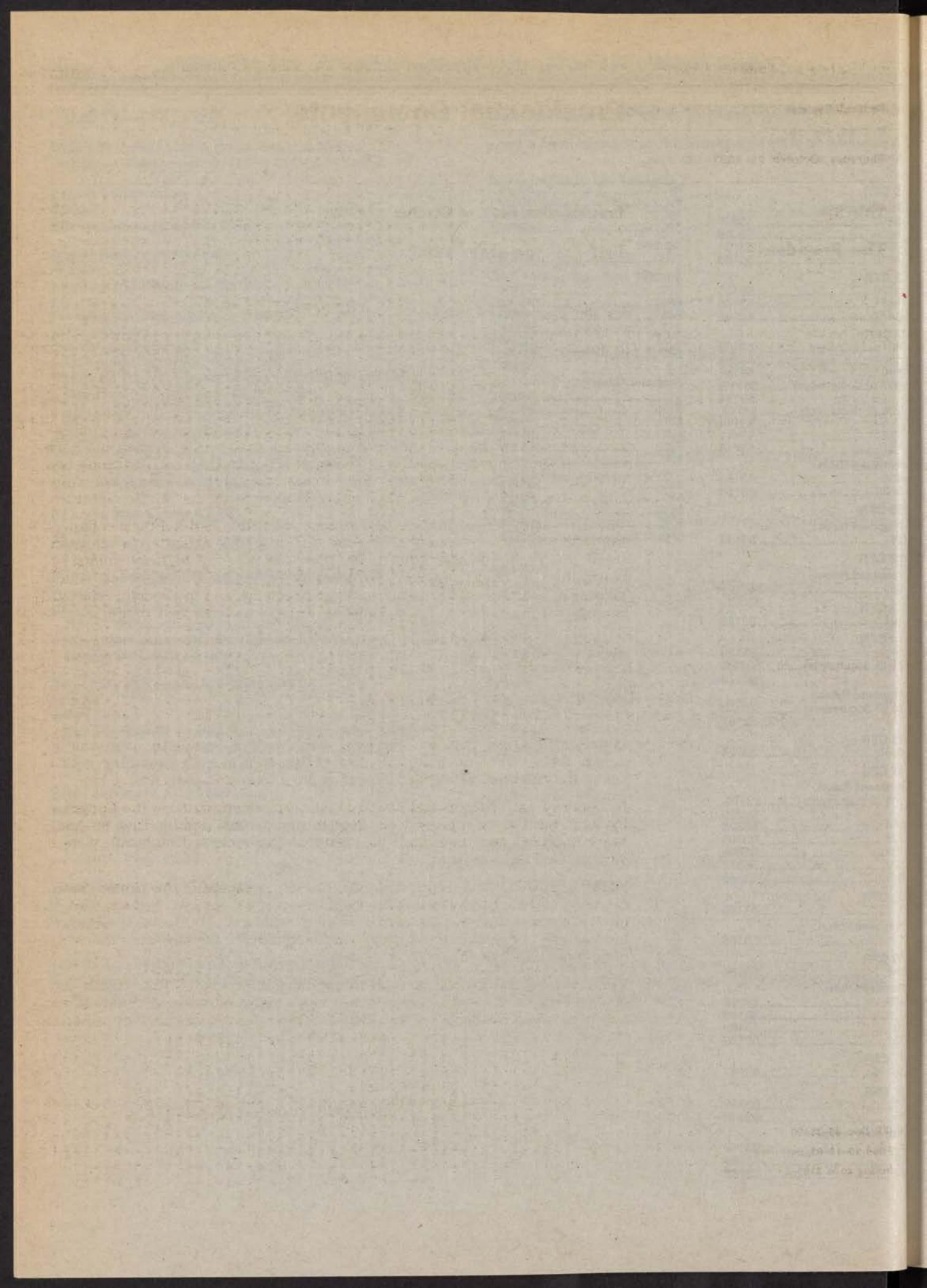
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Free Electronic Bulletin Board service for Public Law numbers and Federal Register finding aids is available on 202-275-1538 or 275-0920.

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Proclamation 6607 of October 8, 1993

The President

Leif Erikson Day, 1993

By the President of the United States of America

A Proclamation

At this time every year, Americans celebrate Leif Erikson Day. In so doing, we commemorate the voyages of the great Norse explorer who first set foot on North America nearly a thousand years ago. At the same time, we also celebrate the enduring ties between America and the Nordic countries and take note of the outstanding contributions that Nordic Americans have made to the United States. In a sense, the bonds that Leif Erikson—son of Iceland, grandson of Norway—forged continue unbroken today. We maintain an impressive exchange of people and ideas with the Nordic countries.

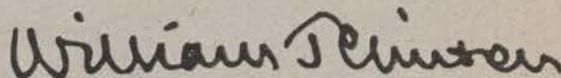
The early settlers inherited an adventurous spirit that had led their ancestors from Scandinavia to much of Europe and into the Atlantic. In addition, these adventurers started from lands that were already halfway points between the Old World and the New. Even today, the Nordic countries, which possess a commitment to open, democratic societies and to peaceful relations among nations, serve as links between Europe and the rest of the world.

At a time when the relations between Europe and America are being redefined, the Nordic countries retain their important role in fostering democracy, transatlantic cooperation, and an open trading system. Their many contributions to international diplomacy, humanitarian assistance, and peacekeeping in the world's trouble spots set a high standard that the rest of the world greatly admires. Americans who trace their roots to the Nordic countries—Denmark, Finland, Iceland, Norway, and Sweden—not only continue to enrich their new homeland, but also play a key part in providing a link across the Atlantic, just as their ancestors did a thousand years ago.

In honor of Leif Erikson and of our Nordic-American heritage, the Congress, by joint resolution approved on September 2, 1964 (Public Law 88-566), has authorized and requested the President to proclaim October 9 of each year as "Leif Erikson Day."

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim October 9, 1993, as Leif Erikson Day. I also encourage the people of the United States to observe this occasion by learning more about our rich Nordic-American heritage and the early history of our continent.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of October, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and eighteenth.



Presidential Documents

Proclamation 6608 of October 8, 1993

Columbus Day, 1993

By the President of the United States of America

A Proclamation

During 1993 the world has embarked on new trails to expand humanity's horizons and to promote the betterment of the human condition. As we look with hope to the future, we also pay homage to our past and to those who have helped shape our Nation and continent. It is therefore fitting that the voyages of Christopher Columbus be remembered. I welcome this opportunity to salute this man of great courage, who, in defiance of popular myth and hardship, had the vision to explore the unknown.

Even though the Quincentennial celebrations of Columbus' landfall are past, it is still our duty to promote understanding between the old and new worlds. It is important to commemorate the mutual discovery of Europeans and Native Americans and the transformations, through toil and pain, that gave birth to brave new hopes for a better future.

For the United States, it is especially significant that we recognize the daring voyages of Christopher Columbus. As a people whose land was founded on dreams, we proceed today, just as Columbus did, with courage to overcome obstacles and search for new paths to lead us into an unknown, but promising, future.

Many people in the United States have special reason to remember and celebrate the histories of the old and new worlds. America, a Nation of diverse peoples, has been enriched by the blending of many heritages. Americans of international descent, along with Native Americans, have contributed mightily to molding the framework of our great land, united by our allegiance to the principles of equality, democracy, and freedom. We all take justifiable pride in our accomplishments and dedicate ourselves to the pursuit of our dreams.

In tribute to Columbus' achievement, the Congress of the United States by joint resolution of April 30, 1934 (48 Stat. 657), and an Act of June 28, 1968 (82 Stat. 250), has requested the President to proclaim the second Monday in October of each year as "Columbus Day."

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim October 11, 1993, as Columbus Day. I call upon the people of the United States to observe this day with appropriate ceremonies and activities. I also direct that the flag of the United States be displayed on all public buildings on the appointed day in honor of Christopher Columbus.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of October, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and eighteenth.

William Clinton

[FR Doc. 93-25401

Filed 10-12-93; 3:38 pm]

Billing code 3195-01-P

Presidential Documents

Proclamation 6609 of October 8, 1993

National School Lunch Week, 1993

By the President of the United States of America

A Proclamation

Since 1946, the National School Lunch Program has demonstrated a partnership between Federal, State, and local officials in providing nutritious low-cost and free meals to America's schoolchildren. Our commitment to the National School Lunch Program reflects our recognition of the importance of nutrition to our children's health and to our Nation's future.

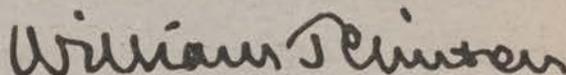
Currently, the National School Lunch Program operates in more than 90 percent of the Nation's public schools and serves about 25 million lunches a day. Many of our children receive their only nutritious meal of the day at school. These school meals not only increase students' attention span and learning capabilities, but also improve their overall health. School lunches also teach children good dietary habits. Cafeterias become learning laboratories, putting into practice the classroom lessons learned by the students on the importance of nutrition to health and well-being.

There is no longer any question that diet is related to good health, and school meal programs should meet the Dietary Guidelines for Americans so that children get nutritious meals. Like preventive medicine, the value of school lunches will multiply and the benefits will last a lifetime. National School Lunch Week affords us the opportunity to take a fresh look at the National School Lunch Program to determine what changes are necessary in order to meet these dietary guidelines. We also can recognize health professionals, school food service personnel, teachers, principals, parents, community leaders, and others for their commitment to ensuring that the lunches served in their schools will provide the nutrition so important to young students.

In recognition of the contributions of the National School Lunch Program to the nutritional well-being of children, the Congress, by joint resolution of October 9, 1962 (Public Law No. 87-780), has designated the week beginning the second Sunday in October in each year as "National School Lunch Week" and has requested the President to issue a proclamation in observance of that week.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim the week beginning October 10, 1993, as National School Lunch Week. I call upon all Americans to recognize those individuals whose efforts contribute to the success of this valuable program.

IN WITNESS WHEREOF, I have hereunto set my hand this eighth day of October, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and eighteenth.



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Presidential Documents

Proclamation 6610 of October 9, 1993

General Pulaski Memorial Day, 1993

By the President of the United States of America

A Proclamation

Each October 11, on the anniversary of his death in battle, America honors General Casimir Pulaski, a hero of two nations.

A patriot to the core, Pulaski loved his native Poland dearly. In unequal battle against far stronger enemies, he fought for his country's freedom.

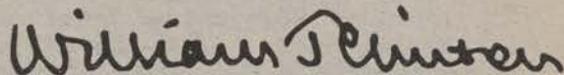
But Pulaski's love of liberty transcended national boundaries, and when the American War of Independence began, he took the colonists' struggle as his own. He came to the United States, put his battlefield experience at the service of the Continental Army, and commanded a cavalry unit. On this day in 1779, during the siege of Savannah, General Pulaski gave his life for the cause of American freedom.

Pulaski's spirit and example have inspired Americans for more than two centuries. Across this country, you will find counties, towns, schools, parks and highways named after that patriot; in my own home state of Arkansas, Pulaski County is the seat of the capital, Little Rock.

But eager as we are to claim General Pulaski as our own, we are also proud to share him with Poland. What Pulaski fought for in the latter part of the 18th century, his compatriots have achieved at the end of the 20th: a free Poland, welcome and respected in the community of independent nations. And the courage General Pulaski displayed in battle is matched by that of his present-day countrymen, who have carried out Poland's history-making revolution without bloodshed.

NOW, THEREFORE, I, WILLIAM J. CLINTON, President of the United States of America, do hereby proclaim Monday, October 11, 1993, as General Pulaski Memorial Day, and I encourage the people of the United States to commemorate this occasion appropriately throughout the land.

IN WITNESS WHEREOF, I have hereunto set my hand this ninth day of October, in the year of our Lord nineteen hundred and ninety-three, and of the Independence of the United States of America the two hundred and eighteenth.



The following rules and regulations shall govern the conduct of all members of the organization. It is the duty of every member to observe these rules and regulations and to report any violation to the proper authorities.

1. All members must adhere to the highest standards of moral and ethical conduct. Any member found guilty of a serious offense may be expelled from the organization.

2. Members are prohibited from engaging in any activity that would bring the organization into disrepute or cause it to be viewed unfavorably by the public.

3. The organization is a non-profit entity, and all members must contribute to the common good of the organization. No member shall engage in self-serving activities that conflict with the organization's mission.

4. Members must maintain confidentiality regarding the organization's internal affairs and the identities of other members. Any disclosure of confidential information may result in disciplinary action.

5. The organization's property, including its funds and assets, must be used solely for the purposes of the organization. Any misuse of these resources is strictly prohibited.

6. Members are expected to attend all meetings and events organized by the organization. Regular attendance is essential for the organization's success.

7. Disputes between members should be resolved through peaceful means and in accordance with the organization's dispute resolution procedures. Members are encouraged to seek mediation or arbitration if necessary.

8. The organization reserves the right to modify these rules and regulations at any time without notice. Members will be notified of any changes.

Disciplinary Procedures

The following procedures shall be followed in the event of a disciplinary action:

1. A complaint or report of a violation must be filed with the appropriate authority.

2. The authority will conduct a preliminary investigation to determine if there is sufficient evidence to proceed with a formal investigation.

3. If a formal investigation is warranted, the accused member will be notified and given an opportunity to present their side of the story.

4. The investigation will be conducted in a fair and impartial manner, and all parties will be given the opportunity to be heard.

5. The findings of the investigation will be reported to the governing body of the organization, which will determine the appropriate disciplinary action.

6. Disciplinary actions may include a warning, suspension, or expulsion from the organization.

7. The organization will maintain records of all disciplinary actions taken, and these records may be reviewed if necessary.

Rules and Regulations

Federal Register

Vol. 58, No. 197

Thursday, October 14, 1993

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.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

FEDERAL LABOR RELATIONS AUTHORITY

5 CFR Parts 2429, 2471, and 2472

New Address and Phone Number; New Hours of Operation

AGENCY: Federal Labor Relations Authority.

ACTION: Final rule.

SUMMARY: The Federal Labor Relations Authority, and one of its entities, the Federal Service Impasses Panel, relocated its headquarters on March 15, 1993. For the purpose of filing documents with the Authority, this amendment to the rules and regulations of the Authority sets forth the Authority's new address and telephone number, and new hours during which such documents must be filed. In addition, the regulations have been amended to incorporate the new address of the Federal Service Impasses Panel.

EFFECTIVE DATE: October 14, 1993.

FOR FURTHER INFORMATION CONTACT: Solly Thomas, Executive Director, (202) 482-6560.

SUPPLEMENTARY INFORMATION: Certain paragraphs of appendix A to 5 CFR chapter XIV, which set forth the addresses, telephone, and fax numbers of the offices of the headquarters of the Federal Labor Relations Authority and certain offices within the Federal Labor Relations Authority, were amended on March 15, 1993. 58 FR 13695, Mar. 15, 1993. Paragraph (a) of § 2429.24 of the Authority's rules and regulations, which concerns the place and method of filing documents, was inadvertently omitted from the amendment. In addition, §§ 2471.2, 2471.4 and 2472.5, which concern communication with the Federal Service Impasses Panel were also inadvertently omitted from the amendment.

List of Subjects in 5 CFR Parts 2429, 2471 and 2472

Administrative practice and procedure, Government employees, Labor management relations.

Accordingly, these provisions are amended as follows:

PART 2429—MISCELLANEOUS AND GENERAL REQUIREMENTS

1. The authority citation for part 2429 continues to read as follows:

Authority: 5 U.S.C. 7134; § 2429.18 also issued under 28 U.S.C. 2112(a).

2. Section 2429.24(a) is revised to read as follows:

§ 2429.24 Place and method of filing; acknowledgement.

(a) All documents filed or required to be filed with the Authority pursuant to this subchapter shall be filed with the Director, Case Control Office, Federal Labor Relations Authority, Docket Room, suite 415, 607 14th Street, NW., Washington, DC 20424-0001 (telephone: FTS or Commercial (202) 482-6540) between 9 a.m. and 5 p.m., Monday through Friday (except Federal holidays). Documents hand-delivered for filing must be presented in the Docket Room not later than 5 p.m. to be accepted for filing on that day.

* * * * *

PART 2471—PROCEDURES OF THE PANEL

3. The authority citation for part 2471 continues to read as follows:

Authority: 5 U.S.C. 7119, 7134.

4. Sections 2471.2 and 2471.4 are revised to read as follows:

§ 2471.2 Request form.

A form has been prepared for use by the parties in filing a request with the Panel for consideration of an impasse or approval of a binding arbitration procedure. Copies are available from the Office of the Executive Director, Federal Service Impasses Panel, suite 220, 607 14th Street, NW., Washington, DC 20424-0001.

* * * * *

§ 2471.4 Where to file.

Requests to the Panel provided for in this part, and inquiries or correspondence on the status of

impasses or other related matters, should be addressed to the Executive Director, Federal Service Impasses Panel, suite 220, 607 14th Street, NW., Washington, DC 20424-0001.

PART 2472—IMPASSES ARISING PURSUANT TO AGENCY DETERMINATION NOT TO ESTABLISH OR TO TERMINATE FLEXIBLE OR COMPRESSED WORK SCHEDULES

5. The authority citation for part 2472 continues to read as follows:

Authority: Pub. L. 97-221, 96 Stat. 227 (5 U.S.C. 6131).

6. Section 2472.5 is revised to read as follows:

§ 2472.5 Where to file.

Requests to the Panel provided for in this subchapter and inquiries or correspondence on the status of impasses or other related matters, should be directed to the Executive Director, Federal Service Impasses Panel, suite 220, 607 14th Street, NW., Washington, DC 20424-0001.

Dated: October 4, 1993.

Solly Thomas,

Executive Director, Federal Labor Relations Authority.

[FR Doc. 93-25034 Filed 10-13-93; 8:45 am]

BILLING CODE 6267-01-M

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 301

[Docket 91-155-8]

Mediterranean Fruit Fly; Addition to and Removal From the Quarantined Areas

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Interim rule and request for comments.

SUMMARY: We are amending the Mediterranean fruit fly regulations by adding new portions of Los Angeles and Orange Counties, CA, to the list of quarantined areas and by removing the quarantined portion of Santa Clara County, CA, from the list. The addition of these new areas to the list of quarantined areas is necessary on an

emergency basis to prevent the spread of the Mediterranean fruit fly into noninfested areas of the United States, while the removal of the Santa Clara County area from the list relieves unnecessary restrictions on the interstate movement of regulated articles from this area.

DATES: Interim rule effective October 8, 1993. Consideration will be given only to comments received on or before December 13, 1993.

ADDRESSES: Please send an original and three copies of your comments to Chief, Regulatory Analysis and Development, PPD, APHIS, USDA, room 804, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782. Please state that your comments refer to Docket No. 91-155-8. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are encouraged to call ahead on (202) 690-2817 to facilitate entry into the comment reading room.

FOR FURTHER INFORMATION CONTACT: Mr. Michael B. Stefan, Operations Officer, Domestic and Emergency Operations, Plant Protection and Quarantine, APHIS, USDA, room 640, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-8247.

SUPPLEMENTARY INFORMATION:

Background

The Mediterranean fruit fly, *Ceratitis capitata* (Wiedemann), is one of the world's most destructive pests of numerous fruits and vegetables. The Mediterranean fruit fly (Medfly) can cause serious economic losses. Heavy infestations can cause complete loss of crops, and losses of 25 to 50 percent are not uncommon. The short life cycle of this pest permits the rapid development of serious outbreaks.

We established the Mediterranean fruit fly regulations (7 CFR 301.78 through 301.78-10; referred to below as the regulations), and quarantined the Hancock Park area of Los Angeles County, CA, in an interim rule effective on November 5, 1991, and published in the Federal Register on November 13, 1991 (56 FR 57573-57579, Docket No. 91-155). The regulations impose restrictions on the interstate movement of regulated articles from quarantined areas in order to prevent the spread of the Medfly to noninfested areas of the United States. We have published a series of interim rules amending these regulations by adding or removing certain portions of Los Angeles, Santa

Clara, Orange, and San Diego Counties, CA, from the list of quarantined areas. Amendments affecting California were made effective on September 10, and November 12, 1992; and on January 19, July 16, August 3, and September 22, 1993 (57 FR 42485-42486, Docket No. 91-155-2; 57 FR 54166-54169, Docket No. 91-155-3; 58 FR 6343-6346, Docket No. 91-155-4; 58 FR 39123-39124, Docket No. 91-155-5; 58 FR 42489-42491, Docket No. 91-155-6; 58 FR 49186-49190, Docket No. 91-155-7).

Recent trapping surveys by inspectors of California State and county agencies and by inspectors of the Animal and Plant Health Inspection Service (APHIS) have revealed that additional infestations of Medfly have been discovered in the Pacoima area of Los Angeles County, CA, and in the Santa Ana area of Orange County, CA.

The regulations in § 301.78-3 provide that the Administrator of APHIS will list as a quarantined area each State, or each portion of a State, in which the Medfly has been found by an inspector, in which the Administrator has reason to believe that the Medfly is present, or that the Administrator considers necessary to regulate because of its inseparability for quarantine enforcement purposes from localities in which the Medfly has been found.

In accordance with these criteria and the recent Medfly finding described above, we are amending § 301.78-3 by expanding the area in Los Angeles County with the addition of an area of approximately 17 square miles and by expanding the area which extends through both Los Angeles and Orange Counties with the addition of an area of approximately 48 square miles in Orange County. The new quarantined areas are as follows:

Los Angeles County

That portion of Los Angeles County bounded by a line drawn as follows: Beginning at the intersection of Interstate Highway 210 and Sunland Boulevard; then west and south along Sunland Boulevard to its intersection with Clybourn Avenue; then south along Clybourn Avenue to its intersection with Saticoy Street; then west along Saticoy Street to its intersection with Vineland Avenue; then south along Vineland Avenue to its intersection with Vanowen Street; then west along Vanowen Street to its intersection with Coldwater Canyon Avenue; then north along Coldwater Canyon Avenue to its intersection with Sheldon Street; then northeast along Sheldon Street to its intersection with Arleta Avenue; then northwest along Arleta Avenue to its intersection with

Branford Street; then northeast along Branford Street to its intersection with San Fernando Road; then northwest along San Fernando Road to its intersection with Osborne Street; then northeast along Osborne Street to its intersection with Foothill Boulevard; then northwest along Foothill Boulevard to its intersection with Van Nuys Boulevard; then northeast along Van Nuys Boulevard to its intersection with Interstate Highway 210; then southeast on Interstate Highway 210 to the point of beginning.

Orange County

That portion of Orange County bounded by a line drawn as follows: Beginning at the intersection of Fairview Road and Interstate Highway 405; then east and south along Interstate Highway 405 to its intersection with Culver Drive; then northeast along Culver Drive to its intersection with Walnut Avenue; then northwest along Walnut Avenue to its intersection with Jamboree Road; then northeast along Jamboree Road to its intersection with Tustin Ranch Road; then west along Tustin Ranch Road to its intersection with Pioneer Way; then north along Pioneer Way to its intersection with Pioneer Road; then northwest on Pioneer Road to its intersection with Foothill Boulevard; then northwest along Foothill Boulevard to its intersection with Old Foothill Boulevard; then northwest on Old Foothill Boulevard to its intersection with Hewes Street; then north on Hewes Street to its intersection with Chapman Avenue; then west along Chapman Avenue to its intersection with Haster Street; then south on Haster Street to its intersection with Garden Grove Boulevard; then east along Garden Grove Boulevard to its intersection with Fairview Street; then south on Fairview Street to its intersection with Fairview Road; then south on Fairview Road to the point of beginning.

We have also determined, based on trapping surveys conducted by APHIS and California State and county agency inspectors, that the Medfly has been eradicated from the quarantined area in Santa Clara County, CA. The last finding of the Medfly thought to be associated with the infestation in this area was made on September 9, 1992. Since then, no evidence of infestation has been found in this area. We have determined that the Medfly no longer exists in this area, and we are therefore removing it from the list of areas in § 301.78-3(c) quarantined because of the Mediterranean fruit fly. As a result of this action there are no longer any quarantined areas in Santa Clara

County, Portions of Los Angeles, Orange, and San Bernardino Counties remain quarantined.

Miscellaneous

We are removing from § 301-78-3(c) the lists of neighborhoods preceding each of the Medfly quarantine area border descriptions for California. These lists are not fully inclusive and thus do not completely or accurately describe the areas affected by the Medfly quarantine. Moreover, it would be impractical to list all of the neighborhoods affected by the quarantine. We believe the street-by-street border descriptions are sufficient to describe the areas affected by the Medfly quarantine.

Emergency Action

The Administrator of the Animal and Plant Health Inspection Service has determined that an emergency exists in Los Angeles and Orange Counties, CA, that warrants publication of this interim rule without prior opportunity for public comment. Immediate action is necessary to prevent the Mediterranean fruit fly from spreading to noninfested areas of the United States.

In addition, the Administrator has determined that emergency conditions regarding Medfly infestation no longer exist in Santa Clara County, CA, and the continued quarantined status of this area would impose unnecessary regulatory restrictions on the public. Immediate action is warranted to remove restrictions from the noninfested areas.

Because prior notice and other public procedures with respect to this action are impracticable and contrary to the public interest under these conditions, we find good cause under 5 U.S.C. 553 to make it effective upon signature. We will consider comments that are received within 60 days of publication of this rule in the *Federal Register*. After the comment period closes, we will publish another document in the *Federal Register*. It will include a discussion of any comments we receive and any amendments we are making to the rule as a result of the comments.

Executive Order 12291 and Regulatory Flexibility Act

We are issuing this rule in conformance with Executive Order 12291, and we have determined that it is not a "major rule." Based on information compiled by the Department, we have determined that this rule will have an effect on the economy of less than \$100 million; will not cause a major increase in costs or prices for consumers, individual

industries, Federal, State or local government agencies, or geographic regions; and will not cause a significant adverse effect on competition, employment, investment, productivity, innovation, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets.

For this action, the Office of Management and Budget has waived the review process required by Executive Order 12291.

This interim rule affects the interstate movement of regulated articles from the Pacoima area of Los Angeles County, CA, the Santa Ana area of Orange County, CA, and the San Jose area of Santa Clara County, CA. There are approximately 336 small entities that could be affected, including 203 retail and wholesale fruit sellers, 67 nurseries, 3 distributors, 20 growers, 2 packers, 1 processor, 39 mobile vendors, and 1 flea market.

These small entities comprise less than 1 percent of the total number of similar small entities operating in the State of California. In addition, most of these small entities sell regulated articles primarily for local intrastate, not interstate, movement and the sale of these articles would not be affected by this interim regulation.

In the new quarantined areas in Los Angeles and Orange Counties, the effect on those few small entities that do move regulated articles interstate from parts of the quarantined areas will be minimized by the availability of various treatments that, in most cases, will allow these small entities to move regulated articles interstate with very little additional cost. Also, many of these entities sell other items in addition to the regulated articles so that the effect, if any, of this regulation on these entities should be minimal. Further, the number of affected entities is small compared with the thousands of small entities that move these articles interstate from nonquarantined areas in California and other States.

Similarly, termination of the quarantine in the Santa Clara County area should have a minimal economic effect on the few small entities operating there. We anticipate that the economic impact of lifting the quarantine, though positive, will be no more significant than was the minimal impact of its imposition.

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

Executive Order 12372

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

Executive Order 12778

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This rule:

- (1) Preempts all State and local laws and regulations that are inconsistent with this rule;
- (2) Has no retroactive effect; and
- (3) Does not require administrative proceedings before parties may file suit in court challenging this rule.

National Environmental Policy Act

An environmental assessment and finding of no significant impact have been prepared for this rule. The assessment provides a basis for our conclusion that implementation of integrated pest management to achieve eradication of the Medfly would not have a significant impact on human health and the natural environment.

The environmental assessment and finding of no significant impact were prepared in accordance with:

- (1) The National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321 *et seq.*);
- (2) Regulations of the Council on Environmental Quality for Implementing the Procedural Provisions of NEPA (40 CFR Parts 1500-1508);
- (3) USDA Regulations Implementing NEPA (7 CFR Part 1(b)); and
- (4) APHIS Guidelines Implementing NEPA (44 FR 50381-50384, August 28, 1979, and 44 FR 51272-51274, August 31, 1979).

Copies of the environmental assessment and finding of no significant impact are available for public inspection at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. In addition, copies may be obtained by writing to the individual listed under FOR FURTHER INFORMATION CONTACT.

Paperwork Reduction Act

This document contains no new information collection or recordkeeping requirements under the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et seq.*).

List of Subjects in 7 CFR Part 301

Agricultural commodities, Plant diseases and pests, Quarantine,

Reporting and recordkeeping requirements, Transportation.

Accordingly, 7 CFR part 301 is amended as follows:

PART 301—DOMESTIC QUARANTINE NOTICES

1. The authority citation for 7 CFR part 301 continues to read as follows:

Authority: 7 U.S.C. 150bb, 150dd, 150ee, 150ff; 161, 162, and 164–167; 7 CFR 2.17, 2.51, and 371.2(c).

2. In § 301.78–3, paragraph (c), the designation of the quarantined areas is amended by revising the entries for Los Angeles County and for Los Angeles and Orange Counties; and by removing the entry for Santa Clara County, as follows:

§ 301.78–3 Quarantined areas.

* * * * *

California

Los Angeles County. That portion of the county beginning at the intersection of Interstate Highway 210 and Sunland Boulevard; then, west and south along Sunland Boulevard to its intersection with Clybourn Avenue; then, south along Clybourn Avenue to its intersection with Saticoy Street; then, west along Saticoy Street to its intersection with Vineland Avenue; then, south along Vineland Avenue to its intersection with Vanowen Street; then west along Vanowen Street to its intersection with Tampa Avenue; then north along Tampa Avenue to its intersection with Nordhoff Street; then west along Nordhoff Street to its intersection with Corbin Avenue; then north along Corbin Avenue to its intersection with Lassen Street; then west along Lassen Street to its intersection with Winnetka Avenue; then north along Winnetka Avenue to its intersection with San Fernando Mission Boulevard; then east along San Fernando Mission Boulevard to its intersection with Winnetka Avenue; then north along Winnetka Avenue to its intersection with Sesnon Boulevard; then east along Sesnon Boulevard to its intersection with Tampa Avenue; then due north along an imaginary line from this intersection to its intersection with the Los Angeles City Limits; then northeast and east along the Los Angeles City Limits to its intersection with Cobalt Street; then south along Cobalt Street to its intersection with Olive View Drive; then east along Olive View Drive to its intersection with Bledsoe Street; then southwest along Bledsoe Street to its intersection with Interstate Highway 210; then southeast along Interstate Highway 210 to the point of beginning.

Los Angeles and Orange Counties. That portion of the counties beginning at the intersection of the Angeles National Forest boundary and Sage Hill Road; then north from the intersection along an imaginary line to its intersection with Brown Mountain Road at Millard Campground; then west along Brown Mountain Road to its intersection with El Prieto Road; then

southwest along El Prieto Road to its intersection with the Pasadena City Limits; then north and west along the Pasadena City Limits to its intersection with the La Canada Flintridge City Limits; then west and south along the La Canada Flintridge City Limits to its intersection with Foothill Boulevard; then northwest along Foothill Boulevard to its intersection with La Crescenta Avenue; then south along La Crescenta Avenue to its intersection with Shirley Jean Street; then southwest from this intersection along an imaginary line to the end of Allen Avenue; then southwest along Allen Avenue to its intersection with Mountain Street; then northwest along Mountain Street to its intersection with Sunset Canyon Drive; then northwest along Sunset Canyon Drive to its intersection with Olive Avenue; then southwest along Olive Avenue to its intersection with Barham Boulevard; then south along Barham Boulevard to its intersection with State Highway 101; then southeast along State Highway 101 to its intersection with Highland Avenue; then south along Highland Avenue to its intersection with Sunset Boulevard; then west along Sunset Boulevard to its intersection with La Cienega Boulevard; then south along La Cienega Boulevard to its intersection with Washington Boulevard; then southwest along Washington Boulevard to its intersection with Culver Boulevard; then southwest along Culver Boulevard to its intersection with Vista Del Mar; then southeast along Vista Del Mar to its intersection with Rosecrans Avenue; then east along Rosecrans Avenue to its intersection with Paramount Boulevard; then south on Paramount Boulevard to its intersection with Carson Street; then east on Carson Street to its intersection with Lakewood Boulevard; then south on Lakewood Boulevard to its intersection with Willow Street; then east on Willow Street to its intersection with Katella Avenue; then east along Katella Avenue to its intersection with Valley View Street; then, south along Valley View Street to its intersection with Bolsa Chica Road; then, south along Bolsa Chica road to its intersection with Bolsa Chica Street; then, south along Bolsa Chica Street to its intersection with Los Patos Avenue; then, southeast from this intersection along an imaginary line to the intersection of East Garden Grove Wintersburg Channel and the Bolsa Chica Ecological Reserve boundary; then, southeast along the Bolsa Chica Ecological Reserve boundary to its intersection with Ellis Avenue; then, east along Ellis Avenue to its intersection with Edwards Street; then, south along Edwards Street to its intersection with Garfield Avenue; then, east along Garfield Avenue to its intersection with North Golden West Street; then, south along North Golden West Street to its intersection with Yorktown Avenue; then, east along Yorktown Avenue to its intersection with Main Street; then, south along Main Street to its intersection with Adams Avenue; then, east along Adams Avenue to its intersection with Fairview Road; then, north along Fairview Road to its intersection with Interstate Highway 405; then, east and south along Interstate Highway 405 to its intersection with Culver Drive;

then, northeast along Culver Drive to its intersection with Walnut Avenue; then, northwest along Walnut Avenue to its intersection with Jamboree Road; then, northeast along Jamboree Road to its intersection with Tustin Ranch Road; then, west along Tustin Ranch Road to its intersection with Pioneer Way; then, north along Pioneer Way to its intersection with Pioneer Road; then, northwest on Pioneer Road to its intersection with Foothill Boulevard; then, northwest along Foothill Boulevard to its intersection with Old Foothill Boulevard; then, northwest on Old Foothill Boulevard to its intersection with Hewes Street; then, north on Hewes Street to its intersection with Chapman Avenue; then, west along Chapman Avenue to its intersection with West Street; then, north along West Street to its intersection with Katella Avenue; then, west along Katella Avenue to its intersection with Western Avenue; then north on Western Avenue to its intersection with Commonwealth Avenue; then east on Commonwealth Avenue to its intersection with Beach Boulevard; then north on Beach Boulevard to its intersection with La Mirada Boulevard; then northwest and north on La Mirada Boulevard to its intersection with Colima Road; then northeast on Colima Road to its intersection with the Whittier City Limits; then northwest along the Whittier City Limits to its intersection with Turnbull Canyon Road; then north from this intersection along an imaginary line to the intersection of Interstate Highway 605 and State Highway 60; then northeast along Interstate Highway 605 to its intersection with Interstate Highway 10; then east along Interstate Highway 10 to its intersection with Francisquito Avenue; then southeast along Francisquito Avenue to its intersection with Hacienda Boulevard; then southwest along Hacienda Boulevard to its intersection with Amar Road; then east along Amar Road to its intersection with Temple Avenue; then northeast along Temple Avenue to its intersection with the Walnut City Limits; then north and northeast along the Walnut City Limits to its intersection with the Forest Lawn Memorial Park, Covina Hills boundary; then northeast along the boundary to its intersection with Interstate Highway 10; then east along Interstate Highway 10 to its intersection with Interstate Highway 210; then northwest along Interstate Highway 210 to its intersection with San Dimas Avenue; then east and north along San Dimas Avenue to its intersection with Foothill Boulevard; then west along Foothill Boulevard to its intersection with Alosta Avenue; then west along Alosta Avenue to its intersection with Foothill Boulevard; then west along Foothill Boulevard to its intersection with Azusa Avenue; then north along Azusa Avenue to its intersection with San Gabriel Canyon Road; then due north from the intersection along an imaginary line to its intersection with the Angeles National Forest boundary; then west along the boundary to the point of beginning; except that the portion of Los Angeles County bounded by a line drawn as follows is not within the area under quarantine: Beginning at the intersection of State Highway 60 and Interstate Highway 710; then west along State

Highway 60 to its intersection with Interstate Highway 10; then west along Interstate Highway 10 to its intersection with Broadway; then northeast along Broadway to its intersection with Olympic Boulevard; then northwest along Olympic Boulevard to its intersection with State Highway 110; then northeast along State Highway 110 to its intersection with Bishops Road; then southeast along Bishops Road to its intersection with North Broadway; then east along North Broadway to its intersection with Interstate Highway 5; then south along Interstate Highway 5 to its intersection with Interstate Highway 10; then east along Interstate Highway 10 to its intersection with Interstate Highway 710; then south along Interstate Highway 710 to the point of beginning.

§ 301.78-3 [Amended]

3. In § 301.78-3, paragraph (c), the description of the quarantined area in Los Angeles and San Bernardino Counties is amended by removing the phrase "in the Ontario area" immediately following the phrase "that portion of the county".

Done in Washington, DC, this 8th day of October 1993.

Patricia Jensen,

Deputy Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93-25175 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-34-P

Federal Crop Insurance Corporation

7 CFR Part 400

General Administrative Regulations; Sanctions

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Final rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) issues a new provision to its General Administrative Regulations. The intent of this provision is to expand the range of sanctions available to address fraud, misrepresentation, false claims, and other violations of contracts for insurance and contracts and agreements to provide insurance services; and prescribe the terms and conditions under which persons and other entities may be suspended or debarred from contracting with FCIC. This rule also serves to remove and reserve the suspension and debarment provisions as they will now be incorporated into these provisions.

EFFECTIVE DATE: October 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mari L. Dunleavy, Regulatory Specialist, Federal Crop Insurance Corporation,

U.S. Department of Agriculture, Washington, DC 20250. Telephone (202) 254-8314.

SUPPLEMENTARY INFORMATION: This action has been reviewed under USDA procedures established by Departmental Regulation 1512-1. This action constitutes a review as to the need, currency, clarity and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is July 1, 1997.

Kathleen Connelly, Acting Manager, FCIC has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of \$100 million or more; (b) major increases in costs or prices for consumers, individual industries, Federal, State, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. The Acting Manager certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons, nor will it have a significant economic effect on a substantial number of small entities. This action imposes no additional burden to the insured farmer. Further, this action requires of the reinsured company or sales and service contractor what is considered normal in the ordinary conduct of business. This rule does not require any action on the part of any individual or entity in compliance with the program provisions. This action is determined to be exempt from the provisions of the Regulatory Flexibility Act and no Regulatory Flexibility Analysis was prepared.

This program is listed in the Catalog of Federal Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which requires intergovernmental consultation with state and local officials. See the Notice related to 7 CFR part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

The Acting Manager, FCIC, has certified to the Office of Management

and Budget (OMB) that these regulations meet the applicable standards provided in sections 2(a) and 2(b)(2) of Executive Order 12778.

This rule has been reviewed in accordance with Executive Order 12778. The provisions of this proposed rule are not retroactive and will preempt state and local laws to the extent such state and local laws are inconsistent herewith. The administrative appeal provisions located at 7 CFR part 400, subpart J must be exhausted before judicial action may be brought for actions taken under proceedings for the imposition of civil penalties or under the Program Fraud Civil Remedies sections of these regulations.

This amendment does not contain information collections that require clearance by the Office of Management and Budget under the provisions of 44 U.S.C. chapter 35, the Paperwork Reduction Act.

The Office of General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies and procedures contained in this rule will not have substantial direct effects on states or their political subdivisions, or on the distribution of power and responsibilities among the various levels of government.

Background

This rule adds civil penalties provisions under the Federal Crop Insurance Act, as an additional sanction, and incorporates provisions for implementing departmental regulations for Debarment and Suspension and the Program Fraud Civil Remedies Act.

FCIC has established a system of sanctions to prevent waste, fraud, and abuse within its programs and insurance delivery systems, and to ensure maximum compliance with the terms and purposes of its issuances. This rule establishes the sanctions system and prescribes the manner of procedures under which the sanctions system will operate.

A proposed rule was published in Wednesday, July 14, 1993, at 58 FR 37874. Following publication of the proposed rule, the public was given 30 days in which to submit comments, data, and opinions. No comments were received.

Accordingly, the proposed rule published at 58 FR 37874 is hereby issued as final rule. FCIC amends the General Administrative Regulations, effective for the 1993 and succeeding calendar years as follows:

List of Subjects in 7 CFR Part 400

General Administrative Regulations, Sanctions.

Final Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended, the Federal Crop Insurance Corporation hereby amends 7 CFR part 400 of the Code of Federal Regulations as follows:

PART 400—GENERAL ADMINISTRATIVE REGULATIONS**Subpart E—Suspension and Debarment [Removed and Reserved]**

1. Subpart E is removed and reserved.
2. A new subpart R is added to read as follows:

Subpart R—Sanctions**Sec.**

- 400.451 General.
400.452 Definitions.
400.453 Exhaustion of administrative remedies.
400.454 Civil penalties.
400.455 Governmentwide debarment and suspension (procurement).
400.456 Governmentwide debarment and suspension (nonprocurement).
400.457 Program Fraud Civil Remedies Act.
400.458–400.499 [Reserved]
400.500 OMB control numbers.

Authority: 7 U.S.C. 1506, 1516.

Subpart R—Sanctions**§ 400.451 General.**

(a) The Federal Crop Insurance Corporation (FCIC) has implemented a system of sanctions to prevent waste, fraud, and abuse within its programs and insurance delivery systems. Such sanctions include civil penalties and disqualification from the crop insurance program under the Federal Crop Insurance Act, 7 U.S.C. 1506(m); government wide debarment and suspension; and civil penalties and assessments under the Program Fraud Civil Remedies Act, 31 U.S.C. 3801–31 U.S.C. 3812.

(b) The provisions of this subpart apply to all contracts and agreements to which FCIC is a party unless otherwise specifically provided for in this subpart, including those in which FCIC provides administrative expense reimbursement, premium subsidy, or reinsurance benefits.

(c) The provisions of this subpart are in addition to any other sanctions specifically provided in applicable contracts and agreements.

(d) This subpart is applicable to any act or omission by any affected party after October 14, 1993.

§ 400.452 Definitions.

For purposes of this subpart, a person means an individual, partnership, association, corporation, estate, trust, or other business enterprise or legal entity, and wherever applicable, a state, a political subdivision of a state, or any agency thereof.

§ 400.453 Exhaustion of administrative remedies.

All administrative remedies contained herein or incorporated herein by reference must be exhausted before Judicial Review in the United States Courts may be sought, unless review is specifically required by statute.

§ 400.454 Civil penalties.

(a) Any person who willfully and intentionally provides any false or inaccurate information to FCIC or to any insurer reinsured by the FCIC with respect to an insurance plan or policy may be subject to a civil fine of up to \$10,000 for each violation and disqualification from the crop insurance program for a period not to exceed 10 years.

(b) FCIC may make the payment of a civil penalty under this section a prior condition for the issuance, renewal, restoration, or continuing validity of any crop insurance policy or other approval.

(c) FCIC may compromise, modify, settle, collect, or remit with or without conditions, any civil penalty which is subject to imposition or which has been imposed under this section whenever it considers it to be appropriate or advisable.

(d) If a director, officer, or agent of a corporation provides false or inaccurate information, they may be separately subject to the fine specified in paragraph (a) of this section without regard to any penalties to which the corporation may be subject.

(e) The liability of any person for any penalty under this subpart or any related charges arising in connection therewith shall be in addition to any other liability of such person under any civil or criminal fraud statute or any other statute or provision of law.

(f) Proceedings under this § 400.454 will be in accordance with subpart H of 7 CFR part 1, "Rules of Practice Governing Formal Adjudicatory Proceedings Instituted by the Secretary under Various Statutes," by which the Manager, FCIC, shall initiate proceedings by filing a complaint with the Hearing Clerk, United States Department of Agriculture.

§ 400.455 Governmentwide debarment and suspension (procurement).

(a) This section prescribes the terms and conditions under which persons or

business entities may be debarred or suspended by FCIC from contracting with the Federal government.

(b) This section is in accordance with 48 CFR part 9, subpart 9.4 and 48 CFR part 409, subpart 409.4 and shall be applicable to all FCIC debarment and suspension proceedings undertaken pursuant to the Federal Acquisition Regulations, except that the authority to debar or suspend is reserved to the Manager, FCIC, or the Manager's designee.

(c) Any individual or entity suspended or debarred under the provisions of 48 CFR part 9, subpart 9.4 will not be eligible to contract with FCIC or be employed by or contract with any insurance company that sells or adjusts FCIC's crop insurance contracts or which company's crop insurance contracts are reinsured by FCIC. FCIC may waive this provision if it is satisfied that the insurance company has taken sufficient action to insure that the suspended or debarred entity or individual will not be involved, in any way, with FCIC or FCIC reinsured crop insurance contracts.

§ 400.456 Governmentwide debarment and suspension (nonprocurement).

(a) This section prescribes the terms and conditions under which individuals or entities may be debarred or suspended by FCIC from participation in Federal assistance and benefits under Federal programs and activities.

(b) This section, in accordance with 7 CFR part 3017, shall be applicable to all FCIC debarment and suspension proceedings other than those undertaken pursuant to the Federal Acquisition Regulations.

(c) Proceedings under this section are not applicable to determinations of eligibility under the provisions of the crop insurance contracts or determinations to be made under 7 CFR 400.454.

(d) The Manager, FCIC, shall be the debarment and suspending official for all debarment or suspension proceedings undertaken by FCIC under the provisions of 7 CFR part 3017.

§ 400.457 Program Fraud Civil Remedies Act.

(a) This section is in accordance with the Program Fraud Civil Remedies Act of 1986 (31 U.S.C. 3801–U.S.C. 3831) which provides for civil penalties and assessments against persons who make, submit, or present, or cause to be made, submitted, or presented, false, fictitious, or fraudulent claims or written statements to Federal authorities or to their agents.

(b) Proceedings under this section will be in accordance with subpart L of

7 CFR part 1, "Procedures Related to Administrative Hearings Under the Program Fraud Civil Remedies Act of 1986."

(c) The Director, Appeals and Litigation Staff, FCIC, or the Director's designee, is authorized to serve as Agency Fraud Claims Officer for the purpose of implementing the requirements of this section.

§§ 400.458 through 400.499 [Reserved]

§ 400.500 OMB control numbers.

Office of Management and Budget (OMB) control numbers are contained in subpart H of 7 CFR part 400.

Done in Washington, DC, on September 22, 1993.

Bob Nash,

Under Secretary, Small Community and Rural Development.

[FR Doc. 93-25144 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-08-M

Agricultural Marketing Service

7 CFR Part 906

[Docket No. FV93-906-11FR; Amendment 1]

Expenses and Assessment Rate for the Marketing Order Covering Oranges and Grapefruit Grown in the Lower Rio Grande Valley in Texas

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule amendment with request for comments.

SUMMARY: This amended interim final rule authorizes an increase in expenses and assessment rate for the Texas Valley Citrus Committee (TVCC) under M.O. No. 906 for the 1993-94 fiscal year. This action will enable the TVCC to incur increased expenses and collect additional assessments that are reasonable and necessary to administer this program. Funds to administer this program are derived from assessments on handlers.

DATES: Effective beginning August 1, 1993, through July 31, 1994. Comments received by November 15, 1993 will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this amended interim final rule. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523-S, Washington, DC 20090-6456, Fax # (202) 720-5698. Comments should reference the docket number and the date and page number of this issue of the Federal Register and

will be available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT:

Britthany E. Beadle, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523-S, Washington, DC 20090-6456, telephone: (202) 720-5127; or Belinda Garza, McAllen Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, 1313 East Hackberry, McAllen, Texas 78501, telephone: (210) 682-2833.

SUPPLEMENTARY INFORMATION: This amended interim final rule is issued under Marketing Agreement and Order No. 906 (7 CFR part 906) regulating the handling of oranges and grapefruit grown in the lower Rio Grande Valley in Texas, hereinafter referred to as the order. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the Act.

This amended interim final rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This amended interim final rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the marketing order provisions now in effect, oranges and grapefruit grown in Texas are subject to assessments. It is intended that the assessment rate specified herein will be applicable to all assessable citrus fruit handled during the 1993-94 fiscal year, beginning August 1, 1993, through July 31, 1994. This amended interim final rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this amended rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 608c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, 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 handler 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 handler is an inhabitant, or has his or her principal place of business, has jurisdiction in

equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to the requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 135 handlers of oranges and grapefruit regulated under the order each season and approximately 2,500 orange and grapefruit producers in Texas. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than \$500,000, and small agricultural service firms are defined as those whose annual receipts are less than \$3,500,000. The majority of these handlers and producers may be classified as small entities.

The Texas orange and grapefruit marketing order, administered by the Department, requires that the assessment rate for a particular fiscal year apply to all assessable citrus fruit handled from the beginning of such year. Annual budgets of expenses are prepared by the TVCC, the agency responsible for local administration of this order, and submitted to the Department for approval. The members of the TVCC are handlers and producers of Texas oranges and grapefruit. They are familiar with the TVCC's needs and with the costs for goods, services, and personnel in their local area, and are thus in a position to formulate appropriate budgets. The TVCC's budget is formulated and discussed in a public meeting. Thus, all directly affected persons have an opportunity to participate and provide input.

The assessment rate recommended by the TVCC is derived by dividing the anticipated expenses by expected shipments of oranges and grapefruit. Because that rate is applied to actual shipments, it must be established at a rate which will provide sufficient income to pay the TVCC's expected expenses.

An interim final rule was issued on July 7, 1993, and published in the *Federal Register* (58 FR 37635, July 13, 1993) effective for the period August 1, 1993, through July 31, 1994, with a 30-day comment period ending August 12, 1993. The interim final rule authorized expenses of \$984,319 and an assessment rate of \$0.15 per 7/10 bushel carton for the 1993-94 fiscal year. No comments were filed on the expenses and assessment rate in the interim final rule.

The TVCC met again on August 3, 1993, and unanimously recommended increasing authorized expenses to \$1,180,925, a \$196,606 increase from the currently authorized amount. The TVCC also unanimously recommended increasing the assessment rate from \$0.15 per 7/10 bushel carton to \$0.18 per 7/10 bushel carton, a \$0.03 increase per 7/10 bushel carton from the currently authorized assessment rate.

This amended interim final rule increases authorized expenses to \$1,180,925, and increases the assessment rate to \$0.18 per 7/10 bushel carton of assessable oranges and grapefruit for the 1993-94 fiscal year under the order. The \$196,606 expense increase is necessary to provide additional funds for order operations, including \$172,606 to fund increased administrative and compliance expenses, primarily for the maintenance of road guard stations, and \$24,000 to cover a shortfall in the Mexican Fruit Fly support program. The increase in the assessment rate along with the withdrawal of additional funds from the committee's reserves, will adequately fund the increased expenses.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs should be significantly offset by the benefits derived from the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant matter presented, including the information and recommendations submitted by the TVCC and other available information, it is hereby found that this amended rule as hereinafter set forth will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this amended rule into effect and that

good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* because:

(1) The TVCC needs to have sufficient funds to pay its increased expenses which are incurred on a continuous basis;

(2) This interim final rule provides a 30-day comment period, and all comments timely received will be considered prior to any finalization of this action.

List of Subjects in 7 CFR Part 906

Grapefruit, Marketing agreements and orders, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 906 is amended as follows:

PART 906—ORANGES AND GRAPEFRUIT GROWN IN THE LOWER RIO GRANDE VALLEY IN TEXAS

1. The authority citation for 7 CFR part 906 is revised to read as follows:

Authority: 7 U.S.C. 601-674.

2. Section 906.233 is revised to read as follows:

Note: This section will not appear in the annual Code of Federal Regulations.

§ 906.233 Expenses and assessment rate.

Expenses of \$1,180,925 by the Texas Valley Citrus Committee are authorized and an assessment rate of \$0.18 per 7/10 bushel carton on assessable oranges and grapefruit is established for the fiscal year ending July 31, 1994. Unexpended funds may be carried over as a reserve.

Dated: October 7, 1993.

Robert C Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 93-25178 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-02-P

7 CFR Parts 907 and 908

[FV93-907-11FR]

Navel and Valencia Oranges Grown in Arizona and Designated Parts of California; Change In Reporting Requirements

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This interim final rule invites comments on changes to the reporting requirements currently prescribed under the California-Arizona navel and Valencia orange marketing orders. The

marketing orders regulate the handling of navel and Valencia oranges grown in Arizona and designated parts of California and are administered locally by the Navel and Valencia Orange Administrative Committees (committees). This rule modifies language in the orders' rules and regulations to discontinue the use of Form 38 (Weekly Report of By-Product Oranges) and specify that Form 3 (Daily Manifest Report of Oranges Subject to Allotment) only be utilized for reporting rail car shipments. These actions will reduce the burden of information collection requirements currently provided for under the marketing orders.

DATES: The interim final rule is effective October 14, 1993; comments received by November 15, 1993, will be considered prior to issuance of a final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this action. Comments must be sent in triplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, room 2525-S, P.O. Box 96456, Washington, DC 20090-6456. All comments should reference the docket number and the date and page number of this issue of the *Federal Register* and will be made available for public inspection in the Office of the Docket Clerk during regular business hours.

FOR FURTHER INFORMATION CONTACT: Caroline C. Thorpe, Marketing Specialist, Marketing Order Administration Branch, F&V, AMS, USDA, room 2522-S, P.O. Box 96456, Washington, DC 20090-6456; Telephone: (202) 720-5127; or Maureen Pello, California Marketing Field Office, Marketing Order Administration Branch, F&V, AMS, USDA, 2202 Monterey Street, Suite 102B, Fresno, California, 93721; telephone: (209) 487-5901.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Order Nos. 907 and 908 (7 CFR Parts 907 and 908), as amended, regulating the handling of navel and Valencia oranges grown in Arizona and designated parts of California, hereinafter referred to as the "orders." These orders are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

This rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This rule has been reviewed under Executive Order 12778, Civil Justice Reform. This action 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 action.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, or any obligation imposed in connection with the order is not in accordance with law and request a modification of the order or to be exempted therefrom. A handler 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 handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 150 handlers of navel oranges and 140 handlers of Valencia oranges who are subject to regulation under the respective marketing order and approximately 4,000 producers of navel oranges and 3,700 producers of Valencia oranges in the regulated areas. In addition, there are about 35 by-product manufacturers that will be affected by this rule. Small agricultural service firms, which includes handlers and by-product manufacturers, have been defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than \$3,500,000, and small agricultural producers are defined as those whose annual receipts are less than \$500,000. The majority of handlers, producers, and processors of California-

Arizona navel and Valencia oranges may be classified as small entities.

This rule invites comments on two changes to the reporting requirements currently prescribed under the California-Arizona orange marketing orders. This rule modifies language in the orders' rules and regulations to discontinue the use of Form 38 (Weekly Report of By-Product Oranges) and specify that Form 3 (Daily Manifest Report of Oranges Subject to Allotment) only be utilized for reporting rail car shipments. These changes were unanimously recommended by the committees.

Sections 907.67 and 908.67 of the navel and Valencia orange marketing orders provide authority for the exemption from order regulation the handling of oranges to commercial processors for processing into products, including juice. Sections 907.131 and 908.131 of the orders' rules and regulations prescribe procedures governing the exemption from order regulation of such by-product oranges. Included in these procedures are certain reporting requirements imposed on handlers and by-product manufacturers to help ensure that order requirements and regulations governing the exemption for by-product oranges are being followed.

For example, persons who wish to acquire oranges as an approved by-products manufacturer for commercial processing into by-products exempt from regulation must submit an application to the committee on Form 14 (Application to be Placed on Approved List of Orange By-Product Manufacturers). These applications are referred to the committees' compliance department for investigation and then, if appropriate, referred to the committee for approval to be placed on an approved list of by-product manufacturers. Commercial processors are also required to submit to the committees copies of Form 15 (Orange Diversion Report) which specify how the oranges were disposed. Finally, approved by-product manufacturers are required to submit Form 38 (Weekly Report of By-Product Oranges) during the crop year when processing is occurring.

The committees have recommended that submission of Form 38 no longer be required under the marketing orders. Submission of Form 38 was added to the orders' rules and regulations in 1990 because the committees believed that the additional information would help to ensure that oranges exempted under the by-products exemption did not enter the fresh fruit market. It was believed that comparisons of the total amount of

oranges received by processors with the total amount of by-products manufactured would give the committees a method to verify that all oranges received were manufactured into by-products.

However, the committees have found that the information collected on Form 38 is not necessary to ensure compliance with order requirements. In addition, much of the information currently collected on Form 38 is collected on other reports required to be submitted under the orders. The committees believe that submission of Form 38 creates an additional burden on by-product manufacturers that is not necessary. Thus, the committees have recommended revising the orders' rules and regulations to discontinue the use of Form 38. The Department has also made some minor modifications to §§ 907.131 and 908.131 for the purpose of clarity.

The second change that the committees recommended concerns Form 3 (Daily Manifest Report of Oranges Subject to Allotment). Sections 907.71 and 908.71 of the orange marketing orders provide that handlers furnish to the committees information regarding cartons of oranges handled, segregated by size, within 24 hours of shipment. Handlers must also indicate whether the shipments were destined to points in the U.S. and Alaska or Canada.

Sections 907.141 and 908.141 of the orders' rules and regulations require handlers to submit, on Form 3, a manifest report of all oranges shipped within a 24 hour period. Currently, handlers must indicate both truck and rail car shipments on Form 3. However, identical information regarding truck shipments is also required to be submitted by handlers on Form 8 (Certificate of Assignment of Allotment). According to the committees, this duplication of information creates an added burden for handlers and is not necessary. Thus, the committees have recommended modifying the orders' rules and regulations to require that handlers only report rail car shipments on Form 3. Handlers will still be required to submit rail manifests and other appropriate documentation to the committees to substantiate rail car shipments.

Based on these considerations, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

The information collection requirements contained in the referenced sections have been previously approved by the Office of Management and Budget (OMB) under

the provisions of 44 U.S.C. chapter 35 and have been assigned OMB numbers 0581-0116 for navel oranges and 0581-0121 for Valencia oranges.

This rule will reduce the reporting burden on approximately 25 processors of navel and Valencia oranges who have been completing Form 38, taking about 0.33 hour to complete each report. This rule will also reduce the reporting burden on approximately 210 handlers who ship primarily by truck, taking about 0.40 hour to complete each report. About 80 handlers who ship by rail at some point during a season will continue to use Form 3, taking approximately 0.20 hour to complete the report.

After consideration of all relevant material presented, including the Committee's recommendation, and other available information, it is found that this interim final rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect and that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* because:

(1) Handlers are currently shipping Valencia oranges and will begin shipping navel oranges for the upcoming 1993-94 season in October and this action will reduce the burden of information collection placed on such handlers and on by-product manufacturers;

(2) The committees unanimously recommended this action at public meetings and all interested persons had an opportunity to provide input;

(3) This action relaxes reporting requirements;

(4) California-Arizona orange handlers are aware of this action and need no additional time to comply with the relaxed requirements; and

(5) This rule provides a 30-day comment period and any comments received will be considered prior to finalization of this rule.

List of Subjects in 7 CFR Parts 907 and 908

Marketing agreements, Oranges, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR parts 907 and 908 are amended as follows:

1. The authority citation for both 7 CFR parts 907 and 908 is revised to read as follows:

Authority: 7 U.S.C. 601-674.

[Note: These sections will appear in the annual Code of Federal Regulations.]

PART 907—NAVEL ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

2. In § 907.131, the first sentence in paragraph (b)(1) is revised to read as set forth below, and paragraph (b)(3)(v) is removed; paragraphs (b)(3)(vi) and (b)(3)(vii) are redesignated as paragraphs (b)(3)(v) and (b)(3)(vi), respectively; paragraphs (b)(4) and (c) are removed, and paragraph (d) is redesignated as paragraph (c).

§ 907.131 By-product oranges.

(b) * * * (1) Any person who desires to acquire oranges as an approved by-products manufacturer for commercial processing into by-products exempt from regulation pursuant to § 907.67(b) must first apply to and obtain approval from the committee. * * *

3. In § 907.141, the first two sentences of paragraph (a) are revised to read as follows:

§ 908.141 Manifest reports.

(a) Within 24 hours after a rail car shipment is made by a handler, the handler shall submit to the committee, on N.O.A.C. Form No. 3, a manifest report of all oranges so shipped. Such report shall show the rail car number for each shipment, together with the quantity by sizes per carton, of each shipment made within the United States or to Canada, or to Alaska. * * *

PART 908—VALENCIA ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

4. In § 908.131, the first sentence of paragraph (b)(1) is revised to read as set forth below, and paragraph (b)(3)(v) is removed; paragraphs (b)(3)(vi) and (b)(3)(vii) are redesignated as paragraphs (b)(3)(v) and (b)(3)(vi), respectively; paragraphs (b)(4) and (c) are removed, and paragraph (d) is redesignated as paragraph (c).

§ 908.131 By-product oranges.

(b) * * * (1) Any person who desires to acquire oranges as an approved by-products manufacturer for commercial processing into by-products exempt from regulation pursuant to § 908.67(b) must first apply to and obtain approval from the committee. * * *

5. In § 908.141, the first two sentences of paragraph (a) are revised to read as follows:

§ 908.141 Manifest reports.

(a) Within 24 hours after a rail car shipment is made by a handler, the handler shall submit to the committee, on V.O.A.C. Form No. 3, a manifest report of all oranges so shipped. Such report shall show the rail car number for each shipment, together with the quantity by sizes per carton, of each shipment made within the United States or to Canada, or to Alaska. * * *

Dated: October 8, 1993.

Robert C. Keeney,
Deputy Director, Fruit and Vegetable Division,
[FR Doc. 93-25282 Filed 10-13-93; 8:45 am]
BILLING CODE 3410-02-P

7 CFR Parts 907 and 908

[Docket No. FV93-907-2FR]

Naval and Valencia Oranges Grown in Arizona and Designated Parts of California; Suspension of Volume Provisions

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule; suspension.

SUMMARY: This action suspends the provisions of the Federal marketing orders (orders) regulating navel and Valencia oranges grown in Arizona and designated parts of California associated with volume regulations. This action is taken in response to evidence of widespread circumvention of the current programs as well as division and turmoil within the orange industry. The suspension will be in effect until a satisfactory resolution of industry differences is achieved.

EFFECTIVE DATE: This action becomes effective on October 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mark A. Hessel, Marketing Specialist, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, room 2522-S, P.O. Box 96456, Washington, D.C. 20090-6456; telephone: (202) 690-0992; or Maureen T. Pello, California Marketing Field Office, Marketing Order Administration Branch, F&V, AMS, USDA, 2202 Monterey Street, suite 102B, Fresno, California, 93721; telephone: (209) 487-5901.

SUPPLEMENTARY INFORMATION: This action is issued under Marketing Order Nos. 907 and 908 (7 CFR parts 907 and 908), as amended, regulating the handling of navel and Valencia oranges grown in Arizona and designated parts of California, hereinafter referred to as the "orders." These orders are effective under the Agricultural Marketing

Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the "Act."

This action has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This action has been reviewed under Executive Order 12778, Civil Justice Reform. This action is not intended to have retroactive effect. This action will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this action.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, 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. A handler 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 handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this action on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 130 handlers of navel oranges and 125 handlers of Valencia oranges who are subject to regulation under the respective marketing orders and approximately 4,000 producers of navel oranges and 3,700 producers of Valencia oranges in the regulated areas. Small agricultural producers have been defined by the Small Business Administration (13 CFR

121.601) as those having annual receipts of less than \$500,000, and small agricultural service firms are defined as those whose annual receipts are less than \$3,500,000. The majority of producers and handlers of California-Arizona navel and Valencia oranges may be classified as small entities.

The orders regulate the handling of navel and Valencia oranges grown in Arizona and parts of California. Both orders provide, among other things, for weekly volume regulations by district as needed throughout the marketing year.

This action suspends, for an indefinite period, certain provisions of the orders associated with volume regulations. Specifically, such provisions of the orders are found in §§ 907.13, 907.14, 907.50, 907.51, 907.52, 907.53, 907.54, 907.55, 907.56, 907.57, 907.59, 907.60, 907.61, 907.61a, 907.62, 907.64, 907.65, 907.80, 907.108, 907.110, 907.111, 907.113, 907.114, 907.116, 907.117, 907.120, 907.131, 907.133, 908.14, 908.15, 908.50, 908.51, 908.52, 908.54, 908.55, 908.56, 908.57, 908.59, 908.60, 908.61, 908.61a, 908.62, 908.64, 908.65, 908.80, 908.108, 908.110, 908.111, 908.113, 908.114, 908.116, 908.117, 908.120, 908.131, and 908.133. Several other volume provisions which also provide the committees information useful for statistical purposes, marketing evaluation, and assessments are not being suspended.

On June 18, 1993, the Secretary announced in a press release that the substantial number of lawsuits associated with the orders indicates that the orders are not working as well as they should and that these lawsuits have hurt growers, pickers, packers, and consumers. Most of these lawsuits involve the volume regulation provisions of the orders. Scrutiny of the orders resulting from the lawsuits indicates that there is widespread circumvention of the current order regulations and that there is division and turmoil within the orange industry related to orange marketing orders and volume controls. The widespread circumvention of volume regulations decreases the effectiveness of the orders in providing for orderly marketing and improved producer returns. The Department is therefore suspending the volume regulation provisions of the orders until a satisfactory resolution of industry differences is achieved.

The information collection requirements contained in the referenced sections have been previously approved by the Office of Management and Budget (OMB) under the provisions of 44 U.S.C. chapter 35 and have been assigned OMB numbers

0581-0116 for navel oranges and 0581-0121 for Valencia oranges.

Based on available information, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

Thus, it is found that the provisions detailed below, at this time, do not tend to effectuate the declared policy of the Act.

It is also found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice or to engage in further public procedure prior to putting this action into effect and that good cause exists for not postponing the effective date of this action until 30 days after publication because: (1) Growers and handlers are aware of this action since it was announced in a press release issued by the Secretary on June 18, 1993; (2) this action relieves restrictions on handlers by suspending the volume requirements regulating the handling of oranges pursuant to the orders; and (3) no useful purpose would be served by delaying this action.

List of Subjects in 7 CFR Parts 907 and 908

Marketing agreements, Oranges, Reporting and recordkeeping requirements.

Accordingly, 7 CFR parts 907 and 908 are amended as follows:

1. The authority citation for 7 CFR parts 907 and 908 continues to read as follows:

Authority: 7 U.S.C. 601-674.

Note: The following sections will appear in the Code of Federal Regulations.

PART 907—NAVEL ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA

§§ 907.13 and 907.14 [Suspended]

2. Sections 907.13 and 907.14, are suspended in their entirety.

§ 907.50 [Suspended in Part]

3. Paragraph (a)(3) of § 907.50 is suspended in its entirety.

§ 907.5 [Suspended in Part]

4. In the heading for § 907.51, the word "volume" is suspended.

5. Paragraph (a) of § 907.51 is suspended in its entirety.

6. In the introductory text of paragraph (b) of § 907.51, the words "shall provide equity of marketing opportunity to handlers in all districts and" are suspended.

7. Paragraphs (c) and (d) in § 907.51 are suspended in their entirety.

§ 907.52 [Suspended]

8. Section 907.52 is suspended in its entirety.

§ 907.53 [Suspended in Part]

9. In paragraph (a) of § 907.53, the words "and for allotments" are suspended.

10. In paragraph (e) of § 907.53, in the second sentence, the words "If it is determined by the committee that any person who has lost control of oranges as required by paragraph (c) of this section has handled a quantity of such oranges less than the quantity that could have been handled under the allotments issued thereon, the quantity of oranges available for current shipment by such person shall be adjusted by deducting therefrom, over such period as may be determined by the committee a quantity of oranges equivalent to the quantity upon which allotments were issued but which were not utilized thereon and," are suspended.

11. In paragraph (f) of § 907.53, the words "or has remaining a quantity smaller than his allotment" and the words "so that his allotment based thereon shall not exceed the quantity of oranges remaining under his control; except that he shall receive his allotments on his full prorated base to the extent necessary to pay back loans for which he is obligated in any week that repayment of loans may be due" are suspended.

12. In paragraph (h) of § 907.53, in the first sentence, the words "Each week during the marketing season when volume regulation is likely to be recommended," and the words "and for allotments" are suspended.

§§ 907.54-907.57, 907.59-907.61a [Suspended]

13. Sections 907.54, 907.55, 907.56, 907.57, 907.59, 907.60, 907.61, 907.61a are suspended in their entirety.

§ 907.62 [Suspended in Part]

14. In § 907.62, the words "and allotments" are suspended.

§ 907.64 [Suspended in Part]

15. In § 907.64, in the second sentence, the words "weekly allotment issued to such handler when volume regulation is in effect, and the" and the words "when volume regulation is not in effect" are suspended.

§ 907.65 [Suspended in Part]

16. In § 907.65, the third sentence "Shipments of oranges under exemption certificates issued pursuant to this section shall be subject to and limited by such regulations as may be effective under § 907.52 at the time of the respective shipment." is suspended.

§ 907.80 [Suspended in Part]

17. In § 907.80, the words "no person shall handle oranges during any week in which a regulation issued by the Secretary pursuant to § 907.52 is in effect, unless such oranges are, or have been, handled pursuant to an allotment therefor, or unless such person is otherwise permitted to handle such oranges under the provisions of this part; and" are suspended.

§ 907.108 [Suspended in Part]

18. In paragraph (a) of § 907.108, the words "and allotments" are suspended.

19. In paragraph (c) of § 907.108 the last sentence reading "Such quantity shall be added during the same periods in which the deductions are effected in accordance with the provisions of paragraph (d) of this section." is suspended.

20. Paragraphs (d) and (e) of § 907.108 are suspended in their entirety.

§§ 907.110 and 907.111; 907.113 and 907.114; and 907.116 and 907.117 [Suspended]

21. Sections 907.110, 907.111, 907.113, 907.114, 907.116, and 907.117, of the Subpart Rules and Regulations are suspended in their entirety.

§ 907.120 [Suspended in Part]

22. In paragraph (e) of § 907.120 the first sentence "If volume regulation is in effect at the time exemption certificates are issued, such exemption certificates may be used only to the extent that allotment has been issued under volume regulations for the oranges covered thereby," and the words "subject to the handler's allotment under volume regulation," in the last sentence, are suspended.

§ 907.131 [Suspended in Part]

23. In paragraph (a) of § 907.131 the words "(1) such oranges, are, or have been, handled pursuant to an allotment therefor; or (2)" are suspended.

§ 907.133 [Suspended in Part]

24. In the first sentence of paragraph (a) of § 907.133, the words "volume or" are suspended.

§ 907.133 [Suspended in Part]

25. In the penultimate sentence of paragraph (a) of § 907.133, the words "volume or" are suspended.

§ 907.133 [Suspended in Part]

26. In paragraph (c) of § 907.133, in the first sentence, the words "volume and" are suspended.

PART 908—VALENCIA ORANGES GROWN IN ARIZONA AND DESIGNATED PART OF CALIFORNIA**§§ 908.14 and 908.15 [Suspended]**

27. Sections 908.14 and 908.15 are suspended in their entirety.

§ 908.50 [Suspended in Part]

28. Paragraph (a)(3) of § 908.50 is suspended in its entirety.

§ 908.51 [Suspended in Part]

29. In the heading for § 908.51, the word "volume" is suspended.

30. Paragraph (a) of § 908.51 is suspended in its entirety.

31. In the introductory text of paragraph (b) of § 908.51, the words "shall provide equity of marketing opportunity to handlers in all districts and" are suspended.

32. Paragraphs (c) and (d) in § 908.51 are suspended in their entirety.

§ 908.52 [Suspended]

33. Section 908.52 is suspended in its entirety.

§ 908.53 [Suspended in Part]

34. In paragraph (a) of § 908.53, the words "and for allotments" are suspended.

35. In paragraph (e) of § 908.53, in the second sentence, the words "If it is determined by the committee that any person who has lost control of oranges as required by paragraph (c) of this section has handled a quantity of such oranges less than the quantity that could have been handled under the allotments issued thereon, the quantity of oranges available for current shipment by such person shall be adjusted by deducting therefrom, over such period as may be determined by the committee a quantity of oranges equivalent to the quantity upon which allotments were issued but which were not utilized thereon and," are suspended.

36. In paragraph (f) of § 908.53, the words "or has remaining a quantity smaller than his allotment" and the words "so that his allotment based thereon shall not exceed the quantity of oranges remaining under his control; except that he shall receive his allotments on his full prorated base to the extent necessary to pay back loans for which he is obligated in any week that repayment of loans may be due" are suspended.

37. In paragraph (h) of § 908.53, in the first sentence, the words "Each week during the marketing season when volume regulation is likely to be recommended," and the words "and for allotments" are suspended.

§§ 908.54-908.57 and 908.59-908.61a
[Suspended]

38. Sections 908.54, 908.55, 908.56, 908.57, 908.59, 908.60, 908.61, 908.61a are suspended in their entirety.

§ 908.62 [Suspended in Part]

39. In § 908.62, the words "and allotments" are suspended.

§ 908.64 [Suspended in Part]

40. In § 908.64, the words "weekly allotment issued to such handler when volume regulation is in effect, and the" and the words "when volume regulation is not in effect" are suspended.

§ 908.65 [Suspended in Part]

41. In § 908.65, the third sentence, "Shipments of oranges under exemption certificates issued pursuant to this section shall be subject to and limited by such regulations as may be effective under § 908.52 at the time of the respective shipment." is suspended.

§ 908.80 [Suspended in Part]

42. In § 908.80, the words "no person shall handle oranges during any week in which a regulation issued by the Secretary pursuant to § 908.52 is in effect, unless such oranges are, or have been, handled pursuant to an allotment therefor, or unless such person is otherwise permitted to handle such oranges under the provisions of this part; and" are suspended.

§ 908.108 [Suspended in Part]

43. In paragraph (a) of § 908.108, the words "and allotments" are suspended.

44. In paragraph (b) of § 908.108 the last sentence reading "Such quantity shall be added during the same periods in which the deductions are effected in accordance with the provisions of paragraph (c) of this section." are suspended.

§ 908.108 [Suspended in Part]

45. Paragraphs (c) and (d) of § 908.108 are suspended in their entirety.

§§ 908.110 and 908.111; 908.113 and 908.114; and 908.116 and 908.117
[Suspended]

46. Sections 908.110, 908.111, 908.113, 908.114, 908.116, and 908.117, of the Subpart Rules and Regulations are suspended in their entirety.

§ 908.120 [Suspended in Part]

47. In paragraph (e) of § 908.120 the first sentence "If volume regulation is in effect at the time exemption certificates are issued, such exemption certificates may be used only to the extent that allotment has been issued under volume regulations for the oranges covered thereby." and the words "subject to the

handler's allotment under volume regulation," are suspended.

§ 908.131 [Suspended in Part]

48. In paragraph (a) of § 908.131 the words "(1) such oranges, are or have been, handled pursuant to an allotment therefor; or (2)" are suspended.

§ 908.133 [Suspended in Part]

49. In the first sentence of paragraph (a) of § 908.133, the words "volume or" and "or both" are suspended.

50. In the penultimate sentence of paragraph (a) of § 908.133, the words "volume or" are suspended.

51. In paragraph (b) of § 908.133, the words "volume and" are suspended in both places where they appear.

52. In paragraph (c) of § 908.133, the words "volume and" are suspended.

Dated: October 4, 1993.

Patricia Jensen,

Deputy Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 93-25077 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-02-P

7 CFR Part 928

[Docket No. FV93-928-2; Amendment 1]

Expenses and Assessment Rate for Papayas Grown in Hawaii

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim final rule with request for comments.

SUMMARY: This amended interim final rule authorizes a decrease in expenses and reduces the assessment rate established for the 1993-94 fiscal year under Marketing Order No. 928. This action will enable the Papaya Administrative Committee (PAC) to decrease expenses and assessment rate in a reasonable manner necessary to administer the program. Funds to administer this program are derived from assessments on handlers.

DATES: Effective July 1, 1993, through June 30, 1994. Comments received by November 15, 1993, will be considered prior to any finalization of this interim final rule.

ADDRESSES: Interested persons are invited to submit written comments concerning this rule to: Docket Clerk, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523-S, Washington, DC 20090-6456, or by Facsimile (202) 720-5698. Three copies of all written material shall be submitted, and they will be made available for public inspection in the office of the Docket Clerk during regular

business hours. All comments should reference the docket number, date, and page number of this issue of the Federal Register.

FOR FURTHER INFORMATION CONTACT:

Britthany E. Beadle, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2525-S, Washington, DC 20090-6456; telephone: (202) 720-5127; or Kurt J. Kimmel, California Marketing Field Office, Fruit & Vegetable Division, AMS, USDA, 2202 Monterey Street, suite 102 B, Fresno, California 93721, telephone: (209) 487-5901.

SUPPLEMENTARY INFORMATION: This amended interim final rule is issued under Marketing Agreement and Marketing Order No. 928, as amended (7 CFR part 928), regulating the handling of papayas grown in Hawaii, hereinafter referred to as the order. The order is effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the Act.

This amended rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This amended interim final rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the marketing order provisions now in effect, papayas grown in Hawaii are subject to assessments. It is intended that the assessment rate as issued herein will be applicable to all assessable papayas handled during the 1993-94 fiscal year, beginning July 1, 1993, through June 30, 1994. This rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, 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 handler 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 handler is an inhabitant, or has his/her principal place of business, has jurisdiction in

equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 120 papaya handlers subject to regulation under the marketing order covering fresh papayas grown in Hawaii, and approximately 300 producers of papayas in Hawaii. Small agricultural producers have been defined by the Small Business Administration [13 CFR 121.601] as those having annual receipts of less than \$500,000, and small agricultural service firms are defined as those whose annual receipts are less than \$3,500,000. The majority of these handlers and producers may be classified as small entities.

This marketing order, administered by the Department, requires that the assessment rate for a particular fiscal period shall apply to all assessable papayas handled from the beginning of such period. An annual budget of expenses and an assessment rate is prepared by the PAC and submitted to the Department for approval. The PAC members are handlers and producers of Hawaii papayas. They are familiar with the PAC's needs and with the costs for goods, services, and personnel in their local area and are thus in a position to formulate appropriate budgets. The budget is formulated and discussed in public meetings. Thus, all directly affected persons have an opportunity to participate and provide input.

The assessment rate recommended by the PAC is derived by dividing anticipated expenses by the expected pounds of fruit shipped. Because that rate is applied to actual shipments, it must be established at a rate which will produce sufficient income to pay the PAC's expected expenses. The annual budget and assessment rate are usually recommended by the PAC shortly before a season starts, and expenses are incurred on a continuous basis. Therefore, budget and assessment rate

approvals must be expedited so that the PAC will have funds to pay its expenses.

An interim final rule was issued on June 14, 1993, and published in the *Federal Register* (58 FR 33759, June 21, 1993) effective for the period July 1, 1993, through June 30, 1994, with a 30-day comment period ending July 21, 1993. The interim final rule authorized expenses of \$700,580 and an assessment rate of \$0.0085 per pound of fresh papayas for the 1993-94 fiscal year. No comments were filed on the expenses and assessment rate in the interim final rule.

However, the PAC met again on August 13, 1993, and unanimously recommended decreasing authorized expenses from \$700,580 to \$597,860, a \$102,720 decrease in expenses from the authorized amount. The PAC also unanimously recommended decreasing the assessment rate from \$0.0085 to \$0.0069, a \$0.0016 decrease in the assessment rate, based upon 58 million pounds of fresh papayas, from the currently authorized assessment rate.

This amended interim final rule decreases authorized expenses to \$597,860, and reduces the assessment rate to \$0.0069 per pound of fresh papayas for the 1993-94 fiscal year under the order. Program income for the PAC is expected to decrease from \$701,660 to \$599,356, a \$102,304 decrease from the previous estimate. Major program income reductions come from a \$92,800 decrease in assessment income due to the lower assessment rate and a \$9,504 reduction in income from the Department's Foreign Agricultural Service.

The \$102,720 decrease in expenses results from expense reductions. Major expense reductions include \$60,600 in salaries and wages, \$18,100 in office rent, \$17,300 in auto expenses, and \$9,500 in Japanese advertising and promotion. The projected income over expenses has increased from \$1,080 to \$1,496, a \$416 increase from the current amount. The excess funds will be added to the PAC's operational reserve.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs would be significantly offset by the benefits derived from the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

After consideration of all relevant material presented, including the

information and recommendation submitted by the PAC and other available information, it is hereby found that this rule, as hereinafter set forth, will tend to effectuate the declared policy of the Act.

Pursuant to 5 U.S.C. 553, it is found and determined upon good cause that it is impracticable, unnecessary, and contrary to the public interest to give preliminary notice prior to putting this rule into effect, and that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* because:

(1) This action authorizes a decrease in expenses and reduces the assessment rate established for the 1993-94 fiscal year and should be made effective as soon as possible;

(2) This interim final rule provides a 30-day comment period, and all comments timely received will be considered prior to finalization of this action.

List of Subjects in 7 CFR Part 928

Marketing agreements, Papayas, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 928 is amended as follows:

PART 928—PAPAYAS GROWN IN HAWAII

1. The authority citation for 7 CFR Part 928 is revised to read as follows:

Authority: 7 U.S.C. 601-674.

2. Section 928.233 is revised to read as follows.

Note: This section will not appear in the annual Code of Federal Regulations.

§ 928.233 Expenses and Assessment Rate.

Expenses of \$597,860 by the Papaya Administrative Committee are authorized and an assessment rate of \$0.0069 per pound on assessable papayas is established for the fiscal year ending June 30, 1994. Unexpended funds may be carried over as a reserve.

Dated: October 7, 1993.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.
[FR Doc. 93-25177 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-02-P

7 CFR Part 931

[Docket No. FV93-931-1FIR]

Fresh Bartlett Pears Grown in Oregon and Washington; Expenses and Assessment Rate

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The Department of Agriculture (Department) is adopting without change, the provisions of the interim final rule that authorized expenses and established an assessment rate for the Northwest Fresh Bartlett Pear Marketing Committee (Committee) under M.O. 931 for the 1993-94 fiscal year. Authorization of this budget enables the Committee to incur expenses that are reasonable and necessary to administer the program. Funds to administer the program are derived from assessments on handlers. **EFFECTIVE DATE:** July 1, 1993, through June 30, 1994.

FOR FURTHER INFORMATION CONTACT: Britthany E. Beadle, Marketing Order Administration Branch, Fruit and Vegetable Division, AMS, USDA, P.O. Box 96456, room 2523-S, Washington, DC 20090-6456, telephone: 202-720-5127; or Teresa L. Hutchinson, Northwest Marketing Field Office, Fruit and Vegetable Division, AMS, USDA, Green-Wyatt Federal Building, room 369, 1220 Southwest Third Avenue, Portland, Oregon 97204, telephone: 503-326-2724.

SUPPLEMENTARY INFORMATION: This rule is issued under Marketing Agreement No. 141 and Marketing Order No. 931, both as amended (7 CFR part 931), regulating the handling of fresh Bartlett pears grown in Oregon and Washington. The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601-674), hereinafter referred to as the Act.

This rule has been reviewed by the Department of Agriculture (Department) in accordance with Departmental Regulation 1512-1 and the criteria contained in Executive Order 12291 and has been determined to be a "non-major" rule.

This interim final rule has been reviewed under Executive Order 12778, Civil Justice Reform. Under the marketing order now in effect, Bartlett pears grown in Oregon and Washington are subject to assessments. Funds to administer the Bartlett pear marketing order are derived from such assessments. It is intended that the assessment rate as specified herein will

be applicable to all assessable pears during the 1993-94 fiscal period beginning July 1, 1993, through June 30, 1994. This final rule will not preempt any state or local laws, regulations, or policies, unless they present an irreconcilable conflict with this rule.

The Act provides that administrative proceedings must be exhausted before parties may file suit in court. Under section 8c(15)(A) of the Act, any handler subject to an order may file with the Secretary a petition stating that the order, any provision of the order, 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 handler 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 handler is an inhabitant, or has his or her principal place of business, has jurisdiction in equity to review the Secretary's ruling on the petition, provided a bill in equity is filed not later than 20 days after date of the entry of the ruling.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service (AMS) has considered the economic impact of this rule on small entities.

The purpose of the RFA is to fit regulatory actions to the scale of business subject to such actions in order that small businesses will not be unduly or disproportionately burdened. Marketing orders issued pursuant to the Act, and the rules issued thereunder, are unique in that they are brought about through group action of essentially small entities acting on their own behalf. Thus, both statutes have small entity orientation and compatibility.

There are approximately 65 handlers regulated under the marketing order each year and approximately 1,800 producers of Bartlett pears. Small agricultural producers have been defined by the Small Business Administration (13 CFR 121.601) as those having annual receipts of less than \$500,000, and small agricultural service firms are defined as those whose annual receipts are less than \$3,500,000. The majority of Bartlett pear handlers and producers in Oregon and Washington may be classified as small entities.

The budget of expenses for the 1993-94 fiscal period was prepared by the Northwest Fresh Bartlett Pear Marketing Committee (Committee), the agency responsible for local administration of the marketing order, and submitted to the Department for approval. The

members of the Committee are producers and handlers of Bartlett pears. They are familiar with the Committee's needs and with the costs for goods and services in their local area and are thus in a position to formulate an appropriate budget. The budget was formulated and discussed in a public meeting. Thus, all directly affected persons have had an opportunity to participate and provide input.

The assessment rate recommended by the Committee was derived by dividing anticipated expenses by expected shipments of fresh Bartlett pears grown in Oregon and Washington. Because that rate will be applied to actual shipments, it must be established at a rate that will provide sufficient income to pay the Committee's expenses.

The Committee met on June 3, 1993, and unanimously recommended a 1993-94 budget of \$112,425, which is \$3,965 less than the previous year. Decreases in budgeted expenses include those for Committee meetings and the contingency fund. These decreases will be partially offset by increases in salaries, benefits, unemployment, and payroll taxes.

The Committee also unanimously recommended an assessment rate of \$0.025 per standard box, or equivalent, the same as last season. This rate, when applied to anticipated pear shipments of 2,673,400 standard boxes, will yield \$66,835 in assessment income. Assessment income, combined with \$5,100 from other income, and \$40,490 from the Committee's authorized reserve, will be adequate to cover budgeted expenses. The withdrawal of \$40,490 from the Committee's authorized reserve will result in no reserve remaining at the end of the 1993-94 fiscal year.

While this action will impose some additional costs on handlers, the costs are in the form of uniform assessments on all handlers. Some of the additional costs may be passed on to producers. However, these costs will be offset by the benefits derived by the operation of the marketing order. Therefore, the Administrator of the AMS has determined that this action will not have a significant economic impact on a substantial number of small entities.

An interim final rule was published in the Federal Register (58 FR 40720, July 30, 1993) and provided a 30-day comment period for interested persons. No comments were received.

It is found that the expenses for the marketing order covered in this rule are reasonable and likely to be incurred and that such expenses and assessment rate to cover such expenses will tend to effectuate the declared policy of the Act.

It is further found that good cause exists for not postponing the effective date of this action until 30 days after publication in the *Federal Register* (5 U.S.C. 553) because the Committee need to have sufficient funds to pay its expenses which are incurred on a continuous basis. The 1993-94 fiscal year for the program began on July 1, 1993. The marketing order requires that the rate of assessment for the fiscal year apply to all assessable Bartlett pears handled during the fiscal year. In addition, handlers are aware of this action which was recommended by the Committee at a public meeting and published in the *Federal Register* as an interim final rule. No comments were received concerning the interim final rule that is adopted in this action as a final rule without change.

List of Subjects in 7 CFR Part 931

Marketing agreements, Pears, Reporting and recordkeeping requirements.

For the reasons set forth in the preamble, 7 CFR part 931 is amended as follows:

PART 931—FRESH BARTLETT PEARS GROWN IN OREGON AND WASHINGTON

1. The authority citation for 7 CFR part 931 is revised to read as follows:

Authority: 7 U.S.C. 601-674.

2. The interim final rule adding § 931.228 which was published at 58 FR 40721, is adopted as a final rule without change.

Dated: October 7, 1993.

Robert C. Keeney,

Deputy Director, Fruit and Vegetable Division.

[FR Doc. 93-25176 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-02-P

SMALL BUSINESS ADMINISTRATION

13 CFR Part 101

Administration; Correction

AGENCY: Small Business Administration.

ACTION: Final rule; correction.

SUMMARY: This document corrects errors in the final rule which appeared in the *Federal Register*, on August 23, 1993, at 58 FR 44436, which amended the delegation of authority granting loan approval authority and authority to approve guaranties of section 503 and section 504 debentures issued by certified development companies. However, the final rule listed incorrectly the value of guaranties of

section 503 or 504 debentures issued by certified development companies that certain SBA officials may approve or decline. This document will correct those errors.

FOR FURTHER INFORMATION CONTACT: Charles R. Hertzberg, Assistant Administrator for Financial Assistance, (202) 205-6490.

SUPPLEMENTARY INFORMATION: On August 23, 1993, SBA published a final rule which amended the delegation of authority granting, *inter alia*, loan approval authority and authority to approve guaranties of section 503 and section 504 debentures issued by certified development companies. (58 FR 44436)

SBA is publishing this document to correct errors contained in the final rule. Specifically, the final rule listed incorrectly the value of guaranties of section 503 and section 504 debentures issued by certified development companies that may be approved or denied by the following SBA officials: Branch Manager; Chief, Financing, D/O; and Assistant Branch Manager for Finance & Investment (F&I). The amounts listed in amendment number 3 (58 FR 44437, first column) should read as follows:

PART III—OTHER FINANCIAL AND GUARANTY PROGRAMS

Section A—Section 503/504 Debenture Guaranty Approval Authority (Small Business Investment Act)

1. Section 503/504 Certified Development Company Debenture Guaranty Approval Authority (SBI Act). To approve or decline guaranties of section 503 or section 504 debentures issued by certified development companies not exceeding the following amount (SBA share) for each small business being assisted:

(1) Regional Administrator.....	\$1,000,000
(2) ARA/F&I.....	1,000,000
(3) District Director.....	1,000,000
(4) Deputy District Director.....	1,000,000
(5) ADD/F&I.....	1,000,000
(6) Branch Managers.....	800,000
(7) Chief, Financing.....	800,000
(8) Assistant Branch Managers/F&I.....	800,000
* * * * *	

Dated: October 6, 1993.

Erskine B. Bowles,

Administrator.

[FR Doc. 93-25234 Filed 10-13-93; 8:45 am]

BILLING CODE 8025-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 93-SW-10-AD; Amendment 39-8630; AD 93-14-06]

Airworthiness Directives; Schweizer Aircraft Corp. and Hughes Helicopters, Inc., Model 269A, 269A-1, 269B, 269C, and TH-55A Series Helicopters

AGENCY: Federal Aviation Administration, DOT.

ACTION: Final rule; request for comments.

SUMMARY: This amendment supersedes an existing priority letter airworthiness directive (AD), applicable to Schweizer Aircraft Corporation and Hughes Helicopters, Inc. Model 269A, 269A-1, 269B, 269C, and TH-55A series helicopters equipped with certain main rotor (M/R) drive shafts (drive shafts) that currently requires, for specified conditions, an immediate visual inspection of the M/R drive shaft for cracks, distortion, corrosion, or other surface damage. This amendment requires a one-time inspection of certain groups of drive shafts and replaces the visual inspection requirements with a non-destructive inspection (NDI) requirement. This amendment is prompted by an accident resulting from a structural failure of a drive shaft and reports of tooling marks on the inside surface of certain groups of drive shafts. The actions specified by this AD are intended to prevent failure of the M/R drive shaft, separation of the M/R from the helicopter, and subsequent loss of control of the helicopter.

DATES: Effective October 29, 1993.

The incorporation by reference of certain publications listed in the regulations is approved by the Director of the Federal Register as of October 29, 1993.

Comments for inclusion in the Rules Docket must be received on or before December 13, 1993.

ADDRESSES: Submit comments in triplicate to the Federal Aviation Administration (FAA), Office of the Assistant Chief Counsel, Attention: Rules Docket No. 93-SW-10-AD, 4400 Blue Mound Road, Fort Worth, Texas 76106.

The service information referenced in this AD may be obtained from Schweizer Aircraft Corporation, P.O. Box 147, Elmira, New York 14902. This information may be examined at the FAA, Office of the Assistant Chief Counsel, 4400 Blue Mound Road, bldg. 3B, room 158, Fort Worth, Texas; or at

the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

FOR FURTHER INFORMATION CONTACT: Mr. Raymond J. O'Neill, Aerospace Engineer, New York Aircraft Certification Office, ANE-170, FAA, New England Region, 181 South Franklin Avenue, room 202, Valley Stream, New York 11581, telephone (516) 791-7422, fax (516) 791-9024.

SUPPLEMENTARY INFORMATION: On December 3, 1992, the FAA issued Priority Letter AD 92-25-14, to require, when there are persistent vibrations or an inability to track and balance the main rotor (M/R), immediate inspection of the M/R drive shaft (drive shaft) for cracks, distortion, corrosion, or other surface damage. That action was prompted by an accident resulting from a drive shaft structural failure and resulting in a loss of the helicopter and two fatalities. An investigation revealed that the drive shaft severed just below the M/R thrust bearing. That condition, if not corrected, could result in a structural failure of the drive shaft, separation of the M/R from the helicopter and subsequent loss of control of the helicopter.

Since the issuance of that AD, there have been reports of stress concentrations caused by deep tooling marks on the inside surface of the drive shaft caused during manufacture. On January 27, 1993, Schweizer Aircraft Corporation instituted a special ultrasonic non-destructive inspection (NDI) for M/R drive shafts. To date, Schweizer Aircraft Corporation reports that five defective drive shafts have been found by using this special inspection. These defective drive shafts had serial numbers higher than S1111.

The FAA has reviewed and approved Schweizer Service Bulletin B-255.1, dated February 1, 1993, (SB) that describes procedures for conducting visual and non-destructive inspections.

Since an unsafe condition has been identified that is likely to exist or develop on other helicopters of this same type design, this AD supersedes Priority Letter AD 92-25-14 to require either an ultrasonic or a radiographic inspection of certain M/R drive shafts as prescribed in the AD. The required actions are to be accomplished in accordance with the service bulletin described previously.

Since a situation exists that requires the immediate adoption of this regulation, it is found that notice and opportunity for prior public comment hereon are impracticable, and that good cause exists for making this amendment effective in less than 30 days.

Comments Invited

Although this action is in the form of a final rule that involves requirements affecting flight safety and, thus, was not preceded by notice and an opportunity for public comment, comments are invited on this rule. Interested persons are invited to comment on this 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 under the caption "ADDRESSES." All communications received on or before the closing date for comments will be considered, and this rule may be amended in light of the comments received. Factual information that supports the commenter's ideas and suggestions is extremely helpful in evaluating the effectiveness of the AD action and determining whether additional rulemaking action would be needed.

Comments are specifically invited on the overall regulatory, economic, environmental, and energy aspects of the rule that might suggest a need to modify the 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 that summarizes each FAA-public contact concerned with the substance of this AD will be filed in the Rules Docket.

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 93-SW-10-AD." The postcard will be date stamped and returned to the commenter.

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation and that it is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been determined further that this action

involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, 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 14 CFR part 39 of the Federal Aviation Regulations as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. App. 1354(a), 1421 and 1423; 49 U.S.C. 106(g); and 14 CFR 11.89.

§ 39.13 [AMENDED]

2. Section 39.13 is amended by adding a new airworthiness directive (AD), Amendment 39-8630, to read as follows:

AD 93-14-06 Schweizer Aircraft Corporation and Hughes Helicopters, Inc.: Amendment 39-8630. Docket Number 93-SW-10-AD. Supersedes Priority Letter AD 92-25-14, issued December 3, 1992, Docket Number 92-ASW-48.

Applicability: Model 269A, 269A-1, 269B, 269C, and TH-55A series helicopters, equipped with main rotor (M/R) drive shafts, part number (P/N) 269A5305-3 and -11, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent structural failure of the M/R drive shaft, that could result in separation of the M/R from the helicopter and subsequent loss of control of the helicopter, accomplish the following:

(a) Inspect the M/R drive shaft, P/N 269A5305-3 and 269A5305-11, except those that have a serial number with a prefix of "SZ" or "ZS", for cracks, distortion, corrosion, or other surface damage using either the radiographic inspection procedure or the non-destructive inspection procedure in accordance with Part I of Schweizer Service Bulletin B-255.1, dated February 1, 1993 (SB). Conduct this inspection at the time intervals and under the conditions stated in the following:

(1) Inspect M/R drive shafts with serial numbers (S/N) S0001 through S1111 and any

drive shaft without an "S" prefix on the S/N, having less than 1,100 hours' time-in-service on the effective date of this AD—

- (i) At the next removal of the drive shaft;
 - (ii) Within the next 600 hours' time-in-service;
 - (iii) Prior to attaining 1,200 hours' total time-in-service; or
 - (iv) Within one year after the effective date of this AD, whichever occurs earlier.
- (2) Inspect M/R drive shafts with S/N S0001 through S1111 and any drive shaft without an "S" prefix on the S/N with 1,100 hours' or more time-in-service on the effective date of this AD—

- (i) Within the next 100 hours' time-in-service; or
 - (ii) At the next removal of the drive shaft;
- or
- (iii) Within one year after the effective date of this AD, whichever occurs earlier.

(3) Inspect Model 269C M/R drive shafts with S/N S1112 and higher, regardless of the number of the total hours' time-in-service on the effective date of this AD—

- (i) Within the next 25 hours' time-in-service;
 - (ii) At the next removal of the drive shaft;
- or
- (iii) Within one year after the effective date of this AD, whichever occurs earlier.

(4) Inspect the M/R drive shaft before further flight if main rotor vibrations occur that cannot be corrected with track and balance procedures, or if main rotor track and balance procedures are required more than once in a 25 hour time-in-service interval.

(b) Inspect any replacement M/R drive shaft prior to installation in accordance with the procedures in Part I of the SB.

(c) Replace any unairworthy M/R drive shaft with an airworthy M/R drive shaft before further flight.

(d) An alternative method of compliance or adjustment of the compliance time, which provides an acceptable level of safety, may be used when approved by the Manager, New York Aircraft Certification Office, FAA, 181 South Franklin Avenue, room 202, Valley Stream, New York 11581. Operators shall submit their requests through an FAA Principal Maintenance Inspector, who may concur or comment and then send it to the Manager, New York Aircraft Certification Office.

Note: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the New York Aircraft Certification Office.

(e) Special flight permits may be issued in accordance with FAR 21.197 and 21.199, only for those helicopters that do not exhibit M/R vibrations, or uncorrected out-of-track or out-of-balance condition specified in paragraph (b) of this AD. The special flight permit allows flight of the helicopter to a location where the requirements of this AD can be accomplished.

(f) The inspections shall be done in accordance with Schweizer SB B-255.1, dated February 1, 1993. 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 Schweizer Aircraft

Corporation, P.O. Box 147, Elmira, New York 14902. Copies may be inspected at the FAA, Office of the Assistant Chief Counsel, 4400 Blue Mound Road, bldg. 3B, room 158, Fort Worth, Texas; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

(g) This amendment becomes effective on October 29, 1993.

Issued in Fort Worth, Texas, on July 13, 1993.

James D. Erickson,
Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 93-25200 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-13-P

14 CFR Part 71

[Airspace Docket No. 93-AWP-9]

Establishment of VOR Federal Airway V-597; CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action establishes VOR Federal Airway V-597 between the San Marcus, CA, Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) and the Mission Bay, CA, VORTAC. Pilots are presently issued several airway segments from San Marcus to Mission Bay. The establishment of this airway will provide pilots with one airway segment between the two points, improve traffic flow, and reduce controller workload.

EFFECTIVE DATE: 0901 UTC, January 6, 1994.

FOR FURTHER INFORMATION CONTACT: Norman W. Thomas, Airspace and Obstruction Evaluation Branch (ATP-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9230.

SUPPLEMENTARY INFORMATION:

History

On June 15, 1993, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to establish VOR Federal Airway V-597 between the San Marcus, CA, VORTAC and the Mission Bay, CA, VORTAC (58 FR 33053). Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. No comments objecting to the proposal were received. Except for editorial changes, this amendment is the same as that proposed in the notice. Domestic

VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The airway listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations establishes VOR Federal Airway V-597 between the San Marcus, CA, VORTAC and the Mission Bay, CA VORTAC. Pilots are presently issued several airway segments from San Marcus to Mission Bay. The establishment of this airway will provide pilots with one airway segment between the two points. This action improves traffic flow and reduces controller workload.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore: (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways**V-597 [New]**

From San Marcus, CA; Fillmore, CA; Van Nuys, CA; INT Van Nuys 100° and Seal Beach, CA, 334° radials; Seal Beach; Oceanside, CA; to Mission Bay, CA.

Issued in Washington, DC, on October 7, 1993.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 93-25213 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 92-ANM-10]

Amendment of Class D Airspace; Fort Carson, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Butts Army Airfield, Fort Carson, Colorado, Class D airspace. This action will provide additional controlled airspace for a new instrument approach procedure. The Class D airspace will be depicted on aeronautical charts for pilot reference.

EFFECTIVE DATE: 0901 UTC, January 6, 1994.

FOR FURTHER INFORMATION CONTACT: Ted Melland, ANM-536, Federal Aviation Administration, Docket No. 92-ANM-10, 1601 Lind Avenue SW., Renton, Washington 98055-4056, Telephone: (206) 227-2536.

SUPPLEMENTARY INFORMATION:**History**

Development of a new instrument approach procedure to Butts Army Airfield, Fort Carson, Colorado, requires additional controlled airspace for the new procedure.

On September 2, 1992, the FAA proposed to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Class D airspace for the Butts Army Airfield, Fort Carson, Colorado, (57 FR 40152).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. The Air Transport Association concurred with the proposal. No other comments were received.

Airspace reclassification, in effect since September 16, 1993, discontinued

the use of the terms "control zone" and "control zone extensions" and replaced them with the designation "Class D airspace" for airspace extending upward from ground level. Other than that change in terminology, this amendment is the same as that proposed in the notice. The geographical coordinates are in North American datum 83. Class D airspace designations are published in Paragraph 5000 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298 July 6, 1993). The Class D airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations amends Class D airspace at Fort Carson, CO, to provide additional controlled airspace for a new instrument approach procedure at Butts Army Airfield. The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A,

Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 5000 General**ANM CO D Fort Carson CO [Revised]**

Butts Army Airfield, CO
(Lat. 38°41'07" N, long. 104°45'54" W)
Iron Horse NDB, CO
(Lat. 38°40'42" N, long. 104°45'14" W)
Colorado Springs Municipal Airport, CO
(Lat. 38°48'42" N, long. 104°42'42" W)

That airspace extending upward from the surface to but not including 8,400 feet MSL within a 4.3-mile radius of Butts Army Airfield and within 2.2 miles each side of the 146° bearing from the Iron Horse NDB extending from the 4.3-mile radius to 5 miles southeast of the airfield, excluding the Colorado Springs Airport Class C airspace. This Class D airspace is effective during the specific dates and times established in advance by Notice to Airmen. The effective dates and times will thereafter be continuously published in the Airport/Facility Director.

Issued in Seattle, Washington, on September 17, 1993.

Temple H. Johnson, Jr.,

Manager, Air Traffic Division.

[FR Doc. 93-25209 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 92-ANM-9]

Amendment of Class E Airspace; Akron, CO

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action amends the Akron, Colorado, Class E airspace. This action is necessary to provide additional controlled airspace for a new instrument approach procedure at the Akron-Washington County Airport. The Class E airspace will be depicted on aeronautical charts for pilot reference.

EFFECTIVE DATE: 0901 UTC, January 6, 1994.

FOR FURTHER INFORMATION CONTACT: Ted Melland, ANM-536, Federal Aviation Administration, Docket No. 92-ANM-9, 1601 Lind Avenue SW., Renton, Washington 98055-4056, Telephone: (206) 227-2536.

SUPPLEMENTARY INFORMATION:**History**

Construction of a new runway, and abandonment of the previous runway, required development of a new

instrument approach procedure at the Akron-Washington County Airport. This process requires amendment of controlled airspace for the new approach procedure.

On September 2, 1993, the FAA proposes to amend part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend the Akron, Colorado Transition Area (Class E airspace) (57 FR 40153).

Interested parties were invited to participate in this rulemaking proceeding by submitting written comments on the proposal to the FAA. The Air Transport Association of America concurred with the proposal. No other comments were received.

Airspace reclassification, in effect since September 16, 1993, discontinued the use of the term "transition area" and replaced it with the designation "Class E airspace" for airspace extending upward from 700 feet or more above ground level. Other than that change in terminology, this amendment is the same as that proposed in the notice. The coordinates in the proposal and in this final rule are in North American datum 83. Class E airspace designations for airspace extending upward from 700 feet or more above ground level are published in Paragraph 6005 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class E airspace designation listed in this document will be published subsequently in the Order.

The Rule

This amendment to part 71 of the Federal Aviation Regulations amends Class E airspace at Akron, Colorado, to provide additional controlled airspace for a new instrument approach procedure.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6005 Class E Airspace Extending Upward From 700 Feet or More Above the Surface of the Earth

* * * * *

ANM CO E5 Akron, CO [Revised]

Akron, Akron-Washington County Airport, CO

(Lat. 40° 10'32" N, long. 103°13'20" W)

Akron VORTAC

(Lat. 40°09'20" N, long. 103°10'47" W)

That airspace extending upward from 700 feet above the surface within a 6.1-mile radius of the Akron-Washington County Airport, and that airspace extending upward from 1,200 feet above the surface within an area bounded by a point beginning at lat. 40°06'35" N, long. 102°37'19" W; to lat. 39°42'28" N, long. 102°58'15" W; to lat. 40°00'15" N, long. 103°33'32" W; to lat. 40°24'30" N, long. 103°13'52" N; thence to point of beginning.

* * * * *

Issued in Seattle, Washington, on September 17, 1993.

Temple H. Johnson, Jr.,
Manager, Air Traffic Division.

[FR Doc. 93-25210 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF COMMERCE

Bureau of Economic Analysis

15 CFR Part 806

[Docket No. 930507-3237]

RIN 0691-AA20

Direct Investment Surveys; Raising the Exemption Level of the BE-15(LF) Long Form of the Annual Survey of Foreign Direct Investment in the United States

AGENCY: Bureau of Economic Analysis, Commerce.

ACTION: Final rule.

SUMMARY: This final rule amends the regulations on direct investment surveys by raising the exemption level for filing the long form of the BE-15, Annual Survey of Foreign Direct Investment in the United States. Under the new rule, the exemption level for filing the long form—Form BE-15(LF)—is raised from \$20 million to \$50 million. Thus, foreign-owned U.S. firms with assets, sales, and net income between \$20 million and \$50 million that previously had to file the long form will now file the more abbreviated short form (Form BE-15(SF)). The survey's overall exemption level below which no reporting is required will remain at \$10 million.

EFFECTIVE DATE: This rule will be effective November 15, 1993.

FOR FURTHER INFORMATION CONTACT: Betty L. Barker, Chief, International Investment Division (BE-50), Bureau of Economic Analysis, U.S. Department of Commerce, Washington, DC 20230; phone (202) 606-9800.

SUPPLEMENTARY INFORMATION: In the July 16, 1993 Federal Register, Volume 58, No. 135, 58 FR 38324, the Bureau of Economic Analysis (BEA) published a notice of proposed rulemaking that would raise the exemption level for filing the long form of the BE-15, Annual Survey of Foreign Direct Investment in the United States, from \$20 million to \$50 million. No comments on the proposed rule were received. Thus, this final rule is the same as the proposed rule.

The final rule will bring reporting by nonbank U.S. affiliates in the BE-15 annual survey into closer conformity with their reporting in the 1992 BE-12, Benchmark Survey of Foreign Direct Investment in the United States. The BE-12 is BEA's quinquennial census of foreign direct investment in the United States; it is intended to cover the universe of U.S. affiliates in value terms. (A U.S. affiliate is a U.S. business

enterprise in which a foreign person owns or controls, directly or indirectly, 10 percent or more of the voting securities if an incorporated business enterprise or an equivalent interest if an unincorporated business enterprise.)

The BE-15 annual survey is part of BEA's regular data collection program for foreign direct investment in the United States. Like the benchmark survey, it is mandatory and is conducted under the International Investment and Trade in Services Survey Act (22 U.S.C. 3101-3108, as amended). It obtains annual data on the financial structure and overall operations of nonbank U.S. affiliates of foreign companies. The data are needed to measure, monitor changes in, assess the impact of, and make informed policy decisions on foreign direct investment in the United States.

The annual survey is a sample survey covering only larger nonbank U.S. affiliates—those with assets, sales, or net income that exceed \$10 million. The sample data reported in this survey will be linked to data from the BE-12 benchmark survey in order to derive annual universe estimates of financial and operating data for nonbank U.S. affiliates in nonbenchmark years.

Under this final rule, the \$10 million overall exemption level for the annual survey will not change. However, the exemption level for filing on the long form will be raised from \$20 million to \$50 million—the level used in the BE-12 benchmark survey for determining whether a U.S. affiliate must file a long form (BE-12(LF)) or a short form (BE-12(SF)). As a result, approximately 1,600 reporters will file on the short form rather than on the long form, significantly reducing their burden and the processing burden on BEA.

The new rule will be effective with the BE-15 annual survey covering a U.S. affiliate's 1993 fiscal year. The 1993 forms will be mailed out in March 1994 and will be due May 31, 1994. The last BE-15 survey conducted covered the year 1991. (It should be noted that a BE-15 annual survey is not conducted for a year, such as 1992, that is covered by a BE-12 benchmark survey.)

Paperwork Reduction Act

The collection of information required in this final rule has been approved by OMB (OMB No. 0608-0034).

Public reporting burden for this collection of information is estimated to vary from 1 to 4 hours per short-form response and from 4 to 550 hours per long-form response, with an overall average of 17 hours for both the short and long forms. This includes time for reviewing instructions, searching

existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information. Comments regarding the burden estimate or any other aspect of this collection of information, including suggestions for reducing burden, may be sent to the Director, Bureau of Economic Analysis (BE-1), U.S. Department of Commerce, Washington, DC 20230; and to the Office of Management and Budget, Paperwork Reduction Project 0608-0034, Washington, DC 20503.

Executive Order 12612

This final rule does not contain policies with Federalism implications sufficient to warrant preparation of a Federalism assessment under E.O. 12612.

Regulatory Flexibility Act

The General Counsel, Department of Commerce, has certified to the Chief Counsel for Advocacy, Small Business Administration, under provisions of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that this final rulemaking will not have a significant economic impact on a substantial number of small entities. Most small businesses are not foreign owned and many that are will not be required to report in the survey because their assets, sales, and net income are each equal to or less than the \$10 million exemption level below which reporting is not required. Furthermore, by raising the exemption level for reporting on the long form, this rulemaking will ease the burden on firms between \$20 million and \$50 million that previously reported on the long form but will now report on the more abbreviated short form. Therefore, a regulatory flexibility analysis was not prepared.

List of Subjects in 15 CFR Part 806

Foreign investment in the United States, Statistical data, Reporting and recordkeeping requirements.

Dated: September 8, 1993.

Carol S. Carson,

Director, Bureau of Economic Analysis.

For the reasons set forth in the preamble, BEA amends 15 CFR part 806 as follows:

PART 806—DIRECT INVESTMENT SURVEYS

1. The authority citation for 15 CFR part 806 continues to read as follows:

Authority: 5 U.S.C. 301, 22 U.S.C. 3101-3108, and E.O. 11961, as amended.

§ 806.15 [Amended]

2. Section 806.15(i) is amended by removing "exceeds \$20,000,000

(positive or negative); a short form, Form BE-15(SF), must be filed by each nonbank U.S. affiliate for which at least one of the three items exceeds \$10,000,000 but no one item exceeds \$20,000,000 (positive or negative)." and adding in its place "exceeds \$50,000,000 (positive or negative); a short form, Form BE-15(SF), must be filed by each nonbank U.S. affiliate for which at least one of the three items exceeds \$10,000,000 but no one item exceeds \$50,000,000 (positive or negative)."

[FR Doc. 93-25124 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-EA-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[T.D. 8491]

RIN 1545-AN15

Regulations Under Section 446 of the Internal Revenue Code of 1986; Application of Section 446 With Respect to Notional Principal Contracts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.

SUMMARY: This document contains final Income Tax Regulations relating to the timing of income and deductions with respect to notional principal contracts. The regulations provide taxpayers and IRS personnel with guidance necessary to account for notional principal contracts. The regulations also define actively traded personal property under section 1092(d).

EFFECTIVE DATES: These regulations are effective October 14, 1993.

For applicability of these regulations, see **EFFECTIVE DATES** under the **SUPPLEMENTARY INFORMATION** portion of the preamble.

FOR FURTHER INFORMATION CONTACT: Alan B. Munro, (202) 622-3950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On July 10, 1991, the IRS published in the Federal Register a notice of proposed rulemaking at 56 FR 31350 (FI-16-89, 1991-2 C.B. 951) under sections 446(b) (relating to general rules for methods of accounting) and 1092(d) (relating to definitions and special rules with respect to straddles) of the Internal Revenue Code of 1986 (Code). The proposed regulations defined a

"notional principal contract" and prescribed rules for the timing of income and deductions from these contracts. The proposed regulations also provided an election by which dealers and traders in notional principal contracts and other derivative financial instruments could mark their derivative instruments to market. Finally, the proposed regulations defined "actively traded personal property" and prescribed the extent to which notional principal contracts are treated as actively traded for purposes of section 1092.

The IRS received a number of written comments on the proposed regulations and held a public hearing on the regulations on October 7, 1991. After consideration of all the comments, the regulations proposed by FI-16-89 are adopted as revised by this Treasury decision. The revisions are discussed below.

Explanation of Provisions

Definitions and Scope

Most commenters felt that the definitions of "notional principal contract," "specified index," and "notional principal amount" provided in the proposed regulations adequately covered most notional principal contracts. Several commenters, however, requested that the definitions be expanded to include specified indices based on property that is not publicly traded and notional principal amounts that amortize or otherwise vary over the term of the contract. To accommodate these requests, the final regulations provide that a specified index may be almost any fixed rate or variable rate, price, or amount based on current, objectively determinable financial or economic information. In light of the broad definition of specified index, the IRS is considering whether notional principal contracts involving certain specified indices (e.g., one issuer's stock) should be excluded from the general sourcing rules of sections 861 through 865 and whether contracts involving other specified indices (e.g., United States real property) are subject to section 897.

The final regulations also allow the notional principal amount to vary and clarify that the regulations apply to currency swaps, except to the extent that section 988 and the regulations thereunder provide different rules for those contracts. The final regulations further provide that notional principal contracts that may be extended or terminated at the option of a party to the contract are contracts covered by this regulation.

Periodic Payments

The provisions in the final regulations for the taxable year of inclusion and deduction of periodic payments generally follow the proposed regulations. In lieu of the proposed rule on short first or last intervals, the definition of a periodic payment is revised to refer to all payments that are made at intervals of one year or less during the entire term of the contract.

To provide further flexibility, payments based on a notional principal amount that varies may be periodic payments if the obligations of the other party are measured by a notional principal amount that varies in the same proportion. For example, if a swap calls for one party to make payments based on a dollar notional amount and the counterparty to make payments based on a fixed number of ounces of gold, the swap may also provide that both notional amounts decline by the same predetermined percentage each year during the term of the swap.

Nonperiodic Payments

The final regulations retain the general rules for amortizing nonperiodic payments for swaps, caps, and floors in accordance with the prices of a series of cash-settled forward contracts (in the case of a swap) or option contracts (in the case of a cap or floor) in order to reflect the economic substance of the contract. Several commenters asked whether these rules mean that periodic payments are treated as if underlying forward or option contracts are being settled or are expiring. For tax purposes, the regulations treat a notional principal contract as a single instrument. Although a series of hypothetical forward or option contracts may be used to determine how to amortize a nonperiodic payment with respect to the contract, nothing in the regulations supports characterizing either periodic or nonperiodic payments as attributable to the settlement, exercise, cancellation, lapse, expiration, or other termination of forward or option contracts.

Several commenters complained that the rules for amortizing nonperiodic payments in the proposed regulations were too complex. The final regulations address these concerns by expanding the availability of simplified alternative methods. The proposed regulations, for example, limited the "level payment constant yield to maturity" amortization method to a nonperiodic payment made with respect to an interest rate swap. Under the final regulations, a nonperiodic payment made or received with respect to any swap contract may be amortized using the level payment

method, and taxpayers may use more than one discount rate (such as the zero coupon bond curve) in determining the level payments.

The preamble to the proposed regulations included a sample revenue procedure that would have provided a table for amortizing cap and floor premiums. The commenters felt that the amortization table was inflexible and therefore of limited utility. Under the final regulations, the payment for a cap or a floor that hedges debt instrument's held or issued by the taxpayer may instead be amortized using the same level payment method permitted for swaps. For example, a cap or floor premium paid at the inception of the contract is amortized as a series of payments made over the term of the contract, and is therefore recognized in increasing amounts that reflect amortization of principal on a deemed level payment self-amortizing loan. For timing purposes, the level payment method has the effect of treating the cap or floor premium as a discount or premium on the debt instrument (or instruments) being hedged. The IRS continues to consider the possibility of integration or hedge accounting rules for notional principal contracts and other derivative financial instruments.

The final regulations also include an example that clarifies the application of the alternative amortization methods to nonperiodic payments that are paid other than at the inception of the contract. The final regulations provide that, solely for timing purposes, these nonperiodic payments are treated as an upfront payment and a loan from the payee to the payor. See *Example 6* in § 1.446-3(f)(4). The IRS considered a number of alternative amortization methods that produce similar results. The IRS selected this method because it was included in the proposed regulation and can be extended to caps, floors, and swaps regardless of when the nonperiodic payments are made. The final regulations do not include any examples of how to treat nonperiodic payments that are not fixed in amount at the inception of the contract. The IRS expects to address contingent payments in future regulations, and welcomes comments on the treatment of those payments.

Special Rules

The special rules in the proposed regulations have been slightly modified in the final regulations. In particular, the proposed regulations did not allow a taxpayer to use the optional methods for amortizing nonperiodic payments if a notional principal contract was hedged with other financial

instruments. The final regulations clarify that this rule does not apply to a notional principal contract that hedges debt. Although many commenters requested that the IRS define more explicitly what constitutes a "significant" nonperiodic swap payment, the final regulations retain the test set out in the proposed regulations. The IRS is working on a project dealing more generally with off-market and prepaid financial instruments, however, and may amend these regulations to accord with the decisions reached in that project. Because the IRS anticipates that the regulations governing off-market and prepaid financial instruments will address in-the-money caps, floors, forwards, and options in a comprehensive fashion, the rules on significantly in-the-money caps and floors found in § 1.446-3(e)(4)(iv) of the proposed regulations remain in proposed form. The IRS welcomes comments and suggestions from taxpayers on when a swap, cap, or floor should be treated as including a loan under the rules being developed.

Termination Payments

Many commenters objected to the rule in the proposed regulations that a termination payment is recognized by all of the parties to the contract. Of particular concern was the effect of this rule where one party to a swap assigns its rights and obligations and the counterparty is deemed to have made or received a termination payment. This rule has been revised to reflect that whether an assignment by one party results in a deemed exchange of contracts by the counterparty (and, therefore, realization of gain or loss by the counterparty) is determined under section 1001 of the Code and the regulations thereunder. A recent notice of proposed rulemaking (FI-31-92, published at 57 FR 57034) deals with similar issues raised by the modification of debt instruments. The final regulations make it clear that any gain or loss realized on an actual or deemed exchange of a notional principal contract is a termination payment. The final regulations also clarify that certain payments made or received to assign only the rights or the obligations under a notional principal contract are not termination payments. These payments are either loans or nonperiodic payments.

Definition of Actively Traded Personal Property

Finally, the IRS received a variety of comments that questioned the decision to treat notional principal contracts as actively traded personal property for

purposes of section 1092. The IRS believes that the term "actively traded" under section 1092 was intended to cover financial instruments that are liquid or easily offset, even when those instruments are not traded on an exchange or in a recognized secondary market.

The final regulations generally adopt the rule in the proposed regulations. In response to several comments, however, the final regulations specify that a notional principal contract is treated as actively traded only when contracts with the same (or substantially similar) indices are purchased, sold, or entered into on established financial markets, and clarifies the interaction of that rule with section 1234A. See § 1.1092(d)-1(c)(2), which states that the rights and obligations of a party to a notional principal contract are rights and obligations with respect to personal property. Taxpayers should note that a straddle under section 1092 may also be treated as a conversion transaction under new section 1258.

The final regulations also reflect comments received on the definition of publicly traded property in the proposed regulations and in proposed regulations under sections 1271 through 1275 of the Code. The IRS will consider requests for administrative relief in instances where the proposed regulations have been changed and a taxpayer detrimentally relied on the proposed regulations.

Regulations Not Made Final

As described above, the special rules for significantly in-the-money caps and floors found in § 1.446-3(e)(4)(iv) of the proposed regulations remain in proposed form. In addition, in view of the enactment of section 475 of the Code, which requires dealers to mark certain securities to market, § 1.446-4 of the proposed regulations is being withdrawn by separate notice.

Effective Dates

Except for § 1.1092(d)-1, these regulations are effective for notional principal contracts entered into on or after December 13, 1993. For contracts entered into before that date, the Commissioner generally will treat a method of accounting as clearly reflecting income if it takes payments into account over the life of the contract under a reasonable amortization method, whether or not the method satisfies the rules in the proposed or final regulations. See Notice 89-21, 1989-1 C.B. 651, 652. The IRS intends to issue a revenue procedure prescribing the terms and conditions for effecting method changes to comply with the

final regulations. The revenue procedure will generally permit expedited method changes on a Form 3115 attached to the tax return for the year of change. Section 1.1092(d)-1(b)(1)(vii) is effective for positions entered into on or after October 14, 1993, and § 1.1092(d)-1(c) is effective for positions entered into on or after July 8, 1991.

Special Analyses

It has been determined that these rules are not major rules as defined in Executive Order 12291. Therefore, a Regulatory Impact Analysis is not required. It has also been determined that section 553(b) of the Administrative Procedure Act (5 U.S.C. chapter 5) and the Regulatory Flexibility Act (5 U.S.C. chapter 6) do not apply to these regulations, and, therefore, a Regulatory Flexibility Analysis is not required. Pursuant to section 7805(f) of the Internal Revenue Code, the notice of proposed rulemaking was submitted to the Chief Counsel for Advocacy of the Small Business Administration for comment on its impact on small business.

Drafting Information

The principal authors of these regulations are Karl T. Walli of the Office of Associate Chief Counsel (International) and Alan B. Munro of the Office of Assistant Chief Counsel (Financial Institutions and Products), within the Office of Chief Counsel, IRS. However, other personnel from the IRS and the Treasury Department participated in their development.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

Adoption of Amendments to the Regulations

Accordingly, 26 CFR part 1 is amended as follows:

PART 1—INCOME TAXES

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

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

Par. 2. Section 1.61-14(b) is amended by adding paragraph (b)(7) to read as follows:

§ 1.61-14 Miscellaneous items of gross income.

* * * * *

(b) * * *

(7) Notional principal contracts, see § 1.446-3.

Par. 3. Section 1.162-1 is amended by adding paragraph (b)(8) to read as follows:

§ 1.162-1 Business expenses.

(b) * * *

(8) For the timing of deductions with respect to notional principal contracts, see § 1.446-3.

Par. 4. Section 1.446-3 is added to read as follows:

§ 1.446-3 Notional principal contracts.

(a) *Table of contents.* This paragraph (a) lists captioned paragraphs contained in § 1.446-3.

§ 1.446-3 Notional principal contracts.

(a) Table of contents.

(b) Purpose.

(c) Definitions and scope.

(1) Notional principal contract.

(i) In general.

(ii) Excluded contracts.

(iii) Transactions within section 475.

(iv) Transactions within section 988.

(2) Specified index.

(3) Notional principal amount.

(4) Special definitions.

(i) Related person and party to the contract.

(ii) Objective financial information.

(iii) Dealer in notional principal contracts.

(d) Taxable year of inclusion and deduction.

(e) Periodic payments.

(1) Definition.

(2) Recognition rules.

(i) In general.

(ii) Rate set in arrears.

(iii) Notional principal amount set in arrears.

(3) Examples.

(f) Nonperiodic payments.

(1) Definition.

(2) Recognition rules.

(i) In general.

(ii) General rule for swaps.

(iii) Alternative methods for swaps.

(A) Prepaid swaps.

(B) Other nonperiodic swap payments.

(iv) General rule for caps and floors.

(v) Alternative methods for caps and floors that hedge debt instruments.

(A) Prepaid caps and floors.

(B) Other caps and floors.

(C) Special method for collars.

(vi) Additional methods.

(3) Term of extendible or terminable contracts.

(4) Examples.

(g) Special rules.

(1) Disguised notional principal contracts.

(2) Hedged notional principal contracts.

(3) Options and forwards to enter into notional principal contracts.

(4) Swaps with significant nonperiodic payments.

(5) Caps and floors that are significantly in-the-money. [Reserved]

(6) Examples.

(h) Termination payments.

(1) Definition.

(2) Taxable year of inclusion and deduction by original parties.

(3) Taxable year of inclusion and deduction by assignees.

(4) Special rules.

(i) Assignment of one leg of a contract.

(ii) Substance over form.

(5) Examples.

(i) Anti-abuse rule.

(j) Effective date.

(b) *Purpose.* The purpose of this section is to enable the clear reflection of the income and deductions from notional principal contracts by prescribing accounting methods that reflect the economic substance of such contracts.

(c) *Definitions and scope—(1)*

Notional principal contract—(i) In

general. A notional principal contract is a financial instrument that provides for the payment of amounts by one party to another at specified intervals calculated by reference to a specified index upon a notional principal amount in exchange for specified consideration or a promise to pay similar amounts. An agreement between a taxpayer and a qualified business unit (as defined in section 989(a)) of the taxpayer, or among qualified business units of the same taxpayer, is not a notional principal contract because a taxpayer cannot enter into a contract with itself. Notional principal contracts governed by this section include interest rate swaps, currency swaps, basis swaps, interest rate caps, interest rate floors, commodity swaps, equity swaps, equity index swaps, and similar agreements. A collar is not itself a notional principal contract, but certain caps and floors that comprise a collar may be treated as a single notional principal contract under paragraph (f)(2)(v)(C) of this section. A contract may be a notional principal contract governed by this section even though the term of the contract is subject to termination or extension. Each confirmation under a master agreement to enter into agreements governed by this section is treated as a separate notional principal contract.

(ii) *Excluded contracts.* A contract described in section 1256(b), a futures contract, a forward contract, and an option are not notional principal contracts. An instrument or contract that constitutes indebtedness under general principles of Federal income tax law is not a notional principal contract. An option or forward contract that entitles or obligates a person to enter into a notional principal contract is not a notional principal contract, but payments made under such an option or forward contract may be governed by paragraph (g)(3) of this section.

(iii) *Transactions within section 475.*

To the extent that the rules provided in paragraphs (e) and (f) of this section are inconsistent with the rules that apply to any notional principal contract that is

governed by section 475 and regulations thereunder, the rules of section 475 and the regulations thereunder govern.

(iv) *Transactions within section 988.* To the extent that the rules provided in this section are inconsistent with the rules that apply to any notional principal contract that is also a section 988 transaction or that is integrated with other property or debt pursuant to section 988(d), the rules of section 988 and the regulations thereunder govern.

(2) *Specified index.* A specified index is—

(i) A fixed rate, price, or amount;

(ii) A fixed rate, price, or amount applicable in one or more specified periods followed by one or more different fixed rates, prices, or amounts applicable in other periods;

(iii) An index that is based on objective financial information (as defined in paragraph (c)(4)(ii) of this section); and

(iv) An interest rate index that is regularly used in normal lending transactions between a party to the contract and unrelated persons.

(3) *Notional principal amount.* For purposes of this section, a notional principal amount is any specified amount of money or property that, when multiplied by a specified index, measures a party's rights and obligations under the contract, but is not borrowed or loaned between the parties as part of the contract. The notional principal amount may vary over the term of the contract, provided that it is set in advance or varies based on objective financial information (as defined in paragraph (c)(4)(ii) of this section).

(4) *Special definitions—(i) Related person and party to the contract.* A related person is a person related (within the meaning of section 267(b) or 707(b)(1)) to one of the parties to the notional principal contract or a member of the same consolidated group (as defined in § 1.1502-1(h)) as one of the parties to the contract. For purposes of this paragraph (c), a related person is considered to be a party to the contract.

(ii) *Objective financial information.* For purposes of this paragraph (c), objective financial information is any current, objectively determinable financial or economic information that is not within the control of any of the parties to the contract and is not unique to one of the parties' circumstances (such as one party's dividends, profits, or the value of its stock). Thus, for example, a notional principal amount may be based on a broadly-based equity index or the outstanding balance of a pool of mortgages, but not on the value of a party's stock.

(iii) *Dealer in notional principal contracts.* A dealer in notional principal contracts is a person who regularly offers to enter into, assume, offset, assign, or otherwise terminate positions in notional principal contracts with customers in the ordinary course of a trade or business.

(d) *Taxable year of inclusion and deduction.* For all purposes of the Code, the net income or net deduction from a notional principal contract for a taxable year is included in or deducted from gross income for that taxable year. The net income or net deduction from a notional principal contract for a taxable year equals the total of all of the periodic payments that are recognized from that contract for the taxable year under paragraph (e) of this section and all of the nonperiodic payments that are recognized from that contract for the taxable year under paragraph (f) of this section.

(e) *Periodic payments—(1) Definition.* Periodic payments are payments made or received pursuant to a notional principal contract that are payable at intervals of one year or less during the entire term of the contract (including any extension periods provided for in the contract), that are based on a specified index described in paragraph (c)(2)(i), (iii), or (iv) of this section (appropriately adjusted for the length of the interval), and that are based on either a single notional principal amount or a notional principal amount that varies over the term of the contract in the same proportion as the notional principal amount that measures the other party's payments. Payments to purchase or sell a cap or a floor, however, are not periodic payments.

(2) *Recognition rules—(i) In general.* All taxpayers, regardless of their method of accounting, must recognize the ratable daily portion of a periodic payment for the taxable year to which that portion relates.

(ii) *Rate set in arrears.* If the amount of a periodic payment is not determinable at the end of a taxable year because the value of the specified index is not fixed until a date that occurs after the end of the taxable year, the ratable daily portion of a periodic payment that relates to that taxable year is generally based on the specified index that would have applied if the specified index were fixed as of the last day of the taxable year. If a taxpayer determines that the value of the specified index as of the last day of the taxable year does not provide a reasonable estimate of the specified index that will apply when the payment is fixed, the taxpayer may use a reasonable estimate of the specified index each year, provided that the

taxpayer (and any related person that is a party to the contract) uses the same method to make the estimate consistently from year to year and uses the same estimate for purposes of all financial reports to equity holders and creditors. The taxpayer's treatment of notional principal contracts with substantially similar specified indices will be considered in determining whether the taxpayer's estimate of the specified index is reasonable. Any difference between the amount that is recognized under this paragraph (e)(2)(ii) and the corresponding portion of the actual payment that becomes fixed under the contract is taken into account as an adjustment to the net income or net deduction from the notional principal contract for the taxable year during which the payment becomes fixed.

(iii) *Notional principal amount set in arrears.* Rules similar to the rules of paragraph (e)(2)(ii) of this section apply if the amount of a periodic payment is not determinable at the end of a taxable year because the notional principal amount is not fixed until a date that occurs after the end of the taxable year.

(3) *Examples.* The following examples illustrate the application of paragraph (e) of this section.

Example 1. Accrual of periodic swap payments. (a) On April 1, 1995, A enters into a contract with unrelated counterparty B under which, for a term of five years, A is obligated to make a payment to B each April 1, beginning April 1, 1996, in an amount equal to the London Interbank Offered Rate (LIBOR), as determined on the immediately preceding April 1, multiplied by a notional principal amount of \$100 million. Under the contract, B is obligated to make a payment to A each April 1, beginning April 1, 1996, in an amount equal to 8% multiplied by the same notional principal amount. A and B are calendar year taxpayers that use the accrual method of accounting. On April 1, 1995, LIBOR is 7.80%.

(b) This contract is a notional principal contract as defined by paragraph (c)(1) of this section, and both LIBOR and a fixed interest rate of 8% are specified indices under paragraph (c)(2) of this section. All of the payments to be made by A and B are periodic payments under paragraph (e)(1) of this section because each party's payments are based on a specified index described in paragraphs (c)(2)(iii) and (c)(2)(i) of this section, respectively, are payable at periodic intervals of one year or less throughout the term of the contract, and are based on a single notional principal amount.

(c) Under the terms of the swap agreement, on April 1, 1996, B is obligated to make a payment to A of \$8,000,000 ($8\% \times \$100,000,000$) and A is obligated to make a payment to B of \$7,800,000 ($7.80\% \times \$100,000,000$). Under paragraph (e)(2)(i) of this section, the ratable daily portions for 1995 are the amounts of these periodic

payments that are attributable to A's and B's taxable year ending December 31, 1995. The ratable daily portion of the 8% fixed leg is \$6,010,929 ($275 \text{ days}/366 \text{ days} \times \$8,000,000$), and the ratable daily portion of the floating leg is \$5,860,656 ($275 \text{ days}/366 \text{ days} \times \$7,800,000$). The net amount for the taxable year is the difference between the ratable daily portions of the two periodic payments, or \$150,273 ($\$6,010,929 - \$5,860,656$). Accordingly, A has net income of \$150,273 from this swap for 1995, and B has a corresponding net deduction of \$150,273.

(d) The \$49,727 unrecognized balance of the \$200,000 net periodic payment that is made on April 1, 1996, is included in A's and B's net income or net deduction from the contract for 1996.

(e) If the parties had entered into the contract on February 1, 1995, the result would not change because no portion of either party's obligation to make a payment under the swap relates to the period prior to April 1, 1995. Consequently, under paragraph (e)(2) of this section, neither party would accrue any income or deduction from the swap for the period from February 1, 1995, through March 31, 1995.

Example 2. Accrual of periodic swap payments by cash method taxpayer. (a) On April 1, 1995, C enters into a contract with unrelated counterparty D under which, for a period of five years, C is obligated to make a fixed payment to D each April 1, beginning April 1, 1996, in an amount equal to 8% multiplied by a notional principal amount of \$100 million. D is obligated to make semi-annual payments to C each April 1 and October 1, beginning October 1, 1995, in an amount equal to one-half of the LIBOR amount as of the first day of the preceding 6-month period multiplied by the notional principal amount. The payments are to be calculated using a 30/360 day convention. C is a calendar year taxpayer that uses the accrual method of accounting. D is a calendar year taxpayer that uses the cash receipts and disbursements method of accounting. LIBOR is 7.80% on April 1, 1995, and 7.46% on October 1, 1995.

(b) This contract is a notional principal contract as defined by paragraph (c)(1) of this section, and LIBOR and the fixed interest rate of 8% are each specified indices under paragraph (c)(2) of this section. All of the payments to be made by C and D are periodic payments under paragraph (e)(1) of this section because they are each based on appropriate specified indices, are payable at periodic intervals of one year or less throughout the term of the contract, and are based on a single notional principal amount.

(c) Under the terms of the swap agreement, D pays C \$3,900,000 ($0.5 \times 7.8\% \times \$100,000,000$) on October 1, 1995. In addition, D is obligated to pay C \$3,730,000 ($0.5 \times 7.46\% \times \$100,000,000$) on April 1, 1996. C is obligated to pay D \$8,000,000 on April 1, 1996. Under paragraph (e)(2)(i) of this section, C's and D's ratable daily portions for 1995 are the amounts of the periodic payments that are attributable to their taxable year ending December 31, 1995. The ratable daily portion of the 8% fixed leg is \$6,000,000 ($270 \text{ days}/360 \text{ days} \times \$8,000,000$), and the ratable daily portion of

the floating leg is \$5,765,000 (\$3,900,000 + (90 days/180 days x \$3,730,000)). Thus, C's net deduction from the contract for 1995 is \$235,000 (\$6,000,000—\$5,765,000) and D reports \$235,000 of net income from the contract for 1995.

(d) The net unrecognized balance of \$135,000 (\$2,000,000 balance of the fixed leg—\$1,865,000 balance of the floating leg) is included in C's and D's net income or net deduction from the contract for 1996.

Example 3. Accrual of swap payments on index set in arrears. (a) The facts are the same as in Example 1, except that A's obligation to make payments based upon LIBOR is determined by reference to LIBOR on the day each payment is due. LIBOR is 8.25% on December 31, 1995, and 8.16% on April 1, 1996.

(b) On December 31, 1995, the amount that A is obligated to pay B is not known because it will not become fixed until April 1, 1996. Under paragraph (e)(2)(ii) of this section, the ratable daily portion of the periodic payment from A to B for 1995 is based on the value of LIBOR on December 31, 1995 (unless A or B determines that the value of LIBOR on that day does not reasonably estimate the value of the specified index). Thus, the ratable daily portion of the floating leg is \$6,198,770 (275 days/366 days x 8.25% x \$100,000,000), while the ratable daily portion of the fixed leg is \$6,010,929 (275 days/366 days x \$8,000,000). The net amount for 1995 on this swap is \$187,841 (\$6,198,770—\$6,010,929). Accordingly, B has \$187,841 of net income from the swap in 1995, and A has a net deduction of \$187,841.

(c) On April 1, 1996, A makes a net payment to B of \$160,000 (\$8,160,000 payment on the floating leg—\$8,000,000 payment on the fixed leg). For purposes of determining their net income or net deduction from this contract for the year ended December 31, 1996, B and A must adjust the net income and net deduction they recognized in 1995 by \$67,623 (275 days/366 days x (\$8,250,000 presumed payment on the floating leg—\$8,160,000 actual payment on the floating leg)).

(f) **Nonperiodic payments—(1) Definition.** A nonperiodic payment is any payment made or received with respect to a notional principal contract that is not a periodic payment (as defined in paragraph (e)(1) of this section) or a termination payment (as defined in paragraph (h) of this section). Examples of nonperiodic payments are the premium for a cap or floor agreement (even if it is paid in installments), the payment for an off-market swap agreement, the prepayment of part or all of one leg of a swap, and the premium for an option to enter into a swap if and when the option is exercised.

(2) **Recognition rules—(i) In general.** All taxpayers, regardless of their method of accounting, must recognize the ratable daily portion of a nonperiodic payment for the taxable year to which that portion relates. Generally, a

nonperiodic payment must be recognized over the term of a notional principal contract in a manner that reflects the economic substance of the contract.

(ii) **General rule for swaps.** A nonperiodic payment that relates to a swap must be recognized over the term of the contract by allocating it in accordance with the forward rates (or, in the case of a commodity, the forward prices) of a series of cash-settled forward contracts that reflect the specified index and the notional principal amount. For purposes of this allocation, the forward rates or prices used to determine the amount of the nonperiodic payment will be respected, if reasonable. See paragraph (f)(4) Example 7 of this section.

(iii) **Alternative methods for swaps.** Solely for purposes of determining the timing of income and deductions, a nonperiodic payment made or received with respect to a swap may be allocated to each period of the swap contract using one of the methods described in this paragraph (f)(2)(iii). The alternative methods may not be used by a dealer in notional principal contracts (as defined in paragraph (c)(4)(iii) of this section) for swaps entered into or acquired in its capacity as a dealer.

(A) **Prepaid swaps.** An upfront payment on a swap may be amortized by assuming that the nonperiodic payment represents the present value of a series of equal payments made throughout the term of the swap contract (the level payment method), adjusted as appropriate to take account of increases or decreases in the notional principal amount. The discount rate used in this calculation must be the rate (or rates) used by the parties to determine the amount of the nonperiodic payment. If that rate is not readily ascertainable, the discount rate used must be a rate that is reasonable under the circumstances. Under this method, an upfront payment is allocated by dividing each equal payment into its principal recovery and time value components. The principal recovery components of the equal payments are treated as periodic payments that are deemed to be made on each of the dates that the swap contract provides for periodic payments by the payor of the nonperiodic payment or, if none, on each of the dates that the swap contract provides for periodic payments by the recipient of the nonperiodic payment. The time value component is needed to compute the amortization of the nonperiodic payment, but is otherwise disregarded. See paragraph (f)(4) Example 5 of this section.

(B) **Other nonperiodic swap payments.** Nonperiodic payments on a swap other than an upfront payment may be amortized by treating the contract as if it provided for a single upfront payment (equal to the present value of the nonperiodic payments) and a loan between the parties. The discount rate (or rates) used in determining the deemed upfront payment and the time value component of the deemed loan is the same as the rate (or rates) used in the level payment method. The single upfront payment is then amortized under the level payment method described in paragraph (f)(2)(iii)(A) of this section. The time value component of the loan is not treated as interest, but, together with the amortized amount of the deemed upfront payment, is recognized as a periodic payment. See paragraph (f)(4) Example 6 of this section. If both parties make nonperiodic payments, this calculation is done separately for the nonperiodic payments made by each party.

(iv) **General rule for caps and floors.** A payment to purchase or sell a cap or floor must be recognized over the term of the agreement by allocating it in accordance with the prices of a series of cash-settled option contracts that reflect the specified index and the notional principal amount. For purposes of this allocation, the option pricing used by the parties to determine the total amount paid for the cap or floor will be respected, if reasonable. Only the portion of the purchase price that is allocable to the option contract or contracts that expire during a particular period is recognized for that period. Thus, under this paragraph (f)(2)(iv), straight-line or accelerated amortization of a cap premium is generally not permitted. See paragraph (f)(4) Examples 1 and 2 of this section.

(v) **Alternative methods for caps and floors that hedge debt instruments.** Solely for purposes of determining the timing of income and deductions, if a cap or floor is entered into primarily to reduce risk with respect to a specific debt instrument or group of debt instruments held or issued by the taxpayer, the taxpayer may amortize a payment to purchase or sell the cap or floor using the methods described in this paragraph (f)(2)(v), adjusted as appropriate to take account of increases or decreases in the notional principal amount. The alternative methods may not be used by a dealer in notional principal contracts (as defined in paragraph (c)(4)(iii) of this section) for caps or floors entered into or acquired in its capacity as a dealer.

(A) **Prepaid caps and floors.** A premium paid upfront for a cap or a

floor may be amortized using the "level payment method" described in paragraph (f)(2)(iii)(A) of this section. See paragraph (f)(4) Example 3 of this section.

(B) *Other caps and floors.* Nonperiodic payments on a cap or floor other than an upfront payment are amortized by treating the contract as if it provided for a single upfront payment (equal to the present value of the nonperiodic payments) and a loan between the parties as described in paragraph (f)(2)(iii)(B) of this section. Under the level payment method, a cap or floor premium paid in level annual installments over the term of the contract is effectively included or deducted from income ratably, in accordance with the level payments. See paragraph (f)(4) Example 4 of this section.

(C) *Special method for collars.* A taxpayer may also treat a cap and a floor that comprise a collar as a single notional principal contract and may amortize the net nonperiodic payment to enter into the cap and floor over the term of the collar in accordance with the methods prescribed in this paragraph (f)(2)(v).

(vi) *Additional methods.* The Commissioner may, by a revenue ruling or a revenue procedure published in the Internal Revenue Bulletin, provide alternative methods for allocating nonperiodic payments that relate to a notional principal contract to each year of the contract. See § 601.601(d)(2)(ii)(b) of this chapter.

(3) *Term of extendible or terminable contracts.* For purposes of this paragraph (f), the term of a notional principal contract that is subject to extension or termination is the reasonably expected term of the contract.

(4) *Examples.* The following examples illustrate the application of paragraph (f) of this section.

Example 1. Cap premium amortized using general rule. (a) On January 1, 1995, when LIBOR is 8%, F pays unrelated party E \$600,000 for a contract that obligates E to make a payment to F each quarter equal to one-quarter of the excess, if any, of three-

month LIBOR over 9% with respect to a notional principal amount of \$25 million. Both E and F are calendar year taxpayers. E provides F with a schedule of allocable premium amounts indicating that the cap was priced according to a reasonable variation of the Black-Scholes option pricing formula and that the total premium is allocable to the following periods:

	Pricing allocation
1995	\$55,000
1996	225,000
1997	320,000
	\$600,000

(b) This contract is a notional principal contract as defined by paragraph (c)(1) of this section, and LIBOR is a specified index under paragraph (c)(2)(iii) of this section. Any payments made by E to F are periodic payments under paragraph (e)(1) of this section because they are payable at periodic intervals of one year or less throughout the term of the contract, are based on an appropriate specified index, and are based on a single notional principal amount. The \$600,000 cap premium paid by F to E is a nonperiodic payment as defined in paragraph (f)(1) of this section.

(c) The Black-Scholes model is recognized in the financial industry as a standard technique for pricing interest rate cap agreements. Therefore, because E has used a reasonable option pricing model, the schedule generated by E is consistent with the economic substance of the cap, and may be used by both E and F for calculating their ratable daily portions of the cap premium. Under paragraph (f)(2)(iv) of this section, E recognizes the ratable daily portion of the cap premium as income, and F recognizes the ratable daily portion of the cap premium as a deduction based on the pricing schedule. Thus, E and F account for the contract as follows:

	Ratable daily portion
1995	\$55,000
1996	225,000
1997	320,000
	\$600,000

(d) Any periodic payments under the cap agreement (that is, payments that E makes to F because LIBOR exceeds 9%) are included in the parties' net income or net deduction

from the contract in accordance with paragraph (e)(2) of this section.

Example 2. Cap premium allocated to proper period. (a) The facts are the same as in Example 1, except that the cap is purchased by F on November 1, 1994. The first determination date under the cap agreement is January 31, 1995 (the last day of the first quarter to which the contract relates). LIBOR is 9.1% on December 31, 1994, and is 9.15% on January 31, 1995.

(b) E and F recognize \$9,192 (61 days/365 days x \$55,000) as the ratable daily portion of the nonperiodic payment for 1994, and include that amount in their net income or net deduction from the contract for 1994. If E's pricing model allocated the cap premium to each quarter covered by the contract, the ratable daily portion would be 61 days/92 days times the premium allocated to the first quarter.

(c) Under paragraph (e)(2)(ii) of this section, E and F calculate the payments using LIBOR as of December 31, 1994. F recognizes as income the ratable daily portion of the presumed payment, or \$4,144 (61 days/92 days x .25 x .001 x \$25,000,000). Thus, E reports \$5,048 of net income from the contract for 1994 (\$9,192-\$4,144), and F reports a net deduction from the contract of \$5,048.

(d) On January 31, 1995, E pays F \$9,375 (.25 x .0015 x \$25,000,000) under the terms of the cap agreement. For purposes of determining their net income or net deduction from this contract for the year ended December 31, 1995, E and F must adjust their respective net income and net deduction from the cap by \$2,072 (61 days/92 days x (\$9,375 actual payment under the cap on January 31, 1995-\$6,250 presumed payment under the cap on December 31, 1994)).

Example 3. Cap premium amortized using alternative method. (a) The facts are the same as in Example 1, except that the cap provides for annual payments by E and is entered into by F primarily to reduce risk with respect to a debt instrument issued by F. F elects to amortize the cap premium using the alternative level payment method provided under paragraph (f)(2)(v)(A) of this section. Under that method, F amortizes the cap premium by assuming that the \$600,000 is repaid in 3 equal annual payments of \$241,269, assuming a discount rate of 10%. Each payment is divided into a time value component and a principal component, which are set out below.

	Level payment	Time value component	Principal component
1995	\$241,269	\$60,000	\$181,269
1996	241,269	41,873	199,396
1997	241,269	21,834	219,335
	\$723,807	\$123,807	\$600,000

(b) The net of the ratable daily portions of the principal component and the payments,

if any, received from E comprise F's annual net income or net deduction from the cap.

The time value components are needed only

to compute the ratable daily portions of the cap premium, and are otherwise disregarded.

Example 4. Cap premium paid in level installments and amortized using alternative method. (a) The facts are the same as in Example 3, except that *F* agrees to pay for the

cap in three level installments of \$241,269 (a total of \$723,807) on December 31, 1995, 1996, and 1997. The present value of three payments of \$241,269, discounted at 10%, is \$600,000. For purposes of amortizing the cap premium under the alternative method

provided in paragraph (f)(2)(v)(B) of this section, *F* is treated as paying \$600,000 for the cap on January 1, 1995, and borrowing \$600,000 from *E* that will be repaid in three annual installments of \$241,269. The time value component of the loan is computed as follows:

	Loan balance	Time value component	Principal component
1995	\$600,000	\$60,000	\$181,269
1996	418,731	41,873	199,396
1997	219,335	21,934	219,335
		\$123,807	\$600,000

(b) *F* is treated as making periodic payments equal to the amortized principal components from a \$600,000 cap paid in advance (as described in Example 3), increased by the time value components of the \$600,000 loan, which totals \$241,269 each year. The time value components of the \$600,000 loan are included in the periodic payments made by *F*, but are not characterized as interest income or expense. The effect of the alternative method in this situation is to allow *F* to amortize the cap premium in level installments, the same way it is paid. The net of the ratable daily portions of *F*'s deemed periodic payments and the payments, if any, received from *E* comprise *F*'s annual net income or net deduction from the cap.

Example 5. Upfront interest rate swap payment amortized using alternative method.

(a) On January 1, 1995, *G* enters into an interest rate swap agreement with unrelated counterparty *H* under which, for a term of five years, *G* is obligated to make annual payments at 11% and *H* is obligated to make annual payments at LIBOR on a notional principal amount of \$100 million. At the time *G* and *H* enter into this swap agreement, the rate for similar on-market swaps is LIBOR to 10%. To compensate for this difference, on January 1, 1995, *H* pays *G* a yield adjustment fee of \$3,790,786. *G* provides *H* with information that indicates that the amount of the yield adjustment fee was determined as the present value, at 10% compounded annually, of five annual payments of

\$1,000,000 (1% x \$100,000,000). *G* and *H* are calendar year taxpayers.

(b) This contract is a notional principal contract as defined by paragraph (c)(1) of this section. The yield adjustment fee is a nonperiodic payment as defined in paragraph (f)(1) of this section.

(c) Under the alternative method described in paragraph (f)(2)(iii)(A) of this section, the yield adjustment fee is recognized over the life of the agreement by assuming that the \$3,790,786 is repaid in five level payments. Assuming a constant yield to maturity and annual compounding at 10%, the ratable daily portions are computed as follows:

	Level payment	Time value component	Principal component
1995	\$1,000,000	\$379,079	\$620,921
1996	1,000,000	316,987	683,013
1997	1,000,000	248,685	751,315
1998	1,000,000	173,554	826,446
1999	1,000,000	90,909	909,091
	\$5,000,000	\$1,209,214	\$3,790,786

(d) *G* also makes swap payments to *H* at 11%, while *H* makes swap payments to *G* based on LIBOR. The net of the ratable daily portions of the 11% payments by *G*, the LIBOR payments by *H*, and the principal component of the yield adjustment fee paid by *H* determines the annual net income or net deduction from the contract for both *G* and *H*. The time value components are

needed only to compute the ratable daily portions of the yield adjustment fee paid by *H*, and are otherwise disregarded.

Example 6. Backloaded interest rate swap payment amortized using alternative method.

(a) The facts are the same as in Example 5, but *H* agrees to pay *G* a yield adjustment fee of \$6,105,100 on December 31, 1999. Under the alternative method in paragraph

(f)(2)(iii)(B) of this section, *H* is treated as paying a yield adjustment fee of \$3,790,786 (the present value of \$6,105,100, discounted at a 10% rate with annual compounding) on January 1, 1995. Solely for timing purposes, *H* is treated as borrowing \$3,790,786 from *G*. Assuming annual compounding at 10%, the time value component is computed as follows:

	Loan balance	Time value component	Principal component
1995	\$3,790,786	\$379,079	
1996	4,169,865	416,987	
1997	4,586,852	458,685	
1998	5,045,537	504,554	
1999	5,550,091	555,009	\$6,105,100

(b) The amortization of *H*'s yield adjustment fee is equal to the amortization of a yield adjustment fee of \$3,790,786 paid in advance (as described in Example 5),

increased by the time value component of the \$3,790,786 deemed loan from *G* to *H*. Thus, the amount of *H*'s yield adjustment fee that is allocated to 1995 is \$1,000,000 (\$620,921

+ \$379,079). The time value components of the \$3,790,786 loan are included in the periodic payments paid by *H*, but are not characterized as interest income or expense.

The net of the ratable daily portions of the 11% swap payments by G, and the LIBOR payments by H, added to the principal components from Example 5 and the time value components from this Example 6, determines the annual net income or net deduction from the contract for both G and H.

Example 7. Nonperiodic payment on a commodity swap amortized under general rule. (a) On January 1, 1995, I enters into a commodity swap agreement with unrelated counterparty J under which, for a term of three years, I is obligated to make annual payments based on a fixed price of \$2.35 per bushel times a notional amount of 100,000 bushels of corn and J is obligated to make

annual payments equal to the spot price times the same notional amount. Assume that on January 1, 1995, the price of a one year forward for corn is \$2.40 per bushel, of a two year forward \$2.55 per bushel, and of a 3 year forward \$2.75 per bushel. To compensate for the below-market fixed price provided in the swap agreement, I pays J \$53,530 for entering into the swap. I and J are calendar year taxpayers.

(b) This contract is a notional principal contract as defined by paragraph (c)(1) of this section, and \$2.35 and the spot price of corn are specified indices under paragraphs (c)(2)(i) and (iii) of this section, respectively. The \$53,530 payment is a nonperiodic

payment as defined by paragraph (f)(1) of this section.

(c) Assuming that I does not use the alternative methods provided under paragraph (f)(2)(iii) of this section, paragraph (f)(2)(ii) of this section requires that I recognize the nonperiodic payment over the term of the agreement by allocating the payment to each forward contract in accordance with the forward price of corn. Solely for timing purposes, I treats the \$53,530 nonperiodic payment as a loan that J will repay in three installments of \$5,000, \$20,000, and \$40,000, the expected payouts on the in-the-money forward contracts. With annual compounding at 8%, the ratable daily portions are computed as follows:

	Expected forward payment	Time value component	Principal component
1995	\$5,000	\$4,282	\$718
1996	20,000	4,225	15,775
1997	40,000	2,963	37,037
	\$65,000	\$11,470	\$53,530

(d) The ratable daily portion of the principal component is added to I's periodic payments in computing its net income or net deduction from the notional principal contract for each taxable year. The time value components are needed only to compute the principal components, and are otherwise disregarded.

(g) **Special rules—(1) Disguised notional principal contracts.** The Commissioner may recharacterize all or part of a transaction (or series of transactions) if the effect of the transaction (or series of transactions) is to avoid the application of this section.

(2) **Hedged notional principal contracts.** If a taxpayer, either directly or through a related person (as defined in paragraph (c)(4)(i) of this section), reduces risk with respect to a notional principal contract by purchasing, selling, or otherwise entering into other notional principal contracts, futures, forwards, options, or other financial contracts (other than debt instruments), the taxpayer may not use the alternative methods provided in paragraphs (f)(2)(iii) and (v) of this section.

Moreover, where such positions are entered into to avoid the appropriate timing or character of income from the contracts taken together, the Commissioner may require that amounts paid to or received by the taxpayer under the notional principal contract be treated in a manner that is consistent with the economic substance of the transaction as a whole.

(3) **Options and forwards to enter into notional principal contracts.** An option or forward contract that entitles or obligates a person to enter into a notional principal contract is subject to

the general rules of taxation for options or forward contracts. Any payment with respect to the option or forward contract is treated as a nonperiodic payment for the underlying notional principal contract under the rules of paragraphs (f) and (g)(4) or (g)(5) of this section if and when the underlying notional principal contract is entered into.

(4) **Swaps with significant nonperiodic payments.** A swap with significant nonperiodic payments is treated as two separate transactions consisting of an on-market, level payment swap and a loan. The loan must be accounted for by the parties to the contract independently of the swap. The time value component associated with the loan is not included in the net income or net deduction from the swap under paragraph (d) of this section, but is recognized as interest for all purposes of the Internal Revenue Code. See paragraph (g)(6) Example 3 of this section. For purposes of section 956, the Commissioner may treat any nonperiodic swap payment, whether or not it is significant, as one or more loans.

(5) **Caps and floors that are significantly in-the-money.** [Reserved]

(6) **Examples.** The following examples illustrate the application of paragraph (g) of this section.

Example 1. Cap hedged with options. (a) On January 1, 1995, K sells to unrelated counterparty L three cash settlement European-style put options on Eurodollar time deposits with a strike rate of 9%. The options have exercise dates of January 1, 1996, January 1, 1997, and January 1, 1998, respectively. If LIBOR exceeds 9% on any of the exercise dates, L will be entitled, by

exercising the relevant option, to receive from K an amount that corresponds to the excess of LIBOR over 9% times \$25 million. L pays K \$650,000 for the three options. Furthermore, K is related to F, the cap purchaser in paragraph (f)(4) Example 1 of this section.

(b) K's option agreements with L reduce risk with respect to F's cap agreement with E. Accordingly, under paragraph (g)(2) of this section, F cannot use the alternative methods provided in paragraph (f)(2)(v) of this section to amortize the premium paid under the cap agreement. F must amortize the cap premium it paid in accordance with paragraph (f)(2)(iv) of this section.

(c) The method that E may use to account for its agreement with F is not affected by the application of paragraph (g)(2) of this section to F.

Example 2. Nonperiodic payment that is not significant. (a) On January 1, 1995, G enters into an interest rate swap agreement with unrelated counterparty H under which, for a term of five years, G is obligated to make annual payments at 11% and H is obligated to make annual payments at LIBOR on a notional principal amount of \$100 million. At the time G and H enter into this swap agreement, the rate for similar on-market swaps is LIBOR to 10%. To compensate for this difference, on January 1, 1995, H pays G a yield adjustment fee of \$3,790,786. G provides H with information that indicates that the amount of the yield adjustment fee was determined as the present value, at 10% compounded annually, of five annual payments of \$1,000,000 (1% x \$100,000,000). G and H are calendar year taxpayers. (These facts are the same as in paragraph (f)(4) Example 5 of this section.)

(b) In this situation, the yield adjustment fee of \$3,790,786 is not a significant nonperiodic payment within the meaning of paragraph (g)(4) of this section, in light of the amount of the fee in proportion to the present value of the total amount of fixed payments

due under the contract. Accordingly, no portion of the swap is recharacterized as a loan for purposes of this section.

Example 3. Significant nonperiodic payment. (a) On January 1, 1995, unrelated parties M and N enter into an interest rate swap contract. Under the terms of the contract, N agrees to make five annual payments to M equal to LIBOR times a notional principal amount of \$100 million. In return, M agrees to pay N 6% of \$100 million annually, plus \$15,163,147 on January 1, 1995. At the time M and N enter into this swap agreement the rate for similar on-market swaps is LIBOR to 10%, and N

provides M with information that the amount of the initial payment was determined as the present value, at 10% compounded annually, of five annual payments from M to N of \$4,000,000 (4% of \$100,000,000).

(b) Although the parties have characterized this transaction as an interest rate swap, the \$15,163,147 payment from M to N is significant when compared to the present value of the total fixed payments due under the contract. Accordingly, under paragraph (g)(4) of this section, the transaction is recharacterized as consisting of both a \$15,163,147 loan from M to N that N repays in installments over the term of the

agreement, and an interest rate swap between M and N in which M immediately pays the installment payments on the loan back to N as part of its fixed payments on the swap in exchange for the LIBOR payments by N.

(c) The yield adjustment fee is recognized over the life of the agreement by treating the \$15,163,147 as a loan that will be repaid with level payments over five years. Assuming a constant yield to maturity and annual compounding at 10%, M and N account for the principal and interest on the loan as follows:

	Level payment	Interest component	Principal component
1995	\$4,000,000	\$1,516,315	\$2,483,685
1996	4,000,000	1,267,946	2,732,054
1997	4,000,000	994,741	3,005,259
1998	4,000,000	694,215	3,305,785
1999	4,000,000	363,636	3,636,364
	\$20,000,000	\$4,836,853	\$15,163,147

(d) M recognizes interest income, and N claims an interest deduction, each taxable year equal to the interest component of the deemed installment payments on the loan. These interest amounts are not included in the parties' net income or net deduction from the swap contract under paragraph (d) of this section. The principal components are needed only to compute the interest component of the level payment for the following period, and do not otherwise affect the parties' net income or net deduction from this contract.

(e) N also makes swap payments to M based on LIBOR, and receives swap payments from M at a fixed rate that is equal to the sum of the stated fixed rate and the rate calculated by dividing the deemed level annual payments on the loan by the notional principal amount. Thus, the fixed rate on this swap is 10%, which is the sum of the stated rate of 6% and the rate calculated by dividing the annual loan payment of \$4,000,000 by the notional principal amount of \$100,000,000, or 4%. Using the methods provided in paragraph (e)(2) of this section, the swap payments from M to N of \$10,000,000 (10% of \$100,000,000) and the LIBOR swap payments from N to M are included in the parties' net income or net deduction from the contract for each taxable year.

Example 4. Swaps recharacterized as a loan. (a) The facts are the same as in Example 3, except that on January 1, 1995, N also enters into an interest rate swap agreement with unrelated counterparty O under which, for a term of five years, N is obligated to make annual payments at 12% and O is obligated to make annual payments at LIBOR on a notional principal amount of \$100 million. At the time N and O enter into this swap agreement, the rate for similar on-market swaps is LIBOR to 10%. To compensate for this difference, O pays N an upfront yield adjustment fee of \$7,581,574. This yield adjustment fee equals the present value, at 10% compounded annually, of five

annual payments of \$2,000,000 (2% of \$100,000,000).

(b) In substance, these two interest rate swaps are the equivalent of a fixed rate borrowing by N of \$22,744,721 (\$15,163,147 from M plus \$7,581,574 from O). Under paragraph (g)(2) of this section, if these positions were entered into to avoid interest character on a net loan position, the Commissioner may recharacterize the swaps as a loan which N will repay with interest in five annual installments of \$6,000,000 each (the difference between the 12% N pays under the swap with O and the 6% N receives under the swap with M, multiplied by the \$100,000,000 notional principal amount).

(c) N recognizes no net income or net deduction from these contracts under paragraph (d) of this section because, as to N, there is no notional principal contract income or expense. However, the recharacterization of N's separate transactions as a loan has no effect on the way M and O must each account for their notional principal contracts under paragraphs (d) through (g) of this section.

(h) **Termination payments—(1) Definition.** A payment made or received to extinguish or assign all or a proportionate part of the remaining rights and obligations of any party under a notional principal contract is a termination payment to the party making the termination payment and the party receiving the payment. A termination payment includes a payment made between the original parties to the contract (an extinguishment), a payment made between one party to the contract and a third party (an assignment), and any gain or loss realized on the exchange of one notional principal contract for another. Where one party assigns its remaining rights and obligations to a

third party, the original nonassigning counterparty realizes gain or loss if the assignment results in a deemed exchange of contracts and a realization event under section 1001.

(2) **Taxable year of inclusion and deduction by original parties.** Except as otherwise provided (e.g., in section 453 or 1092), a party to a notional principal contract recognizes a termination payment in the year the contract is extinguished, assigned, or exchanged. When the termination payment is recognized, the party also recognizes any other payments that have been made or received pursuant to the notional principal contract, but that have not been recognized under paragraph (d) of this section. If only a proportionate part of a party's rights and obligations is extinguished, assigned, or exchanged, then only that proportion of the unrecognized payments is recognized under the previous sentence.

(3) **Taxable year of inclusion and deduction by assignees.** A termination payment made or received by an assignee pursuant to an assignment of a notional principal contract is recognized by the assignee under the rules of paragraphs (f) and (g)(4) or (g)(5) of this section as a nonperiodic payment for the notional principal contract that is in effect after the assignment.

(4) **Special rules—(i) Assignment of one leg of a contract.** A payment is not a termination payment if it is made or received by a party in exchange for assigning all or a portion of one leg of a notional principal contract at a time when a substantially proportionate amount of the other leg remains

unperformed and unassigned. The payment is either an amount loaned, an amount borrowed, or a nonperiodic payment, depending on the economic substance of the transaction to each party. This paragraph (h)(4)(i) applies whether or not the original notional principal contract is terminated as a result of the assignment.

(ii) *Substance over form.* Any economic benefit that is given or received by a taxpayer in lieu of a termination payment is a termination payment.

(5) *Examples.* The following examples illustrate the application of this paragraph (h). All of the examples assume that no loss deferral rules apply.

Example 1. Termination by extinguishment. (a) On January 1, 1995, P enters into an interest rate swap agreement with unrelated counterparty Q under which, for a term of seven years, P is obligated to make annual payments based on 10% and Q is obligated to make semi-annual payments based on LIBOR and a notional principal amount of \$100 million. P and Q are both calendar year taxpayers. On January 1, 1997, when the fixed rate on a comparable LIBOR swap has fallen to 9.5%, P pays Q \$1,895,393 to terminate the swap.

(b) The payment from P to Q extinguishes the swap contract and is a termination payment, as defined in paragraph (h)(1) of this section, for both parties. Accordingly, under paragraph (h)(2) of this section, P recognizes a loss of \$1,895,393 in 1997 and Q recognizes \$1,895,393 of gain in 1997.

Example 2. Termination by assignment. (a) The facts are the same as in Example 1, except that on January 1, 1997, P pays unrelated party R \$1,895,393 to assume all of P's rights and obligations under the swap with Q. In return for this payment, R agrees to pay 10% of \$100 million annually to Q and to receive LIBOR payments from Q for the remaining five years of the swap.

(b) The payment from P to R terminates P's interest in the swap contract with Q and is a termination payment, as defined in paragraph (h)(1) of this section, for P. Under paragraph (h)(2) of this section, P recognizes a loss of \$1,895,393 in 1997. Whether Q also has a termination payment with respect to the payment from P to R is determined under section 1001.

(c) Under paragraph (h)(3) of this section, the assignment payment that R receives from P is a nonperiodic payment for an interest rate swap. Because the assignment payment is not a significant nonperiodic payment within the meaning of paragraph (g)(1) of this section, R amortizes the \$1,895,393 over the five year term of the swap agreement under paragraph (f)(2) of this section.

Example 3. Assignment of swap with yield adjustment fee. (a) The facts are the same as in Example 2, except that on January 1, 1995, Q paid P a yield adjustment fee to enter into the seven year interest rate swap. In accordance with paragraph (f)(2) of this section, P and Q included the ratable daily portions of that nonperiodic payment in their net income or net deduction from the

contract for 1995 and 1996. On January 1, 1997, \$300,000 of the nonperiodic payment has not yet been recognized by P and Q.

(b) Under paragraph (h)(2) of this section, P recognizes a loss of \$1,595,393 (\$1,895,393-\$300,000) in 1997. R accounts for the termination payment in the same way it did in Example 2; the existence of an unamortized payment with respect to the original swap has no effect on R.

Example 4. Assignment of one leg of a swap. (a) On January 1, 1995, S enters into an interest rate swap agreement with unrelated counterparty T under which, for a term of five years, S will make annual payments at 10% and T will make annual payments at LIBOR on a notional principal amount of \$50 million. On January 1, 1996, unrelated party U pays T \$15,849,327 for the right to receive the four remaining \$5,000,000 payments from S. Under the terms of the agreement between S and T, S is notified of this assignment, and S is contractually bound thereafter to make its payments to U on the appropriate payment dates. S's obligation to pay U is conditioned on T making its LIBOR payment to S on the appropriate payment dates.

(b) Because T has assigned to U its rights to the fixed rate payments, but not its floating rate obligations under the notional principal contract, U's payment to T is not a termination payment as defined in paragraph (h)(1) of this section, but is covered by paragraph (h)(4)(i) of this section. The economic substance of the transaction between T and U is a loan that does not affect the way that S and T account for the notional principal contract under this section.

(i) *Anti-abuse rule.* If a taxpayer enters into a transaction with a principal purpose of applying the rules of this section to produce a material distortion of income, the Commissioner may depart from the rules of this section as necessary to reflect the appropriate timing of income and deductions from the transaction.

(j) *Effective date.* These regulations are effective for notional principal contracts entered into on or after December 13, 1993.

Par. 5. Section 1.451-1 is amended by adding paragraph (f) to read as follows:

§ 1.451-1 General rule for taxable year of inclusion.

* * * * *

(f) *Timing of income from notional principal contracts.* For the timing of income with respect to notional principal contracts, see § 1.446-3.

Par. 6. Section 1.461-4 is amended by adding paragraph (f) to read as follows:

§ 1.461-4 Economic performance.

* * * * *

(f) *Timing of deductions from notional principal contracts.* Economic performance on a notional principal contract occurs as provided under § 1.446-3.

Par. 7. Section 1.988-2 is amended by adding paragraph (h) to read as follows:

§ 1.988-2 Recognition and computation of exchange gain or loss.

* * * * *

(h) *Timing of income and deductions from notional principal contracts.* Except as otherwise provided (e.g., in § 1.988-5 or 1.446-3(g)), income or loss from a notional principal contract described in § 1.988-1(a)(2)(iii)(B) (other than a currency swap) is exchange gain or loss. For the rules governing the timing of income and deductions with respect to notional principal contracts, see § 1.446-3. See paragraph (e)(2) of this section with respect to currency swaps.

Par. 8. Section 1.1092(d)-1 is added to read as follows:

§ 1.1092(d)-1 Definitions and Special Rules.

(a) *Actively traded.* Actively traded personal property includes any personal property for which there is an established financial market.

(b) *Established financial market—(1) In general.* For purposes of this section, an established financial market includes—

(i) A national securities exchange that is registered under section 6 of the Securities Exchange Act of 1934 (15 U.S.C. 78f);

(ii) An interdealer quotation system sponsored by a national securities association registered under section 15A of the Securities Exchange Act of 1934;

(iii) A domestic board of trade designated as a contract market by the Commodities Futures Trading Commission;

(iv) A foreign securities exchange or board of trade that satisfies analogous regulatory requirements under the law of the jurisdiction in which it is organized (such as the London International Financial Futures Exchange, the Marche a Terme International de France, the International Stock Exchange of the United Kingdom and the Republic of Ireland, Limited, the Frankfurt Stock Exchange, and the Tokyo Stock Exchange);

(v) An interbank market;

(vi) An interdealer market (as defined in paragraph (b)(2)(i) of this section); and

(vii) Solely with respect to a debt instrument, a debt market (as defined in paragraph (b)(2)(ii) of this section).

(2) *Definitions—(i) Interdealer market.* An interdealer market is characterized by a system of general circulation (including a computer listing disseminated to subscribing brokers,

dealers, or traders) that provides a reasonable basis to determine fair market value by disseminating either recent price quotations (including rates, yields, or other pricing information) of one or more identified brokers, dealers, or traders or actual prices (including rates, yields, or other pricing information) of recent transactions. An interdealer market does not include a directory or listing of brokers, dealers, or traders for specific contracts (such as yellow sheets) that provides neither price quotations nor actual prices of recent transactions.

(ii) *Debt market.* A debt market exists with respect to a debt instrument if price quotations for the instrument are readily available from brokers, dealers, or traders. A debt market does not exist with respect to a debt instrument if—

(A) No other outstanding debt instrument of the issuer (or of any person who guarantees the debt instrument) is traded on an established financial market described in paragraph (b)(1)(i), (ii), (iii), (iv), (v), or (vi) of this section (other than debt);

(B) The original stated principal amount of the issue that includes the debt instrument does not exceed \$25 million;

(C) The conditions and covenants relating to the issuer's performance with respect to the debt instrument are materially less restrictive than the conditions and covenants included in all of the issuer's other traded debt (e.g., the debt instrument is subject to an economically significant subordination provision whereas the issuer's other traded debt is senior); or

(D) The maturity date of the debt instrument is more than 3 years after the latest maturity date of the issuer's other traded debt.

(c) *Notional principal contracts.* For purposes of section 1092(d)—

(1) A notional principal contract (as defined in § 1.446-3(c)(1)) constitutes

personal property of a type that is actively traded if contracts based on the same or substantially similar specified indices are purchased, sold, or entered into on an established financial market within the meaning of paragraph (b) of this section; and

(2) The rights and obligations of a party to a notional principal contract are rights and obligations with respect to personal property and constitute an interest in personal property.

(d) *Effective dates.* Paragraph (b)(1)(vii) of this section applies to positions entered into on or after October 14, 1993. Paragraph (c) of this section applies to positions entered into on or after July 8, 1991.

Approved: October 4, 1993
Margaret Milner Richardson,
Commissioner of Internal Revenue.
Leslie Samuels,
Assistant Secretary of the Treasury.
[FR Doc. 93-25192 Filed 10-8-93; 1:26 pm]
BILLING CODE 4830-01-U

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 258

[FRL-4788-5]

Solid Waste Disposal Facility Criteria; Delay of the Effective Date

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule; corrections.

SUMMARY: EPA is making technical corrections to the Table "Summary of Changes to the Effective Dates of the MSWLF Criteria" which was included in the preamble to the final rule "Solid Waste Disposal Facility Criteria; Delay of the Effective Date" that appeared in the Federal Register on October 1, 1993 (58 FR 51536). This correction notice

will amend errors that appear in the portion of the table related to "Effective date of ground-water monitoring and corrective action."

EFFECTIVE DATE: October 14, 1993.

FOR FURTHER INFORMATION CONTACT: Mr. David Hockey (202) 260-7596.

SUPPLEMENTARY INFORMATION: On October 1, 1993, EPA promulgated a final rule under Subtitle D of the Resource Conservation and Recovery Act and section 405 of the Clean Water Act delaying the effective date of the Municipal Solid Waste Landfill Criteria (58 FR 51536). The preamble to the rule included a table on pages 51543 and 51544 that summarized the effective dates of the final rule. That rule contained minor editorial errors that EPA is correcting in this action. The corrections are for the table "Summary of Changes to the Effective Dates of the MSWLF Criteria" for the row titled "Effective date of ground-water monitoring and corrective action." For the category of MSWLF units accepting 100 TPD or less; are not on the NPL; and are located in a state that has submitted an application for approval by 10/9/93; the effective date for new units should read October 9, 1993 and not October 9, 1994. For the category of MSWLF units that meet the small landfill exemption in 40 CFR 258.1(f); the effective date for existing units and lateral expansions should read October 9, 1995 through October 9, 1996 and not October 9, 1996 only. For the category of MSWLF units receiving flood-related waste; the effective date for new units should read October 9, 1993 and not October 9, 1994.

Correction of Publication

Accordingly, the final rule is corrected by revising the table on pages 51543 and 51544 to read as follows:

SUMMARY OF CHANGES TO THE EFFECTIVE DATES OF THE MSWLF CRITERIA¹

	MSWLF units accepting greater than 100 TPD	MSWLF units accepting 100 TPD or less; are not on the NPL; and are located in a state that has submitted an application for approval by 10/9/93	MSWLF units that meet the small landfill exemption in 40 CFR § 258.1(f)	MSWLF units receiving flood-related waste
General effective date ²	October 9, 1993	April 9, 1994	October 9, 1995	Up to October 9, 1994 as determined by State.
This is the effective date for location, operation, design, and closure/post-closure.				
Date by which to install final cover if cease receipt of waste by the general effective date.	October 9, 1994	October 9, 1994	October 9, 1996	Within one year of date determined by State; no later than October 9, 1995.

SUMMARY OF CHANGES TO THE EFFECTIVE DATES OF THE MSWLF CRITERIA¹—Continued

	MSWLF units accepting greater than 100 TPD	MSWLF units accepting 100 TPD or less; are not on the NPL; and are located in a state that has submitted an application for approval by 10/9/93	MSWLF units that meet the small landfill exemption in 40 CFR § 258.1(f)	MSWLF units receiving flood-related waste
Effective date of ground-water monitoring and corrective action.	Prior to receipt of waste for new units; October 9, 1994 through October 9, 1996 for existing units and lateral expansions.	October 9, 1993 for new units; October 9, 1994 through October 9, 1996 for existing units and lateral expansions.	October 9, 1995 for new units; October 9, 1995 through October 9, 1996 for existing units and lateral expansions.	October 9, 1993 for new units; October 9, 1994 through October 9, 1996 for existing units and lateral expansions.
Effective date of financial assurance requirements.	April 9, 1995	April 9, 1995	October 9, 1995	April 9, 1995.

¹ This Table provides a summary of the major changes to the effective dates. See the final rule and preamble published on October 1, 1993 (58 FR 51536) for a full discussion of all changes and related conditions. All other versions of this table, including the version in the October 1, 1993 Federal Register (58 FR 51536) on pages 51543 and 51544, are obsolete.

² If a MSWLF unit receives waste after this date, the unit must comply with all of Part 258.

Authority

EPA is promulgating these regulations under the authority of sections 2002 and 4010(c) of the Resource Conservation and Recovery Act of 1976, as amended. 42 USC 6912.

Dated: October 5, 1993.

Walter W. Kovalick, Jr.,

Acting Assistant Administrator, Office of Solid Waste and Emergency Response.

[FR Doc. 93-25100 Filed 10-13-93; 8:45 am]

BILLING CODE 6560-50-P

GENERAL SERVICES ADMINISTRATION**41 CFR Part 302-6**

[FTR Amendment 31]

RIN 3090-AE92

Federal Travel Regulation; Increase in Maximum Reimbursement Limitations for Real Estate Sale and Purchase Expenses

AGENCY: Federal Supply Service, GSA.

ACTION: Final rule.

SUMMARY: This final rule amends the Federal Travel Regulation (FTR) to increase the maximum dollar limitations on reimbursement for allowable real estate sale and purchase expenses incident to a change of official station. Section 5724a(a)(4)(B) of title 5, United States Code requires that the dollar limitations be updated effective October 1 of each year based on the percent change, if any, in the Consumer Price Index for All Urban Consumers, United States City Average, Housing Component, for December of the

preceding year over December of the second preceding year. This final rule will have a favorable impact on Federal employees authorized to relocate in the interest of the Government since it increases relocation allowance maximums.

EFFECTIVE DATE: This final rule is effective October 1, 1993, and applies to employees whose effective date of transfer is on or after October 1, 1993. For purposes of this regulation, the effective date of transfer is the date on which the employee reports for duty at the new official station.

FOR FURTHER INFORMATION CONTACT: Jane E. Groat, Transportation Management Division (FBX), Washington, DC 20406, telephone 703-305-5745.

SUPPLEMENTARY INFORMATION: This final rule makes the annual adjustment to the maximum reimbursement limitations for the sale and purchase of an employee's residence when the employee transfers in the interest of the Government. The total amount of expenses that may be reimbursed in connection with the sale of a residence shall not exceed 10 percent of the actual sale price or \$21,340, whichever is the lesser amount. The total amount of expenses that may be reimbursed in connection with the purchase of a residence shall not exceed 5 percent of the purchase price or \$10,669, whichever is the lesser amount.

The General Services Administration (GSA) has determined that this rule is not a major rule for the purposes of Executive Order 12291 of February 17, 1981, because it is not likely to result in an annual effect on the economy of \$100 million or more; a major increase in

costs to consumers or others; or significant adverse effects. GSA has based all administrative decisions underlying this rule on adequate information concerning the need for, and consequences of, this rule; has determined that the potential benefits to society from this rule outweigh the potential costs and has maximized the net benefits; and has chosen the alternative approach involving the least net cost to society.

List of Subjects in 41 CFR Part 302-6

Government employees, Relocation allowances and entitlements, Transfers

For the reasons set out in the preamble, 41 CFR part 302-6 is amended as follows:

PART 302-6—ALLOWANCE FOR EXPENSES INCURRED IN CONNECTION WITH RESIDENCE TRANSACTIONS

1. The authority citation for part 302-6 continues to read as follows:

Authority: 5 U.S.C. 5721-5734; 20 U.S.C. 905(a); E.O. 11609, 36 FR 13747, 3 CFR, 1971-1975 Comp., p. 596.

302-6.2 [Amended]

2. Section 302-6.2 is amended by removing the amount "\$20,799" in paragraph (g)(1), and adding in its place the amount "\$21,340"; and by removing the amount "\$10,399" in paragraph (g)(2) and adding in its place the amount "\$10,669".

Dated: September 8, 1993.

Roger W. Johnson,

Administrator of General Services.

[FR Doc. 93-25183 Filed 10-13-93; 8:45 am]

BILLING CODE 8820-24-F

FEDERAL COMMUNICATIONS COMMISSION**47 CFR Part 97**

[DA 93-1158]

Deletion of Station Location on Amateur Application Form

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: The Order deletes the requirement in the amateur service rules that a station location be specified on the application. The Order recognizes that the extensive use of mobile and portable equipment results in frequent changes of the station's transmitting location. In addition, this action will expedite the processing of amateur service license applications.

EFFECTIVE DATE: November 15, 1993.

FOR FURTHER INFORMATION CONTACT:

Maurice J. DePont, Federal Communications Commission, Washington, DC 20554, (202) 632-4964.

SUPPLEMENTARY INFORMATION:**Order**

Adopted: September 24, 1993.

Released: October 7, 1993.

By the Chief, Private Radio Bureau:

1. Section 97.21 of the Commission's Rules, 47 CFR 97.21, currently provides that each application for an amateur service license and each application for a reciprocal permit for alien amateur licensee must show, among other things, a station location in an area where the amateur service is regulated by the FCC. The rule also provides that the station location must be a place where a station can be physically located.

2. In order to expedite the processing of amateur service license applications, it is desirable to delete the requirement that a station location be specified on the application. Further, because portable and mobile equipment is currently widely used in the amateur service, a station's location when transmitting often changes, sometimes even daily.

3. We believe that this rule amendment is not likely to be controversial. Further, it relates to a nonsubstantive change in the Commission's licensing procedures. The notice and comment provisions of Section 553 of the Administrative Procedure Act, 5 U.S.C. 553, therefore, need not be complied with. Authority for this action is contained in Section 0.331(a)(1) of the Commission's Rules, 47 CFR 0.331(a)(1).

4. Accordingly, § 97.21, is amended, effective November 15, 1993, as set forth below.

List of Subjects in 47 CFR Part 97

Radio.

Federal Communications Commission.

Ralph A. Haller,
Chief, Private Radio Bureau.**Rule Change**

Part 97 of chapter I of title 47 of the Code of Federal Regulations is amended as follows:

PART 97—AMATEUR RADIO SERVICE

1. The authority citation for Part 97 continues to read as follows:

Authority: 48 Stat. 1066, 1082, as amended; 47 U.S.C. 154, 303. Interpret or apply 48 Stat. 1064-1068, 1081-1105, as amended; 47 U.S.C. 151-155, 301-609, unless otherwise noted.

2. Section 97.21 is revised to read as follows:

§ 97.21 Mailing address.

Each application for an amateur service license and each application for a reciprocal permit for alien amateur licensee must show a mailing address in an area where the amateur service is regulated by the FCC. The mailing address must be one where the licensee can receive mail delivery by the United States Postal Service.

[FR Doc. 93-25137 Filed 10-13-93; 8:45 am]

BILLING CODE 6712-01-M

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION**48 CFR Part 1833****Change to the NASA FAR Supplement Reflecting the Discontinuance of the NASA Board of Contract Appeals (NASA BCA) and its Merger With the Armed Services Board of Contract Appeals (ASBCA)**

AGENCY: Office of Procurement, Procurement Policy Division, National Aeronautics and Space Administration (NASA).

ACTION: Final rule.

SUMMARY: This notice amends the NASA FAR Supplement, part 1833, to reflect that the NASA BCA no longer exists as a separate entity and that its functions are now accomplished by the ASBCA.

EFFECTIVE DATE: October 14, 1993.

FOR FURTHER INFORMATION CONTACT:

Tom O'Toole, NASA Headquarters, Office of Procurement, Procurement Policy Division (Code HP), Washington, DC 20546. Telephone: (202) 358-0482.

SUPPLEMENTARY INFORMATION:**Background**

On August 23, 1993, an interim rule to amend the NASA FAR Supplement to reflect the discontinuance of the NASA BCA and the assumption of its functions by the ASBCA was published in the Federal Register for comment (58 FR 44462). No public comments were received. Consequently, under the authority of 42 U.S.C. 2473(c)(1), NASA is adopting as a final rule the text set out as the interim rule at 58 FR 44462 with no changes.

Impact

NASA certifies that this regulation will not have a significant economic effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. et seq.). This rule does not impose any reporting or recordkeeping requirements subject to the Paperwork Reduction Act.

List of Subjects in 48 CFR Part 1833

Government Procurement.

Tom Luedtke,

Acting Deputy Associate Administrator for Procurement.

[FR Doc. 93-25253 Filed 10-14-93; 8:45 am]

BILLING CODE 7510-01-M

DEPARTMENT OF COMMERCE**National Oceanic and Atmospheric Administration****50 CFR Parts 227, 672, and 675**

[Docket No. 930949-3249; I.D. 092393A]

Threatened Fish and Wildlife; Groundfish of the Gulf of Alaska; Groundfish Fishery of the Bering Sea and Aleutian Islands Area; Steller Sea Lion Protection Areas

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

ACTION: Final rule; technical amendment.

SUMMARY: NMFS announces technical amendments to final rules implementing Steller sea lion protection areas authorized under the Endangered Species Act (ESA), the Fishery Management Plan (FMP) for Groundfish of the Gulf of Alaska (GOA), and the FMP for the Groundfish Fishery of the Bering Sea and Aleutian Islands management area (BSAI). The technical amendments revise regulations by correcting seven tables listing longitude and latitude of Steller sea lion

protection areas and correcting an illustration. The purpose of this action is to correct errors in the published regulations. These corrections are consistent with the goals and objectives of the ESA and the FMPs.

EFFECTIVE DATE: October 13, 1993.

FOR FURTHER INFORMATION CONTACT: Susan Mello, Protected Resources Management Division, Alaska Region, NMFS, 907-586-7235.

SUPPLEMENTARY INFORMATION:

Background

In late 1990, NMFS listed Steller sea lions as a threatened species under the ESA because of a drastic population decline (55 FR 49204, November 26, 1990). Coincident with the listing, NMFS implemented regulations at § 227.12 to protect Steller sea lions by restricting opportunities for intentional and unintentional harassment of sea lions. Specifically, these regulations: (1) Prohibit shooting at or near Steller sea lions; (2) prohibit, with limited exceptions, vessels from entering within 3 nautical miles (nm) (5.5 km) of listed Steller sea lion rookeries; (3) prohibit individuals on land from approaching within one-half mile (0.8 km) or within sight of listed Steller sea lion rookeries in the GOA and BSAI; and (4) limit the allowable annual take of Steller sea lions incidental to commercial fisheries to 675 animals in Alaskan waters and adjacent areas of the Exclusive Economic Zone (EEZ) west of 141° W. longitude.

The domestic groundfish fisheries in the EEZ of the BSAI and GOA are managed by the Secretary of Commerce under the FMPs. The FMPs were prepared by the North Pacific Fishery Management Council under the Magnuson Fishery Conservation and Management Act (Magnuson Act) and are implemented by regulations governing groundfish fishing at 50 CFR parts 672 and 675. General regulations that also apply to domestic fisheries are codified at 50 CFR part 620.

The growth of the BSAI and GOA groundfish trawl fisheries coincides temporally with the observed decline of the Steller sea lion population in Alaska. Negative interactions between these fisheries and Steller sea lions have been documented (e.g., intentional and unintentional lethal takes) and hypothesized (e.g., depletion of Steller sea lion prey resources by temporally and spatially compressed fishing). Subsequent to the ESA listing of Steller sea lions as threatened in 1990, NMFS further restricted groundfish trawling under the Magnuson Act to reduce the potential for the GOA and BSAI groundfish fisheries to affect negatively Steller sea lions, their habitat, and food resources. Currently, BSAI/GOA groundfish trawling is prohibited within 10 nm of all listed Steller sea lion rookeries year round, and within 20 nm of six listed rookeries during the BSAI winter pollock roe fishery (57 FR 2683, January 23, 1992, and 58 FR 13561, March 12, 1993).

The purpose of these technical amendments is to correct errors in the cited locations of certain listed Steller sea lion rookeries in the existing regulations. These corrections are consistent with positions of rookeries found in Table 1 of the final description of critical habitat for Steller sea lions (58 FR 45269, August 27, 1993). Minor corrections are needed to amend earlier transcription errors in the regulations, and to incorporate improved locational data from NMFS surveys. Amendments to 50 CFR parts 227, 672 and 675 include: (1) Corrections to seven tables listing longitude and latitude of Steller sea lion protection areas; and (2) corrections to an illustration of one rookery.

Classification

Because these technical amendments make minor corrections to existing rules, notice and public comment thereon and a delay in effective date would serve no purpose. Accordingly, under 5 U.S.C. 553 (b) and (d), notice

and public comment thereon and a delay in the effective date are unnecessary.

Because this rule is being issued without prior comment, it is not subject to the Regulatory Flexibility Act requirement for a regulatory flexibility analysis; none has been prepared.

This rule makes minor corrections to a rule that does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612 and does not contain a collection-of-information requirement for the purposes of the Paperwork Reduction Act. No changes in the regulatory impacts previously reviewed and analyzed will result from implementation of the technical amendment.

List of Subjects

50 CFR Part 227

Endangered and threatened species, Exports, Imports, Marine mammals, Transportation.

50 CFR Parts 672 and 675

Fisheries, Reporting and recordkeeping requirements.

Dated: October 5, 1993.

Samuel W. McKeen,

Program Management Officer, National Marine Fisheries Service.

For the reasons set out in the preamble, 50 CFR parts 227, 672, and 675 are amended as follows:

PART 227—THREATENED FISH AND WILDLIFE

1. The authority citation for part 227 continues to read as follows:

Authority: 16 U.S.C. 1531 *et seq.*

2. In § 227.12, paragraph (a)(3), Table 1 is amended by revising items 12, 20, 21, 26, 27 and 35 to read as follows:

§ 227.12 Steller sea lion.

(a) * * *

(3) * * *

Table 1.—LISTED STELLER SEA LION ROOKERY SITES¹

	From		To		NOAA Chart	Notes
	Lat.	Long.	Lat.	Long.		
12. Akun I	54°18.0N	165°32.5W	54°18.0N	165°31.5W	16547	Billings Head Bight.
20. Kasatochi I	52°10.0N	175°31.5W	52°10.5N	175°29.0W	16480	N half of Island.
21. Adak I	51°36.5N	176°59.0W	51°38.0N	176°59.5W	16460	SW Point, Lake Point.

Table 1.—LISTED STELLER SEA LION ROOKERY SITES¹—Continued

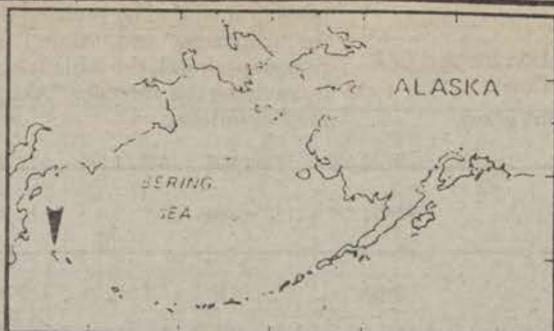
	From		To		NOAA Chart	Notes
	Lat.	Long.	Lat.	Long.		
26. Amchitka I	51°22.5N	179°28.0E	51°21.5N	179°25.0E	16440	East Cape.
27. Amchitka I	51°32.5N	178°49.5E			16440	Column Rocks.
35. Attu I	52°54.5N	172°38.5E	52°57.5N	172°31.5E	16681	S Quadrant.

¹ Each site extends in a clockwise direction from the first set of geographic coordinates along the shoreline at mean lower low water to the second set of coordinates; or, if only one set of geographic coordinates is listed, the site extends around the entire shoreline of the island at mean lower low water.

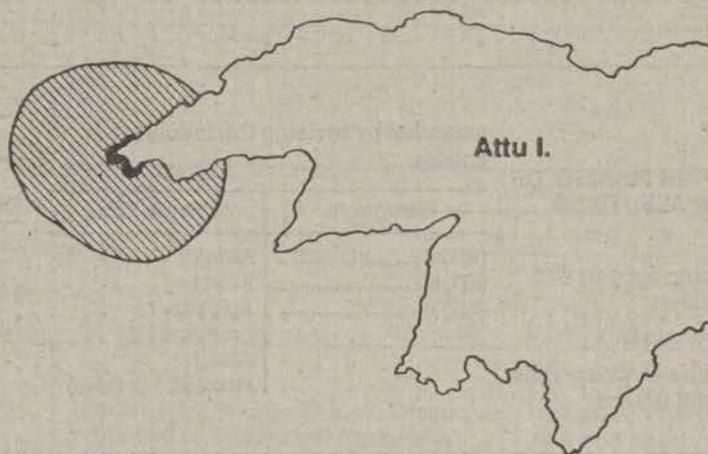
3. In § 227.12(a)(3), the illustration for the Attu Island Rookery is revised to read as follows:

BILLING CODE 3510-22-M

Bering Sea



Attu Island Rookery



53°10'N

52°50'

 Rookery  3 mile no entry zone

Chart 16420

172°30'E

173°00'

PART 672—GROUND FISH OF THE GULF OF ALASKA

4. The authority citation for part 672 continues to read as follows:

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

5. In § 672.24, paragraph (e)(1), the table is amended by revising the entries for "Chirikof I" and "Akun I" and in paragraph (e)(2), the table is amended by revising the entry for "Akun I" to read as follows:

§ 672.24 Gear limitations.

* * * * *
(e) * * *
(1) * * *

Island	From		To	
	Lat.	Long.	Lat.	Long.
Chirikof I	55° 46.5N	155° 39.5W	55° 46.5N	155° 43.0W
Akun I	54° 18.0N	165° 32.5W	54° 18.0N	165° 31.5W

* * * * *
(2) * * *

Island	From		To	
	Lat.	Long.	Lat.	Long.
Akun I	54° 18.0N	165° 32.5W	54° 18.0N	165° 31.5W

* * * * *

PART 675—GROUND FISH FISHERY OF THE BERING SEA AND ALEUTIANS ISLANDS AREA

6. The authority citation for part 675 continues to read as follows:

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

7. In § 675.24, the tables in paragraphs (f)(1) (i), (ii), (f)(2) (i), and (ii) are

amended by revising the following entries:

Paragraph	Entry in Table
(f)(1)(i)	Akun I
(f)(1)(ii)	Akun I
(f)(2)(i)	Agligadak I Kasatochi I Adak I Amchitka I (2 times)

Paragraph	Entry in Table
(f)(2)(ii)	Attu I Agligadak I

The revisions read as follows:

§ 675.24 Gear limitations.
* * * * *
(f) * * *
(1) * * *
(i) * * *

Island	From		To	
	Lat.	Long.	Lat.	Long.
Akun I	54° 18.0N	165° 32.5W	54° 18.0N	165° 31.5W

* * * * *
(ii) * * *

Island	From		To	
	Lat.	Long.	Lat.	Long.
Akun I	54° 18.0N	165° 32.5W	54° 18.0N	165° 31.5W

Island	From		To	
	Lat.	Long.	Lat.	Long.
.

(2) * * *
(i) * * *

Island	From		To	
	Lat.	Long.	Lat.	Long.
Agligadak I	52° 06.5N	172° 54.0W	.	.
Kasatochi I	52° 10.0N	175° 31.5W	52° 10.5N	175° 29.0W
Adak I	51° 36.5N	176° 59.0W	51° 38.0N	176° 59.5W
Amchitka I	51° 22.5N	179° 28.0E	51° 21.5N	179° 25.0E
Amchitka I	51° 32.5N	178° 49.5E	.	.
Gillion Point:
Attu I	52° 54.5N	172° 28.5E	52° 57.5N	172° 31.5E

(ii) * * *

Island	From		To	
	Lat.	Long.	Lat.	Long.
Agligadak I	52° 06.5N	172° 54.0W	.	.

[FR Doc. 93-24967 Filed 10-13-93; 8:45 am]
BILLING CODE 3510-22-M

50 CFR Part 661

[Docket No. 930402-3134; I.D. 100493C]

Ocean Salmon Fisheries Off the Coasts of Washington, Oregon, and California

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

ACTION: Inseason adjustments and closures.

SUMMARY: NMFS announces the following series of inseason management actions: The recreational fishery from Leadbetter Point,

Washington, to Cape Falcon, Oregon, will open on September 12 under a revised subarea coho salmon quota of 35,100 fish and will close at midnight, September 23, 1993; the recreational fisheries in the two subareas between Cape Alava and Leadbetter Point, Washington, will close at midnight, September 23, 1993; and the commercial fishery in the revised subarea between Leadbetter Point, Washington, and Cape Falcon, Oregon, will reopen for its final fishing period on September 16-19, 1993, with a possession and landing limit of a total of 70 coho salmon for this open period. These adjustments are intended to provide additional fishing opportunity to recreational fishermen and minimize disruption to the commercial fishery without exceeding the ocean share allocated to the recreational and commercial fisheries in the affected

subareas. The closures are necessary to respond to serious conservation concerns for coho salmon.

DATES: Adjustment of the recreational fishery from Leadbetter Point, Washington, to Cape Falcon, Oregon, effective at 0001 hours local time, September 17, 1993. Closure of the recreational fisheries from Cape Alava, Washington, to Cape Falcon, Oregon effective at 2400 hours local time, September 23, 1993. Adjustment of the commercial fishery from Leadbetter Point, Washington, to Cape Falcon, Oregon, effective at 0001 hours local time, September 16, 1993, through 2400 hours local time, September 19, 1993, and closure of this fishery effective at 2400 hours local time, September 19, 1993. Comments will be accepted through October 28, 1993.

ADDRESSES: Comments may be mailed to Rolland A. Schmitt, Director,

Northwest Region, National Marine Fisheries Service, NOAA, 7600 Sand Point Way NE., BIN C15700-Bldg. 1, Seattle, WA 98115-0070. Information relevant to this notice has been compiled in aggregate form and is available for public review during business hours at the office of the NMFS Northwest Regional Director.

FOR FURTHER INFORMATION CONTACT: William L. Robinson at (206) 526-6140.

SUPPLEMENTARY INFORMATION: In its amended emergency interim rule (58 FR 31664, June 4, 1993), NMFS announced the 1993 recreational and commercial fisheries north of Cape Falcon, Oregon. Inseason modifications of quotas, fishing seasons, limited retention regulations, recreational fishing days per calendar week, and boundaries are authorized by regulations governing the ocean salmon fisheries at 50 CFR 661.21(b)(1) (i), (ii), (iii), and (v). At the September 14-17, 1993 meeting of the Pacific Fishery Management Council in Portland, Oregon, the Washington Department of Fisheries presented a status report on coastwide coho salmon fisheries which indicated serious conservation concerns for natural and hatchery coho stocks, specifically Puget Sound and possibly Washington north coastal stocks. Coho salmon catch rates in many major fisheries were far below the rates that were expected if coho abundance was at the level forecast pre-season. The coho salmon catch in the Canadian West Coast of Vancouver Island troll fishery, for example, will be less than 1 million fish when the expected harvest was 1.7 million. Catch rates for coho salmon in other pre-terminal, terminal, and in-river test fisheries operated by the State and tribes have confirmed that many major wild Puget Sound coho stocks were returning in numbers significantly less than expected. As the month of September progressed, poor ocean catch rates and test fisheries in the Columbia River confirmed that Columbia River early and late hatchery coho stocks too were returning in lower numbers than expected. The Director, Northwest Region, NMFS (Regional Director) considered these conservation concerns in his determinations to close the remaining recreational and commercial salmon fisheries north of Cape Falcon, Oregon, in an orderly manner before the scheduled ending dates for these fisheries and the attainment of their respective quotas. These inseason management actions are described below.

The first inseason management action concerns the recreational fishery from Leadbetter Point, Washington, to Cape

Falcon, Oregon, which was scheduled to have two seasons: The first from July 5 through the earliest of September 9, or attainment of either the overall chinook quota north of Cape Falcon or the subarea coho salmon quota of 96,300 fish. The second from September 12 through the earliest of September 30 or attainment of either the overall chinook quota or the subarea coho salmon quota of 5,000 fish. The first season closed on September 9 as scheduled. Based on the best available information, the catch during the first season totaled 66,200 coho salmon, leaving 30,100 fish of the subarea coho quota unharvested. These fish were transferred to the second season which opened on September 12, resulting in a modified subarea quota of 35,100 coho salmon. This modification does not affect the overall recreational coho salmon quota north of Cape Falcon of 202,500 fish. The second season was scheduled to open Sunday through Thursday only.

The best available information on September 9, before conservation concerns for Puget Sound coho salmon were readily apparent, indicated that large amounts of coho salmon would remain unharvested at the end of the regularly scheduled season. Columbia River hatchery-produced coho salmon are the primary stock caught in this area. Thus, the recreational fishery in this subarea was opened September 12-23, and was scheduled to revert to the Sunday through Thursday fishing week by closing on September 24-25. This action would allow fishermen the opportunity to harvest returning hatchery coho salmon and would provide two additional fishing days, September 17-18. However, the best available information on September 24 indicated extremely poor coho salmon catch rates and effort levels in the Columbia River ocean area and inriver test fisheries confirmed possible conservation concerns for late-run hatchery coho. Thus, it was determined that the recreational fishery in the subarea between Leadbetter Point, Washington, and Cape Falcon, Oregon, should not reopen for the remainder of the season, and the fishery was closed for the remainder of the season effective 2400 hours local time, September 23 in order to conserve late-run Columbia River hatchery coho salmon.

The second inseason action concerns the recreational fisheries in the two subareas between Cape Alava and Leadbetter Point, Washington, which were scheduled to open July 5 and continue through the earliest of September 30 or attainment of either the overall chinook quota or the respective subarea coho salmon quotas. The best

available information on September 17 indicated substantial conservation concerns for Puget Sound coho, with several major stocks returning to terminal areas in much smaller numbers than expected. The remaining recreational subarea between Cape Alava and the United States/Canada border had already been closed to ensure the coho quota for this subarea was not exceeded (58 FR 46093, September 1, 1993). Thus, it was determined that the recreational fisheries in the subareas between Cape Alava and Leadbetter Point, Washington, should close for the remainder of the season, effective 2400 hours local time, September 23 in order to reduce impacts on returning Puget Sound coho salmon.

The third inseason action concerns the commercial fishery from the Queets River, Washington, to Cape Falcon, Oregon, which was scheduled to open August 27 and continue through the earliest of October 31 of attainment of subarea quotas of either 13,300 coho salmon or 900 chinook salmon. Preseason restrictions included a cycle of 2 days open and 3 days closed and a possession and landing limit of 35 coho salmon per opening. Earlier inseason actions increased the subarea quotas; lengthened the fishery's open period; and increased the possession and landing limit (58 FR 48001, September 14, 1993; 58 FR 50524, September 28, 1993). The best available information on September 14 indicated that sufficient fish remained to allow the commercial fishery in this subarea to reopen for 4 days, but that the northern boundary of the fishery should be moved from the Queets River southward to Leadbetter Point, Washington, to minimize impacts on Puget Sound coho stocks. Therefore, the commercial fishery from Leadbetter Point, Washington, to Cape Falcon, Oregon, was reopened from 0001 hours local time, September 16 through 2400 hours local time, September 19. Vessels were allowed to possess, land and deliver not more than a total of 70 coho salmon for the open period. However, the best available information on September 21 indicated extremely poor catch rates and effort levels in all areas. Because of urgent conservation concerns for Puget Sound coho, the commercial fishery from Leadbetter Point, Washington, to Cape Falcon, Oregon, was not reopened, and the fishery was closed for the remainder of the season effective 2400 hours local time, September 18.

The Regional Director consulted with representatives of the Pacific Fishery Management Council, the Washington

Department of Fisheries, and the Oregon Department of Fish and Wildlife, and the Washington coastal treaty Indian tribes regarding these adjustments affecting the recreational and commercial fisheries from Cape Alava, Washington, to Cape Falcon, Oregon. The States of Washington and Oregon will manage the commercial and recreational fisheries in state waters adjacent to this area of the EEZ in accordance with these Federal actions. In accordance with the inseason notice procedures of 50 CFR 661.23, actual notice to fishermen of these actions was given prior to the effective dates noted above by telephone hotline number (206) 526-6667 or (800) 662-9825 and by U.S. Coast Guard Notice to Mariners broadcasts on Channel 16 VHF-FM and 2182 Khz. Because of the need for immediate action, the Secretary of Commerce has determined that good cause exists for this notice to be issued without affording a prior opportunity for public comment. This notice does not apply to treaty Indian fisheries or to other fisheries that may be operating in other areas.

Classification

This action is authorized by 50 CFR 661.21 and 661.23 and is in compliance with Executive Order 12291.

List of Subjects in 50 CFR Part 661

Fisheries, Fishing, Indians, Reporting and recordkeeping requirements.

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

Dated: October 8, 1993.

Joe P. Clem,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93-25241 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-22-M

50 CFR Part 669

[Docket No. 930773-3247; I.D. 090893A]

RIN 0648-AE53

Reef Fish Fishery of Puerto Rico and the U.S. Virgin Islands

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

ACTION: Final rule.

SUMMARY: NMFS issues this final rule to implement Amendment 2 to the Fishery Management Plan for the Reef Fish Fishery of Puerto Rico and the U.S. Virgin Islands (FMP). Amendment 2 and this final rule incorporate the major species of the deep-water reef fish

fishery and the marine aquarium finfish fishery into the reef fish management unit; retitle the FMP to encompass the revised management unit; restrict the collection of marine aquarium fishes to hand-held dip nets and slurp guns; prohibit the harvest/possession/sale of certain species used in the marine aquarium trade; remove a requirement that the two escape panels required for each fish trap be located on opposite sides of the trap; prohibit the harvest or possession of jewfish; close two additional red hind spawning aggregation areas from December through February, in addition to the areas already closed; and close a spawning aggregation area for mutton snapper from March through June of each year. This final rule is intended to protect and conserve the highly exploited reef fish resources of Puerto Rico and the U.S. Virgin Islands.

EFFECTIVE DATE: November 15, 1993.

FOR FURTHER INFORMATION CONTACT:

Miguel A. Rolon, 809-753-6910 or William R. Turner, 813-893-3161.

ADDRESSES: Requests for copies of Amendment 2, the final supplemental environmental impact statement, the final regulatory impact review, and the final regulatory flexibility analysis should be sent to the Caribbean Fishery Management Council, 268 Ave Munoz Rivera, suite 1108, San Juan, PR, 00918-4577.

SUPPLEMENTARY INFORMATION: The shallow-water reef fish fishery is managed under the FMP prepared by the Caribbean Fishery Management Council (Council), and its implementing regulations at 50 CFR part 669, under authority of the Magnuson Fishery Conservation and Management Act (Magnuson Act).

Amendment 2 addresses continuing and growing concerns by the Council over scarce resources, the need to protect important species when they aggregate for spawning, and the need to extend protection to other reef-associated species not presently in the management unit. The specific management measures, and their backgrounds and rationales, were discussed in the proposed rule to implement Amendment 2 (58 FR 39186, July 22, 1993) and are not repeated here.

The NMFS Regional Director, Southeast Region, approved Amendment 2 on September 23, 1993. No public comments were received on the proposed rule or on Amendment 2; accordingly, the proposed rule is adopted as final without change.

Classification

The Secretary of Commerce (Secretary) determined that Amendment 2 is necessary for the conservation and management of the reef fish fishery and that it is consistent with the national standards, other provisions of the Magnuson Act, and other applicable law, except for the provision in Amendment 2 that would have authorized the use of 18-gauge ungalvanized wire as fasteners of escape panels on fish traps. Accordingly, the Secretary disapproved that provision. The basis for the disapproval was included in the proposed rule and is not repeated here.

The Council prepared a regulatory impact review (RIR), which concludes this rule would have national net economic benefits. A summary of those benefits was included in the proposed rule and is not repeated here.

The Council prepared an initial regulatory flexibility analysis (RFA) for this action. The initial RFA has been adopted as final without change. The final RFA concludes that this rule would have a significant economic impact on a substantial number of small entities.

The Council prepared a final supplemental environmental impact statement (SEIS) for Amendment 2. The final SEIS was filed with the Environmental Protection Agency which published in the *Federal Register*, on August 6, 1993, a notice of availability for public comment until September 7, 1993.

The Council determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal zone management programs of Puerto Rico and the U.S. Virgin Islands. This determination was submitted for review by the responsible state agencies under section 307 of the Coastal Zone Management Act. The state agencies did not respond within the statutory time period; therefore, state agency agreement with the consistency determination is presumed.

This final rule does not contain a collection-of-information requirement for purposes of the Paperwork Reduction Act.

This final rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

List of Subjects in 50 CFR Part 669

Fisheries, Fishing, Puerto Rico, Reporting and recordkeeping requirements, Virgin Islands.

Dated: October 7, 1993.

Samuel W. McKeen,
Program Management Officer, National
Marine Fisheries Service.

For the reasons set forth in the
preamble, 50 CFR part 669 is amended
as follows:

**PART 669—REEF FISH FISHERY OF
PUERTO RICO AND THE U.S. VIRGIN
ISLANDS**

1. The authority citation for part 669
continues to read as follows:

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

2. The heading for part 669 is revised
to read as set forth above.

3. Section 669.1 is revised to read as
follows:

§ 669.1 Purpose and scope.

(a) The purpose of this part is to
implement the Fishery Management
Plan for the Reef Fish Fishery of Puerto
Rico and the U.S. Virgin Islands,
prepared by the Caribbean Fishery
Management Council under the
Magnuson Act.

(b) This part governs conservation and
management of reef fish in or from the
EEZ around Puerto Rico and the U.S.
Virgin Islands.

4. In § 669.2, the definition for "*Fish
in the shallow-water reef fish fishery*" is
removed and a definition for "*Fish in
the reef fish fishery*" is added in its
place to read as follows:

§ 669.2 Definitions.

* * * * *

Fish in the reef fish fishery means any
of the following species:

Morays—Muraenidae
Chain moray, *Echidna catenata*
Green moray, *Gymnothorax funebris*
Goldentail moray, *Gymnothorax miliaris*
Snake eels—Ophichthidae
Goldspotted eel, *Myrichthys ocellatus*
Lizardfishes—Synodontidae
Sand diver, *Synodus intermedius*
Frogfishes—Antennariidae
Frogfish, *Antennarius* spp.
Batfishes—Ogcocephalidae
Batfish, *Ogcocephalus* spp.
Squirrelfishes—Holocentridae
Squirrelfish, *Holocentrus adscensionis*
Longspine squirrelfish, *Holocentrus rufus*
Blackbar soldierfish, *Myripristis jacobus*
Cardinal soldierfish, *Plectrypops
retrospinis*
Trumpetfishes—Aulostomidae
Trumpetfish, *Aulostomus maculatus*
Pipefishes—Syngnathidae
Seahorses, *Hippocampus* spp.
Pipefishes, *Syngnathus* spp.
Flying gurnards—Dactylopteridae
Flying gurnard, *Dactylopterus volitans*
Scorpionfishes—Scorpaenidae
Sea basses—Serranidae
Rock hind, *Epinephelus adscensionis*
Graysby, *Epinephelus cruentatus*

Yellowedge grouper, *Epinephelus
flavolimbatus*
Coney, *Epinephelus fulvus*
Red hind, *Epinephelus guttatus*
Jewfish, *Epinephelus itajara*
Red grouper, *Epinephelus morio*
Misty grouper, *Epinephelus mystacinus*
Nassau grouper, *Epinephelus striatus*
Butter hamlet, *Hypoplectrus unicolor*
Swissguard basslet, *Liopropoma rubre*
Yellowfin grouper, *Mycteroperca venenosa*
Tiger grouper, *Mycteroperca tigris*
Creole-fish, *Paranthias furcifer*
Greater soapfish, *Rypticus saponaceus*
Orangeback bass, *Serranus annularis*
Lantern bass, *Serranus baldwini*
Tobaccofish, *Serranus tabacarius*
Harlequin bass, *Serranus tigrinus*
Chalk bass, *Serranus tortugarum*
Basslets—Grammatidae
Royal gramma, *Gramma loreto*
Bigeyes—Priacanthidae
Bigeye, *Priacanthus arenatus*
Glasseye snapper, *Priacanthus cruentatus*
Cardinalfishes—Apogonidae
Flamefish, *Apogon maculatus*
Conchfish, *Astrapogon stellatus*
Tilefishes—Malacanthidae
Blackline tilefish, *Caulolatilus cyanops*
Sand tilefish, *Malacanthus plumieri*
Jacks—Carangidae
Yellow jack, *Caranx bartholomaei*
Blue runner, *Caranx crysos*
Horse-eye jack, *Caranx latus*
Black jack, *Caranx lugubris*
Bar jack, *Caranx ruber*
Greater amberjack, *Seriola dumerili*
Almaco jack, *Seriola rivoliana*
Snappers—Lutjanidae
Black snapper, *Apsilus dentatus*
Queen snapper, *Etelis oculatus*
Mutton snapper, *Lutjanus analis*
Schoolmaster, *Lutjanus apodus*
Blackfin snapper, *Lutjanus buccanella*
Gray snapper, *Lutjanus griseus*
Dog snapper, *Lutjanus jocu*
Mahogany snapper, *Lutjanus mahogani*
Lane snapper, *Lutjanus synagris*
Silk snapper, *Lutjanus vivanus*
Yellowtail snapper, *Ocyurus chrysurus*
Wenchman, *Pristipomoides aquilonaris*
Vermilion snapper, *Rhomboplites
aurorubens*
Grunts—Haemulidae
Porkfish, *Anisotremus virginicus*
Margate, *Haemulon album*
Tomtate, *Haemulon aurolineatum*
French grunt, *Haemulon flavolineatum*
White grunt, *Haemulon plumieri*
Bluestriped grunt, *Haemulon sciurus*
Porgies—Sparidae
Sea bream, *Archosargus rhomboidalis*
Jolthead progy, *Calamus bajonado*
Sheepshead progy, *Calamus penna*
Pluma, *Calamus pennatula*
Drums—Sciaenidae
High-hat, *Equetus acuminatus*
Jackknife-fish, *Equetus lanceolatus*
Spotted drum, *Equetus punctatus*
Goatfishes—Mullidae
Yellow goatfish, *Mulloidichthys martinicus*
Spotted goatfish, *Pseudupeneus maculatus*
Spadefishes—Ephippidae
Atlantic spadefish, *Chaetodipterus faber*
Butterflyfishes—Chaetodontidae
Longsnout butterflyfish, *Chaetodon
aculeatus*

Four-eye butterflyfish, *Chaetodon
capistratus*
Spotfin butterflyfish, *Chaetodon ocellatus*
Banded butterflyfish, *Chaetodon striatus*
Angelfishes—Pomacanthidae
Cherubfish, *Centropyge argi*
Queen angelfish, *Holacanthus ciliaris*
Rock beauty, *Holacanthus tricolor*
Gray angelfish, *Pomacanthus arcuatus*
French angelfish, *Pomacanthus paru*
Damsel-fishes—Pomacentridae
Sergeant major, *Abudefduf saxatilis*
Blue chromis, *Chromis cyanea*
Sunshinefish, *Chromis insolata*
Yellowtail damselfish, *Microspathodon
chrysurus*
Dusky damselfish, *Pomacentrus fuscus*
Beaugregory, *Pomacentrus leucostictus*
Bicolor damselfish, *Pomacentrus partitus*
Threespot damselfish, *Pomacentrus
planifrons*
Hawkfishes—Cirrhitidae
Redspotted hawkfish, *Amblycirrhitus pinos*
Wrasses—Labridae
Spanish hogfish, *Bodianus rufus*
Creole wrasse, *Clepticus parrae*
Yellowcheek wrasse, *Halichoeres
cyanocephalus*
Yellowhead wrasse, *Halichoeres garnoti*
Clown wrasse, *Halichoeres maculipinna*
Puddingwife, *Halichoeres radiatus*
Pearly razorfish, *Hemipteronotus novacula*
Green razorfish, *Hemipteronotus splendens*
Hogfish, *Lachnolaimus maximus*
Bluehead wrasse, *Thalassoma bifasciatum*
Parrotfishes—Scaridae
Midnight parrotfish, *Scarus coelestinus*
Blue parrotfish, *Scarus coeruleus*
Striped parrotfish, *Scarus croicensis*
Rainbow parrotfish, *Scarus guacamaia*
Princess parrotfish, *Scarus taeniopterus*
Queen parrotfish, *Scarus vetula*
Redband parrotfish, *Sparisoma
aurofrenatum*
Redtail parrotfish, *Sparisoma
chrysopteron*
Redfin parrotfish, *Sparisoma rubripinne*
Stoplight parrotfish, *Sparisoma viride*
Jawfishes—Opistognathidae
Yellowhead jawfish, *Opistognathus
aurifrons*
Dusky jawfish, *Opistognathus whitehursti*
Combtooth blennies—Blenniidae
Redlip blenny, *Ophioblennius atlanticus*
Gobies—Gobiidae
Neon goby, *Gobiosoma oceanops*
Rusty goby, *Priolepis hipoliti*
Surgeonfishes—Acanthuridae
Ocean surgeonfish, *Acanthurus bahianus*
Doctorfish, *Acanthurus chirurgus*
Blue tang, *Acanthurus coeruleus*
Lefeye flounders—Bothidae
Peacock flounder, *Bothus lunatus*
Soles—Soleidae
Caribbean tonguefish, *Symphurus arawak*
Leatherjackets—Balistidae
Scrawled filefish, *Aluterus scriptus*
Queen triggerfish, *Balistes vetula*
Whitespotted filefish, *Cantherhines
macrocerus*
Ocean triggerfish, *Canthidermis sufflamen*
Black durgon, *Melichthys niger*
Sargassum triggerfish, *Xanthichthys rigens*
Boxfishes—Ostraciidae
Spotted trunkfish, *Lactophrys bicaudalis*
Honeycomb cowfish, *Lactophrys polygona*

Scrawled cowfish, *Lactophrys quadricornis*
 Trunkfish, *Lactophrys trigonus*
 Smooth trunkfish, *Lactophrys triqueter*
 Puffers—Tetraodontidae
 Sharpnose puffer, *Canthigaster rostrata*
 Porcupinefish, *Diodon hystrix*

5. Section 669.7 is revised to read as follows:

§ 669.7 Prohibitions.

In addition to the general prohibitions specified in § 620.7 of this chapter, it is unlawful for any person to do any of the following:

(a) Fish with a fish trap in the EEZ without a vessel identification number and color code, as specified in § 669.6(a).

(b) Falsify or fail to display and maintain vessel and gear identification, as specified in § 669.6(c), (d), and (e).

(c) Fish in an area during a seasonal closure, as specified in § 669.21.

(d) Harvest or possess a Nassau grouper, jewfish, seahorse, or four-eye, banded, or longsnout butterflyfish in or from the EEZ, or fail to release such fish immediately with a minimum of harm; as specified in § 669.22(a) and (b).

(e) Harvest in the EEZ a marine aquarium fish by means other than a hand-held dip net or a hand-held slurp gun, as specified in § 669.22(c).

(f) Possess a yellowtail snapper in or from the EEZ that is smaller than the minimum size limit or is without its head and fins intact; or fail to release immediately with a minimum of harm an undersized yellowtail snapper caught in the EEZ; as specified in § 669.22(d).

(g) Fish in the EEZ with explosives or possess on board a vessel in the reef fish fishery any dynamite or similar explosive substance, as specified in § 669.23(a)(1).

(h) Fish in the EEZ with poisons, drugs, other chemicals, or a powerhead, as specified in § 669.23(a)(2) and (a)(3).

(i) Use or possess in the EEZ a fish trap that does not conform to the requirements for mesh sizes and escape panels, as specified in § 669.23(b)(1) and (b)(2).

(j) Tend, open, pull, molest, or have in possession another person's fish trap in the EEZ, except as specified in § 669.23(b)(3).

(k) Sell, purchase, trade, or barter, or attempt to sell, purchase, trade, or barter, a live red hind or live mutton snapper, as specified in § 669.24.

(l) Interfere with, obstruct, delay, or prevent by any means an investigation, search, seizure, or disposition of seized property in connection with enforcement of the Magnuson Act.

(m) Make any false statement, oral or written, to an authorized officer

concerning the taking, catching, harvesting, landing, sale, purchase, trade, barter, possession, or transfer of a reef fish.

6. Subpart B of part 669 is revised to read as follows:

Subpart B—Management Measures

Sec.

- 669.20 Fishing year.
 669.21 Seasonal area closures.
 669.22 Harvest limitations.
 669.23 Gear restrictions.
 669.24 Limitations on sale.
 669.25 Specifically authorized activities.

Subpart B—Management Measures

§ 669.20 Fishing year.

The fishing year for the reef fish fishery begins on January 1 and ends on December 31.

§ 669.21 Seasonal area closures.

(a) *Red hind spawning aggregation areas.* From December 1 through February 28, each year, fishing is prohibited in the following three areas. Each area is bounded by rhumb lines connecting the points in the order listed.

(1) South of St. Thomas:

Point	Latitude	Longitude
A	18°13.2'N.	65°06.0'W.
B	18°13.2'N.	64°59.0'W.
C	18°11.8'N.	64°59.0'W.
D	18°10.7'N.	65°06.0'W.
A	18°13.2'N.	65°06.0'W.

(2) West of Puerto Rico:

Point	Latitude	Longitude
A	18°11.0'N.	67°25.5'W.
B	18°11.0'N.	67°20.4'W.
C	18°08.0'N.	67°20.4'W.
D	18°08.0'N.	67°25.5'W.
A	18°11.0'N.	67°25.5'W.

(3) East of St. Croix:

Point	Latitude	Longitude
A	17°50.2'N.	64°27.9'W.
B	17°50.1'N.	64°26.1'W.
C	17°49.2'N.	64°25.8'W.
D	17°48.6'N.	64°25.8'W.
E	17°48.1'N.	64°26.1'W.
F	17°47.5'N.	64°26.9'W.
A	17°50.2'N.	64°27.9'W.

(b) *Mutton snapper spawning aggregation area.* From March 1 through June 30, each year, fishing is prohibited in the following area bounded by rhumb lines connecting the points in the order listed:

Point	Latitude	Longitude
A	17°37.9'N.	64°52.6'W.
B	17°38.2'N.	64°52.1'W.
C	17°38.3'N.	64°51.8'W.
D	17°38.1'N.	64°51.4'W.
A	17°37.9'N.	64°52.6'W.

§ 669.22 Harvest limitations.

(a) *Nassau grouper and jewfish.* Nassau grouper or jewfish may not be harvested or possessed in or from the EEZ. A Nassau grouper or jewfish caught in the EEZ must be released immediately with a minimum of harm.

(b) *Seahorses and four-eye, banded, and longsnout butterflyfish.* Seahorses and four-eye, banded, and longsnout butterflyfish may not be harvested or possessed in or from the EEZ. Such fish caught in the EEZ must be released immediately with a minimum of harm.

(c) *Marine aquarium fish.* A marine aquarium fish may be harvested in the EEZ only by a hand-held dip net or by a hand-held slurp gun. For the purposes of § 669.7(e) and this paragraph (c), a hand-held slurp gun is a device that rapidly draws seawater containing fish into a self-contained chamber, and a marine aquarium fish is a fish in the reef fish fishery that is smaller than 5.5 inches (14.0 cm), total length.

(d) *Yellowtail snapper—(1) Minimum size limit.* The minimum size limit for the possession of yellowtail snapper in or from the EEZ is 12 inches (30.5 cm) total length. An undersized yellowtail snapper caught in the EEZ must be released immediately with a minimum of harm.

(2) *Head and fins intact.* A yellowtail snapper possessed in the EEZ must have its head and fins intact and a yellowtail snapper taken from the EEZ must have its head and fins intact through offloading at a dock, berth, beach, seawall, or ramp. Such yellowtail snapper may be eviscerated but must otherwise be maintained in a whole condition.

§ 669.23 Gear restrictions.

(a) *Explosives, poisons, and powerheads.*

(1) Explosives may not be used in the EEZ to fish for fish in the reef fish fishery. A vessel in the reef fish fishery may not possess on board any dynamite or similar explosive substances.

(2) Poisons, drugs, or other chemicals may not be used in the EEZ to fish for fish in the reef fish fishery.

(3) A powerhead may not be used in the EEZ to fish for fish in the reef fish fishery. Possession of a powerhead and a mutilated fish in the reef fish fishery aboard a vessel in the EEZ or aboard a vessel after having fished in the EEZ

constitutes *prima facie* evidence that such reef fish was taken with a powerhead in the EEZ.

(b) *Fish traps*—(1) *Mesh size*. A bare-wire fish trap used or possessed in the EEZ that has hexagonal mesh openings must have a minimum mesh size of 1.5 inches (3.8 cm), in the smallest dimension measured between centers of strands. A bare-wire fish trap used or possessed in the EEZ that has other than hexagonal mesh openings must have a minimum mesh size of 2.0 inches (5.1 cm), in the smallest dimension measured between centers of strands. A fish trap of other than bare wire, such as coated wire or plastic, used or possessed in the EEZ must have a minimum mesh size of 2.0 inches (5.1 cm), in the smallest dimension of the opening (rather than between centers of strands).

(2) *Escape panels*. A panel must be located on each of two sides of the trap, excluding the top, bottom, and side containing the trap entrance. The opening covered by a panel must measure not less than 8 inches (20.3 cm) by 8 inches (20.3 cm). The mesh size of a panel may not be smaller than the mesh size of the trap. A panel must be attached to the trap with untreated jute twine with a diameter not exceeding 3/8 inch (.3 cm). An access door may serve as one of the panels, provided it is on an appropriate side, it is hinged only at its bottom, its only other fastening is at the top of the door so that the door will fall open when such other fastening degrades, and such other fastening is untreated jute twine with a diameter not exceeding 3/8 inch (.3 cm). Jute twine used to secure a panel may not be wrapped or overlapped.

(3) *Tending traps*. A fish trap in the EEZ may be tended or pulled only by a person (other than an authorized officer) aboard the fish trap owner's vessel(s), or aboard another vessel if such vessel has on board written consent of the fish trap owner, or if the fish trap owner is aboard and has documentation verifying his identification number and color code. An owner's written consent must specify the time period such consent is effective and the trap owner's identification number and color code. (See § 669.6 regarding identification numbers and color codes.)

§ 669.24 Limitations on sale.

A live red hind or live mutton snapper in or from the EEZ may not be sold, purchased, traded, or bartered, or attempted to be sold, purchased, traded, or bartered, that is, used in the marine aquarium trade.

§ 669.25 Specifically authorized activities.

The Secretary may authorize, for the acquisition of information and data, activities which are otherwise prohibited by these regulations.

§§ 669.4 and 669.6 [Amended]

7. In addition to the amendments set forth above, in 50 CFR part 669, the words "shallow-water" are removed where they appear in the following places: § 669.4 and § 669.6(a), (e)(1) introductory text, (e)(2) (two places), and (e)(3).

[FR Doc. 93-25185 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-22-M

50 CFR Part 672

[Docket No. 921107-3068; I.D. 100793A]

Groundfish of the Gulf of Alaska

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

ACTION: Prohibition of retention.

SUMMARY: NMFS is prohibiting retention of Pacific ocean perch (POP) in the Central Regulatory Area of the Gulf of Alaska (GOA) and is requiring that incidental catches be treated in the same manner as prohibited species and discarded at sea with a minimum of injury. This action is necessary because the POP total allowable catch (TAC) in this area has been reached.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), October 8, 1993, until 12 midnight, A.l.t., December 31, 1993.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, Resource Management Specialist, Fisheries Management Division, NMFS, 907-586-7228.

SUPPLEMENTARY INFORMATION: The groundfish in the GOA exclusive economic zone is managed by the Secretary of Commerce according to the Fishery Management Plan for Groundfish of the Gulf of Alaska (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations implementing the FMP at 50 CFR parts 620 and 672.

In accordance with § 672.20(c)(1)(ii)(B), the POP TAC for the Central Regulatory Area was established by the final 1993 initial specifications (58 FR 33778, June 21, 1993) as 949 metric tons.

The Director of the Alaska Region, NMFS, has determined, in accordance

with § 672.20(c)(3), that the TAC for POP in the Central Regulatory Area has been reached. Therefore, NMFS is requiring that further catches of POP in the Central Regulatory Area be treated in the same manner as prohibited species in accordance with § 672.20(e), effective from 12 noon, A.l.t., October 8, 1993, until 12 midnight, A.l.t., December 31, 1993.

Classification

This action is taken under 50 CFR 672.20.

List of Subjects in 50 CFR Part 672

Fisheries, Reporting and recordkeeping requirements.

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

Dated: October 7, 1993.

Joe P. Clem,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93-25237 Filed 10-8-93; 3:40 pm]

BILLING CODE 3510-22-M

50 CFR Part 675

[Docket No. 921185-3021; I.D. 100793]

Groundfish of the Bering Sea and Aleutian Islands Area

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

ACTION: Closure.

SUMMARY: NMFS is closing the directed fishery for pollock by the inshore component in the Aleutian Islands subarea (AI) of the Bering Sea and Aleutian Islands management area (BSAI). This action is necessary to prevent exceeding the allowance of the total allowable catch (TAC) of pollock for the inshore component in the AI.

EFFECTIVE DATE: 12 noon, Alaska local time (A.l.t.), October 8, 1993, until 12 midnight, A.l.t., December 31, 1993.

FOR FURTHER INFORMATION CONTACT: Andrew N. Smoker, Resource Management Specialist, Fisheries Management Division, NMFS, 907-586-7228.

SUPPLEMENTARY INFORMATION: The groundfish fishery in the BSAI exclusive economic zone is managed by the Secretary of Commerce according to the Fishery Management Plan for the Groundfish Fishery of the BSAI (FMP) prepared by the North Pacific Fishery Management Council under authority of the Magnuson Fishery Conservation and Management Act. Fishing by U.S. vessels is governed by regulations

implementing the FMP at 50 CFR parts 620 and 675.

In accordance with § 675.20(a)(2), the final 1993 initial specifications for groundfish in the BSAI (58 FR 8703, February 17, 1993), and subsequent reserve release (58 FR 14172, March 16, 1993), established the allowance of pollock TAC for vessels catching pollock for processing by the inshore component in the AI as 16,706 metric tons (mt).

The Director of the Alaska Region, NMFS (Regional Director), determined, in accordance with § 675.20(a)(8), that the allowance of pollock TAC for the

inshore component in the AI soon will be reached. Therefore, the Regional Director established a directed fishing allowance of 16,206 mt after determining that 500 mt will be taken as incidental catch in directed fishing for other species in the AI. Consequently, NMFS is prohibiting directed fishing for pollock by operators of vessels catching pollock for processing by the inshore component in the AI, effective from 12 noon A.l.t., October 8, 1993, until 12 midnight, A.l.t., December 31, 1993.

Directed fishing standards for applicable gear types may be found in the regulations at § 675.20(h).

Classification

This action is taken under § 675.20.

List of Subjects in 50 CFR Part 675

Fisheries, Reporting and recordkeeping requirements.

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

Dated: October 8, 1993.

Joe P. Clem,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93-25236 Filed 10-8-93; 3:40 pm]

BILLING CODE 3510-22-M

Proposed Rules

Federal Register

Vol. 58, No. 197

Thursday, October 14, 1993

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

Federal Crop Insurance Corporation

7 CFR Part 400

General Administrative Regulations; Actual Production History (APH) Coverage Program

AGENCY: Federal Crop Insurance Corporation, USDA.

ACTION: Proposed rule.

SUMMARY: The Federal Crop Insurance Corporation (FCIC) hereby issues proposed regulations to establish a plan of insurance called the Actual Production History (APH) Program. APH is an insurance coverage based on the insured's actual production history. An approved APH yield, when multiplied by a percentage of an elected coverage level and price per commodity unit, results in a dollar amount of insurance coverage per acre.

This rule is being proposed in accordance with the requirements of the Omnibus Budget Reconciliation Act of 1993. The intended effect of this rule is to help reduce FCIC's overall loss ratio to 1.1.

DATES: Written comments, data, and opinions on this proposed rule must be submitted not later than November 15, 1993, to be sure of consideration.

ADDRESSES: Written comments on this proposed rule should be sent to Mari Dunleavy, Regulatory Specialist, Regulatory and Procedural Development, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC 20250.

FOR FURTHER INFORMATION CONTACT: Mari Dunleavy, Regulatory Specialist, Regulatory and Procedural Development, Federal Crop Insurance Corporation, U.S. Department of Agriculture, Washington, DC, 20250, telephone (202) 254-8314.

SUPPLEMENTARY INFORMATION: This action has been reviewed under Executive Order 12291 and USDA procedures established by Departmental Regulation No. 1512-1. This action

constitutes a review as to the need, currency, clarity, and effectiveness of these regulations under those procedures. The sunset review date established for these regulations is September 1, 1998.

Kathleen Connelly, Acting Manager, FCIC, has determined that this action is not a major rule as defined by Executive Order 12291 because it will not result in: (a) An annual effect on the economy of \$100 million or more; (b) major increases in costs or prices for consumers, individual industries, federal, state, or local governments, or a geographical region; or (c) significant adverse effects on competition, employment, investment, productivity, innovation, or the ability of U.S.-based enterprises in domestic or export markets. The Acting Manager certifies that this action will not increase the federal paperwork burden for individuals, small businesses, and other persons and will not have a significant economic impact on a substantial number of small entities.

This action imposes no added burden on the insured farmer or on the private insurance company serving as the delivery agent. APH has been the basis for computing insurance guarantees under The Federal Crop Insurance Program for over eight years and has its genesis in The Individual Yield Coverage Plan (7-CFR 400.15-400.21). This proposed rule codifies procedure already effective. Therefore, this action is exempt from the provisions of the Regulatory Flexibility Act and no Regulatory Flexibility Analysis was prepared.

The program is listed in the Catalog of Domestic Assistance under No. 10.450.

This program is not subject to the provisions of Executive Order 12372 which require intergovernmental consultation with State and local officials. See the Notice related to 7 CFR Part 3015, subpart V, published at 48 FR 29115, June 24, 1983.

This action is not expected to have any significant impact on the quality of the human environment, health, and safety. Therefore, neither an Environmental Assessment nor an Environmental Impact Statement is needed.

The collection requirements for this proposed regulation have been previously approved by the Office of

Management and Budget under the provisions of 44 U.S.C. chapter 35, the Paperwork Reduction Act of 1980. Control numbers are found in 7 CFR part 400, subpart H.

The Office of General Counsel, as the Designated Official under section 6(a) of Executive Order 12612, Federalism, has determined that the policies and procedures contained in this interim rule will not have an increased substantial direct effect on states or their political subdivisions, or on the distribution of power and responsibilities among the various levels of government.

This rule has been reviewed in accordance with Executive Order 12778. The provisions of this interim rule are not retroactive and will preempt state and local laws to the extent such state and local laws are inconsistent. The administrative appeal provisions located at 7 CFR part 400, subpart J must be exhausted before judicial action may be brought for actions taken under these proceedings, for the imposition of civil penalties, or under the Program Fraud Civil Remedies sections of these regulations.

Background

The Omnibus Budget Reconciliation Act of 1993 (Pub. L. 103-66), amended the Federal Crop Insurance Act (7 U.S.C. 1501 *et seq.*) to require the establishment of a plan and the publication of regulations for the use of the producer's actual production to determine yield coverage. FCIC has used such a plan for a number of years. FCIC hereby proposes regulations in accordance with the statutory requirement.

An approved APH (Actual Production History) yield, multiplied by a percentage of an elected coverage level and price per commodity unit, provides the dollar amount of insurance coverage per acre. If the insured does not submit production records for insurance purposes, 65 percent of an FCIC estimated yield (transitional or determined yield) is the default approved APH yield. The FCIC estimated yield, after applicable adjustment, is used in conjunction with actual production records to compute the approved APH yield when less than four years of actual production records are available.

List of Subjects in 7 CFR Part 400

Actual Production History Coverage Plan, Crop Insurance.

Proposed Rule

Accordingly, pursuant to the authority contained in the Federal Crop Insurance Act, as amended by the Omnibus Budget Reconciliation Act of 1993, the Federal Crop Insurance Corporation hereby proposes to amend 7 CFR part 400 of the Code of Federal Regulations by adding a new subpart to read as follows:

Part 400—GENERAL ADMINISTRATIVE REGULATIONS**Subpart G—Actual Production History**

Sec.

- 400.50 Availability of actual production history program.
 400.51 Definitions.
 400.52 Yield certification and acceptability.
 400.53 Submission and accuracy of production reports.
 400.54 Qualifications for actual production history coverage program.
 400.55 Administrative appeal exhaustion.
 400.56 OMB control numbers.
 Authority: 7 U.S.C. 1506, 1516.

Subpart G Actual Production History**§ 400.50 Availability of actual production history program.**

An Actual Production History (APH) Coverage Program is offered under the provisions contained in the following regulations:

- 7 CFR 401.110 Almond Endorsement
 7 CFR part 405 Apple Crop Insurance
 7 CFR 401.103 Barley Endorsement
 7 CFR 401.118 Canning and Processing Bean Endorsement
 7 CFR 401.111 Corn Endorsement
 7 CFR part 409 Arizona-California Citrus Crop Insurance
 7 CFR 401.119 Cotton Endorsement
 7 CFR 401.121 Extra Long Staple Cotton Endorsement
 7 CFR 401.127 Cranberry Endorsement
 7 CFR part 433 Dry Beans Crop Insurance
 7 CFR 401.125 Fig Endorsement
 7 CFR 401.116 Flaxseed Endorsement
 7 CFR part 415 Forage Production Crop Insurance
 7 CFR 401.113 Grain Sorghum Endorsement
 7 CFR 401.130 Grape Endorsement
 7 CFR part 455 Macadamia Nut Crop Insurance
 7 CFR 401.105 Oat Endorsement
 7 CFR 401.126 Onion Endorsement
 7 CFR part 447 Popcorn Crop Insurance
 7 CFR part 403 Peach Crop Insurance
 7 CFR 401.140 Pear Endorsement
 7 CFR part 416 Pea Crop Insurance
 7 CFR 401.146 Fresh Plum Endorsement
 7 CFR part 422 Potato Crop Insurance
 7 CFR part 450 Prune Crop Insurance
 7 CFR 401.120 Rice Endorsement
 7 CFR 401.106 Rye Endorsement
 7 CFR 401.123 Safflower Seed Endorsement

- 7 CFR 401.117 Soybean Endorsement
 7 CFR 401.122 Stonefruit Endorsement
 7 CFR 401.133 Sugarcane Endorsement
 7 CFR part 430 Sugar Beet Crop Insurance
 7 CFR 401.124 Sunflower Seed Endorsement
 7 CFR part 437 Sweet Corn Crop Insurance
 7 CFR part 441 Table Grape Crop Insurance
 7 CFR 401.129 Guaranteed Tobacco Endorsement
 7 CFR 401.114 Canning and Processing Tomato Endorsement
 7 CFR part 454 Guaranteed Production Plan of Fresh Market Tomato
 7 CFR part 446 Walnut Crop Insurance
 7 CFR 401.101 Wheat Endorsement
 7 CFR part 457 Common Crop Insurance Regulations; and all special provisions thereto unless specifically excluded by the Special provisions.

The APH program operates within limits prescribed by, and in accordance with, the provisions of the Federal Crop Insurance Act, as amended (7 U.S.C. 1501 *et seq.*), only on those crops identified in this section in those areas where the actuarial table provides coverage. Except when in conflict with this subpart, all provisions of the applicable crop insurance contract for these crops apply.

§ 400.51 Definitions

In addition to the definitions contained in the crop insurance contract, the following definitions apply for the purposes of the APH Coverage Program:

- (a) *APH—Actual Production History.*
 (b) *Actual yield*—The yield per acre for a crop year calculated from the producer's records or claims for indemnities. The actual yield is determined by dividing total production (which includes harvested and appraised production) by planted acres. Assigned yields also are considered actual yields except for purposes of the Nonstandard Classification System.
 (c) *Adjusted yield*—The transitional or determined yield reduced by the applicable percentage for lack of records. The adjusted yield will equal 65% of the Transitional yield if no producer records are submitted; 80% if one year of records is submitted; and 90% if two years of records are submitted.
 (d) *Appraised production*—Production determined by Agricultural Stabilization and Conservation Service (ASCS), FCIC, or a company reinsured by FCIC, that was unharvested but which reflected the crop's yield potential at the time of the appraisal.
 (e) *Approved APH yield*—A yield, calculated and approved by the verifier, used to determine the production guarantee and determined by the sum of the yearly actual, assigned, and adjusted

or unadjusted transitional or determined yields in the database divided by the number of consecutive crop years in the database up to ten. (At least four consecutive crop years will always exist in the data base).

(f) *Assigned yield*—A yield assigned by FCIC in accordance with crop insurance contract if the insured does not file production reports as required by the crop insurance contract.

(g) *Base period*—Ten consecutive crop years (except peaches, which has a five crop year base period), immediately preceding the crop year for which the approved APH yield is being established (except for sugarcane, which begins the crop year preceding the immediate previous crop year).

(h) *Continuous production reports*—Reports submitted by a producer for each crop year that the unit was planted to the crop and for the most recent crop year in the base period.

(i) *Crop year*—Defined in the Crop Insurance Contract, however, for APH purposes the term does not include any year when the crop was not planted or when the crop was prevented from being planted by an insurable cause. For example, if an insured plants acreage in a county to wheat one year that year is a crop year in accordance with the policy definition. If the land is placed in summerfallowed the next year, that next year is not a crop year for the purpose of APH. If the insured is prevented from planting all the acreage in the county due to flood and does not plant, for harvest, any other crop, FCIC will assign a yield for that year.

(j) *Database*—A minimum of four crop years up to a maximum of ten crop years of production data used to calculate the approved APH yield.

(k) *Determined Yield (D-Yield)*—An estimated yield for certain crops which can be determined by multiplying an average yield for the crop, developed using data available from The National Agricultural Statistics Service or comparable sources, by a percentage established by FCIC for each county.

(l) *Master Yields*—Approved APH yields, as designated by FCIC, based on a minimum of four-years of production records within a county for a crop as designated by FCIC.

(m) *New producer*—A person who has not been actively engaged in farming for a share of the production of a crop for more than two years.

(n) *Production report*—A written record showing the insured's annual production and used by us to determine the insured's yield for insurance purposes. The report contains yield information including planted acreage and harvested production for the

previous crop year. This report must be supported by written verifiable records from a warehouseman or buyer of the insured crop or by measurement of farm stored production, or by other records of production approved by FCIC on an individual case basis. A Claim for Indemnity is considered a production report for the crop year for which the claim was filed.

(o) *Production Reporting Date (PRD)*—The PRD is defined in the crop insurance contract and is the last date production reports will be accepted for inclusion in the database for the current crop year.

(p) *Transitional Yield (T-Yield)*—An estimated yield, for certain crops, generally determined by multiplying the ASCS program yield by a percentage determined by FCIC for each county and provided on the actuarial table to be used in the APH yield calculation process when less than four years of actual or assigned yields are available.

(q) *Verifiable records*—Records of acreage and production provided by the insured which may be verified by FCIC through an independent source, and which may be used to substantiate the acreage and production that have been reported on the production report.

(r) *Verifier*—A person authorized by FCIC to calculate approved APH yields.

(s) *Yield variance tables*—Tables for certain crops that indicate unacceptable yield variations and yield trends that require the approved APH yield to be determined by FCIC.

§ 400.52 Yield certification and acceptability.

(a) Production reports must be provided to the crop insurance agent no later than the production reporting date for the crop insured.

(1) Production reports must provide an accurate account of planted acreage and harvested and appraised production by unit.

(2) The insured must certify to the accuracy of the information by signing the certification statement approved by FCIC.

(3) Production reported for more than one crop year must be continuous. A year in which no acreage was planted to the crop on a unit or no acreage was planted to a practice, type, or variety requiring an APH yield will not be considered a break in continuity. Assigned yields are an acceptable means to maintain continuity of yield data on file. Production on uninsured (for those years a crop insurance policy under the FCI Act is in effect) or uninsurable acreage (for other years of the period) will not be used to determine APH yield unless production from such acreage is

commingled with production from insured or insurable acreage.

(b) Production reports and supporting records are subject to audit or review to verify the accuracy of the information certified. At FCIC's discretion, audits and reviews will be performed to maintain the integrity of the APH program.

(1) Inaccurate reporting or failure to retain acceptable records may result in the verifier combining farm units and recomputing the APH yield. These actions may be taken at any time after reporting or record discrepancies are identified and may result in reduction of the APH yield for any crop year.

(2) Records must be provided by the insured at the time of an audit, review, or as otherwise requested, to verify that the acreage and production certified are accurate. Records of any other person having shares in the insured crop which are used by the insured to establish the approved APH yield must also be provided upon request.

(3) In the event acreage or production data certified by two or more persons sharing in the crop is different, the verifier shall, upon discretion, determine which acreage and production data will be used to determine the approved APH yield.

(4) Failure to report acreage and production completely and accurately may result in voidance of the crop insurance contract and criminal or civil false claims penalties pursuant to 18 U.S.C. 1006, 1014; 7 U.S.C. 1506; and 31 U.S.C. 3729, 3730.

§ 400.53 Submission and accuracy of production reports.

(a) The insured is solely responsible for the timely submission of accurate, complete production reports to the agent. Production reports must be provided for all units.

(b) Records may be requested by FCIC, or an insurance company reinsured by FCIC or by anyone acting on behalf of FCIC or the insurance company. The insured must provide such records upon request.

(c) The agent will explain the APH Program to insureds and prospective insureds. When necessary, the agent will assist the insured in preparation of production reports. The agent will determine the adjusted or unadjusted transitional or determined yields in accordance with § 400.54(b). The agent will review the production reports and forward them to the verifier along with any required supporting records for determination of an approved APH yield.

(d) The verifier will determine if production reports are acceptable and calculate the approved APH yield.

(e) It is the insured's sole responsibility to accurately and completely certify yield history.

§ 400.54 Qualification for actual production history coverage program.

(a) The approved APH yield is calculated from a database containing production reports from at least the four most recent crop years and will be updated each subsequent crop year. The database may contain a maximum of the ten most recent crop years and may include actual, assigned, and adjusted or unadjusted transitional or determined yields. Transitional or Determined yields, adjusted or unadjusted, will only occur in the database to replace actual yields for the four most recent crop years.

(b) The insured must provide production records of yield to determine the approved APH yield if production records for the most recent crop year are available. If acceptable records of actual production are provided, the records must be continuous and contain at least the most recent crop year of actual yields.

(1) If no acceptable production records are available the approved APH yield is the adjusted T-yield (65% of T-yield).

(2) If acceptable production records containing information for only the most recent crop year are provided, the actual yield and three transitional or determined yields adjusted by 80%, are used to complete the database and calculate the approved APH yield.

(3) If acceptable production records containing information for only the two most recent crop years are provided, the two actual yields and two transitional or determined yields adjusted by 90%, are used to complete the database and calculate the approved APH yield.

(4) If acceptable production records containing information for only the three most recent crop years are provided, the three actual yields and one unadjusted transitional or determined yield is used to complete the database and calculate the approved APH yield.

(5) When the database contains four or more (up to ten) continuous actual yields, the approved APH yield is a simple average of the actual yields.

(6) New producers may have their approved APH yields based on unadjusted transitional, determined, or actual yields

(c) If no insurable acreage of the insured crop is planted for a year, a production report indicating zero

acreage will maintain continuity of production reports for APH purposes and will not be included in the yield average computations.

(d) Optional units are not available to an insured not providing sufficient production records for at least the most recent crop year to compute an approved APH yield. Actual yields calculated from the Claim for Indemnity will be entered in the database. The resulting average yield will be used to determine the premium rate and approved APH yield, at the discretion of FCIC.

(e) FCIC reserves the authority to determine approved APH yields for designated crops in the following situations:

(1) If less than four years of yield history is certified and transitional or determined yields are not provided in the actuarial documents,

(2) If actual yields exceed tolerances specified in yield variance tables, and

(3) For perennial crops:

(i) If significant upward or downward yield trends are indicated,

(ii) If tree or vine damage or cultural practices will reduce production levels,

(iii) If more than 10 percent of the trees or vines have been removed within the last two years, or

(iv) If yield trends are evident, and yields greater than the average yield are requested by the insured.

(f) APH yields will not be approved the first insurance year on perennial crops until an inspection has been performed and the acreage is accepted for insurance purposes in accordance with the crop insurance contract.

(g) An APH Master Yield may be established whenever crop rotation requirements and land leasing limit the yield history available during the base period. FCIC will establish crops and locations for which Master Yields are available. To qualify, at least four continuous crop years of annual production reports must be certified for the crop within the base period. Acreage and production from all acreage of the crop in which the insured has an interest in the county may be used to establish Master Yields.

(h) FCIC may use any production reports available under the provisions of any crop insurance contract, whether continuous or not, which involve the interests of the insured person in determining the approved APH yield.

§ 400.55 Administrative appeal exhaustion.

The insured may appeal the approved APH yield in accordance with the procedures contained in 7 CFR part 400, subpart J. Administrative remedies through the appeal process must be

exhausted prior to any action for judicial review. The approved APH yield determined as a result of the appeal process will be the yield applicable to the crop year.

§ 400.56 OMB control numbers.

OMB control numbers are contained in 7 CFR part 400, subpart H.

Done in Washington, DC, on September 21, 1993.

Bob Nash,

Under Secretary, Small Community and Rural Development.

[FR Doc. 93-25143 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-06-M

Cooperative State Research Service

7 CFR Part 3408

Administrative Manual for Federal Excess Personal Property Loaned to State Cooperative Research Activities

AGENCY: Cooperative State Research Service, USDA.

ACTION: Notice of proposed rulemaking.

SUMMARY: In 1981, Congress passed a law, which included an amendment to the Federal Property and Administrative Services Act to permit the Secretary of Agriculture to loan Federal excess personal property to Land-Grant Institutions engaged in cooperative extension or cooperative research programs funded by the U.S.

Department of Agriculture (USDA). Although the Federal Property Management Regulations (FPMRs) contained the basic rules governing Federal property, they did not deal with the specific procedures for participation by the Land-Grant Institutions. The office of USDA delegated responsibility for management of this program is the Cooperative Management Staff (CMS), which provides administrative services to the Extension Service and the Cooperative State Research Service. CMS developed a handbook to clearly spell out the specific agency requirements for participating in this new program as well as the applicable rules contained in the FPMRs. Since this handbook and the procedures it contains are used by non-Federal recipients of Government property, a decision was made to publish the handbook in the *Federal Register* and solicit comments before final publication of the rule. This proposed rulemaking sets forth procedures for utilization of Federal excess personal property loaned by the Cooperative State Research Service (CSRS) as authorized by the amendment to the

Federal Property and Administrative Services Act. This proposed rule includes not only the CSRS procedures for participation by State Cooperative Research Activities in the Program, but also summarizes the Department of Agriculture and General Services Administration requirements. Although this Program will be administered for CSRS by the Extension Service (ES), USDA, this proposed rule does not apply to Federal excess personal property loaned by ES to State and County Extension Services authorized by the same Federal Property and Administrative Services Act amendment.

DATES: Comments are invited from interested individuals and organizations and must be received in writing on or before November 15, 1993.

ADDRESSES: Comments should be sent to Betty Bolt, Property Management Officer, USDA, ES, CMS, AG BOX 0993, Washington, DC 20250-0993.

FOR FURTHER INFORMATION CONTACT: Betty Bolt, Property Management Officer, at 202/401-4502.

SUPPLEMENTARY INFORMATION:

Comments

Please note that because CSRS is unable to change the portions of this part which reflect General Services Administration policy, comments on those portions are not appropriate for this proposed rulemaking.

Paperwork Reduction

The forms necessary to implement these procedures have been cleared by OMB as required in the Paperwork Reduction Act (44 U.S.C. 3500 *et seq.*). The only form that has been included in this document relates to the transfer of date-expired pharmaceuticals to Colleges of Veterinary Medicine. The form, which is set out as appendix A, is the Agreement that must be entered into by each College of Veterinary Medicine that wishes to obtain date-expired pharmaceuticals.

The procedures outlined in this part do not require the collection of information as outlined in the Paperwork Reduction Act of 1980 and therefore it has been determined that clearance by the Office of Management and Budget is not needed.

Classification

This rule has been reviewed under Executive Order No. 12291, and it has been determined that it is not a major rule because it does not involve a substantial or major impact on the Nation's economy or on large numbers of individuals or businesses. It will not

have a significant economic impact upon a substantial number of small entities as defined in the Regulatory Flexibility Act; therefore, no regulatory flexibility analysis needs to be performed under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*).

The following information is given in compliance with Executive Order 12778. All State and local laws and regulations that are in conflict with this rule are preempted. No retroactive effect is to be given to this rule. This rule does not require administrative proceedings before parties may file suit in court.

Regulatory Analysis

Not required for this rulemaking.

Environmental Impact Statement

This proposed rule does not significantly affect the environment. Therefore, an environmental impact statement is not required under the National Environmental Policy Act of 1969, as amended (42 U.S.C. 4321 *et seq.*).

Catalog of Federal Domestic Assistance

Not required for this rulemaking.

List of Subjects in 7 CFR Part 3408

Government property, Government property management, Excess Government property.

For the reasons set forth in the preamble, 7 CFR part 3408 is proposed to be added to read as follows:

PART 3408—ADMINISTRATIVE MANUAL FOR FEDERAL EXCESS PERSONAL PROPERTY LOANED TO STATE COOPERATIVE RESEARCH ACTIVITIES

Sec.	
3408.1	Purpose.
3408.2	Abbreviations and definitions.
3408.3	Policy.
3408.4	Responsibility.
3408.5	Accountable property officer.
3408.6	Accountability and control of Federal excess personal property.
3408.7	Acquisition of Federal excess personal property.
3408.8	Use of Federal excess personal property.
3408.9	Reporting Federal excess personal property.
3408.10	Transfer of Federal excess personal property.
3408.11	Donation of surplus property.
3408.12	Unserviceable property.
3408.13	Lost, damaged, stolen, or destroyed property.

Appendix A to part 3408—Agreement for Transfer of Date-expired Pharmaceuticals to Colleges of Veterinary Medicine by the Cooperative State Research Service

Authority: 5 U.S.C. 501.

§3408.1 Purpose.

(a) This part sets forth the basic requirements to be followed by State Cooperative Research Activity personnel in establishing and maintaining control of Federal excess personal property provided by the Cooperative State Research Service (CSRS) under 40 U.S.C. 483 (d)(2)(E). 40 U.S.C. 483 (d)(2)(E) permits the Secretary to obtain Federal excess personal property and loan such property to State or County Extension Services, State Agricultural Experiment Stations, 1890 Land-Grant Colleges, including Tuskegee University, accredited colleges of veterinary medicine, and cooperating forestry schools, to further the purposes of the Smith-Lever Act, the Hatch Act of 1887, the McIntire-Stennis Act of 1962, and the research and extension programs authorized by sections 1433, 1434, 1444, and 1445 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977. Title to Federal excess personal property furnished—pursuant to 40 U.S.C. 483(d)(2)(E) remains vested in the United States.

(b) This part covers only the acquisition, utilization, control, and disposal of Federal excess personal property acquired by State Cooperative Research Activities (as defined herein) through the CSRS Federal Excess Personal Property Loan Program (Program) administered for CSRS by the Extension Service (ES), USDA. This part does not apply to Federal excess personal property loaned to State and County Extension Services by ES pursuant to 40 U.S.C. 483(d)(2)(E).

§3408.2 Abbreviations and definitions.

The following definitions apply to this part:

Accountable Property. All nonexpendable personal property having an acquisition cost of \$1,000 or more (except furniture which is \$500 or more) or items of property valued less than \$1,000 but determined by an Agency Property Management Officer to be sensitive.

Administrative Head. The official designated in the following list at each State Cooperative Research Activity:

- (1) Director, State Agricultural Experiment Station;
- (2) Administrator, 1890 Cooperative Agricultural Research Program;
- (3) Dean, College of Veterinary Medicine; and
- (4) Administrative-Technical Representative, School of Forestry, who has overall responsibility for management of the Program.

Administrator of Cooperative State Research Service. The USDA official to

whom the Secretary of Agriculture has delegated his authority under 40 U.S.C. 483(d)(2)(E), to obtain Federal excess personal property and loan it to State Cooperative Research Activities.

APO. Accountable Property Officer. The State Cooperative Research Activity employee designated by the Administrative Head to act as his/her representative in personal property matters.

Approved Research Program. A set of approved projects which define the research to be conducted by a State Cooperative Research Activity with Federal funds appropriated pursuant to an act listed in 40 U.S.C. 483(d)(2)(E).

Approved Research Project. A State Cooperative Research Activity administrative or research project (having specific objectives, defined research procedures, specific date of initiation and completion) which has been approved by the Cooperative State Research Service for the expenditure of funds appropriated pursuant to 7 U.S.C. 361a. *et seq.*; 7 U.S.C. 3195, 3196, 3221, and 3222; or 16 U.S.C. 582a *et seq.*

AUO. Area Utilization Officer, A GSA regional property specialist.

Cannibalize. The act of dismantling a piece of property for usable parts when the property is unserviceable as a unit.

CMS. Cooperative Management Staff, CSRS/ES—USDA.

CSRS. Cooperative State Research Service of the United States Department of Agriculture.

DEPPC. Departmental Excess Personal Property Coordinator. The USDA national excess property clearinghouse, located in St. Louis, Missouri.

Excess Personal Property. Any personal property under the control of any Federal agency which is not required for its needs and the discharge of its responsibilities, as determined by the head thereof (41 CFR 101-43.001-6).

Expendable Property. An article of property which is consumed or loses its identity when placed in use or has an expected service life of less than two years.

FPMR. Federal Property Management Regulations (41 CFR chapter 101).

Freeze. The process of reserving at a holding activity, or at a controlling GSA regional office, an item of excess personal property that has been requested by a user or selected by a GSA area utilization officer or other GSA representative to fill an existing or known requirement (41 CFR 101-43.001-11).

Gross Negligence. The intended, willful, or wanton failure to exercise a reasonable degree of care to protect property in one's custody or his/her

reckless disregard for that degree of care.

GSA. The General Services Administration, acting by or through the Administrator of General Services, or a designated official to whom the Administrator has delegated relevant functions (41 CFR 101-43.001-12).

MSB. Management Services Branch, Personnel and Management Services Division, CMS, CSRS/ES—USDA.

Non-Expendable Property. Personal property which is complete in itself, retains its identity when placed in use and has an expected service life of over 2 years.

OMB. Office of Management and Budget.

Personal Property. Any property, except real property, records of the Federal Government, and Naval Vessels of the following categories: Battleships, Cruisers, Aircraft carriers, Destroyers, and Submarines (41 CFR 101-43-001-23).

PMO. Property Management Officer, CMS, CSRS/ES—USDA.

PMSD. Personnel and Management Services Division, CMS, CSRS/ES—USDA.

Screen. Onsite examination of excess property.

Sensitive Personal Property. Any item of accountable property valued less than \$1,000 which is highly susceptible to loss or theft as determined by the Agency Property Management Officer.

SRD. Surplus Release Date. The predetermined date on which Federal utilization of excess personal property is terminated. The date signifies the transition of the property from excess to surplus status. This term is equivalent to "automatic release date" or "ARD". (41 CFR 101-43.001-32).

State Cooperative Research Activity. An eligible participant under the provisions of 40 U.S.C. 483(d)(2)(E). These include:

- (1) State Agricultural Experiment Stations;
- (2) Cooperative Agricultural Research, 1890 institutions;
- (3) McIntire-Stennis Schools of Forestry; and
- (4) Colleges of Veterinary Medicine.

Surplus Personal Property. Any excess personal property not required for the needs and the discharge of the responsibilities of all Federal agencies, as determined by the Administrator of General Services (41 CFR 101-43.001-31).

Unserviceable Property. Property beyond economical repair and not worth the cost to continue storage or handling.

USDA. United States Department of Agriculture.

§ 3408.3 Policy.

(a) It is the policy of CSRS that Federal excess personal property loaned to State Cooperative Research Activities under the authority of 40 U.S.C. 483(d)(2)(E) will be used only to further the purposes of the cooperative agricultural research programs of the acts identified in 40 U.S.C.(d)(2)(E). Further, it is the policy of the CSRS to ensure that all Federal excess personal property acquired through CSRS for the use of a State Cooperative Research Activity is properly and effectively managed in accordance with applicable guidelines as expressed in the FPMR's, OMB Circular A-110 (Copies of the circular are available at the address listed in 5 CFR 1310.3.), USDA Uniform Federal Assistance Regulations (7 CFR part 20), and this part. All Federal excess personal property and equipment shall be properly maintained using equipment manufacturer's suggested maintenance procedures. All Federal excess personal property items will be utilized properly and to the fullest extent possible.

(b) Administrative Heads are encouraged to consider the use of Federal excess personal property in order to minimize procurement of new items. Federal excess personal property should be acquired in accordance with plans for immediate and specific use. In addition, Administrative Heads should provide for a continuous survey of all Federal excess property in their inventory to determine if any items have become excess to their needs. All such property should be declared in accordance with § 3408.9.

§ 3408.4 Responsibility.

(a) **Accountability.** Each Administrative Head will be directly responsible and accountable for all Federal excess personal property furnished by or through CSRS. Each Administrative Head shall establish and maintain a property management and accounting system in accordance with the provisions of this part to control, protect, preserve, and maintain all Federal excess personal property obtained for CSRS projects and programs. Property records and other supporting information shall be made available as required for audits or reviews. State Cooperative Research Activity property systems shall be reviewed periodically by a CMS staff official, and written reports of performance shall be provided to the State Administrative Head.

(b) **Liability of Administrative Heads.** Administrative Heads may be held liable for Federal excess personal property that is lost, damaged, stolen, or

abused if it is determined that the loss was attributed to gross negligence. Liability will be based upon all of the circumstances surrounding each case.

§ 3408.5 Accountable property officer.

(a) **APO.** Each Administrative Head shall designate from his organization a person to serve as his/her representative and liaison with the PMO, CMS, and with GSA on personal property management matters. This person shall be APO for a given location or jurisdiction over which he/she is responsible.

(b) **Duties.** The principal duties and responsibilities of the APO are to:

- (1) Assign and control all personal property under his/her jurisdiction.
- (2) Assure that property is effectively utilized for only the authorized purposes and properly maintained.
- (3) Obtain approval from the PMO, CMS, for all Federal excess personal property acquisitions, transfers, modifications, cannibalizations, and disposals.
- (4) Conduct the biennial physical inventory and other inventories as appropriate.
- (5) Safeguard Government property against theft, damage, and misuse.
- (6) Report all lost, damaged, stolen, and unserviceable Federal excess personal property to the PMO, CMS.
- (7) Approve and document loans of Federal excess personal property to employees for authorized purposes outside the office.
- (8) Maintain a personal property inventory listing of all items assigned. Write in all changes as they occur, such as reassignments, physical changes, excess/disposal, etc.

§ 3408.6 Accountability and control of Federal excess personal property.

(a) **Accountable (non-expendable) personal property.** Accountable (non-expendable) personal property represents the Federal Government's investment in major equipment items, furniture, appliances, motor vehicles, etc. These items are to be strictly accounted for in each State Cooperative Research Activity inventory system.

(1) **Classification guidelines.** Administrative Heads and APO's are guided in their classification of accountable property by the following criteria. An item must:

- (i) Have a unit acquisition cost of \$1,000 or more except furniture which is \$500 or more;
- (ii) Be complete in itself;
- (iii) Not lose its identity or become a component part of other equipment; and
- (iv) Have an expected service life of 2 years or more.

(2) *Property controls.* Each Administrative Head or his/her APO is responsible for the proper control, accountability, and use of Federal property in his/her area of responsibility. These controls include:

(i) Obtaining approval from the PMO, CMS for all acquisitions, transfers, modifications, cannibalizations, and disposals;

(ii) Certifying that all requests for Federal excess personal property are needed and are used in connection with an approved CSRS-sponsored project or program;

(iii) Providing for appropriate identification of all Federal excess personal property by prominently placed decals or other suitable and approved methods of identification. (The PMO, CMS will provide decals for identifying Federal property.);

(iv) Establishing an accurate inventory system approved by CMS;

(v) Assuring full utilization of Federal excess personal property obtained; and

(vi) Requesting prompt disposal instructions for property items which are no longer needed.

(3) *Official property records.* The official property records for Federal excess personal property shall contain, as a minimum, the following information:

(i) Property identification (serial number, property or ID number),

(ii) Name and description of the property, including manufacturer;

(iii) Manufacturer's model/part number, serial number, stock number, and year manufactured (when available);

(iv) Source of acquisition;

(v) Acquisition date, document reference, Federal Supply Classification number, and unit cost or value;

(vi) Location, use, and custodian of the property; and

(vii) Disposition data, including document reference, date, and any other pertinent information to provide a complete audit trail.

(4) *Inventory and reconciliation.* (i) Physical inventories of Federal excess personal property shall be taken every two (2) years. Physical inventories may be scheduled to correspond with established inventory schedules provided they meet the minimum requirements outlined in this part. State APO's are responsible for reconciling their inventories with the official property records. Any discrepancies between the quantities revealed in the physical inventory and those shown on the property records shall be investigated by the APO to determine the cause of differences. Unserviceable and missing Federal excess personal

property shall be reported to the PMO, CMS on Form AD-112, Report of Unserviceable, Lost, or Damaged Property (see § 3408.12). A detailed explanation of the circumstances involving lost, damaged, stolen, or destroyed property, including the employee's name to whom the property was assigned, the time and date of loss (or approximation), and last known location of the property is required.

(ii) Report all Federally owned property that is excess to program needs on Form SF-120, Report of Excess Personal Property (see § 3408.9); and

(iii) Copies of reconciled physical inventories shall be sent to the PMO, CMS upon completion. Administrative Heads or Accountable Property Officers shall certify the accuracy of inventory submissions by signing the following statement which would accompany the reconciled report:

I have reviewed the enclosed documents for all Federal excess personal property acquisitions by this organization since 1982. I certify that I have taken or caused to be taken, a physical inventory of all the property transferred to this State Cooperative Research Activity, and for which I am responsible. All of the items listed, unless otherwise indicated, continue to be needed and in use. I further certify that all property not currently needed to carry out the approved responsibilities and functions of this location has been or will be reported as excess.

Date: _____
Signature: _____
Name & Title: _____
State: _____

(b) *Sensitive property.* Certain personal property items may be charged to individuals. These items are normally classified as sensitive property because of their uniqueness, value, or high vulnerability to theft and misuse. Such property should be controlled and recorded but not kept in the official inventory records unless the acquisition cost is \$1,000 or more (except furniture with an acquisition cost of \$500 or more). Examples of sensitive items are cameras, pocket-size electronic calculators, laptop computers, dictating machines, etc. Employees who have been so charged should be cleared of the items upon separation.

(c) *Non-accountable property.* Non-accountable property consists of items that have an acquisition cost of less than \$1,000 (or less than \$500 for furniture) and an expected service life of less than two years. Non-accountable property is not to be included in the official records. Non-accountable items judged sensitive should be kept separate from the official property records but charged to the appropriate individuals. Although non-accountable property is not a part

of the official inventory, these items should be kept under reasonable control to assure proper utilization and to provide protection against theft, misuse, or unnecessary deterioration.

§ 3408.7 Acquisition of Federal excess personal property.

(a) *Authorization.* Each State Cooperative Research Activity is authorized to acquire Federal excess personal property through CSRS acting as the sponsoring agency. The Program is managed by the PMO, CMS, who is responsible for approval of requests, maintenance of official property records, training, site reviews, and the conduct of inventories. This authorization is granted to each Administrative Head of each State Cooperative Research Activity or his/her APO who shall carry out the following requirements:

(1) Certify for accuracy and propriety all documents related to the acquisition, transfer, modification, cannibalization, or disposal of Federal excess personal property;

(2) Identify all Federal excess personal property with appropriate labels or decals;

(3) Report promptly all Federal excess personal property that becomes excess to program requirements;

(4) Assume responsibility for Federal excess personal property, including accountability and utilization, in connection with approved Cooperative Research projects or programs;

(5) Provide assurance that the procedures contained in this Part are followed; and

(6) Only request property for use in approved research projects (see § 3408.2(g)).

(b) *USDA excess personal property.* DEPPC is the organization in USDA that acts as a clearinghouse for excess property generated by the Department nationwide. DEPPC publishes a monthly bulletin listing USDA excess property by location and condition and provides a contact for further inquiries.

(1) *Procedures for acquisition.* (i) Requests for Federal excess personal property made available through DEPPC should be prepared on Form SF-122, Transfer Order Excess Personal Property and submitted to the PMO, CMS, for review and Federal approval. Approved requests will be forwarded to DEPPC. A separate SF-122 must be submitted for each reporting (holding) agency and for each property location.

(ii) Submit the completed SF-122, Transfer Order Excess Personal Property for Agency review and approval to: USDA, CSRS; Attn: PMO; Ag Box 0993; Washington, DC 20250-0993.

(iii) Also, be sure to include the FSC Group Number and condition code for each property item.

(2) *DEPPC selection procedures.* DEPPC has sole authority for the assigning of Departmental excess personal property to requesting agencies. DEPPC selection procedures are:

(i) All requests will be held until the closing date of the list, unless immediate transfer authorization is justified because of need or other circumstances;

(ii) When more than one request is received for the same item, preference will be given to a unit of the agency reporting the item. Otherwise, the transfer authorization will be determined after consideration of such factors as need statements, proximity of transferee in regard to transportation, packing and loading facilities, etc.; and

(iii) Promptly after the list closes, a copy of each request will be returned to the requestor showing whether the items were authorized for transfer.

(c) *General Services Administration excess personal property.* Personal property declared excess by an agency of the Federal Government is made available to other government agencies through the Federal excess personal property program administered by GSA.

(1) Property available for acquisition can be identified through:

(i) Review of GSA Regional Excess Property catalogs and bulletins distributed by GSA;

(ii) Personal contact with the GSA, AUO, or the holding installation; and

(iii) Examination and inspection of reports and samples of excess property assembled for this purpose in GSA Regional Offices.

(2) Property needed in the conduct of an approved research program as defined in § 3408.2(f) may be requested by submission of GSA Form 1539, Request for Excess Personal Property, outlining current and future personal property requirements. GSA Form 1539, submitted to the appropriate GSA regional office, will be reviewed by property utilization specialists in an effort to match agency needs with property becoming available for transfer. Requests to excess personal property should be limited to single line items valued at \$500 or more. Include a full description of the item requested and the minimum condition acceptable.

(3) Each Administrative Head will identify a limited number of State Cooperative Research Activity employees (usually no more than three) to screen property available for acquisition through GSA. Those appointed must have a GSA Screener's

Identification Card or a U.S. Government ID to inspect Federal excess personal property available through GSA. GSA Form 2946 may be obtained from the PMO, GMS. Completed forms must be submitted to the PMO, CMS, for review and approval. GSA Form 2946 will then be submitted to GSA for approval. When a screener's authorization is terminated or the card has expired, GSA Form 2946 must be returned to the PMO, CMS, for cancellation. Excess personal property screeners should be familiar with GSA AUO's. They can provide valuable assistance in locating and filling specific property requests.

(4) *Procedures for acquisition.* Federal excess personal property identified for possible acquisition may be secured through the following procedures:

(i) Place a "Freeze Request" call to the GSA regional office, listing the property to be acquired. This will reserve the property for inspection and preparation of forms for possible acquisition;

(ii) Personally inspect the property to determine its condition and usefulness to the project or program for which it is to be acquired (see § 3408.7 (c)(3), Screener's Identification Card). On-site inspections are strongly recommended to assure stated condition. Should personal inspection be impractical, information as to the nature and condition of the property may be secured from the reporting agency official with personal knowledge of the property in question; and

(iii) (A) Submit completed SF-122, Transfer Order Excess Personal Property for Agency review and approval to: USDA, CSRS; Attn: PMO, Ag Box 0993; Washington, DC 20250-0993.

(B) This form will be forwarded to the appropriate GSA Regional Office for final action. Submit a separate SF-122 for each reporting (holding) agency and each property location. Each property item must be identified by the correct FSC group number and condition code.

(C) The Administrative Head, or his/her APO, must approve a certification typed on the SF-122 that the property acquired will be used in the conduct of approved CSRS projects or programs.

(d) *Transfer of date-expired pharmaceuticals to Colleges of Veterinary Medicine.* (1) Under authority of 41 CFR 101-43.307-2(b), drugs (other than controlled substances) in FSC class 6505 that are determined unfit for human use due to expiration of shelf life may be transferred to Colleges of Veterinary Medicine for animal experimental use on a case-by-case basis subject to prior approval of GSA.

(2) An authorized representative of the College of Veterinary Medicine

(eligible under 7 U.S.C. 3195 and 3196) will screen and select expired 6505 items and submit a list of those items which could be used in research on a Defense Property Reutilization and Marketing Supply (DPRMS) Form 103. The following items will be approved for transfer: Parenteral fluids; over-the-counter preparations; and prescription label pharmaceuticals, including inhalant anesthetics. No controlled substances in Drug Enforcement Administration (DEA) Class I and Class II will be requested. No tranquilizers will be requested.

(3) In order to participate in this program, each College of Veterinary Medicine must enter into an agreement with CMS (acting as the agent for CSRS). This agreement will set forth the procedures and requirements for participation (see appendix A of this part for Agreement).

(4) Each College of Veterinary Medicine is responsible for submitting its own requests for pharmaceuticals to the PMO, CMS, for approval. The PMO will obtain GSA approval. Items will not be transferred from one school to another.

(5) (i) Each SF-122 prepared by the College of Veterinary Medicine must include the following statements:

(A) These pharmaceuticals will not be used for human purposes;

(B) These pharmaceuticals will be used only to further the purposes of the research program conducted under section 1433 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3195), as amended;

(C) No pharmaceutical which could potentially compromise the validity of the research findings will be used in a research protocol; and

(D) The College of Veterinary Medicine expressly agrees to assume all liabilities arising out of the use of the transferred items, and to indemnify and hold harmless the United States, its agents, and employees for any loss that arises from such use.

(ii) Each SF-122 must be signed by the APO and either a Doctor of Veterinary Medicine or a Registered Pharmacist and the Drug Enforcement Agency Authorization number must be included.

(6) Each College of Veterinary Medicine must assume all liabilities and indemnify the Federal Government against loss.

(7) All transferred pharmaceuticals are to be used in the conduct of formula-funded animal health research programs conducted under section 1433 of the National Agricultural Research,

Extension, and Teaching Policy Act of 1977 (7 U.S.C. 3195), as amended.

(8) Each College of Veterinary Medicine is solely responsible for the security, storage and accountability of such items, including compliance with applicable Federal, state, and local laws. Items are to be stored and inventoried in a physically separate location from regular operating inventory.

(9) The Accountable Property Officer, or his/her designate, will be responsible for disbursement for use and/or disposal of all items received under the Program. Inventory records will be made available on request to authorized USDA representatives.

(10) Any pharmaceutical no longer required for research purposes will be destroyed by the College of Veterinary Medicine in accordance with Federal, State, and local statutes, under supervision of the Accountable Property Officer.

(11) The College of Veterinary Medicine will be responsible for all transportation and disposal costs.

§ 3408.8 Use of Federal excess personal property.

Property acquired through the CSRS Federal excess personal property program must be intended for a specific purpose and consistent with this part, and must be put into immediate use to further that purpose. Therefore, the stockpiling of non-expendable excess personal property is not permitted. Limited stockpiling (not to exceed a one-year supply) is permitted for expendable excess personal property. Federal excess personal property shall be used as long as needed on the projects or programs for which it was acquired. During the time Federal excess personal property is held by the eligible State participant, it may be made available for other approved projects or programs if such use will not interfere with the project or program for which it was originally acquired.

§ 3408.9 Reporting Federal excess personal property.

(a) When Federal excess personal property is no longer needed on the project or program for which it was acquired, the property may be utilized on other approved projects conducted by the State Cooperative Research Activity holding custody of the property.

(b) When Federal excess personal property is no longer needed by the State Cooperative Research Activity holding custody of the property, it shall be declared excess and reported promptly to the PMO, CMS.

(c) Federally owned personal property declared excess by a State Cooperative

Research Activity shall be reported to DEPPC and GSA through CMS on Form SF-120, Report of Excess Personal Property. Property reported by locations outside the 50 States shall be reported only to GSA. Submit the completed form to the PMO, CMS. A separate SF-120 shall be filed for each property location and FSC Group. Typewriters should be listed on a separate SF-120.

(d) Form SF-120 must list: (1) All descriptive information of the property included on the Official Property Record, including the order number from the original acquisition document;

(2) True condition of the property as of the date it is reported excess by assigning an appropriate condition code; and

(3) Any available operating manual, diagram, maintenance record, log, or other instructional material.

(e) CMS will submit Form SF-120 to DEPPC for inclusion in the list of excess property available to USDA agencies, including CSRS. For locations outside the 50 States, CMS will submit the SF-120s only to GSA. Disposition instructions will be issued by DEPPC within 60 days after receipt of Form SF-120 if the property is claimed by a USDA agency. Federal excess personal property not secured by a USDA agency will be reported as excess by DEPPC to GSA for inclusion in the list of excess personal property available to other Federal agencies. Final disposition instructions will be issued by GSA through the PMO, CMS.

§ 3408.10 Transfer of Federal excess personal property.

(a) *Within a State Cooperative Research Activity.* Federally owned personal property declared excess by a State Cooperative Research Activity, that can be utilized within another State Cooperative Research Activity, may be transferred with prior approval of the PMO, CMS. Form AD-107, Report of Transfer or Other Disposition or Construction of Property, signed by the reporting and receiving State Cooperative Research Activity, is to document the transfer. A copy is to be submitted to CMS for record and inventory purposes.

(b) *To other USDA agencies.* The transfer of Federally owned personal property, declared excess by a State Cooperative Research Activity and secured by another USDA agency, is to be documented on Form AD-107, Report of Transfer or Other Disposition or Construction of Property. Following CMS approval, a completed copy, signed by the reporting activity and the receiving USDA agency, is to be forwarded to the PMO, CMS.

§ 3408.11 Donation of surplus property.

(a) Federally owned personal property, declared surplus by GSA, may be donated by GSA to certain public agencies and nonprofit institutions as determined by the Administrator of General Services. Property becomes eligible for donation when there is no further requirement within the Federal establishment for its use. Donated property is generally handled by GSA through the State Agencies for Surplus Property (SASPs) which are responsible for its distribution.

(b) All items requested by the SASPs are submitted to GSA for approval on an SF-123 (Transfer Order Surplus Personal Property). SF-123s received by the PMO, CMS for property on loan to the States (which has been reported to GSA for reutilization or donation on an SF-120), will be forwarded to the appropriate APO and will serve as authorization to release the property to the designated SASP.

§ 3408.12 Unserviceable property.

(a) *Unserviceable property.* Unserviceable Federal excess personal property which is accountable is to be reported to the PMO, CMS on Form SF-120, Report of Excess Personal Property. Nonaccountable Federal excess personal property that is unserviceable is to be reported on Form AD-112, Report of Unserviceable, Lost or Damaged Property. Unserviceable property refers to items worn through normal use, that have no reasonable prospect of use as a unit, and whose repair or rehabilitation for use as a unit is clearly impracticable. Unserviceable property is generally characterized as having one of the following conditions:

(1) Not worth continued care and handling; or

(2) Having no commercial value except for its basic material content.

(b) *Disposition instructions.* The PMO, CMS, will submit all SF-120s to GSA for disposition instructions. When appropriate action has been determined by GSA, CMS will notify the State Cooperative Research Activity. If the property is to be disposed of locally, the AD-112 will be completed for USDA records. Following final disposition, the property records will be adjusted to reflect the action taken.

§ 3408.13 Lost, damaged, stolen, or destroyed property.

(a) *Reporting lost, damaged, stolen, or destroyed property.* Stolen property should be reported to the local law enforcement authorities immediately after discovery of the theft. All lost, damaged, stolen, or destroyed property is to be reported to the PMO, CMS, on

Form AD-112, Report of Unserviceable, Lost or Damaged Property. This report should provide a detailed explanation of the facts and circumstances involved with the case, the condition of the item(s), and actions taken to recover the item(s). Form AD-112 should include the name of the person to whom the property was assigned, room number, time, date (or approximate date), and last known location. A police report should accompany the AD-112 submission for stolen property.

(b) *Liability.* The State Cooperative Research Activity may be held liable for property that is lost, damaged, stolen, or destroyed through gross negligence. The PMO, CMS, will determine whether gross negligence is involved with the loss of property based on the facts, explanations, and record as presented on the AD-112. If the evidence indicates gross negligence, the case will be referred to the agency head or his designee for consideration of appropriate action under the Debt Collection Act.

Appendix A to Part 3408—Agreement for Transfer of Date-Expired Pharmaceuticals to Colleges of Veterinary Medicine by the Cooperative State Research Service

I. Authority

40 U.S.C. 483(d)(2)(E); 41 CFR 101-43.307-2(b), Controlled Substances, Drugs, and Biologicals

II. Acquisition Procedure

A. All transactions involving the transfer of property in FSC Group 6505 are to be handled as follows:

1. An authorized representative of the College of Veterinary Medicine (eligible under 7 U.S.C. 3195 and 3196) will screen and select expired 6505 items and submit a list of those items which could be used in research on a Defense Property Reutilization and Marketing Supply (DPRMS) Form 103. The classes of items which will be accepted for transfer are parenteral fluids, over-the-counter preparations, and prescription label pharmaceuticals including inhalant anesthetics. No controlled substances in Drug Enforcement Administration (DEA) Class I and Class II will be requested. No tranquilizers will be requested.

2. The College of Veterinary Medicine will be responsible for submitting its own requests for pharmaceuticals which must be transmitted to the Cooperative Management Staff, Property Management Officer for approval. The Property Management Officer will obtain the necessary approval of the General Services Administration prior to authorizing the transfer of any items under this agreement to a College of Veterinary Medicine. Items will not be transferred from one school to another.

3. Once the DPRMS has accepted accountability, an SF-122 will be prepared by the College of Veterinary Medicine. Each

SF-122 must include the following statements:

- These pharmaceuticals will not be used for human purposes.
- These pharmaceuticals will be used only to further the purposes of the research program conducted under section 1433 of the National Agricultural Research, Extension, and Teaching Policy Act of 1977, as amended.

- No pharmaceutical which could potentially compromise the validity of the research findings will be used in a research protocol.

- The College of Veterinary Medicine expressly agrees to assume all liabilities arising out of the use of the transferred items, and to indemnify and hold harmless the United States, its agents and employees, for any loss that arises from such use.

4. All requests must be signed by the Accountable Property Officer and a registered pharmacist or Doctor of Veterinary Medicine.

5. All SF-122s (Transfer Order Excess Personal Property) are to be submitted to the Property Management Officer, Cooperative Management Staff, USDA: the designated official to approve transfer orders for the Cooperative State Research Service, USDA.

III. Other Requirements

A. The College of Veterinary Medicine is solely responsible for the security, storage, and accountability of such items, including compliance with applicable Federal, State, and local laws. Items are to be stored and inventoried in a physically separate location from regular operating inventory.

B. The Accountable Property Officer, or his/her designate, will be responsible for disbursement of use and/or disposal of all items received under the Program. Inventory records will be made available on request to authorized USDA representatives.

C. Any pharmaceutical no longer required for research purposes will be destroyed by the College of Veterinary Medicine in accordance with Federal, State, and local statutes, under supervision of the Accountable Property Officer.

D. The College of Veterinary Medicine will be responsible for all transportation and disposal costs.

E. The DEA authorization number for the College of Veterinary Medicine is:

Administrator, Cooperative State Research Service

Dean, College of Veterinary Medicine

University

Done at Washington, DC this 1st day of October 1993.

John Patrick Jordan,
Administrator.

[FR Doc. 93-24762 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-22-M

NUCLEAR REGULATORY COMMISSION

10 CFR Part 21

[Docket No. PRM-21-2]

Nuclear Management and Resources Council; Receipt of Petition for Rulemaking

AGENCY: Nuclear Regulatory Commission.

ACTION: Petition for rulemaking; Notice of receipt.

SUMMARY: The Nuclear Regulatory Commission (NRC) is publishing for public comment a notice of receipt of a petition for rulemaking, dated June 21, 1993, which was filed with the Commission by the Nuclear Management and Resources Council. The petition was docketed by the NRC on June 22, 1993, and has been assigned Docket No. PRM-21-2. The petitioner requests that the NRC amend its regulations to revise the definition of the term "commercial grade item"; to include a flexible generic process for dedication of commercial grade items for safety-related use; and to clarify that the entity performing the dedication of a commercial grade item is responsible for discovering, evaluating, and reporting deficiencies as required by NRC's regulations.

DATES: Submit comments by December 28, 1993. Comments received after this date will be considered if it is practical to do so, but the Commission is able to assure consideration only for comments received on or before this date.

ADDRESSES: Submit written comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch. Hand deliver comments to: 11555 Rockville Pike, Rockville, Maryland, between 7:45 a.m. and 4:15 p.m. Federal workdays.

For a copy of the petition, write the Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

The petition and copies of comments received may be inspected and copied for a fee at the NRC Public Document Room, 2120 L Street, NW. (Lower Level), Washington, DC.

FOR FURTHER INFORMATION CONTACT: Michael T. Lesar, Chief, Rules Review Section, Rules Review and Directives Branch, Division of Freedom of Information and Publications Services, Office of Administration, U.S. Nuclear Regulatory Commission, Washington,

DC 20555, Telephone: 301-492-7758 or
Toll Free: 800-368-5642.

SUPPLEMENTARY INFORMATION:

Petitioner

The Nuclear Management and Resources Council (NUMARC) is an organization of the nuclear power industry. NUMARC is responsible for coordinating the combined efforts of all utilities licensed by the NRC to construct or operate nuclear power plants, and of other nuclear industry organizations, in all matters involving generic regulatory policy issues and regulatory aspects of generic operational and technical issues affecting the nuclear power industry. NUMARC's members include all utilities responsible for constructing or operating a commercial nuclear power plant in the United States, major architect/engineering firms, and all of the major nuclear steam supply system vendors.

Background

Section 206 of the Energy Reorganization Act of 1974, as amended, requires that all licensees, as well as nonlicensees who construct facilities for licensees, supply basic components to licensees, and provide services associated with basic components to licensees, report defects that could create a substantial safety hazard. The NRC regulations that implement Section 206 are contained in 10 CFR part 21. This part, in conjunction with 10 CFR part 50, appendix B, also covers the procurement of parts for nuclear power plants, including basic components and commercial grade items to be used in safety-related applications.

The petitioner has focused this petition on the procurement of parts described as commercial grade items because, according to the petitioner, the current procurement environment is different from the environment extant when Part 21 was adopted. The petitioner states that because nuclear power plants have been operating for several years, many pieces of equipment now require replacement or refurbishment of their components. According to the petitioner, current nuclear utility procurement needs primarily involve replacement parts for existing equipment rather than the purchase of major new pieces of equipment. However, many of the original suppliers and manufacturers no longer maintain Appendix B-qualified programs because of the diminished market, because no new plants are being ordered or are currently under construction, and because of the burden

of maintaining such a quality assurance program. Frequently, replacement parts are not available from original or other Appendix B-qualified vendors. The combined effect of the decreased availability of parts from Appendix B-qualified vendors and the greater expense of obtaining these parts is that licensees are increasingly forced to procure commercial grade replacement parts and dedicate them for use in safety-related applications.

Discussion

According to the petitioner, the provisions of part 21 that relate to commercial grade items, the dedication of these items for use in safety-related applications, and the reporting requirements associated with these items that are imposed on manufacturers, suppliers, and sub-tier suppliers are unworkable, ineffective, and may be counterproductive. The petitioner states that safety may be adversely affected by delay caused by the inability to obtain the replacement parts needed for use as basic components.

The petitioner believes that Part 21, as it relates to commercial grade items and their dedication, is not accomplishing its intended objectives effectively. The petitioner believes that the current Part 21 regulations involving posting, document retention, and deficiency evaluation and reporting make the implementation of these regulations unnecessarily burdensome and create substantial liability for licensees subject to Part 21. The petitioner believes that the effect of these provisions has been to discourage vendors from maintaining Appendix B-qualified programs.

Although Part 21 provided a reasonable foundation for regulating procurement and imposing reporting requirements at the time it was promulgated, the petitioner believes that the current requirements of Part 21 often impede a utility's ability to obtain the highest quality part available for use in a safety-related application in a cost- and time-efficient manner. The inability to procure appropriate parts promptly could adversely affect plant safety.

The petitioner discusses several options available to nuclear utilities in procuring replacement parts, most of which have serious drawbacks directly or indirectly related to the current regulatory approach set out under Part 21. These options and drawbacks, as discussed by the petitioner, are as follows:

1. Nuclear utilities could procure items from a supplier who maintains an Appendix B-qualified program, but the cost of procuring an item from such a

source is much higher than if comparable items are procured through commercial channels.

2. Nuclear utilities could procure replacement parts that are slightly different than the original parts, but even if replacement parts are obtained from an Appendix B-qualified supplier, a design change is likely to be required to justify the use of the proposed replacement parts.

3. Nuclear utilities could obtain the item from the surplus market or another utility, but this option may be impossible if the product does not fit into the basic component or commercial grade definitions.

4. Nuclear utilities could procure the item as commercial grade, but it may be difficult to meet all of the definitional requirements of Part 21.

5. Nuclear utilities may file an application for an exemption, but this process is impractical because of the time generally required to obtain a decision.

The petitioner believes that the substitution of a more practicable definition of the term "commercial grade item" and the addition of a flexible generic process for dedication would assist in resolving many of the drawbacks cited for the options available to a nuclear utility.

The petitioner states that its suggested change to the NRC's regulations would broaden the definition of commercial grade item under 10 CFR 21.3(a)(4) and (a-1). The petitioner also states that Part 21 does not allow an item to qualify as commercial grade unless the item meets all three of the requirements defined in 10 CFR 21.3(a)(4) and (a-1). Because many of the replacement parts needed are no longer available from the original manufacturers or suppliers who maintain Appendix B-qualified programs, the petitioner believes that the current definition of the term "commercial grade item" presents a significant obstacle for licensees in procuring appropriate parts in the most cost- and time-efficient manner. According to the petitioner, the proposed changes would expand the definition of "commercial grade item" to include any item obtained on the open market. Under the petitioner's suggested amendment, it would be incumbent upon the dedication process to provide reasonable assurance that the item will perform its intended function in the safety-related application and upon the dedication entity to report any deficiencies covered under Part 21.

The petitioner believes that allowing commercially available items to qualify as commercial grade items would provide significant benefits without any

adverse impact on safe plant operation. According to the petitioner, the suggested amendment not only allows procurement from the original manufacturer or supplier even if that entity no longer maintains an Appendix B-qualified program, as well as from other commercial sources, but it also reduces the potential need for design changes and permits a more reasonable price and delivery time.

In the petitioner's suggested amendment, the regulations would define the dedication process as one that will provide reasonable assurance that the commercial grade item will perform its intended function. According to the petitioner, the following are ways to assure that the commercial grade item will perform its intended function:

- (1) Testing and/or inspection;
- (2) Surveying the commercial grade supplier to determine that the appropriate quality control is in place;
- (3) Observing the manufacturing process; and
- (4) Analyzing the historical record of the item for acceptable performance.

The petitioner indicates that other methods of verification for dedication may exist that are acceptable to the NRC and that should be considered in evaluating whether the reasonable assurance standard is met in this context.

The petitioner also proposes that the dedication entity maintain documentation of the dedication process for the purpose of an audit or inspection. The petitioner believes that the primary benefit of establishing the dedication process suggested in the petition is that the user or other party performing the dedication, who understands the safety significance of the proposed component and, therefore, is better able to identify the characteristics necessary to perform its intended function than the manufacturer, is responsible for the quality of the commercial grade item. In order for the dedication entity to maintain documentation of the dedication process for the purpose of an audit or inspection, the utility party performing the dedication would have to evaluate the suitability of the component by analyzing the effect of the commercial grade item on the component's performance in a safety-related application.

The petitioner believes that it is appropriate to place the responsibility for reporting deficiencies in commercial grade items with the entity performing the dedication process. The petitioner believes that suppliers and sub-tier suppliers do not necessarily know

whether a commercial grade item is destined for a safety-related application. The petitioner also indicates that no time limitation exists on the part 21 reporting responsibility for suppliers. The petitioner recommends that language be added to § 21.21(b) to make clear that the entity performing the dedication of a commercial grade item is responsible for discovering, evaluating, and reporting deficiencies.

The Suggested Amendments

The petitioner believes that part 21 should be modified to accommodate the current procurement needs of the nuclear power industry. The petitioner recommends changes to 10 CFR 21.3 to broaden the definition of a commercial grade item and to define and set out a standard for the dedication process. The petitioner believes that all parties would benefit from the inclusion of language in 10 CFR 21.21(b) clarifying the responsibility associated with dedication. According to the petitioner, the recommended changes would not have any adverse impact on safety as the use of properly dedicated commercially available parts neither decreases equipment performance nor affects safe plant operation.

The changes requested by the petitioner are set out as follows:

1. In § 21.3, paragraphs (a-1) and (c-1) are revised to read as follows:

§ 21.3 Definitions

* * * * *

(a-1) *Commercial grade item* means any item that has not been dedicated for use as a basic component.

* * * * *

(c-1) *Dedication* is the evaluation process undertaken to provide reasonable assurance that a commercial grade item to be used as a basic component will perform its intended function.

* * * * *

2. In § 21.21, the existing text of paragraph (b) is redesignated as paragraph (b)(1) and a paragraph (b)(2) is added to read as follows:

§ 21.21 Notification of failure to comply or existence of a defect and its evaluation.

* * * * *

(b) * * *

(2) The entity that performs the dedication is responsible for identifying, evaluating, and reporting the deviations and failures to comply associated with substantial safety hazards of a commercial grade item.

* * * * *

Dated at Rockville, Maryland, this 7th day of October 1993.

For the Nuclear Regulatory Commission.
Samuel J. Chilk,
Secretary of the Commission.
 [FR Doc. 93-25230 Filed 10-13-93; 8:45 am]
 BILLING CODE 7590-01-P

FARM CREDIT ADMINISTRATION

12 CFR Part 650

RIN 3052-AB49

Federal Agricultural Mortgage Corporation

AGENCY: Farm Credit Administration.

ACTION: Proposed rule.

SUMMARY: The Farm Credit Administration (FCA), by the Farm Credit Administration Board (Board), proposes for public comment a new regulation relating to reporting and disclosure of conflicts of interest by directors, officers, and employees of the Federal Agricultural Mortgage Corporation (Corporation). The regulation is proposed in response to section 514 of the Farm Credit Banks and Associations Safety and Soundness Act of 1992. Section 514 of the 1992 Act directs the FCA to ensure that its regulations require the disclosure of financial information and the reporting of potential conflicts of interest by directors, officers, and employees of all Farm Credit System (System) institutions and that such requirements are adequate to fulfill the purposes of the section.

The proposed regulations would require the Corporation to adopt a conflict-of-interest policy. In its policy the Corporation must define the types of transactions, relationships, or activities that might reasonably be expected to give rise to a potential conflict of interest and require the reporting of sufficient information about transactions, relationships, and activities to inform the Corporation about potential conflicts of interest. The proposed regulation would also require, in addition to disclosures already required under the Federal securities laws, disclosure to shareholders, investors, and potential investors of any unresolved conflicts of interest involving its directors, officers, and employees.

DATES: Comments must be received by November 15, 1993.

ADDRESSES: Comments should be submitted in writing, in triplicate, to Suzanne McCrory, Director, Office of Secondary Market Oversight, in care of Cindy Nicholson, Paralegal Specialist, Regulation Development Division,

Office of Examination, Farm Credit Administration, McLean, Virginia 22102-5090. Copies of all communications received will be available for examination by interested parties in the Regulation Development Division, Farm Credit Administration.

FOR FURTHER INFORMATION CONTACT: Suzanne J. McCrory, Director, Office of Secondary Market Oversight, Farm Credit Administration, McLean, VA 22102-5090, (703) 883-4280, TDD (703) 883-4444.

SUPPLEMENTARY INFORMATION: Section 514 of the Farm Credit Banks and Associations Safety and Soundness Act of 1992 (1992 Act), Pub. L. 102-552, 106 Stat. 4102, directed the FCA to review its current regulations regarding the disclosure of financial information and the reporting of potential conflicts of interest by the directors, officers, and employees of Farm Credit System institutions to determine whether the regulations: (1) Are adequate to fulfill the purpose of section 514 and other purposes determined by the FCA to be necessary or appropriate, consistent with the Farm Credit Act of 1971 (1971 Act); (2) require the disclosure of financial information and reporting of potential conflicts of interest by the directors, officers, and employees of all Farm Credit System institutions; and (3) require such disclosure of all of the appropriate directors, officers, or employees of Farm Credit System institutions. The 1992 Act further directed the FCA to amend its current financial disclosure and conflict-of-interest regulations to carry out the purpose of section 514 and to address any deficiencies in the regulations revealed by the required review.

The stated purpose of section 514 is to ensure that FCA regulations require the disclosure of financial information and the reporting of potential conflicts of interest to provide sufficient information for: (1) Stockholders to make informed decisions regarding the operation of the institutions; (2) investors and potential investors to make informed investment decisions; and (3) the FCA to examine and regulate all Farm Credit System institutions effectively and efficiently.

Specifically, Congress found that:

(1) Disclosure of compensation paid to, loans made to, and transactions made with a Farm Credit System institution by its directors and senior officers provides stockholders with information necessary to manage the institution, provides the FCA with information necessary to regulate the institution efficiently and effectively, and enhances the integrity of the Farm

Credit System by making the information available to potential investors;

(2) Reporting of potential conflicts of interest by directors, officers, and employees benefits the stockholders of the institution, helps to ensure the financial viability of the institution, and provides information valuable to the FCA in periodic examinations, thereby enhancing the safety and soundness of the System; and

(3) Directors, officers, or employees of some Farm Credit System institutions may not be subject to the regulations of the Farm Credit Administration requiring the disclosure of financial information and the reporting of potential conflicts of interest.

(As a result of its review, the FCA concluded that certain of the purposes of section 514 are already served by disclosure required as a result of the registration of the Corporation's securities with the Securities Exchange Commission (SEC) under the Securities Exchange Act of 1934 (1934 Act) and by the requirements of FCA regulations relating to shareholder disclosure. SEC rules require the disclosure to shareholders of the compensation of senior officers and directors, transactions of the institution exceeding \$60,000 with parties in which such persons have an interest; certain business relationships with persons doing business with the institution; and loans in excess of \$60,000 made by the institution to senior officers and directors, their immediate families, and any organization of which they are an executive officer, partner, or 10 percent (or more) stockholder, unless such loans are transactions in the ordinary course of business. FCA regulations in part 620 require disclosure to shareholders consistent with SEC rules.

The FCA has adequate access to information possessed by the Corporation through the examination process, and the disclosures to shareholders required by the SEC and FCA regulations provide sufficient information to allow stockholders to make informed decisions regarding the operation of the institution, compensation of officers and directors, and related-party transactions. This information is publicly available to investors and potential investors in SEC filings under the 1934 Act. Although these requirements may elicit disclosure of situations that may present a potential for conflicts of interest, there is no regulatory requirement that potential conflicts of interest be reported to the Corporation.

In proposing these regulations, the FCA considered several issues. First,

should the regulation specifically prohibit certain transactions, relationships, and activities that involve the potential for conflicts of interest as is done for other System institutions? The FCA currently has standards-of-conduct regulations for the banks and associations of the Farm Credit System. These standards-of-conduct regulations include both general and specific prohibitions designed to prevent conflicts of interest and the appearance of conflicts of interest. Under a proposed amendment to these regulations adopted on July 15, 1993, (58 FR 44139, August 19, 1993) these institutions would be given more responsibility for defining appropriate conduct, but some transactions, relationships, and activities that involve the potential for conflicts of interest would continue to be prohibited by regulation.

The FCA Board considered adopting a similar approach for the Corporation, but proposes instead a rule that would require the Corporation to define its own conflict-of-interest policy within the requirements of section 514. Several reasons underlie this different regulatory approach. First, by defining prohibited conduct for System banks and associations, which number in the hundreds and which report combined financial information to investors, the FCA established a standard of uniform applicability. The FCA Board believes a uniform standard of conduct should be in effect for System institutions who are jointly and severally liable for Systemwide obligations. Implementing a uniform standard would have been difficult to achieve without a regulation. By contrast, the Corporation is a single institution and there appears to be no need for the FCA to establish a standard of uniform applicability by regulation. Second, the FCA's historical experience with System banks and associations enabled it to identify situations associated with abuse in System operations; the operational history of the Corporation has been too short to provide similar information. Moreover, the structure and business operations of the Corporation differ from the rest of the System. For example, conflicts of interest in System banks and associations often involve decisions related to loans since these institutions are lenders whose borrowers are the cooperative owners. By contrast, the Corporation is a guarantee agency that plays an active role in asset securitization and conflicts of interest may involve a wider variety of transactions than loans.

Consequently, the FCA proposes that the Corporation be required to adopt a

conflict-of-interest policy defining those types of transactions, relationships, and activities that might adversely affect a person's ability to perform his or her official duties and responsibilities in a totally impartial manner and in the best interest of the Corporation. The proposed regulation would require sufficient reporting of potential conflicts of interest to permit the Corporation to monitor, resolve, and, if unresolved, disclose conflicts of interest.

The second regulatory issue considered by the FCA Board involved the type and extent of internal reporting and public disclosure. The proposed rule is based on the premise that all transactions, relationships, and activities that may present the potential for a conflict of interest should be reported to the Corporation. Therefore, the proposed rule would require the Corporation to develop requirements for the reporting of sufficient information about transactions, relationships, and activities to inform the Corporation of potential conflicts. The Board takes this position because the 1992 Act requires FCA regulations to require reporting of all "potential conflicts of interest" and because it may be difficult for the person involved to evaluate the gravity of a possible conflict fully and objectively. Reporting would be required annually and at such other times as potential conflicts arise. Directors, officers, and employees having no transactions, relationships, or activities to report would be required to file a statement to that effect.

The proposed rule would require the Corporation to prescribe "materiality" guidelines consistent with the regulation to establish when a conflict of interest must be publicly disclosed if not otherwise resolved. The proposed regulation defines a material conflict of interest as one of sufficient magnitude or significance that a reasonable observer with knowledge of the relevant facts would question the person's ability to discharge official duties in an objective and impartial manner. A material conflict would be deemed to be resolved if the circumstances were altered so that a reasonable observer with knowledge of the relevant facts would conclude that the person's performance of official duties in an objective and impartial manner would not be adversely affected. Circumstances could be altered, for example, by the person with the conflicting interest terminating the relationship, transaction, or activity at issue, or by control mechanisms established by the Corporation, such as recusal from all decisionmaking that could have a direct

and predictable effect on the person's interest in the matter.

Since the Corporation is subject to SEC disclosure requirements for public companies, the materiality standard adopted by the Corporation could result in no less stringent a disclosure requirement than SEC rules would allow. Conflict-of-interest policies; reports filed by directors, officers, and employees; and other documentation of the policy's implementation would be subject to FCA examination, allowing the FCA to evaluate the effectiveness of the Corporation in identifying and resolving conflicts and any safety and soundness concerns presented by such conflicts.

The third major issue involved defining the duties and responsibilities of directors, officers, and employees of the Corporation. As a federally chartered entity, the Corporation has both public and private purposes. Conflicts of interest must be understood and interpreted not only in the context of the fiduciary responsibilities to the Corporation and its shareholders, but also in the context of the statutory duty to further the congressional purposes the Corporation was chartered to achieve. The proposed regulation reflects the FCA Board's belief that the statutory structure of the Corporation's board¹ and the statutory direction that voting stock be equitably distributed among classes of voting stock and among stockholders within each class were designed to ensure that the Corporation would be managed in an evenhanded manner, without favoring either System users or non-System users. The proposed regulation reflects the FCA Board's recognition that, irrespective of the source of appointment, directors owe fiduciary duties to all shareholders, and that the Corporation must not act in a way that discriminates against or favors any class of stockholders or users. However, the proposed regulation also recognizes that fiduciary duties to shareholders must be understood in the context of the duty of the directors to further the statutory purposes of the Corporation.²

¹ The Agricultural Credit Act of 1967, Pub. L. 100-233 (1987 Act), established three classes of five directors each—one class to be elected by banks, insurance companies and other financial institutions that are stockholders, one class to be elected by institutions of the Farm Credit System that are stockholders, and one class to be appointed by the President. The five appointive directors must be representatives of the general public and must not have been officers or directors of any financial institutions. At least two of the five must be experienced in farming or ranching and not more than three may be of the same political party.

² The 1987 Act, which amended the Farm Credit Act of 1971, 12 U.S.C. 2001 *et seq.*, established the

Unlike directors of corporations incorporated under State statutes of incorporation, directors of statutorily chartered Federal Government-sponsored enterprises are not free to alter the purposes or powers of such enterprises, even when such alteration would be in the best interest of the stockholders. Such changes can only be made by law. Rather, it is the responsibility of the directors to manage the Corporation in the manner that best effectuates the public policy it was designed to serve. Therefore, the proposed regulation would impose upon directors, officers, and employees the duty to conduct the business of the Corporation in a manner that promotes the best interest of the Corporation and furthers its statutory mission. The proposed regulation would further require these individuals, in the discharge of these duties, to adhere to the highest standards of honesty, integrity, impartiality, loyalty, and care, and to discharge official responsibilities impartially in a manner consistent with applicable law and regulation in furtherance of the Corporation's public purpose. The FCA Board believes that the public purpose of the Corporation warrants application of high standards of conduct. The proposed regulation would also require directors, officers, and employees to adhere to the conflict-of-interest policy of the Corporation; individuals in violation of the regulation or the Corporation's policy would be subject to the penalties of part C of title V of the Act, including civil money penalties.

List of Subjects in 12 CFR Part 650

Agriculture, Banks, banking, Conflicts of interest, Rural areas.

For the reasons stated in the preamble, a new part 650 of chapter VI, title 12 of the Code of Federal Regulations is proposed to be added to read as follows:

Corporation as a Federal instrumentality and as a part of the Farm Credit System for the purpose of facilitating a secondary market in agricultural real estate and rural home loans originated by Farm Credit institutions and other lenders. The statutory purpose to be served by the secondary market thus created was to increase the availability of long-term credit to farmers and ranchers at stable interest rates, to provide greater liquidity and lending capacity for lenders extending credit to farmers and ranchers, to facilitate capital market investments in providing long-term agricultural funding, including funds at fixed rates of interest, and to enhance the ability of individuals in small rural communities to obtain financing for moderate-priced homes. See section 701 of the 1987 Act.

PART 650—FEDERAL AGRICULTURAL MORTGAGE CORPORATION**Subpart A—Conflicts of Interest**

Sec.

- 650.1 Definitions.
 650.2 Conflict-of-interest policy.
 650.3 Disclosure of conflicts of interest.
 650.4 Director, officer, and employee responsibilities.

Authority: Secs. 5.9, 5.17, 8.11 of the Farm Credit Act; 12 U.S.C. 2243, 2252, 2279aa-11; sec. 514 of Pub. L. 102-552, 106 Stat. 4102.

Subpart A—Conflicts of Interest**§ 650.1 Definitions.**

(a) *Corporation* means the Federal Agricultural Mortgage Corporation.

(b) *Employee* means any salaried officer or part-time, full-time, or temporary salaried employee.

(c) *Entity* means a corporation, company, association, firm, joint venture, partnership (general or limited), society, joint stock company, trust (business or otherwise), fund, or other organization or institution.

(d) *Material*, when applied to a potential conflict of interest, means the conflicting interest is of sufficient magnitude or significance that a reasonable observer with knowledge of the relevant facts would question the ability of the person having such interest to discharge official duties in an objective and impartial manner in furtherance of the interest of the Corporation and its statutory purposes.

(e) *Officer* means the salaried president, vice presidents, secretary, treasurer, and general counsel, or other person, however designated, who holds a position of similar authority.

(f) *Person* means an individual or entity.

(g) A *potential conflict of interest* means a director, officer, or employee of the Corporation has an interest in a transaction, relationship, or activity that might adversely affect, or appear to adversely affect, the ability of the director, officer, or employee to perform his official duties on behalf of the Corporation in an objective and impartial manner in furtherance of the interest of the Corporation and its statutory purposes. For the purpose of determining whether a potential conflict of interest exists, transactions, relationships, and activities of the following persons shall be imputed to a director, officer, or employee subject to this regulation:

- (1) Spouse of the director, officer, or employee;
- (2) Minor child of the director, officer, or employee;
- (3) General partner of the director, officer, or employee;

(4) Organization or entity for which the Corporation's director, officer, or employee serves as officer, director, trustee, general partner, or employee; and

(5) Person(s) with whom the director, officer, or employee is negotiating for or has an arrangement concerning prospective employment.

(h) *Resolved*, when applied to a potential conflict of interest, means that although the Corporation has determined that a conflicting interest is material, circumstances have been altered so that a reasonable observer with knowledge of the relevant facts would conclude that the conflicting interest would not adversely affect the person's performance of official duties in an objective and impartial manner in furtherance of the interest of the Corporation and its statutory purposes.

§ 650.2 Conflict-of-interest policy.

The Corporation shall establish and administer a conflict-of-interest policy that will provide reasonable assurance that its directors, officers, and employees discharge their official responsibilities in an objective and impartial manner in the best interest of the Corporation and in furtherance of its statutory mission. The policy shall, at a minimum:

(a) Define the types of transactions, relationships, and activities that could reasonably be expected to give rise to potential conflicts of interest.

(b) Require each director, officer, and employee to report in writing, annually, and at such other times as conflicts may arise, sufficient information about transactions, relationships, and activities to inform the Corporation of potential conflicts of interest;

(c) Require any director, officer, and employee who had no transaction, relationship, or activity required to be reported under paragraph (b) of this section at any time during the year to file a signed statement to that effect;

(d) Establish guidelines for determining when a potential conflict is material in accordance with this regulation; and

(e) Provide internal controls to ensure that reports and statements are filed as required and that conflicts are resolved or disclosed in accordance with this regulation.

§ 650.3 Disclosure of conflicts of interest.

(a) The Corporation shall disclose any unresolved conflicts of interest involving its directors, officers, and employees to:

- (1) Shareholders through annual reports and proxy statements; and

(2) Investors and potential investors through disclosure documents supplied to them.

(b) The Corporation shall make available to any shareholder, investor, or potential investor, upon request, a copy of its conflict-of-interest policy. The Corporation may charge a nominal fee to cover the costs of reproduction and handling.

(c) The Corporation shall maintain all reports and statements on potential conflicts of interests and documentation of materiality determinations and resolutions of conflicts of interest for a period of 6 years.

§ 650.4 Director, officer, and employee responsibilities.

(a) Each director, officer, and employee of the Corporation shall:

(1) Conduct the business of the Corporation following the highest standards of honesty, integrity, impartiality, loyalty, and care, consistent with applicable law and regulation in furtherance of the Corporation's public purpose; and

(2) Adhere to the requirements of the conflict-of-interest policy established by the Corporation and provide any information the Corporation deems necessary to discharge its responsibilities under this regulation.

(b) Directors, officers, and employees of the Corporation shall be subject to the penalties of part C of title V of the Act for violations of this regulation, including failure to adhere to the conflict-of-interest policy established by the Corporation.

Dated: October 7, 1993.

Curtis M. Anderson,
 Secretary, Farm Credit Administration Board.
 [FR Doc. 93-25180 Filed 10-13-93; 8:45 am]
 BILLING CODE 6705-01-P

DEPARTMENT OF TRANSPORTATION**Federal Aviation Administration****14 CFR Part 71**

[Airspace Docket No. 93-ANE-22]

Proposed Alteration of VOR Federal Airway V-1

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would modify Federal Airway V-1 by extending the airway from the Hartford, CT, Very High Frequency Omnidirectional Range/Tactical Air Navigation (VORTAC) to Boston, MA, VORTAC. Modifying V-1 would

simplify air traffic control (ATC) clearances and reduce the controllers' workload. This action would also change the airway description in the vicinity of the South Florida Low Control Area. The description would be modified to incorporate changes associated with the offshore airspace reconfiguration.

DATES: Comments must be received on or before December 1, 1993.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, ANE-500, Docket No. 93-ANE-22, Federal Aviation Administration, 12 New England Executive Park, Burlington, MA 01803.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Patricia P. Crawford, Airspace and Obstruction Evaluation Branch (ATP-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9255.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made:

"Comments to Airspace Docket No. 93-ANE-22." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be

considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-220, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3485.

Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to modify Federal Airway V-1 by extending the airway from the Hartford, CT, VORTAC to the Boston, MA, VORTAC. This action would simplify ATC clearances along this extremely high activity airway. Extending the airway would eliminate nonessential communications and the requirement for pilots to read back clearance instructions. This action would reduce the workload for pilots and controllers.

In addition, this proposed rule would change the floor of V-1 in the vicinity of the South Florida Low Control Area. On June 22, 1993, the northern boundary of the South Florida Low Control Area was moved from latitude 28°00'00"N. to latitude 34°00'00"N., to ensure that certain ATC operations were conducted in controlled airspace (58 FR 33907). Relocating the northern boundary of that control area prompted changes to the floor of the airway. The floor of V-1 would be raised from 2,000 feet mean sea level (MSL) to 2,700 feet MSL to coincide with the floor of the control area. Domestic VOR Federal airways are published in paragraph 6010(a) of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The airway listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "significant regulatory action" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6010(a)—Domestic VOR Federal Airways

* * * * *

V-1 [Revised]

From Craig, FL, via INT Craig 020° and Charleston, SC, 214° radials; Charleston; Grand Strand, SC; INT Grand Strand 031° and Kinston, NC, 214° radials; Kinston; Cofield, NC; Norfolk, VA; Cape Charles, VA; INT Cape Charles 006° and Salisbury, MD, 206° radials; Salisbury; Waterloo, DE; INT Waterloo 024° and Coyle, NJ, 216° radials; Coyle; INT Coyle 036° and Kennedy, NY, 209° radials; Kennedy; Deer Park NY; Madison, CT; Hartford, CT; INT Hartford 040°T(053°M) and Boston, MA, 252°T(268°M) radials; to Boston, MA; excluding the airspace below 2,700 feet MSL outside the United States between STARY INT and Charleston, SC. The portions within

R-5002A, R-5002C and R-5002D are excluded during their times of use. The airspace within R-4006 is excluded.

* * * * *

Issued in Washington, DC, on October 5, 1993.

Harold W. Becker,

Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 93-25214 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 93-ASW-31]

Proposed Alteration of Jet Route J-142

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would remove a segment of Jet Route J-142 between San Simon, AZ, and Socorro, NM. J-142 was initially established for air traffic control (ATC) purposes when Restricted Area R-5113 was in use. Since R-5113 is used for thunderstorm research approximately one month per year, this segment of J-142 is rarely utilized. If this proposal is adopted, aircraft would be vectored clear of the area when R-5113 is active.

DATES: Comments must be received on or before December 1, 1993.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, Air Traffic Division, ASW-500, Docket No. 93-ASW-31, Federal Aviation Administration, 4400 Blue Mound Road, Fort Worth, TX 76193-0500.

The official docket may be examined in the Rules Docket, Office of the Chief Counsel, room 916, 800 Independence Avenue, SW., Washington, DC, weekdays, except Federal holidays, between 8:30 a.m. and 5 p.m.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT:

Lewis W. Still, Airspace and Obstruction Evaluation Branch (ATP-240), Airspace-Rules and Aeronautical Information Division, Air Traffic Rules and Procedures Service, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone: (202) 267-9250.

SUPPLEMENTARY INFORMATION:

Comments Invited

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views,

or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal.

Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 93-ASW-31." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination in the Rules Docket both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, Office of Public Affairs, Attention: Public Inquiry Center, APA-220, 800 Independence Avenue, SW., Washington, DC 20591, or by calling (202) 267-3485. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to remove a portion of J-142 between San Simon, AZ, and Socorro, NM. J-142 is a dogleg route established for use when R-5113 is in use. R-5113 is used for thunderstorm research approximately one month a year. Since that portion of J-142 is rarely used, FAA proposes to remove that segment. Aircraft would be vectored clear of the area when R-5113 is active. This action would reduce chart clutter. Jet routes are published in

paragraph 2004 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The jet route listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore—(1) is not a "major rule" under Executive Order 12291; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 2004—Jet Routes

* * * * *

J-142 [Revised]

From Anton Chico, NM; to Borger, TX.

* * * * *

Issued in Washington, DC, on October 5, 1993.

Harold W. Becker,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 93-25214 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 71

[Airspace Docket No. 93-ANM-32]

Proposed Amendment to Class E Airspace; Roosevelt, UT

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This proposed rule would amend the Roosevelt, Utah, Class E Airspace. This action is necessary to accommodate a new instrument approach procedure at Roosevelt Municipal Airport, Roosevelt, Utah. Airspace reclassification, in effect as of September 16, 1993, has discontinued the use of the term "transition area," replacing it with the designation "Class E airspace." The area would be depicted on aeronautical charts.

DATES: Comments must be received on or before November 30, 1993.

ADDRESSES: Send comments on the proposal in triplicate to: Manager, System Management Branch, ANM-530, Federal Aviation Administration, Docket No. 93-ANM-32, 1601 Lind Avenue SW., Renton, Washington 98055-4056.

The official docket may be examined at the same address.

An informal docket may also be examined during normal business hours at the address listed above.

FOR FURTHER INFORMATION CONTACT: James Riley, ANM-537, Federal Aviation Administration, Docket No. 93-ANM-32, 1601 Lind Avenue SW., Renton, Washington 98055-4056; telephone number: (206) 227-2537.

SUPPLEMENTARY INFORMATION:**Comments Invited**

Interested parties are invited to participate in this proposed rulemaking by submitting such written data, views, or arguments as they may desire. Comments that provide the factual basis supporting the views and suggestions presented are particularly helpful in developing reasoned regulatory decisions on the proposal. Comments are specifically invited on the overall regulatory, aeronautical, economic, environmental, and energy-related aspects of the proposal. Communications should identify the airspace docket number and be submitted in triplicate to the address listed above. Commenters wishing the FAA to acknowledge receipt of their comments on this notice must submit with those comments a self-addressed, stamped postcard on which the following statement is made: "Comments to Airspace Docket No. 93-

ANM-32." The postcard will be date/time stamped and returned to the commenter. All communications received on or before the specified closing date for comments will be considered before taking action on the proposed rule. The proposal contained in this notice may be changed in light of comments received. All comments submitted will be available for examination at the address listed above both before and after the closing date for comments. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

Availability of NPRM's

Any person may obtain a copy of this Notice of Proposed Rulemaking (NPRM) by submitting a request to the Federal Aviation Administration, System Management Branch, ANM-530, 1601 Lind Avenue SW., Renton, Washington 98055-4056. Communications must identify the notice number of this NPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11-2A, which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 71 of the Federal Aviation Regulations (14 CFR part 71) to amend Class E airspace at Roosevelt, Utah, to accommodate a new instrument approach procedure at Roosevelt Municipal Airport. Airspace reclassification, in effect as of September 16, 1993, has discontinued the use of the term "transition area," and airspace extending upward from 700 feet or more above the surface of the earth is now Class E airspace. The area would be depicted on aeronautical charts for pilot reference. The coordinates for this airspace docket are based on North American Datum 83. Class E airspace areas extending upward from 700 feet or more above the surface of the earth are published in Paragraph 6005 of FAA Order 7400.9A dated June 17, 1993, and effective September 16, 1993, which is incorporated by reference in 14 CFR 71.1 (58 FR 36298; July 6, 1993). The Class E airspace designation listed in this document would be published subsequently in the Order.

The FAA has determined that this proposed regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. It, therefore, (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) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule, when promulgated, will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

List of Subjects in 14 CFR Part 71

Airspace, Incorporation by reference, Navigation (Air).

The Proposed Amendment

In consideration of the foregoing, the Federal Aviation Administration proposes to amend 14 CFR part 71 as follows:

PART 71—[AMENDED]

1. The authority citation for 14 CFR part 71 continues to read as follows:

Authority: 49 U.S.C. app. 1348(a), 1354(a), 1510; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389; 49 U.S.C. 106(g); 14 CFR 11.69.

§71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9A, Airspace Designations, and Reporting Points, dated June 17, 1993, and effective September 16, 1993, is amended as follows:

Paragraph 6005 Class E Airspace areas extending upward from 700 feet or more above the surface of the earth.

* * * * *

ANM UT E5 Roosevelt, UT [Revised]

Roosevelt Municipal Airport, UT
(Lat. 40°16'42"N, long. 110°03'05"W)
Myton VORTAC
(Lat. 40°08'42"N, Long. 110°07'40"W)

That airspace extending upward from 700 feet above the surface within a 6.53-mile radius of the Roosevelt Municipal Airport, and within 1.8 miles either side of the Myton VORTAC 024 degree radial extending from the 6.53-mile radius of the airport to the Myton VORTAC; that airspace extending upward from 1,200 feet above the surface bounded by a line beginning at lat. 39°52'04"N., long. 110°15'12"W.; to lat. 40°27'47"N., long. 110°16'01"W.; to lat. 40°19'20"N., long. 109°33'16"W.; to lat. 40°03'27"N., long. 109°24'49"W.; to lat. 40°04'04"N., long. 109°44'52"W.; to lat. 39°52'27"N., long. 109°44'36"W.; to the point of beginning.

* * * * *

Issued in Seattle, Washington, on September 24, 1993.

Temple H. Johnson, Jr.,

Manager, Air Traffic Division.

[FR Doc. 93-25211 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Part 1

[FI-16-89]

RIN 1545-AN15

Regulations Under Section 446 of the Internal Revenue Code of 1986; Application of Section 446 With Respect to Notional Principal Contracts

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Partial withdrawal of proposed rulemaking.

SUMMARY: This document withdraws the proposed regulations relating to the mark-to-market election for dealers and traders in derivative financial instruments.

FOR FURTHER INFORMATION CONTACT: Alan B. Munro, (202) 622-3950 (not a toll-free number).

SUPPLEMENTARY INFORMATION:

Background

On July 10, 1991, the IRS published in the *Federal Register* a notice of proposed rulemaking at 56 FR 31350 (FI-16-89, 1991-2 C.B. 951) under sections 446(b) (relating to general rules for methods of accounting) and 1092(d) (relating to definitions and special rules with respect to straddles) of the Internal Revenue Code of 1986. The proposed regulations provided an election by which dealers and traders in notional principal contracts and other derivative financial instruments could mark their derivative instruments to market.

In view of the enactment of the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, section 13223, 107 Stat. 312 (codified at I.R.C. section 475), which requires dealers to mark certain securities to market, § 1.446-4 of the proposed regulations is hereby withdrawn.

List of Subjects in 26 CFR Part 1

Income taxes, Reporting and recordkeeping requirements.

§ 1.446-4 [Partial Withdrawal of Notice of Proposed Rulemaking]

Accordingly, under the authority of 26 U.S.C. 7805, proposed § 1.446-4

published in the *Federal Register* on July 10, 1991 (56 FR 31350) is withdrawn.

Margaret Milner Richardson,

Commissioner of Internal Revenue.

[FR Doc. 93-25193 Filed 10-8-93; 1:26 pm]

BILLING CODE 4830-01-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Parts 122, 123, 131, and 132

[FRL-4788-6]

RIN 2040-AC08

Proposed Water Quality Guidance for the Great Lakes System

AGENCY: Environmental Protection Agency.

ACTION: Notice of public meeting.

SUMMARY: The purpose of this notice is to announce an open public meeting scheduled for November 15-16, 1993, to discuss comments on the proposed Water Quality Guidance for the Great Lakes System. The notice also establishes procedures to notify interested persons of any future meetings on the same subject.

DATES: The open public meeting to discuss comments on the proposed Water Quality Guidance for the Great Lakes System will be held on November 15 and 16, 1993. The meeting will begin at 10 a.m. and will conclude at 4:30 p.m. on November 15, 1993. The meeting will continue at 8:30 a.m. on November 16, 1993, and conclude at 4:30 p.m. or as otherwise arranged. Continuation of this meeting, if necessary, will be held December 2 and 3, 1993.

ADDRESSES: The open public meeting and its continuation will be held in Chicago, Illinois. The exact location in Chicago for the meeting was not available as of publication of this notice. Interested persons may call Phillippa Cannon (telephone: 312-353-6218) for the meeting location not sooner than two weeks prior to the meeting.

Requests for changes or additions to the mailing list for notification of continuations of this meeting or of any subsequent meetings should be sent to Phillippa Cannon, Office of Public Affairs, U.S. EPA, Region 5, 77 West Jackson Blvd., Chicago, Illinois, 60604-3590 (telephone: 312-353-6218). Additional information on this, and any subsequent meeting dates, times, and locations may also be obtained by calling:

(1) Illinois, Indiana, Michigan, Minnesota, Ohio, and Wisconsin (telephone: 800-621-8431);

(2) Pennsylvania (telephone: 215-597-6911); and

(3) New York (telephone: 716-285-8842).

Materials in the public docket for the proposed Water Quality Guidance for the Great Lakes System are available for viewing by calling Wendy Schumacher (telephone: 312-886-0142). Microfiche copies of many of the supporting documents for the proposal, as well as microfiche copies of the comments are available at the locations listed in the proposal (April 16, 1993; 58 FR 20802).

FOR FURTHER INFORMATION CONTACT: John J. O'Grady, Great Lakes Water Quality Guidance Team Leader, (WQS-16J), U.S. EPA, Region 5, 77 West Jackson Blvd., Chicago, Illinois, 60604-3590 (telephone: 312-353-1938).

SUPPLEMENTARY INFORMATION: On April 16, 1993, EPA published the proposed Water Quality Guidance for the Great Lakes System in the *Federal Register* (58 FR 20802). The period for receiving public comments on the proposal closed on September 13, 1993. EPA subsequently announced the availability of three additional reports that EPA is considering as it develops the final Guidance. (August 9, 1993, 58 FR 42266; September 13, 1993, 58 FR 47845) The period for receiving comments on issues raised in the three reports closed on October 13, 1993.

The preamble to the April 16, 1993, proposal described EPA's intent to hold an open public meeting with representatives of the States that implement water pollution control programs in the Great Lakes Basin for the purpose of receiving the views of both the Great Lakes States and other members of the public on the written comments submitted during the public comment period (58 FR 20823).

The open public meeting will be held on November 15 and 16, 1993, in Chicago, Illinois, at the times listed above. The exact location in Chicago for the meeting was not available as of publication of this notice. Interested persons may call Phillippa Cannon for the meeting location not sooner than two weeks prior to the meeting. EPA will reserve a portion of the meeting for comments by interested members of the public.

EPA believes it may be necessary to hold one or more continuations of the open public meeting. If so, EPA will provide not less than 30 days notice of the date(s), time(s), and location(s) of such meeting(s) to persons on the mailing list for the meeting. If such a

continuation is necessary, the first such continuation will be held on December 2 and 3, 1993. The mailing list for the open public meeting currently consists of members of the Great Lakes Initiative Steering Committee, Technical Work Group, and Public Participation Group. Interested persons may request that their names be added to the mailing list by writing to Phillippa Cannon at the address listed above.

EPA will place a summary or transcript of the open public meeting and its continuations, if any, in the public docket at the address listed above.

Dated: October 6, 1993.

Valdas V. Adamkus,

Regional Administrator, U.S. EPA, Region 5.

[FR Doc. 93-25226 Filed 10-13-93; 8:45 am]

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FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 22, 25, 80, 87, 90, 95, and 99

[GN Docket No. 93-252; FCC 93-454]

Implementation of Sections 3(n) and 332 of the Communications Act; Regulatory Treatment of Mobile Services

AGENCY: Federal Communication Commission.

ACTION: Proposed rule.

SUMMARY: The Commission has adopted a Notice of Proposed Rule Making (Notice) in response to Congress's mandate directing the agency to implement sections 3(n) and 332 of the Communications Act of 1934 as amended by title VI, section 6002(b) of the Omnibus Budget Reconciliation Act of 1993, Pub. L. 103-66, 107 Stat. 312, 392 (Budget Act). The intended effect of this Notice is to implement this legislation by soliciting comment on (1) definitional issues raised by the Budget Act; (2) regulatory classification of mobile services, including Personal Communications Service (PCS), affected by the legislation; and (3) which provisions of title II of the Communications Act should be applied to commercial mobile services and which should be forborne.

DATES: Comments must be filed on or before November 8, 1993, and reply comments must be filed on or before November 23, 1993.

ADDRESSES: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT:

Common Carrier Bureau Contacts: Peter Batacan, (202) 632-6450 or Nancy Boocker, (202) 632-0935 (Mobile Services Division); Judy Argentieri, (202) 632-6917 (Tariff Division). Private Radio Bureau Contact: David Furth, (202) 634-2443 (Land Mobile and Microwave Division).

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, GN Docket No. 93-252, FCC 93-454, adopted September 23, 1993, and released October 8, 1993. The full text of the Notice is available for inspection and copying during normal business hours in the FCC Public Reference Center, room 239, 1919 M Street, NW., Washington, DC. The complete text may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M St., NW., suite 140, Washington, DC 20037, (202) 857-3800.

Summary of Notice of Proposed Rule Making

1. Section 6002(b)(2) of the Budget Act amends sections 3(n) and 332 of the Communications Act to create a comprehensive framework for the regulation of all mobile radio services. Under revised section 332, each mobile service is classified as either "commercial mobile service" or "private mobile service." The new legislation requires the Commission to define or specify particular elements of these terms by regulation. In addition, the statute states that commercial mobile service providers are to be treated as common carriers under the Communications Act, except that the Commission may exempt these entities from certain provisions of title II. Private mobile services are not subject to any common carrier regulation.

2. The new legislation states that a "commercial mobile service" is any mobile service that (1) is "provided for profit," and (2) makes "interconnected service" available to "the public" or to "such classes of eligible users as to be effectively available to a substantial portion of the public." The first issue discussed in the Notice is how the "for profit" element should be interpreted. The Commission believes that this language was intended to broadly distinguish between those mobile radio licenses that seek to provide mobile radio service on a for-profit basis to customers and those licenses that do not. The Commission solicits comment on this interpretation and on how it should devise rules reflecting this basic distinction. In particular, the

Commission requests comment on how the "for profit" test should be applied to shared use systems currently operating under part 90.

3. Another element of the definition of a "commercial mobile service" is that "interconnected service" must be available. "Interconnected service," in turn, is defined as service that is "interconnected with the public switched network" or "service for which a request for interconnection is pending * * *." The Commission solicits comment on whether interconnected service should be interpreted to mean (1) that in order for a particular service offering to be considered "interconnected service," interconnected service must be offered at the end user level, i.e., the service must provide an end user with the ability to directly control access to the public switched network for purposes of sending or receiving messages to or from points on the network; or (2) that Congress was concerned that certain "private line" type services might interconnect with and use facilities of the public switched network but that a subscriber would be able to send or receive messages only between limited points in the network. Under the latter interpretation, such private line services would not be considered interconnected service, but a service that would allow the subscriber to send or receive messages over the public switched network would constitute interconnected service. The Commission also seeks comment on whether a carrier that interconnects with a commercial mobile service provider necessarily offers interconnected service because its messages would be transmitted between its system and the rest of the public switched network.

4. Relatedly, the Commission requests comment on the degree to which its precedent concerning interconnection may be helpful in defining the term "interconnected." One option is to define "interconnected" in a manner similar to that set forth in the Commission's International Satellite Systems order, in which the agency determined that a system is interconnected if it uses a PBX or the manual interconnection of a switchboard operator or if a data circuit terminates in a computer than can store and process the data and subsequently retransmit it over the network. Another alternative is to define as interconnected only those services that permit subscribers direct, real-time access to the public switched telephone network, which could cause systems that use

"store-and-forward" technology to be considered non-interconnected.

5. The Commission also seeks comment on the definition of "public switched network." Specifically, commenters are asked to discuss whether the traditional use of the similar term "public switched telephone network," referring to the local exchange and interexchange common carrier switched network, should be applied, or whether Congress intended for this element of the new statutory test to be more expansive.

6. Next, the Commission requests comment on what is meant by "service available to the public or to such classes of eligible users as to be effectively available to a substantial portion of the public." One option is to define "service to the public" to include any service that is offered to all people indifferently, and to interpret "classes of eligible users so as to be effectively available to a substantial portion of the public" to turn on whether the service is being held out to classes of eligible users that constitute a large sector of the general public in that service area. Another option is to distinguish between services that are, as a practical matter, available to a substantial portion of the public and those that are offered to small or specialized user groups or that, because of low system capacity, cannot compete with high-capacity services and have little impact on the availability of mobile service to the public as a whole.

7. Comment is also solicited on two possible interpretations of section 332(d)(3), which defines a "private mobile service" as any mobile service that is not a commercial mobile service or the "functional equivalent of a commercial mobile service." Under one approach, a mobile service would be classified as private if (1) it fails to meet the statutory definition of a commercial mobile service, or (2) it is not the functional equivalent of a commercial mobile service, even if it meets the literal definition of a commercial mobile service. Under another reading of the legislation, a mobile service would be classified as private if (1) it fails to meet the statutory definition of a commercial mobile service and (2) it is not the functional equivalent of a commercial mobile service. Also, the Commission seeks comment on what specific standards it should use to determine whether a given mobile service is the functional equivalent of a commercial mobile service.

8. The Commission requests comment on which existing mobile services will become commercial mobile services and which will become private mobile

services under section 332(d). In accordance with the exclusion of not-for-profit services from the statutory definition of commercial mobile service, the Commission proposes that existing government, public safety, and private non-commercial services under part 90 of the Commission's rules will remain private mobile service under section 332(d)(3). With respect to existing for-profit services regulated under part 90, classification will depend on whether such services fit within the definition of commercial mobile service or are the functional equivalent of commercial mobile service. The Commission seeks comment on how this test will affect the classification of all existing services licensed under part 90 that are offered on a for-profit basis.

9. The Commission also requests comment on how existing common carrier services should be classified. Generally, the Commission believes that existing common carrier mobile services that provide interconnected radiotelephone service to the public (e.g., cellular) will be classified as commercial mobile services. Depending on how the Commission resolves the definitional issues presented by the new legislation, however it is possible that some common carrier mobile services could be reclassified as private mobile services. The Commission seeks comment on whether it should amend its rules to allow existing common carriers that are classified as commercial mobile services to provide dispatch service in the future.

10. The Commission notes that mobile services using the system capacity of a satellite licensee are defined as mobile services under new section 3(n) of the Communications Act. Under existing policy, the Commission may authorize a domestic satellite licensee to offer system capacity for the provision of mobile service on a non-common carriage basis. However, the Commission will refuse to allow a satellite licensee to offer system capacity on a private carriage basis if there is a showing that such regulatory treatment will run counter to the public interest. Under the new section 332(c)(5), Congress did not prohibit the Commission from continuing to determine whether the provision of space segment capacity by satellite systems to providers of commercial mobile services shall be treated as common carriage. The Commission tentatively concludes that it should continue its existing procedures for making this determination.

11. The Commission seeks comment on how the new regulatory framework should affect the classification of PCS.

The Commission tentatively concludes that no single regulatory classification should be applied to all PCS services, but rather that PCS licensees should be given the option to provide commercial mobile or private mobile service. This would allow licensees to select the type of services they will provide based on market demand rather than on regulatory preconditions. The Notice further seeks comment on whether PCS licensees should be required to choose one category of service to provide on a primary basis or whether licensees should be allowed to provide both commercial and private mobile service on a co-primary basis.

12. New sections 332(c)(1)(A) and 332(c)(1)(C) authorize the Commission to promulgate regulations exempting some or all commercial mobile services from regulation under any provision of title II other than sections 201, 202 and 208, so long as certain conditions are satisfied. In consideration of the three-pronged test set forth in the statute, the Notice asks commenters, *inter alia*, to apply the three-pronged test when evaluating whether forbearance is appropriate for any provisions of title II, to address the impact of forbearance on the competitive conditions for each commercial mobile service, and to comment on what information the Commission should consider when performing these evaluations.

13. The Notice tentatively concludes that the Commission has the authority to establish classes or categories of commercial mobile services for purposes of applying such regulations and seeks comment on the types of categories and classifications that should be established, if any. The Commission seeks comment on whether the public interest would be served by forbearance from application of most of title II, including tariff regulation, and the related entry and exit provisions in sections 203, 204, 205, 211, and 214, as well as sections 210, 212, 213, 215, 218, 219, 220 and 221, to any commercial mobile service provider.

14. The Commission tentatively concludes that it should not forbear from applying sections 206, 207 and 209, as these are provisions associated with the compliant remedy described in section 208, which remains mandatory under the statute. The Commission also tentatively concludes that it should not forbear from applying sections 216 and 217, which extend the application of the Act to receivers and agents. The Commission requests comment on these tentative conclusions as well as whether it should forbear from applying sections 223, 225, 226, 227, and 228, which are provisions of more recent origin that

contain specific types of protection for consumers.

15. The Notice seeks comment with respect to the rights of commercial mobile service providers and private mobile service providers to demand interconnection with the public switched telephone network. Revised section 332(c)(1)(B) requires the Commission to order common carrier to interconnect with a commercial mobile service provider on reasonable request, but states that "this subparagraph shall not be construed as a limitation or expansion of the Commission's authority to order interconnection pursuant to * * * [the Communications] Act." The Commission has previously addressed the application of its section 201 authority to require local exchange carriers (LECs) to interconnect with common carrier mobile services. The Commission sees no distinction between the interconnection rights of these entities and those of commercial mobile service providers. The Commission also tentatively concludes that, in the commercial mobile context, LEC provision of interstate and intrastate interconnection and the type of interconnection the LEC provides are inseparable, and therefore proposes that state regulation of the right to interconnect and the type of interconnection should be preempted. The Commission requests comment on whether it should require commercial mobile service providers to provide interconnection to other mobile service providers, and on whether, under section 332(c)(3) of the Act, state regulation of interconnection rates of commercial mobile service providers is preempted. The Notice further seeks comment on whether PCS providers of commercial mobile service should be subject to equal access obligations like those imposed on LECs.

16. The Commission also tentatively concludes that its power to require common carriers to provide interconnection to private mobile service providers is unaffected by the statute. Further, the Commission proposes that PCS licensees should have a federally protected right to interconnect with LEC facilities regardless of whether the PCS licensees are classified as commercial or private mobile service providers, and that inconsistent state regulation should be preempted. The Commission believes that the new legislation should not affect its original proposal that PCS providers be entitled to obtain interconnection of a type that is reasonable for the PCS system and no less favorable than that offered by the

LEC to any other customer or carrier. The Notice requests comment on whether LECs should be required to file tariffs specifying interconnection rates. The Commission continues to believe that with respect to the rates for interconnection, it is unnecessary to preempt state and local regulation at this time.

17. Under the new legislation, all reclassified private licensees are immediately subject to the foreign ownership restrictions imposed on common carriers by section 310(b) of the Communications Act. The statute allows affected licensees to maintain the level of foreign ownership that existed as of May 24, 1993, only if they petition the Commission for waiver within six months of enactment (by February 10, 1994). The Commission proposes to establish a petition procedure for affected private land mobile licensees to "grandfather" existing foreign ownership under the statute.

18. Section 332(c)(3)(A) preempts state and local rate and entry regulation of all commercial mobile services. Under section 332(c)(3)(B), however, any state that has rate regulation in effect for a commercial mobile service as of June 1, 1993, may, prior to August 10, 1994, petition the Commission to extend that authority based on a showing that (1) market conditions will not protect subscribers from unjust, unreasonable, or discriminatory rates, or (2) such conditions exist and the service is a replacement for landline telephone exchange service in the state. In addition, states may petition the Commission to initiate rate regulation based on these same criteria. The Commission intends to establish procedures for the filing of such petitions, and seeks comment on what factors should be considered in establishing them.

Initial Regulatory Flexibility Analysis

As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared an Initial Regulatory Flexibility Analysis (IRFA) of the expected impact on small entities of the proposals contained in the Notice. Written public comments are requested on the IRFA.

A. Reason for Action

This rule making proceeding was initiated to secure comment on various proposals for the implementation of sections 3(n) and 332 of the Communications Act, 47 U.S.C. 153(n), 332, as amended by title VI of the Omnibus Budget Reconciliation Act. The proposals advanced herein are designed to carry out Congress' intent to

establish a new regulatory framework for all mobile radio services.

B. Objectives

Congress has directed the Commission to implement sections 3(n) and 332, as amended. In accordance with this directive, the Commission seeks to devise a regulatory scheme that will allow for the equitable treatment of comparable mobile services providers, as categorized under the terms of the new legislation. In turn, this will promote regulatory certainty and allow for the enhanced provision of service to the public.

C. Legal Basis

The proposed action is authorized under the Omnibus Budget Reconciliation Act of 1993, Public Law 103-66, title VI, section 6002(b), and sections 3(n), 4(i), 303(r), 332(c) and 332(d) of the Communications Act of 1934, 47 U.S.C. 153(n), 154(i), and 303(r), 332(c), and 332(d), as amended.

D. Reporting, Recordkeeping and Other Compliance Requirements

The proposals under consideration in this Notice may impose certain new reporting and recordkeeping requirements on mobile services licensees whose regulatory status has changed from private to commercial as a result of the new legislation. The extent of this increase will depend in substantial part on the degree of title II regulation imposed on such licensees.

E. Federal Rules Which Overlap, Duplicate or Conflict With These Rules

None.

F. Description, Potential Impact, and Number of Small Entities Involved

Many small entities could be affected by the proposals contained in the Notice. Depending on the final resolution of the issues, the regulatory classification of some existing private land mobile licensees and possibly some existing common carrier services may be changed. The full extent of these changes cannot be predicted until various other issues raised in the proceeding have been resolved. After evaluating the comments filed in response to the Notice, the Commission will examine further the impact of all rule changes on small entities and set forth its findings on the Final Regulatory Flexibility Analysis.

G. Any Significant Alternatives Minimizing the Impact on Small Entities Consistent With the Stated Objectives

The Notice solicits comment on a variety of alternatives. Any additional

significant alternatives presented in the comments will also be considered.

H. IRFA Comments

The Commission requests written public comment on the foregoing Initial Regulatory Flexibility Analysis. Comments must have a separate and distinct heading designating them as responses to the IRFA and must be filed by the deadlines specified in the summary above.

List of Subjects in 47 CFR Parts 22, 25, 80, 87, 90, 95, and 99

Mobile radio services, Radio.

Federal Communications Commission.

William P. Caton,

Acting Secretary.

[FR Doc. 93-25308 Filed 10-13-93; 8:45 am]

BILLING CODE 6712-01-M

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 622, 625, 628, 649, 650, 651, 652, and 655

[Docket No. 930771-3171; I.D. 011293C]

Northeast Region General Fisheries Permit and Reporting Procedures

AGENCY: National Marine Fisheries Service (NMFS), NOAA, Commerce.

ACTION: Proposed rule; request for comments.

SUMMARY: NMFS proposes to amend the regulations implementing the fishery management plans (FMPs) for the Summer Flounder Fishery, Atlantic Bluefish Fishery, American Lobster Fishery, Atlantic Sea Scallop Fishery, Northeast Multispecies Fishery, Atlantic Surf Clam and Ocean Quahog Fisheries, and Atlantic Mackerel, Squid, and Butterfish Fisheries by consolidating provisions that pertain to permits and reporting requirements in the Northeast Region, NMFS, in a new CFR part common to these domestic, Northeast Region fisheries. The rule would also authorize fees to be collected as a requirement for specified fishing permits, allow NMFS to stagger permit issuance throughout the calendar year, require copies of official legal documentation with permit applications, make technical changes for consistency, and clarify weekly reporting requirements in the Atlantic Surf Clam and Ocean Quahog Fisheries. This is intended to assure consistency among the permitting activities and requirements for various fisheries,

eliminate redundancy, and reduce Federal Register publication costs.

DATES: Comments on the proposed rule must be received on or before November 15, 1993.

ADDRESSES: Comments on the proposed rule may be mailed to Richard B. Roe, Regional Director, National Marine Fisheries Service, One Blackburn Drive, Gloucester, MA 01930. Mark the outside of the envelope "Comments on Northeast Region Permitting Procedures." Comments regarding the burden-hour estimates or any other aspect of the collection-of-information requirements contained in this proposed rule should be sent to the Northeast Regional Director (address listed above) and the Office of Management and Budget (Attention: NOAA Desk Officer), Washington, DC 20503.

FOR FURTHER INFORMATION CONTACT: E. Martin Jaffe, (Resource Management Specialist, Northeast Region, NMFS), 508-281-9272.

SUPPLEMENTARY INFORMATION: This proposed rule would consolidate NMFS Northeast Regional administrative and permitting provisions in a new part 622 of title 50 CFR, which would be referenced in the parts governing domestic fisheries activities in the Northeast Region. This proposed rule would amend 50 CFR parts 625, 628, 649, 650, 651, 652, and 655 by revising affected sections and consolidating provisions now contained in §§ 628.4, 649.4, 649.6, 650.4, 650.6, 651.4, 651.6, 652.4 through 652.7, 655.4 and 655.6 in new 50 CFR part 622. Because many vessel owners and dealers/processors are permitted in multiple fisheries, this proposed rule would significantly ease the burden of the current application process.

Consolidation would also eliminate redundancy, ensure consistency and ease revision of permitting requirements. The inclusion of permit-related activities, such as recordkeeping and reporting, vessel identification, and other provisions would assist in avoiding duplication, lessen the bulk of the regulations, and reduce future Federal Register printing costs without inconveniencing users. In addition, this rule would: Authorize fees to be collected as a requirement for obtaining fishing permits where fees are authorized in the FMP—the fee charged would not exceed the administrative costs of permit issuance as provided for by section 304(d) of the Magnuson Fishery Conservation and Management Act (Magnuson Act); allow NMFS to stagger permit issuance by establishing permit renewal dates throughout the calendar year; require applicants for

permits, when applicable, to submit a copy of their official U.S. Coast Guard vessel documentation, charter/party boat license, Certificate of Incorporation, and/or Partnership Agreement; clarify when dealers, processors and vessel owners/operators in the Atlantic surf clam and ocean quahog fisheries must submit weekly reports; update the office address and telephone numbers of the Northeast Regional Office, NMFS, where they appear in the regulations; consolidate reporting requirements wherever possible; and make minor changes in wording to assure internal consistency. This rule would also add data items, to be completed by the applicant, to the permit application and remove items that have either become unnecessary or are collected through another data collection method.

Classification

The Regional Director has initially determined that this proposed rule is necessary for the conservation and management of the Northeast Region fisheries and is consistent with the Magnuson Act and other applicable law.

The Regional Director has determined that this rule is consistent with the FMPs implemented through the regulations proposed to be amended by this rule.

This proposed rule does not change the scope or intent of the regulations implementing the FMPs or amendments and is categorically excluded from the requirement to prepare an environmental assessment under the National Environmental Policy Act by NOAA Administrative Order 216-6.

The Assistant Administrator for Fisheries, NOAA (Assistant Administrator), has determined that this proposed rule is not a "major rule" requiring a regulatory impact analysis under E.O. 12291. The proposed action will not have a cumulative effect on the economy of \$100 million or more, nor will it result in a major increase in costs to consumers, industries, government agencies, or geographical regions. No significant adverse effects on competition, employment, investment, productivity, innovation, or competitiveness of U.S.-based enterprises are anticipated. The rule primarily proposes technical revisions to improve the effectiveness of existing regulations.

The General Counsel of the Department of Commerce certified to the Small Business Administration that this proposed rule, if adopted, will not have a significant economic impact on a substantial number of small entities. As a result, a regulatory flexibility

analysis was not prepared. All of the vessels operating in the Northeast Region fisheries are considered small entities.

This proposed rule revises two existing collection-of-information requirements subject to the Paperwork Reduction Act (OMB Approval No. 0648-0202). Additionally, this rule references, but does not change, four collections previously approved by OMB (OMB Approval No. 0648-0212, 5 minutes/response; OMB Approval No. 0648-0229, 2 minutes/response; OMB Approval No. 0648-0235, 15 minutes/response; and OMB Approval No. 0648-0202, 5 minutes/response regarding § 651.4). A request for approval of these revisions has been submitted to the Office of Management and Budget. The public's reporting burdens for these collection-of-information requirements are indicated in the parentheses in the following statements and include the time necessary for reviewing instructions, searching existing data sources, gathering and maintaining data needed, and completing and reviewing the collection-of-information requirements. Revisions to the existing requirements are: (1) Dealer permits (5 minutes/response); and vessel permits (30 minutes/initial application and 15 minutes/renewal). Send comments regarding these burden-hour estimates or any other aspect of these collection-of-information requirements, including suggestions for reducing the burden hours, to Richard Roe (NMFS) and to the Office of Management and Budget (Attention: NOAA Desk Officer) (see ADDRESSES).

The Assistant Administrator has determined that this rule will be implemented in a manner that is consistent to the maximum extent practicable with the approved coastal management programs of Maine, New Hampshire, Massachusetts, Rhode Island, Connecticut, New York, New Jersey, Pennsylvania, Delaware, Maryland, Virginia, and North Carolina. Since this rule consolidates regulatory measures from previous actions, it has been determined that previous coastal zone determinations are sufficient and no new determinations are necessary.

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

List of Subjects in 50 CFR Chs. II and VI

Fisheries.

Dated: October 7, 1993.

Samuel W. McKeen,

Program Management Officer, National Marine Fisheries Service.

For the reasons set forth in the preamble, title 50 CFR parts 625, 628, 649 through 652, and 655 are proposed to be amended, and a new part 622 is proposed to be added, as follows:

Part 622 is added to read as follows:

PART 622—NORTHEAST REGION GENERAL FISHERIES ADMINISTRATIVE AND PERMIT PROCEDURES

Subpart A—Introduction

Sec.

- 622.1 General.
- 622.2 Purpose of regulations.
- 622.3 Scope of regulations.
- 622.4 Definitions.
- 622.5 Vessel identification.

Subpart B—Permit Categories and Requirements

- 622.11 Summer flounder fishery.
- 622.12 Atlantic bluefish fishery.
- 622.13 American lobster fishery.
- 622.14 Atlantic sea scallop fishery.
- 622.15 Northeast multispecies fishery.
- 622.16 Atlantic surf clam and ocean quahog fisheries.
- 622.17 Atlantic mackerel, squid, and butterfish fisheries.

Subpart C—Permit Administration and Conditions

- 622.31 Application.
- 622.32 Issuance.
- 622.33 Information requirements.
- 622.34 Conditions.
- 622.35 Prohibitions.

Subpart D—Recordkeeping and Reporting

- 622.41 Summer flounder fishery.
- 622.42 Atlantic surf clam and ocean quahog fisheries.

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

Subpart A—Introduction

§ 622.1 General.

Each person intending to engage in an activity for which a permit is required by parts 625, 628, 649 through 652, or part 655 of this title shall, before commencing such activity, obtain a valid permit authorizing such activity. Each person who desires to obtain the permit privileges authorized by parts 625, 628, 649 through 652, or part 655 of this title must apply for such permit in accordance with the requirements of this part and the other regulations in parts 625, 628, 649 through 652, or part 655 of this title, which set forth additional requirements for the specific permits desired. If the activity for which permission is sought is covered by the requirements of more than one of the parts listed in this section, the

requirements of each part must be met. If the information required for each specific permitted activity is included, one application may be accepted for all permits required and single or multiple permit(s) may be issued.

§ 622.2 Purpose of regulations.

The regulations contained in this part provide uniform rules and procedures for application, issuance, renewal, conditions, reporting requirements, and general administration of permits issued pursuant to parts 625, 628, 649 through 652, and part 655 of this title.

§ 622.3 Scope of regulations.

The provisions of this part are in addition to, and are not in lieu of, other regulatory requirements of parts 625, 628, 649 through 652, and part 655 of this title and apply to all permits issued thereunder.

§ 622.4 Definitions.

In addition to the definitions in the Magnuson Act, parts 625, 628, 649 through 652, and part 655 of this title, and in § 620.2 of this chapter, the terms used in this part have the following meanings (definitions are repeated here to aid understanding of the rules):

American lobster means the species *Homarus americanus*.

Atlantic bluefish means the species *Pomatomus saltatrix*. Bluefish, for the purposes of this part, refers to bluefish in the Atlantic EEZ from the eastern coast of Florida to Maine.

Atlantic butterfish or *butterfish* means the species *Pepilus triacanthus*.

Atlantic mackerel or *mackerel* means the species *Scomber scombrus*.

Atlantic sea scallop or *scallop* means the species *Placopecten magellanicus* throughout its range.

Atlantic surf clam or *surf clam* means the species *Spisula solidissima*.

Authorized officer means:

(1) Any commissioned, warrant, or petty officer of the U.S. Coast Guard; or any U.S. Coast Guard personnel accompanying and acting under the direction of a commissioned, warrant, or petty officer of the U.S. Coast Guard.

(2) Any special agent or fisheries enforcement officer of NMFS;

(3) Any person designated by the head of any Federal or state agency that has entered into an agreement with the Secretary and the Commandant of the U.S. Coast Guard to enforce the provisions of the Magnuson Act.

Dealer means any person who first receives fish or shellfish from a fishing vessel by way of purchase, barter, or trade, except for the following fisheries:

(1) *Atlantic surf clam* and *ocean quahog*—*dealer* means any person who

receives surf clams and ocean quahogs for a commercial purpose and who does not remove them from the cage. This definition does not include persons who receive surf clams and ocean quahogs solely for transport on land.

(2) *Summer flounder—dealer* means any person who receives summer flounder for a commercial purpose directly from a vessel issued a permit under § 622.11(a), other than solely for transport on land.

Exclusive economic zone (EEZ) means the zone established by Presidential Proclamation 5030, dated March 10, 1983, and is that area adjacent to the United States which, except where modified to accommodate international boundaries, encompasses all waters from the seaward boundary of each of the coastal states to a line on which each point is 200 nautical miles from the baseline from which the territorial sea of the United States is measured.

Fish means finfish, mollusks, crustaceans, and all other forms of marine animal and plant life other than marine mammals and birds.

Fishing, or to fish, means any activity, other than a scientific research activity, conducted by a scientific research vessel, that involves:

(1) The catching, taking, or harvesting of fish;

(2) The attempted catching, taking, or harvesting of fish;

(3) Any other activity that can reasonably be expected to result in the catching, taking, or harvesting of fish; or

(4) Any operations at sea in support of, or in preparation for, any activity described in paragraph (1), (2), or (3) of this definition.

Fishing record means all records of navigation and operations, as well as all records of catching, harvesting, transporting, landing, purchase or sale of fish.

Fishing vessel means any vessel, boat, ship, or other craft that is used for, equipped to be used for, or of a type that is normally used for:

(1) Fishing; or

(2) Aiding or assisting one or more vessels at sea in the performance of any activity relating to fishing, including, but not limited to, preparation, supply, storage, refrigeration, transportation, or processing.

Illex means the species *Illex illecebrosus* (short-finned or summer squid).

Loligo means the species *Loligo pealei* (long-finned or bone squid).

Multispecies finfish includes, but is not limited to, the following finfish in the northeast portion of the Atlantic Ocean EEZ:

Gadus morhua, Atlantic cod.

Glyptocephalus cynoglossus, witch flounder.

Hippoglossoides platessoides, American plaice.

Limanda ferruginea, yellowtail flounder.

Macrozoarces americanus, ocean pout.

Melanogrammus aeglefinus, haddock.

Merluccius bilinearis, silver hake.

Pollachius virens, pollock.

Pseudopleuronectes americanus, winter flounder.

Scophthalmus aquosus, windowpane flounder.

Sebastes marinus, redfish.

Urophycis chuss, red hake.

Urophycis tenuis, white hake.

NMFS means the National Marine Fisheries Service, NOAA.

Ocean quahog or *quahog* means the species *Arctica islandica*.

Owner, with respect to any vessel, means:

(1) Any person who owns that vessel in whole or in part;

(2) Any charterer of the vessel, whether bareboat, time, or voyage;

(3) Any person who acts in the capacity of a charterer, including, but not limited to, parties to a management agreement, operating agreement, or any similar agreement that bestows control over the destination, function, or operation of the vessel; or

(4) Any agent designated as such by a person described in paragraph (1), (2), or (3) of this definition.

Party or charter boat means any vessel that carries passengers for hire to engage in fishing.

Postmark means independently verifiable evidence of date of mailing such as U.S. Postal Service postmark, United Parcel Service (U.P.S.) or other private carrier postmark, certified mail receipt, overnight mail receipt or receipt received upon hand delivery to an authorized representative of the NMFS.

Processor means, in the Atlantic surf clam and ocean quahog fisheries, a person who receives surf clams or ocean quahogs for a commercial purpose and removes them from a cage.

Regional Director means the Director, Northeast Region, NMFS, One Blackburn Drive, Federal Building, Gloucester, MA 01930, 508-281-9300, or a designee.

Re-rigged for the summer flounder fishery means physical alteration of the vessel or its gear has begun to transform the vessel into one capable of fishing commercially for summer flounder.

Secretary means the Secretary of Commerce, or a designee.

Substantially similar harvesting capacity for the summer flounder fishery means the same or less Gross Registered Tonnage (GRT) and vessel registered length.

Summer flounder means the species *Paralichthys dentatus*.

Under construction means that the keel has been laid.

Vessel registered length means the registered length specified on the U.S. Coast Guard documentation or on the state registration (for undocumented vessels) if the state registered length is verified by a NMFS authorized official.

§ 622.5 Vessel Identification.

(a) *Vessel name*. Each fishing vessel subject to this part and over 25 feet (7.62 m) in length must display its name on the port and starboard sides of its bow and, as possible, on its stern.

(b) *Official number*. Each fishing vessel subject to this part and over 25 feet (7.62 m) in length must display its official number on the port and starboard sides of the deckhouse or hull and on an appropriate weather deck, so as to be visible from enforcement vessels and aircraft. The official number is the U.S. Coast Guard documentation number or the vessel's state registration number issued to a vessel not required to be documented under title 46 of the U.S. Code.

(c) *Numerals*. Except as provided in paragraph (e) of this section, the official number must be permanently affixed in contrasting block Arabic numerals at least 18 inches (45.7 cm) in height for vessels over 65 feet (19.81 m) in length, and at least 10 inches (25.4 cm) in height for all other vessels over 25 feet (7.62 m) in length. The length of a vessel, for purposes of this section, will be that length set forth in U.S. Coast Guard or state records.

(d) *Duties of owner and operator*. The owner and operator of each vessel subject to this part will:

(1) Keep the vessel's name and official number clearly legible and in good repair; and

(2) Ensure that no part of the vessel, its rigging, its fishing gear, or any other object obstructs the view of the official number from an enforcement vessel or aircraft.

(e) *Non-permanent marking*. Vessels carrying recreational fishing parties on a per capita basis or by charter must use markings that meet the above requirements, except for the requirement that they be affixed permanently to the vessel. The non-permanent markings must be displayed in conformity with the above requirements when the vessel is fishing for summer flounder, multispecies finfish, and/or Atlantic mackerel, squid or butterfish.

Subpart B—Permit Categories and Requirements

§ 622.11 Summer flounder fishery.

(a) *Vessel permit.* Any owner of a vessel of the United States must obtain a permit under this part to fish for or retain summer flounder in the EEZ. A vessel, other than party or charter boat, subject to the possession limit in § 625.25 of this chapter, is exempt from the permitting requirements. Vessel owners who apply for a fishing vessel permit under this section must agree as a condition of the permit that the vessel's fishing, catch and pertinent gear (without regard to whether such fishing occurs in the EEZ, or landward of the EEZ, and without regard to where such fish or gear are possessed, taken or landed) will be subject to all requirements of this part and 625 of this chapter. All such fishing, catch and gear will remain subject to all applicable state requirements.

(1) *Commercial (moratorium) permit.* A vessel must qualify for a commercial permit to fish for and retain summer flounder in excess of the recreational possession limit in the EEZ by meeting any of the following criteria:

(i) The vessel landed and sold summer flounder between January 26, 1985, and January 26, 1990; or

(ii) The vessel was under construction for, or was being riggered for, use in the directed fishery for summer flounder on January 26, 1990, provided the vessel landed summer flounder for sale prior to November 30, 1992; or

(iii) The vessel is replacing a vessel of substantially similar harvesting capacity that involuntarily left the summer flounder fishery during the moratorium, and both the entering and replaced vessels are owned by the same person. Vessel permits issued to vessels that involuntarily leave the fishery may not be combined to create larger replacement vessels.

(iv) Vessels that are judged unseaworthy by the U.S. Coast Guard for reasons other than lack of maintenance may be replaced by a vessel of substantially similar harvesting capacity.

(v) Applications for a commercial (moratorium) permit under this section will not be accepted more than 12 months after November 30, 1992, or the events specified under § 622.34(a)(2)(i) and (ii) of this part. This section does not affect annual permit renewals.

(vi) Owners and operators of vessels fishing under the terms of a commercial (moratorium) permit issued pursuant to this section must also agree, as a condition of the permit, not to land summer flounder in any state that the

Regional Director has determined no longer has commercial quota available.

(vii) If there is no further amendment of this section, the restrictions on eligibility to apply for and receive a commercial (moratorium) permit expire after 1997.

(2) *Party and charter boat permits.* Any party or charter boat is eligible for a permit to fish, other than a commercial (moratorium) permit, if it is carrying passengers for hire, and is then subject to the possession limits specified in § 625.25 of this chapter.

(b) *Dealer permit.* Dealers of summer flounder must have a permit issued under this section.

(c) Additional management requirements are set forth in part 625 of this chapter. Additional permit requirements are set forth in subpart C of this part.

§ 622.12 Atlantic bluefish fishery.

(a) *Individual permit.* Any person selling Atlantic bluefish harvested in the EEZ must have either a valid permit issued under this part or a valid state of landing permit to sell bluefish.

(1) An application for a Federally issued individual permit under this section must be obtained from the Regional Director, signed and submitted to the Regional Director. The applicant must provide the following information: Applicant name, mailing address, including ZIP code, and telephone number; height, weight, hair color, and eye color; a copy of the Certificate of Incorporation (if the applicant represents a corporation); percentage of annual income derived from the sale of bluefish; and any other information required by the Regional Director.

(2) Any person who applies for a permit under this section, or who uses a valid state permit to sell fish harvested from the EEZ, must agree as a condition of using either permit that his/her bluefish catch and gear (without regard to whether fishing occurs in the EEZ or landward of the EEZ, and without regard to where such bluefish or gear are possessed, taken, or landed) will be subject to all the requirements of this part and part 628 of this chapter. All such catch and gear will remain subject to any applicable state or local requirements.

(b) Additional management requirements are set forth in part 628 of this chapter.

§ 622.13 American lobster fishery.

(a) *Vessel permit.* Any vessel of the United States fishing for American lobster in the EEZ must have a permit required by this part on board the vessel.

(1) The Regional Director may, by agreement with state agencies, recognize permits or licenses issued by those agencies endorsed for fishing for lobster in the EEZ, providing that such permitting programs accurately identify persons who fish in the EEZ and that the Regional Director can, either individually or in concert with the state agency, act to suspend the permit or license for EEZ fishing for any violation under this part or part 649 of this chapter.

(2) To implement alternate state EEZ permitting programs, the Regional Director and the director of the concerned state marine fisheries agency will establish a letter of agreement. The letter of agreement will specify the information to be collected by the alternate EEZ permitting program and the mode and frequency of provision of that information to the Regional Director. The Regional Director will, in cooperation with the state director, arrange for notification of the existence and terms of any such agreements to the affected persons. Persons intending to fish in the EEZ should determine whether an alternate EEZ permitting program is in force for their state before applying for a Federal permit under this section.

(3) Vessel owners who apply for a fishing vessel permit under this section, or for a state permit endorsed for EEZ fishing under § 622.13(a)(1), must agree, as a condition of the permit, that all the vessel's lobster fishing, catch, and gear (without regard to whether such fishing occurs in the EEZ or landward of the EEZ, and without regard to where such lobster, lobster meats, or parts, or gear are possessed, taken or landed) will be subject to all the requirements of this part and part 649 of this chapter. All such fishing, catch, and gear will remain subject to any applicable state or local requirements.

(b) Additional management requirements are set forth in part 649 of this chapter. Additional permit requirements are set forth in subpart C of this part.

§ 622.14 Atlantic sea scallop fishery.

(a) *Vessel permit.* Any vessel of the United States harvesting Atlantic sea scallops in quantities greater than 5 bushels (176.2 L) in the shell or 40 pounds (18.1 kg) of shucked scallop meats per trip shall have a permit required by this part aboard the vessel.

(b) Additional management requirements are set forth in part 650 of this chapter. Additional permit requirements are set forth in subpart C of this part.

§ 622.15 Northeast multispecies fishery.

(a) *Vessel permit.* (1) Any vessel of the United States fishing for multispecies finfish, except commercial vessels fishing exclusively within state waters and recreational fishing vessels, must have a permit required by this part aboard the vessel. A recreational vessel is any vessel from which no fishing other than recreational fishing is conducted. Recreational fishing means fishing for finfish that does not result in their barter, trade or sale. Party and charter boats are not considered recreational fishing vessels.

(2) Vessel owners or operators who apply for a fishing vessel permit under this section must agree as a condition of the permit that the vessel's fishing, catch, and pertinent gear (without regard to whether such fishing occurs in the EEZ or landward of the EEZ and without regard to where such fish or gear are possessed, taken, or landed) will be subject to all the requirements of this part and part 651 of this chapter. All such fishing, catch, and gear will remain subject to any applicable State requirements.

(b) Additional management requirements are set forth in part 651 of this chapter. Additional permit requirements are set forth in subpart C of this part.

§ 622.16 Atlantic surf clam and ocean quahog fisheries.

(a) *Vessel permit.* (1) Any vessel of the United States fishing for surf clams or ocean quahogs, except vessels taking surf clams or ocean quahogs for personal use or fishing exclusively within state waters, must have a permit issued under this section aboard the vessel.

(2) Vessel owners who apply for a fishing vessel permit under this section must agree, as a condition of the permit, that the vessel's fishing, catch, and pertinent gear (without regard to whether such fishing occurs in the EEZ or landward of the EEZ, and without regard to where such fish or gear are possessed, taken, or landed) will be subject to all the requirements of this part and part 652 of this chapter; provided, however, that such owners and their employees or agents fishing within waters under the jurisdiction of any state that requires cage tags shall not be subject to conflicting Federal minimum sizes or tagging requirements. All such fishing, catch, and gear will remain subject to any applicable state requirements. If a requirement of this part or part 652 of this chapter differs from a management measure required by a state that does not require cage tagging, any vessel owner permitted to

fish in the EEZ must comply with the more restrictive requirement while fishing in state waters. However, surrender of a Federal vessel permit pursuant to § 652.4(n) of this chapter allows an individual to comply with a less restrictive state minimum size requirement so long as fishing is conducted exclusively within state waters.

(b) *Dealer/processor permit.* Dealers and processors of surf clams or ocean quahogs must have a permit issued under this section.

(c) Additional management requirements are set forth in part 652 of this chapter. Additional permit requirements are set forth in subpart C of this part.

§ 622.17 Atlantic mackerel, squid, and butterfish fisheries.

(a) *Vessel permit.* Any vessel of the United States that fishes for Atlantic mackerel, *Illex* and *Loligo* squid, or butterfish must have a permit issued under this section, except vessels used by recreational fishermen taking Atlantic mackerel, *Illex* and *Loligo* squid, or butterfish for the personal use of such recreational fishermen.

(b) Additional management requirements are set forth in part 655 of this chapter. Additional permit requirements are set forth in subpart C of this part.

Subpart C—Permit Administration and Conditions**§ 622.31 Application.**

(a) *Forms.* Applicants must submit a completed permit application on an appropriate form obtained from the Regional Director containing all necessary information, attachments, certification, signature and fees. In no case will oral, telephone or FAX applications be accepted.

(b) *Forwarding instructions.* Applications must be submitted to the Regional Director.

(c) *Time requirement.* Applications must be submitted to the Regional Director at least 30 calendar days prior to the date on which the applicant desires the permit to be effective.

(d) *Fees.* After publication in the Federal Register, the Regional Director may charge a fee to recover the administrative expenses of permit issuance for any permit issued under § 622.11(a), 622.12 and 622.16. The amount of the fee is calculated in accordance with the procedures of the NOAA Finance Handbook for determining administrative costs of each special product or service. The fee may not exceed such costs and is specified

with each application form. The appropriate fee must accompany each application. Failure to pay the fee will preclude issuance of the permit.

§ 622.32 Issuance.

(a) The Regional Director shall issue the appropriate permit within 30 days of receipt of a completed application unless—

(1) Denial of a permit has been made pursuant to subpart D of 15 CFR part 904;

(2) The applicant has failed to disclose material information required, or has made false statements as to any material fact, in connection with the application;

(3) The applicant has failed to enclose a check or money order for the appropriate fee with the application; or, such check does not clear;

(4) The applicant has failed to submit a completed application. An application is complete when all requested forms, information, and documentation has been received and the applicant has submitted all applicable reports specified at subpart D;

(5) The Regional Director finds, through further inquiry or investigation, or otherwise, that the applicant is not qualified or eligible.

(b) Upon receipt of an incomplete or improperly executed application, the Regional Director shall notify the applicant of the deficiency in the application. If the applicant fails to correct the deficiency within 15 days following the date of notification, the application shall be considered abandoned.

(c) The applicant shall be notified in writing of the denial of any permit request and the reasons therefor. If authorized in the notice of denial, the applicant may submit further information, or reasons why the permit should not be denied. Such further submissions shall not be considered a new application.

(d) *Summer flounder.* (1) Any applicant denied a commercial (moratorium) permit may appeal to the Regional Director within 30 days of the notice of denial. Any such appeal shall be in writing. The only ground for appeal is that the Regional Director erred in concluding that the vessel did not meet the criteria set forth in § 622.11(a)(1). The appeal shall set forth the basis for the applicant's belief that the Regional Director erred in his decision.

(2) The appeal may be presented, at the option of the applicant, at a hearing before an officer appointed by the Regional Director.

(3) The decision on the appeal by the Regional Director is the final decision of the U.S. Department of Commerce.

§ 622.33 Information requirements.

(a) *Vessel permit.* (1) The application must contain the following information and any other information required by the Regional Director: Vessel name; owner name, mailing address, and telephone number; U.S. Coast Guard documentation number and a copy of vessel's U.S. Coast Guard documentation or, if undocumented, state registration number and a copy of the state registration; home port and principal port of landing; length; gross tonnage; engine horsepower; pump horsepower; squid, mackerel and butterfish landings during the year prior to the year for which the permit is being applied; year the vessel was built; type of construction; type of propulsion; approximate fish-hold capacity; type of fishing gear used by the vessel; crew size; permit category; if the owner is a corporation, a copy of the Certificate of Incorporation and the names and addresses of all shareholders owning 25 percent or more of the corporation's shares; if the owner is a partnership, a copy of the Partnership Agreement and the names and addresses of all partners; if a party or charter boat, the number of passengers the vessel is licensed to carry and a copy of the license; and signature of the owner or the owner's agent.

(2) *Summer flounder.* Applicants for commercial (moratorium) permits shall provide information in accordance with § 622.11(a)(1) sufficient for the Regional Director to determine if the vessel meets the eligibility requirements. Dealer weighout forms signed by the dealer and notarized statements from marine architects, surveyors or shipyard officials will be considered acceptable forms of proof.

(b) *Dealer/processor permit.* The application must contain the following information and any other information required by the Regional Director: Company name; principal place of business; owner's or owners' names; copy of Certificate of Incorporation and the names and addresses of all shareholders owning 25 percent or more of the corporation's shares; and applicant's name (if different from owner or owners) and mailing address and telephone number.

§ 622.34 Conditions.

(a) *Expiration.* (1) A permit will expire upon any change in the information provided on the application form or upon the renewal date specified by the Regional Director.

(2) *Summer flounder.* Except as provided in § 622.11(a)(1)(iii), a permit to fish for summer flounder also expires:

(i) When the owner or operator retires the vessel from the fishery; or

(ii) When the vessel fails to land any summer flounder for 52 consecutive weeks; or

(iii) When the ownership of the vessel changes; however, the Regional Director may authorize the continuation of a commercial (moratorium) permit for the summer flounder fishery if the new owner requests. Applications for permit continuations must be addressed to the Regional Director.

(b) *Duration.* A permit shall entitle the person to whom issued to engage in the activity, within the limitations of the applicable statute and regulations contained in parts 625, 628, 649 through 652, and part 655 of this title, until it expires or is sooner modified, suspended, or revoked pursuant to subpart D of 15 CFR part 904. Federal fishing vessel permits must be renewed annually.

(c) *Replacement.* Replacement permits may be issued by the Regional Director when requested in writing by the owner or authorized representative, stating the need for replacement, the name of the vessel, and the fishing permit number assigned. An application for a replacement permit will not be considered a new application. An appropriate fee, consistent with the Magnuson Act, will be charged for issuance of the replacement permit.

(d) *Transfer.* Permits issued under parts 628, 649 through 652, or part 655 of this title are not transferable or assignable. A permit is valid only for the vessel, individual, or dealer/processor to which it is issued.

(e) *Change in application information.* Within 15 days after a change in the information contained in an application submitted under this section, the person issued the permit must report the change in writing to the Regional Director. If written notice of the change in information is not received by the Regional Director within 15 days from the change in information, the permit is void.

(f) *Discontinuance of activity.* When any permittee discontinues his/her activity, he/she shall, within 15 days thereof, mail his/her permit and a request for cancellation to the issuing office, and said permit shall be deemed void upon receipt. No refund of any part of an amount paid as a permit application fee shall be made where the operations of the permittee are, for any reason, discontinued during the tenure of an issued permit.

(g) *Alteration.* Any permit that has been altered, erased, or mutilated shall immediately become void.

(h) *Display.* Any permit issued under this part must be maintained in legible condition and displayed for inspection upon request by any authorized officer.

(i) *Federal versus state requirements.* If a requirement of this part or of parts 625, 628, 649 through 652, or part 655 of this title differs from a management measure required by state law, any vessel owner, operator or individual issued a Federal permit to fish in, or sell fish harvested from, the EEZ must comply with the more restrictive requirement.

(j) *Sanctions.* Procedures governing enforcement-related permit sanctions and denials are found at subpart D of 15 CFR part 904.

§ 622.35 Prohibitions.

It is unlawful for any person to do any of the following:

(a) Make any false statement in connection with an application submitted under 50 CFR part 622, or to fail to report to the Regional Director, within 15 days, any change in the information contained in a permit application; or

(b) Violate any other provision of this part, the Magnuson Act, or any regulations or permit issued under the Magnuson Act.

Subpart D—Recordkeeping and Reporting

§ 622.41 Summer flounder fishery.

(a) *Dealers.* Dealers issued a permit under § 622.11(b) must provide at least the following information to the Regional Director, or official designee, on forms supplied by NMFS or approved by the Regional Director (each dealer will be sent forms and instructions, including the address to which to submit reports, following receipt of a dealer permit):

(1) *Weekly report.* Name and mailing address of dealer; name and permit number of the vessel from which summer flounder are landed or received; port landed; dates of purchases; pounds of summer flounder purchased; price per pound; pounds purchased of all other species landed by the vessel landing summer flounder; and any additional information the Regional Director determines is necessary for the orderly management of the summer flounder resource. Reports must be postmarked within 3 days after the end of each reporting week;

(2) *Annual report.* All dealers required to submit reports under paragraph (a)(1) are required to

complete the "Employment Data" section of the "Annual Processed Products Report." Other information on the form is voluntary. Reports should be submitted to: NMFS Statistics, 166 Water St., Woods Hole, MA 02543, to be postmarked no later than February 10 of the following year.

(3) *At-sea activities.* All persons purchasing, receiving, or processing any summer flounder at sea for landing at any port of the United States must submit information identical to that required by paragraphs (a)(1) and (2) of this section and must provide those reports to the Regional Director or designee on the same frequency basis.

(b) *Vessel owners issued a commercial (moratorium) permit—(1) Fishing log.* The owners of a vessel issued a moratorium permit that is not fishing as a vessel for hire shall maintain on board the vessel, an accurate fishing log for each fishing trip, on forms supplied by, or approved by, the Regional Director, showing at least: Vessel name; vessel permit number; date sailed; date landed; port landed; gear fished; size/quantity of gear; mesh size; area fished; depth range fished; number of tows or sets; days fished; average tow/set time; Loran coordinates; pounds kept by species; pounds discarded by species; number of crew; date sold; dealer name; dealer permit number; and other information as required by the Regional Director.

(2) *When to fill in the fishing log.* Vessel owners shall ensure that such logbooks are completed prior to beginning offloading at the end of each fishing trip, except for information pertaining to date sold, dealer name and dealer permit number, which is unavailable until catch is sold. All logbook information required in paragraph (b)(1) of this section must be filled in for each fishing trip prior to the start of the next fishing trip.

(3) *Inspection.* The owner or operator shall, immediately upon request, make the logbook currently in use available for inspection by an authorized officer, or by an employee of NMFS designated by the Regional Director to make such inspections, at any time during or after a trip.

(4) *Record retention.* For one year after the date of the last entry in the completed log, the owner shall retain a copy of each logbook and make them available upon request by an authorized officer.

(5) *Fishing log reports.* The owner shall submit fishing log reports to the Regional Director or an official designee, on forms supplied by, or approved by, the Regional Director and postmarked within 15 days of the last calendar day of the month during which the trip is

landed. Each owner will be sent forms and instructions, including the address to which to submit reports, shortly after receipt of a fishing permit. If no fishing trip or summer flounder were landed during a month, a fishing log report so stating must be submitted and postmarked by the 15th of the following month.

(c) *Owners of party and charter boats.—(1) Fishing log.* The owner of any party or charter boat issued a permit under § 622.11(a)(2) and carrying passengers for hire shall maintain on board the vessel, an accurate fishing log for each charter or party fishing trip, on forms supplied by or approved by the Regional Director, showing at least: Vessel name; vessel permit number; date sailed; date landed; port landed; gear fished; size/quantity of gear; area fished; depth range fished; days fished; number and pounds retained, by species; number and pounds discarded, by species; number of crew; number of anglers; other information as required by the Regional Director.

(2) *When to fill in the fishing log.* Vessel owners shall ensure that all logbook information required in paragraph (c)(1) of this section must be filled in for each fishing trip at the end of each fishing trip.

(3) *Inspection.* The owner or operator shall, immediately upon request, make the logbook currently in use available for inspection by an authorized officer, or by an employee of NMFS designated by the Regional Director to make such inspections, at any time during or after a trip.

(4) *Record retention.* For one year after the date of the last entry in the completed log, the owner shall retain a copy of each logbook and make them available upon request by an authorized officer.

(5) *Fishing log reports.* The owner shall submit fishing log reports to the Regional Director or an official designee, on forms supplied by, or approved by, the Regional Director and postmarked within 15 days of the last calendar day of the month during which the trip is landed. Each owner will be sent forms and instructions, including the address to which to submit reports, shortly after receipt of a fishing permit. If no fishing trip or summer flounder were landed during a month, a fishing log report so stating must be submitted and postmarked by the 15th of the following month.

§ 622.42 Atlantic surf clam and ocean quahog fisheries.

(a) *Dealers.* All dealers issued a permit under § 622.16(b) must submit to the Regional Director a weekly report on

forms supplied by NMFS. Said report must be postmarked within 3 days after the end of each reporting week and each report must specify accurately and completely: Date of purchase or receipt; name, permit number, and address; number of bushels, by species; cage tag numbers; allocation permit number; vessel name and permit number; price per bushel by species; and disposition of surf clams or ocean quahogs, including name and permit number of recipient.

(b) *Processors.* All processors issued a permit under § 622.16(b) must provide at least the following information to the Regional Director on forms supplied by NMFS:

(1) *Weekly report.* Said report must be postmarked within 3 days after the end of each reporting week and each report must specify accurately and completely: Date of purchase or receipt; name, permit number, and mailing address; number of bushels, by species; cage tag numbers; allocation permit number; vessel name and permit number; price per bushel by species; size distribution; and meat yield per bushel by species.

(2) *Annual report.* All persons required to submit reports under paragraph (b)(1) of this section are required to submit annual Processed Products Reports to NMFS Statistics, 166 Water St., Woods Hole, MA 02543, to be postmarked within 90 days of receipt of the forms. Each report must specify accurately and completely: Average number of processing plant employees during each month of the year just ended; average number of employees engaged in production of processed surf clam and ocean quahog products, by species, during each month of the year just ended; plant capacity to process surf clam and ocean quahog shellstock, or to process surf clam and ocean quahog meats into finished products, by species, as well as an estimate, for the next year, of these capacities; and total payroll for surf clam and ocean quahog processing, by month.

(c) *Vessel owners and operators.* The operator of any vessel conducting fishing operations for Atlantic surf clams or ocean quahogs must, as the agent of the vessel owner, maintain on board the vessel an accurate daily fishing log for each fishing trip, on forms supplied by NMFS. This log must be filled in before any surf clams or ocean quahogs are landed and must be submitted on a weekly basis to the Regional Director. If no fishing trip is made during any week, a report so stating must be submitted. This weekly report must be postmarked within 3 days after the end of each reporting

week. Vessels fishing exclusively within state waters of a state that requires cage tags, or that have surrendered their Federal fishing vessel permit are exempt from this requirement. The daily/weekly logs must contain at least the following: Name and permit number of the vessel; total amount in bushels of each species taken; date(s) caught; time at sea; duration of fishing time; locality fished; crew size; crew share, by percentage; landing port; date sold; price per bushel; buyer; tag numbers from cages used; quantity of surf clams or ocean quahogs discarded; and allocation permit number.

(d) *Inspection.* All reports required by this section must be available for inspection at any time, during or after a trip, upon the request of an authorized officer or by an employee of NMFS designated by the Regional Director.

(e) *Record retention.* All reports required by this section must be retained at the permit holder's principal place of business for 1 year after the date of the last entry.

PART 625—SUMMER FLOUNDER FISHERY

1a. The authority citation for 50 CFR part 625 continues to read as follows:

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

2. Section 625.4 is revised to read as follows:

§ 625.4 Vessel permits.

(a) *General.* Subject to the eligibility requirements specified in § 622.11(a)(1) and (2) of this chapter, the owner of a vessel of the United States, including a party or charter vessel, must obtain an appropriate permit issued pursuant to §§ 622.11(a), and 622.31 through 622.34, inclusive, of this chapter.

(b) *Exemption permits.* Owners of vessels seeking an exemption from the minimum mesh requirement under the provisions of § 625.24(b) must apply to the Regional Director in writing at least 7 days prior to the date they wish the permit to become effective. The applicant shall mark "Exemption Permit Request" on the permit application at the top. A permit issued under this paragraph does not meet the requirements of paragraph (a) of this section. Persons issued an exemption permit must surrender it to the Regional Director at least one day prior to the date they wish to fish not subject to the exemption. The Regional Director may impose temporary additional procedural requirements by publication of a notice in the Federal Register.

3. Section 625.5 is revised to read as follows:

§ 625.5 Dealer permit.

Each dealer must obtain an appropriate permit issued pursuant to §§ 622.11(b), and 622.31 through 622.34, inclusive, of this chapter.

4. Section 625.6 is revised to read as follows:

§ 625.6 Recordkeeping and reporting requirements.

Any person issued a dealer permit under § 622.11(b) of this chapter must comply with the recordkeeping and reporting provisions of § 622.41 of this chapter.

5. Section 625.7 is revised to read as follows:

§ 625.7 Vessel identification.

Each fishing vessel subject to this part must comply with the provisions of § 622.5 of this chapter.

6. Section 625.8 is amended by revising paragraphs (a) introductory text, (a)(2), (a)(8), (a)(9), (a)(10), (b) introductory text, (c)(1), (c)(2), (c)(3), (c)(4), (c)(10) and (d) to read as follows:

§ 625.8 Prohibitions.

(a) In addition to the general prohibitions specified in § 620.7 of this chapter, it is unlawful for any person owning or operating a vessel issued a permit, including a commercial (moratorium) permit, under § 622.11(a) of this chapter, to do any of the following:

* * * * *

(2) Fail to affix and maintain markings as required by § 622.5;

* * * * *

(8) Fish west or south, as appropriate, of the line specified in § 625.24(b)(1) if exempted from the minimum mesh-size requirement specified in § 625.24 by an exemption permit issued under § 622.11(a)(3);

(9) Sell or transfer to another person for a commercial purpose, other than transport, any summer flounder, unless the transferee has a dealer permit issued under § 622.11(b) of this chapter;

(10) Carry passengers for hire, or carry more than three crew members for a charter boat of five crew members for a party boat, while fishing commercially pursuant to a commercial (moratorium) permit issued pursuant to § 622.11(a)(1) of this chapter; or

* * * * *

(b) It is unlawful for the owner and operator of a party or charter boat issued a permit, including a commercial (moratorium) permit, pursuant to § 622.11(a) of this chapter, when the boat is carrying passengers for hire or carrying more than three crew members

if a charter boat or more than five members if a party boat, to:

* * * * *

(c) * * *

(1) Possess in, or harvest from, the EEZ summer flounder before or after the time period specified in § 625.22 or in excess of the possession limit specified in § 625.25, unless the person is operating a vessel issued a commercial (moratorium) permit under § 622.11(a)(1) of this chapter and the commercial (moratorium) permit is on board the vessel and has not been surrendered, revoked, or suspended;

(2) Offload, cause to be offloaded, sell or buy any summer flounder, whether on land or at sea, as an owner, operator, dealer, buyer or receiver in the summer flounder fishery without accurately preparing and submitting in a timely fashion the documents required by § 622.41 of this chapter;

(3) Purchase or otherwise receive, except for transport, summer flounder from the owner or operator of a vessel issued a commercial (moratorium) permit under § 622.11(a)(1) of this chapter unless in possession of a valid permit issued under § 622.11(b) of this chapter;

(4) Purchase or otherwise receive for commercial purposes summer flounder caught by other than a vessel with a commercial (moratorium) permit or caught by a vessel subject to the possession limit;

* * * * *

(10) Violate any other provision of this part or part 622 of this chapter, the Magnuson Act, or any regulation or permit issued under the Magnuson Act.

(d) All summer flounder possessed aboard a party or charter boat issued a permit under § 622.11(a)(2) are deemed to have been harvested from the EEZ.

7. Section 625.22 is amended by revising the first sentence to read as follows:

§ 625.22 Time restrictions.

Owners and operators of vessels that are not eligible for a commercial (moratorium) permit under § 622.11(a)(1) of this chapter and fishermen subject to the possession limit may fish for summer flounder only during the period May 15th to September 30th. * * *

8. Section 625.23 is amended by revising paragraphs (a) and (b) to read as follows:

§ 625.23 Minimum sizes.

(a) The minimum size for summer flounder is 13 inches (33 cm) total length for all vessels issued a commercial (moratorium) permit under § 622.11(a)(1) of this chapter, except on

board party and charter boats carrying passengers for hire or carrying more than three crew members, if a charter boat, or more than five crew members, if a party boat;

(b) The minimum size for summer flounder is 14 inches (35.6 cm) total length for all vessels that do not qualify for a commercial (moratorium) permit, or for party and charter boats holding commercial (moratorium) permits, but fishing with passengers for hire or carrying more than three crew members, if a charter boat or more than five crew members, if a party boat.

9. Section 625.24 is amended by revising paragraphs (a), (b)(1) introductory text and (b)(1)(ii) to read as follows:

§ 625.24 Gear restrictions.

(a) *General.* Otter trawlers whose owners are issued a permit, including a commercial (moratorium) permit, under § 622.11(a)(1) of this chapter that land or possess 100 or more pounds (45.4 or more kg) of summer flounder, per trip, must fish with nets that have a minimum mesh size of 5½ inches (14.0 cm) diamond mesh or 6 inches (15.2 cm) square mesh applied throughout the codend for at least 75 continuous meshes forward of the terminus of the net, or, for codends with less than 75 meshes, the minimum-mesh-size codend must be a minimum of one-third of the net, measured from the terminus of the codend to the head rope, excluding any turtle excluder device extension.

(b) * * *

(1) Vessels issued a permit under paragraph (b) of § 625.4 and fishing from 1 November through 30 April in the "exemption area" * * *

(i) * * *

(ii) Vessels issued a permit under paragraph (b) of § 625.4 may transit the area west and south of the line described in paragraph (b)(1) of this section if the vessel's fishing gear is stowed in a manner prescribed under 50 CFR 651.20(f) so that it is not "available for immediate use" outside the exempted area.

10. Section 625.25 is amended by revising paragraph (a) and the first sentence of paragraph (d) to read as follows:

§ 625.25 Possession limit.

(a) No person shall possess more than six summer flounder in, or harvested from, the EEZ unless that person is the owner or operator of a fishing vessel issued a commercial (moratorium) permit under § 622.11(a)(1) of this

chapter. Persons on board a commercial vessel that is not eligible for a commercial (moratorium) permit under § 622.11(a)(1) of this chapter are subject to this possession limit. The owner and operator and crew of a charter or party boat issued a commercial (moratorium) permit under § 622.11(a)(1) of this chapter are not subject to the possession limit when not carrying passengers for hire and when the crew size does not exceed five for a party boat or three for a charter boat.

* * * * *

(d) Owners and operators of otter trawlers issued a permit, including a commercial (moratorium) permit, under § 622.11(a)(1) and fishing with, or possessing on board, nets or pieces of net that do not meet the minimum mesh-size requirements, except pieces of netting no larger than 3 feet square (0.9 m square) that may be necessary to repair smaller mesh sections of the net forward of the terminal portion of the net to which the minimum mesh-size requirement applies, may not possess more than 100 pounds (45.4 kg) of summer flounder. * * *

11. Section 625.26 is amended by revising the first sentence of paragraph (a) to read as follows:

§ 625.26 Sea sampler program.

(a) *Request to take sea sampler.* The Regional Director may request a fishing vessel issued a permit under § 622.11 of this chapter to take on board an observer or sea sampler to accompany the vessel on all fishing trips conducted during the period specified in the request. * * *

12. Section 625.27 is amended by revising the first sentence of paragraph (h)(1) to read as follows:

§ 625.27 Sea turtle conservation.

(h) * * *

(1) *Request to take observer.* The Regional Director may request a fishing vessel issued a commercial (moratorium) permit under § 622.11(a)(1) of this chapter to take on board an observer to accompany the vessel on all fishing trips conducted during the period specified in the request. * * *

PART 628—ATLANTIC BLUEFISH FISHERY

13. The authority citation for 50 CFR part 628 continues to read as follows:

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

14. Section 628.4 is revised to read as follows:

§ 628.4 Permits and fees.

Any person selling Atlantic bluefish harvested in the EEZ must have a valid permit issued pursuant to the provisions of §§ 622.12(a), 622.31, 622.32 and 622.34 of this chapter.

15. Section 628.5 is amended by revising paragraphs (a) and (c) through (g) to read as follows:

§ 628.5 Prohibitions.

* * *

(a) Possess in, or harvest from, the EEZ, Atlantic bluefish in excess of the daily possession limit specified in § 628.21, unless the person in possession has a permit meeting the requirements of § 622.12(a) of this chapter;

* * * * *

(c) Fish under a permit meeting the requirements of § 622.12(a) of this chapter in violation of a notice of restriction published under § 628.22;

(d) Fish in the EEZ under a permit meeting the requirements of § 622.12(a) of this chapter during a closure under § 628.23;

(e) Fail to report to the Regional Director, within 15 days, any change in the information in the application for a permit under § 622.12 of this chapter;

(f) Fail to present any permit meeting the requirements of § 622.12(a) of this chapter upon the request of an authorized officer;

(g) Sell any Atlantic bluefish harvested from the EEZ unless the seller has a permit that meets the requirements of § 622.12(a) of this chapter;

* * * * *

16. Section 628.21 is amended by revising paragraphs (a)(1), (a)(2), and the first two sentences of paragraph (a)(4) to read as follows:

§ 628.21 Possession limit.

(a) * * *

(1) No person shall possess more than ten bluefish unless he/she has a permit meeting the requirements of § 622.12(a) of this chapter.

(2) Bluefish caught while in possession of a permit meeting the requirements of § 622.12(a) of this chapter must be kept separate from the pooled catch and in the possession of the permit holder at all times.

* * * * *

(4) Atlantic bluefish harvested from party and charter boats or other vessels carrying more than one person may be commingled. Compliance with the daily possession limit will be determined by dividing the number of Atlantic bluefish on board by the number of persons on board, provided, however, that if a

person or persons on board are fishing under a permit meeting the requirements of § 622.12(a) of this chapter, his/her catch shall not be counted for determining compliance with the possession limit if it is maintained in the possession of such person(s). * * *

PART 649—AMERICAN LOBSTER FISHERY

17. The authority citation for 50 CFR part 649 continues to read as follows:

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

18. Section 649.4 is revised to read as follows:

§ 649.4 Vessel permits.

Any vessel of the United States fishing for American lobster in the EEZ must obtain a permit issued pursuant to §§ 622.13(a), and 622.31 through 622.34, inclusive, of this chapter.

19. Section 649.6 is revised to read as follows:

§ 649.6 Vessel identification.

Each fishing vessel subject to this part must comply with the provisions of § 622.5 of this chapter.

20. Section 649.7 is amended by revising paragraphs (a) introductory text, (a)(7), (b)(1), (b)(2), (b)(3), (b)(5) and (c) to read as follows:

§ 649.7 Prohibitions.

(a) In addition to the general prohibitions specified in § 620.7 of this chapter, it is unlawful for any person issued a permit under § 622.13 of this chapter, or for any person fishing in the EEZ, to do any of the following:

(7) Fail to affix and maintain permanent markings as required by § 622.5 of this chapter.

(1) Use any vessel for taking, catching, harvesting, fishing for, or landing of any American lobster in, or from, the EEZ unless the vessel or operator has a valid permit issued under § 622.13 of this chapter, and the permit is aboard the vessel.

(2) Make any false statement in connection with an application under § 622.13 of this chapter; or to fail to report to the Regional Director, within 15 days, any change in the information contained in a permit application for a vessel.

(3) Possess, have custody or control of, ship, transport, offer for sale, sell, purchase, land, import or export any American lobster taken or retained in violation of the Magnuson Act, this part

part 622 of this chapter, or any other regulation under the Magnuson Act.

(5) Interfere with, obstruct, delay, or prevent by any means a lawful investigation or search by an authorized officer in the process of enforcing this part or part 622 of this chapter.

(c) The possession of egg-bearing female American lobsters, V-notched female American lobsters, or American lobsters that are smaller than the minimum size set forth in § 649.20(b) of this part, will be prima facie evidence that such lobsters were taken or imported in violation of these regulations. Evidence that such lobsters were harvested by a vessel not holding a permit under § 622.13 of this chapter that fished exclusively within state or foreign waters will be sufficient to rebut the presumption.

21. Section 649.20 is amended by revising paragraph (a) to read as follows:

§ 649.20 Harvesting and landing requirements.

(a) *Conditions.* By accepting a Federal permit or a state permit endorsed for EEZ fishing, the permittee agrees that any lobster found on board, buoyed in a container or landed by a vessel with a permit issued, authorized, or required by this part and/or part 622 of this chapter will be treated as if it had been harvested in the EEZ subject to these regulations.

22. Section 649.22 is amended by revising paragraph (a)(1) and the first sentence of paragraph (a)(3) to read as follows:

§ 649.22 Exemption and area closure.

(1) Upon the recommendation of the New England Fishery Management Council, the Regional Director may exempt any person or vessel from the requirements of this part and/or part 622 of this chapter for the conduct of research or education beneficial to the lobster resource or lobster fishery.

(3) Each vessel participating in any exempt activity is subject to all provisions of this part and/or part 622 of this chapter except those necessarily relating to the purpose and nature of the exemption. * * *

PART 650—ATLANTIC SEA SCALLOP FISHERY

23. The authority citation for 50 CFR part 650 continues to read as follows:

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

24. Section 650.4 is revised to read as follows:

§ 650.4 Vessel permits.

Any vessel of the United States harvesting Atlantic sea scallops in quantities greater than 5 bushels (176.2 l) in the shell or 40 pounds (18.2 kg) of shucked scallop meats per trip must obtain a permit issued pursuant to §§ 622.14, and 622.31 through 622.34 inclusive, of this chapter.

25. Section 650.6 is revised to read as follows:

§ 650.6 Vessel identification.

Each fishing vessel subject to this part must comply with the provisions of § 622.5 of this chapter.

26. Section 650.7 is amended by revising paragraphs (d), (e), (f), and (h) to read as follows:

§ 650.7 Prohibitions.

(d) Use any vessel for taking, catching, harvesting, or landing any Atlantic sea scallops in excess of the amounts prescribed in § 622.14(a) of this chapter, unless the vessel has a valid permit issued under § 622.14(a) of this chapter, and the permit is on board the vessel.

(e) Make any false statement in connection with an application under § 622.14(a) of this chapter, or to fail to report to the Regional Director, within 15 days, any change in the information contained in a permit application for a vessel.

(f) Fail to affix and maintain permanent markings as required by § 622.5 of this chapter.

(h) Interfere with, obstruct, delay, or prevent by any means a lawful investigation or search by an authorized officer in the process of enforcing this part and/or part 622 of this chapter.

27. Section 650.22 is amended by revising paragraph (b)(4) to read as follows:

§ 650.22 Review of resource status; temporary adjustment of standards.

(4) The Regional Director may modify his recommendation on the basis of comments from the Council or the public. After consideration of the full record, the Regional Director may adjust the standards contained in § 650.20 and will publish in the *Federal Register* notice of such change and the date when the adjusted standard will revert to a 30 meat count. Notice of any such adjustment will be mailed to each holder of a permit issued under § 622.14 of this chapter.

28. Section 650.23 is amended by revising paragraph (a) and the first sentence of paragraph (c) to read as follows:

§ 650.23 Experimental fishing exemption.

(a) Upon the recommendation of the Council, the Regional Director may exempt any person or vessel from the requirements of this part and/or part 622 of this chapter for the conduct of experimental fishing beneficial to the management of the sea scallop resource or fishery.

(c) Each vessel participating in any exempted experimental fishing activity is subject to all provisions of this part and part 622 of this chapter except those necessarily relating to the purpose and nature of the exemption. * * *

29. Section 650.25 is amended by revising paragraph (b)(2) to read as follows:

§ 650.25 Modification of offloading period.

(b) * * *

(2) Be mailed to each holder of a permit issued under § 622.14(a) of this chapter.

PART 651—NORTHEAST MULTISPECIES FISHERY

30. The authority citation for 50 CFR part 651 continues to read as follows:

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

31. Section 651.4 is revised to read as follows:

§ 651.4 Vessel permits.

(a) Each vessel of the United States fishing for multispecies finfish, except commercial vessels fishing exclusively within state waters and recreational fishing vessels, must obtain a permit pursuant to §§ 622.15(a), and 622.31 through 622.34 inclusive, of this chapter.

(b) *Exempted fisheries program.* Any permit holder may initially request entry into the exempted fisheries program under § 651.22 by telephoning 508-281-9335. The permit holder must give his/her name, vessel name, vessel permit number, the specific exemption requested, the starting date and estimated duration of participation in the program, and the area of operation. The permit holder must have the letter of certification, which will be issued within 1 week, aboard at all times while engaged in an exempted fishery.

32. Section 651.6 is revised to read as follows:

§ 651.6 Vessel identification.

Each fishing vessel subject to this part must comply with the provisions of § 622.5 of this chapter.

33. Section 651.7 is amended by revising paragraphs (a) introductory text, (a)(2), (b)(1), (b)(7), (b)(10), (c) and the first two sentences of paragraph (d) to read as follows:

§ 651.7 Prohibitions.

(a) In addition to the general prohibitions specified in § 620.7 of this chapter, it is unlawful for any person owning or operating a vessel issued a permit under § 622.15(a) of this chapter to do any of the following:

(2) Fail to affix and maintain permanent markings as required by § 622.5 of this chapter.

(1) Use any vessel of the United States (except recreational fishing vessels) for taking, catching, harvesting or landing any regulated species taken from the EEZ unless the vessel has a valid permit issued under part 622 of this chapter and the permit is aboard the vessel.

(7) make any false statement in connection with an application under § 622.15(a) of this chapter.

(10) Interfere with, obstruct, delay, or prevent by any means a lawful investigation or search by an authorized officer in the process of enforcement of this part and/or part 622 of this chapter.

(c) It is unlawful to violate any other provision of this part or part 622 of this chapter, the Magnuson Act, or any regulations or permit issued under the Magnuson Act.

(d) *Presumption.* The possession for sale of regulated species that do not meet the minimum sizes specified in § 651.23 will be prima facie evidence that such regulated species were taken or imported in violation of these regulations. Evidence that such fish were harvested by a vessel not holding a permit under part 622 of this chapter and fishing exclusively within state waters will be sufficient to rebut the presumption. * * *

34. Section 651.20 is amended by revising the first sentence of paragraph (f) introductory text to read as follows:

§ 651.20 Regulated mesh area and gear limitations.

(f) Except as provided in paragraphs (b) and (d) of this section, no vessel issued a permit under § 622.15(a) of this chapter may have available for

immediate use any net, or any piece of a net, not meeting the requirements specified in this section or while in the areas described in paragraph (a) of this section. * * *

35. Section 651.22 is amended by revising paragraph (b) (1) and the first sentence of paragraph (g) to read as follows:

§ 651.22 Exempted fishery program.

(b) * * *. (1) Any person owning a vessel issued a valid Federal multispecies finfish permit may apply to fish under the exempted fisheries program by following the procedures set forth in § 651.4(b).

(g) *Expiration or withdrawal.* Participation in the program expires at the end of the participation period under § 651.4(b), or when the owner's or vessel's name changes, or when a participant who has been duly operating in the program for at least 7 days notifies the Regional Director of his/her intent to withdraw from the program. * * *

PART 652—ATLANTIC SURF CLAM AND OCEAN QUAHOG FISHERIES

36. The authority citation for 50 CFR part 652 continues to read as follows:

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

37. Section 652.4 is revised to read as follows:

§ 652.4 Vessel permits.

Each vessel of the United States fishing for surf clams or ocean quahogs, except vessels taking surf clams or ocean quahogs for personal use or fishing exclusively within state waters, must obtain a permit issued pursuant to §§ 622.16(a), and 622.31 through 622.34 inclusive, of this chapter.

38. Section 652.5 is revised to read as follows:

§ 652.5 Dealer/processor permits.

Dealers and processors of surf clams or ocean quahogs must obtain a permit issued pursuant to §§ 622.16(b), and 622.31 through 622.34 inclusive, of this chapter.

39. Section 652.6 is revised to read as follows:

§ 652.6 Recordkeeping and reporting.

Any person issued a dealer permit under § 622.16(b) of this chapter must comply with the recordkeeping and reporting provisions of § 622.42 of this chapter.

40. Section 652.7 is revised to read as follows:

§ 652.7 Vessel Identification.

Each fishing vessel subject to this part must comply with the provisions of § 622.5 of this chapter.

41. Section 652.8 is amended by revising paragraphs (a), (b) introductory text, (b)(2), (c)(3), (c)(4), (c)(5), (c)(10), (c)(13), (c)(16) and (c)(20) to read as follows:

§ 652.8 Prohibitions.

(a) In addition to the general prohibitions specified in part 620 of this chapter, it is unlawful for any person owning or operating a vessel issued a permit under § 622.16(a) of this chapter to land or possess any surf clams that do not meet the minimum sizes specified in § 652.22, except when fishing exclusively within state waters as provided in § 622.16(a)(2) of this chapter.

(b) It is unlawful for any person owning or operating a vessel issued a permit under § 622.16(a) of this chapter, or issued an allocation permit under § 652.20, to do any of the following:

(2) Transfer any surf clams or ocean quahogs to any person for a commercial purpose other than transport, unless that person has a permit issued under § 622.16(b).

(3) Use a vessel of the United States for taking, catching, harvesting, or landing any surf clams or ocean quahogs taken from the EEZ unless the vessel has a valid permit required under this part and/or part 622 of this chapter and the permit is aboard the vessel and has not been surrendered, revoked, or suspended;

(4) Offload, cause to be offloaded, sell or buy any surf clams or ocean quahogs, whether on land or at sea, as an owner, operator, dealer, processor, buyer, or receiver in the surf clam or ocean quahog fishery, without preparing and submitting the documents required by § 622.42 of this chapter;

(5) Alter, erase, or mutilate any permit issued under § 622.16 of this chapter, or § 652.20;

(10) Possess surf clams taken in violation of the size limits prescribed in § 652.22, unless taken consistently with § 622.16(a)(2) of this chapter;

(13) Fail to submit or maintain information, or to submit or maintain false information in records and reports required to be kept or filed under § 622.42 of this chapter;

(16) Receive, for a commercial purpose other than transport, surf clams or ocean quahogs landed under an allocation pursuant to § 652.20 without a permit issued under § 622.16(b) of this chapter;

(20) Violate any other provision of the Magnuson Act, these regulations, or any applicable permit issued under § 622.16 of this chapter, or § 652.20.

42. Section 652.12 is amended by revising the first two sentences of paragraph (h) to read as follows:

§ 652.12 Cage Identification.

(h) *Presumptions.* Surf clams or ocean quahogs found in cages without a valid state tag are deemed to have been harvested in the EEZ, and are part of an individual's allocation. This shall not apply if the individual can demonstrate that he/she has surrendered his/her Federal vessel permit issued under § 622.16(a) of this chapter and has conducted fishing operations exclusively within waters under the jurisdiction of any state.

43. Section 652.24 is amended by revising paragraph (a)(4) to read as follows:

§ 652.24 Shucking at sea.

(4) The observer specified by the Regional Director shall certify at the end of each trip the amount of surf clams or ocean quahogs harvested in the shell by the vessel. Such certification shall be made by the observer's signature on the daily fishing log required by § 622.42 of this chapter.

PART 655—ATLANTIC MACKEREL, SQUID, AND BUTTERFISH FISHERIES

44. The authority citation for 50 CFR part 655 continues to read as follows:

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

45. Section 655.4 is revised to read as follows:

§ 655.4 Vessel permits.

Each vessel of the United States that catches Atlantic mackerel, *Illex* and *Loligo* squid, or butterfish must obtain a permit issued pursuant to §§ 622.17(a) and 622.31 through 622.34, inclusive, or this chapter except vessels used by recreational fishermen taking Atlantic mackerel, *Illex* and *Loligo* squid, or butterfish for the personal use of such recreational fishermen.

46. Section 655.6 is revised to read as follows:

§ 655.6 Vessel Identification.

Each fishing vessel subject to this part must comply with the provisions of § 622.5 of this chapter.

47. Section 655.7 is amended by revising paragraphs (a) through (d), (g) and (i) to read as follows:

§ 655.7 Prohibitions.

(a) To fish commercially for Atlantic mackerel, squid, and butterfish without a permit issued pursuant to § 622.17(a) of this chapter.

(b) To use any vessel for taking, catching, harvesting, or landing of any Atlantic mackerel, squid, or butterfish (except as provided in § 622.17(a) of this chapter) unless the vessel has on board a valid permit issued under § 622.17(a) of this chapter.

(c) To fail to report to the Regional Director within 15 days any change in the information contained in the permit application for a vessel, as specified in § 622.33(a) of this chapter.

(d) To falsify or fail to affix and maintain vessel markings as required by § 622.5 of this chapter.

(g) Violate any other provision of this part and/or part 622 of this chapter, the Magnuson Act, any notice issued under subpart B of this part, or any other regulation or permit promulgated under the Magnuson Act.

(i) To interfere with, obstruct, delay, or prevent by any means a lawful investigation or search by an authorized officer conducted in the process of enforcing this part and/or part 622 of this chapter.

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50 CFR Part 646

South Atlantic Fishery Management Council (Council); Snapper-Grouper Regulations; Public Hearings

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

ACTION: Notice of public hearings and request for comments.

SUMMARY: The Council will hold public hearings and provide a comment period to solicit public input on proposed snapper-grouper regulations contained in draft Amendment 7 to the Fishery Management Plan for the Snapper-Grouper Fishery of the South Atlantic (FMP) (includes the regulatory impact review, initial regulatory flexibility

analysis determination, and environmental assessment).

DATES: Written comments must be received by October 27, 1993. All public hearings will be held from 7 p.m. to 10 p.m. (except Atlantic Beach, NC, which will be held 6:30 p.m. to 9 p.m.), as follows:

1. Tuesday, October 19, 1993, in Jacksonville Beach, Florida;
2. Wednesday, October 20, 1993, in Savannah, Georgia;
3. Monday, October 25, 1993, in Charleston, South Carolina;
4. Monday, November 1, 1993, in Atlantic Beach, North Carolina.

ADDRESSES: Comments should be addressed to Robert K. Mahood, Executive Director, South Atlantic Fishery Management Council, One Southpark Circle, suite 306, Charleston, SC 29407-4699.

The hearings will be held at the following locations:

1. Jacksonville Beach—Holiday Inn Oceanfront, 1617 N. First Street, Jacksonville Beach, Florida (904-249-9071).
2. Savannah—Holiday Inn Mid-Town, 7100 Abercorn Street, Savannah, Georgia (912-352-7100).
3. Charleston—Town & Country Inn, 2008 Savannah Highway, Charleston, South Carolina (803-571-1000).
4. Atlantic Beach—Sheraton Atlantic Beach Resort, Salter Path Road, Atlantic Beach, North Carolina (919-240-1155).

FOR FURTHER INFORMATION CONTACT:

Carrie Knight, Public Information Officer, South Atlantic Fishery Management Council (803-571-4366, fax: 803-769-4520).

SUPPLEMENTARY INFORMATION: The Council is soliciting comments on the following:

- Establish a bycatch allowance and trip limits for red porgy.
- Restrict harvest of gag grouper January through March annually.

Require seafood dealers who handle snapper and grouper to obtain a federal dealer permit. A seafood dealer would only be allowed to purchase snapper and grouper from permitted fishermen. Permitted fishermen would only be allowed to sell to permitted dealers. This would result in requiring the federal commercial permit (50 percent earned income or \$20,000 gross sales) to sell bag-limit caught fish.

Allow a part-time permit for fishermen who do not qualify for a commercial permit. These fishermen would be considered part-time commercial fishermen, however, they would be restricted to the recreational bag limits.

Change prohibition on bottom longline gear in the snapper-grouper fishery from south of Cape Canaveral, Florida, to south of St. Lucie Inlet, Florida.

Additional comments are being accepted on the following proposed measures, which were deferred from Amendment 6 (approved in August 1993). These proposals would also be included in Amendment 7.

Require charterboats and headboats to obtain a federal snapper-grouper permit.

Allow a maximum of two possession limits for all charter and headboats on multi-day trips regardless of the number of captains on board.

Maintain the crew requirement of three unless a vessel possesses a certificate of inspection, in which case crew size is limited to the crew number on the certificate.

Maintain current minimum size and bag limit for red snapper.

Continue prohibition on commercial harvest of greater amberjack during April south of Cape Canaveral, Florida. However, sale would be prohibited in the area south of Cape Canaveral.

Impose no restrictions on white grunt at this time.

Establish a 12-inch fork length minimum size limit for hogfish and include in the 10-snapper aggregate bag limit.

Impose no restrictions on gray triggerfish at this time.

Increase mutton snapper minimum size limit from 12 inches total length to 16, and consider possibility of a two-fish bag limit. Maintain May-June prohibition on harvest above the bag limit.

Impose no new restrictions on cubera or yellowtail snapper at this time.

Prohibit use of explosive charges (including powerheads) to harvest species in snapper-grouper management unit in federal waters off South Carolina.

Require that black sea bass pots be tended (taken out on a vessel and brought back at the end of a trip).

These hearings are physically accessible to people with disabilities. Requests for sign language interpretation or other auxiliary aids should be directed to Carrie Knight at the above Council address by October 14, 1993.

Dated: October 8, 1993.

Joe P. Clem,

Acting Director, Office of Fisheries Conservation and Management, National Marine Fisheries Service.

[FR Doc. 93-25249 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-22-M

Notices

Federal Register

Vol. 58, No. 197

Thursday, October 14, 1993

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

Forms Under Review by Office of Management and Budget

October 8, 1993.

The Department of Agriculture has submitted to OMB for review the following proposal for the collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35) since the last list was published. This list is grouped into new proposals, revisions, extension, or reinstatements. Each entry contains the following information:

(1) Agency proposing the information collection; (2) Title of the information collection; (3) Form number(s), if applicable; (4) How often the information is requested; (5) Who will be required or asked to report; (6) An estimate of the number of responses; (7) An estimate of the total number of hours needed to provide the information; (8) Name and telephone number of the agency contact person.

Questions about the items in the listing should be directed to the agency person named at the end of each entry. Copies of the proposed forms and supporting documents may be obtained from: Department Clearance Officer, USDA, OIRM, Room 404-W Admin. Bldg., Washington, DC 20250, (202) 690-2118.

Reinstatement

• *Rural Electrification Administration*
Preloan Procedures and Requirements
for Telephone Program
REA Forms 490, 494, 495, 507, 567, 569
On occasion
Small businesses or organizations; 855
responses; 7177 hours
Jon Claffey, (202) 720-9539.

Larry K. Roberson,

Deputy Department Clearance Officer.

[FR Doc. 93-25247 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-01-M

Animal and Plant Health Inspection Service

[Docket No. 93-133-1]

Receipt of a Permit Application for Release into the Environment of Genetically Engineered Organisms

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Notice.

SUMMARY: We are advising the public that an application for a permit to release genetically engineered organisms into the environment is being reviewed by the Animal and Plant Health Inspection Service. The application has been submitted in accordance with 7 CFR part 340, which regulates the introduction of certain genetically engineered organisms and products.

ADDRESSES: Copies of the application referenced in this notice, with any confidential business information deleted, are available for public inspection in room 1141, South Building, U.S. Department of Agriculture, 14th Street and Independence Avenue SW.,

Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect an application are encouraged to call ahead on (202) 690-2817 to facilitate entry into the reading room. You may obtain copies of the documents by writing to the person listed under FOR FURTHER INFORMATION CONTACT.

FOR FURTHER INFORMATION CONTACT: Dr. Arnold Foudin, Deputy Director, Biotechnology Permits, Biotechnology, Biologicals, and Environmental Protection, APHIS, USDA, room 850, Federal Building, 6505 Belcrest Road, Hyattsville, MD 20782, (301) 436-7612.

SUPPLEMENTARY INFORMATION: The regulations in 7 CFR part 340, "Introduction of Organisms and Products Altered or Produced Through Genetic Engineering Which Are Plant Pests or Which There Is Reason to Believe Are Plant Pests," require a person to obtain a permit before introducing (importing, moving interstate, or releasing into the environment) into the United States certain genetically engineered organisms and products that are considered "regulated articles." The regulations set forth procedures for obtaining a permit for the release into the environment of a regulated article, and for obtaining a limited permit for the importation or interstate movement of a regulated article.

Pursuant to these regulations, the Animal and Plant Health Inspection Service has received and is reviewing the following application for a permit to release genetically engineered organisms into the environment:

Application No.	Applicant	Date received	Organisms	Field test location
93-252-1	Monsanto Agricultural Company.	09-09-93	Potato plants genetically engineered to express resistance to potato leaf roll virus.	Florida.

Done in Washington, DC, this 8th day of October 1993.

Lonnie J. King,

Acting Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 93-25248 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-34-P

Forest Service

Mono Tunnel Geothermal Lease Area, Inyo National Forest, CA; Intent To Prepare Environmental Impact Statement

AGENCY: Forest Service, USDA.

ACTION: Notice of intent to prepare environmental impact statement.

SUMMARY: The Forest Service will prepare an environmental impact statement on a proposal to lease geothermal resources on the Mono Lake

Ranger District, Inyo National Forest, Mono County, California.

DATES: Comments concerning the scope of the analysis should be received in writing by December 1, 1993.

ADDRESSES: Submit written comments and suggestions concerning the scope of the analysis to Dennis W. Martin, Forest Supervisor, Inyo National Forest, 873 N. Main Street, Bishop, California 93514.

FOR FURTHER INFORMATION CONTACT:

Questions about the proposed action and environmental impact statement should be sent to Vernon McLean, Forest Geologist, phone 619-873-2424.

SUPPLEMENTARY INFORMATION: The Mono Tunnel Geothermal Lease Area is within the Mono-Long Valley Known Geothermal Resource Area. Standards and Guidelines in the Inyo National Forest's Land and Resource Management Plan provide for leasing of geothermal resources and require analysis and documentation of environmental effects associated with development of geothermal resources before making a leasing decision. The decision to be made is whether to lease geothermal resources in this area, and if so under what conditions.

The Forest Service will consider a range of reasonable alternatives. One alternative will examine the option of not leasing geothermal resources at this site. Other alternatives will examine various options for leasing with surface occupancy restrictions.

Preliminary issues include the effects of geothermal development on surface and subsurface hydrology, wildlife, and recreation resources, and potential conflicts between local and federal policy. The Bureau of Land Management will cooperate with the Forest Service to prepare this environmental impact statement.

The responsible official is Ronald E. Stewart, Regional Forester, Pacific Southwest Region, 630 Sansome Street, San Francisco, CA 94111.

Public participation will be especially important at several points during this analysis. The first point is during the scoping process (40 CFR 1501.7). The scoping process for this proposal began on September 14, with a public meeting in Mammoth Lakes, California, hosted by the Inyo National Forest. Through the end of November, the Forest Service will continue the scoping process to obtain information, comments, and assistance from Federal, State, and local agencies and other individuals or organizations interested in or affected by the proposed action. Information obtained during scoping will be used to prepare the draft environmental impact statement (DEIS). The most useful

information in preparing a DEIS will be that pertaining to significant issues, reasonable alternatives, potential environmental effects, and identification of other agencies whose cooperation may be needed.

Individuals and agencies who participated in the September 14 meeting will be kept informed about progress on this analysis through mailings. Workshops and open houses, if held, will be announced locally. Federal, State, and local agencies, user groups, and other organizations known to be interested in this action are being invited to participate in the scoping process.

The DEIS will be filed with the Environmental Protection Agency (EPA) and is expected to be available for public review by November 1994. At that time the EPA will publish a notice of availability of the DEIS in the *Federal Register*.

The comment period on the DEIS will be 45 days from the date the EPA publishes the notice of availability in the *Federal Register*.

The Forest Service believes, at this early stage, it is important to give reviewers notice of several court rulings related to public participation in the environmental review process. First, reviewers of DEISs must structure their participation in the environmental review of the proposal so that it is meaningful and alerts an agency to the reviewer's position and contentions. *Vermont Yankee Nuclear Power Corp. v. NRDC*, 435 U.S. 519, 533 (1978). Also, environmental objections that could be raised at the draft environmental impact statement stage but that are not raised until after completion of the final environmental impact statement (FEIS) may be waived or dismissed by the courts. *City of Angoon v. Hodel*, 803 F.2d 1016, 1022 (9th Cir. 1986) and *Wisconsin Heritages, Inc. v. Harris*, 490 F. Supp. 1334, 1338 (E.D. Wis. 1980). Because of these court rulings, it is very important that those interested in this proposed action participate by the close of the 45-day comment period so that substantive comments and objections are made available to the Forest Service at a time when it can meaningfully consider them and respond to them in the FEIS.

To assist the Forest Service in identifying and considering issues and concerns, comments on the DEIS should be as specific as possible. It is also helpful if comments refer to specific pages or chapters of the draft statement. Comments may also address the adequacy of the DEIS or the merits of the alternatives formulated and discussed in the DEIS. Reviewers may

wish to refer to the Council on Environmental Quality Regulations for implementing the procedural provisions of the National Environmental Policy Act at 40 CFR 1503.3 in addressing these points.

After the comment period ends on the DEIS, written comments will be analyzed and considered by the Forest Service in preparing the final environmental impact statement (FEIS). The FEIS is scheduled to be completed by March 1995. The Forest Service is required to respond in the FEIS to the comments received (40 CFR 1503.4). The Regional Forester will consider the comments, responses, and environmental consequences discussed in the FEIS, and applicable laws, regulations, and policies in making his decision regarding leasing of geothermal resources in the Mono Tunnel Geothermal Lease Area. The responsible official will document the decision and rationale in the Record of Decision. That decision will be subject to appeal under 36 CFR part 217.

Dated: October 5, 1993.

Dale N. Bosworth,

Deputy Regional Forester.

[FR Doc. 93-25041 Filed 10-13-93; 8:45 am]

BILLING CODE 3410-11-M

Bull Salvage Sale Administrative Appeal Exemption

AGENCY: Forest Service, USDA.

ACTION: Notice.

SUMMARY: On September 21, 1993, District Ranger, Michael G. Gardner, made a decision to approve the logging of fire killed timber in the Bull Basin Canyon area of the Gila National Forest, Reserve Ranger District in Catron County, New Mexico.

An estimated 86 MBF of timber on 170 acres was killed by fire. The Reserve Ranger District has completed an environmental analysis on the impact of salvage logging this timber. It will be necessary to salvage this timber resource in a short, emergency timeframe to prevent a reduction in value due to rapid deterioration. If the decision document resulting from the environmental analysis is appealed under 36 CFR part 217, valuable time in recovering this timber resource will be lost. I have therefore determined that, pursuant to 36 CFR 217.4(a)(11), decisions involving the Bull Salvage Sale are exempt from administrative appeal.

Copies of the Decision Memo are available at the Reserve Ranger District Office, Gila National Forest, Box 170, Reserve, NM 87830.

DATES: This notice is effective October 14, 1993.

ADDRESSES: Direct comments to: Larry Henson, Regional Forester, Southwestern Region, USDA Forest Service, 517 Gold Avenue, SW., Albuquerque, New Mexico, 87102.

FOR FURTHER INFORMATION CONTACT: Milo Larson, Director, Timber Management, (503) 842-3240. Direct requests for a copy of the appeal regulation to Pat Jackson at the above address.

Dated: September 30, 1993.

Larry Henson,
Regional Forester.

[FR Doc. 93-25385 Filed 10-13-93; 9:34 am]

BILLING CODE 3410-11-M

DEPARTMENT OF COMMERCE

Agency Forms Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposals for collection of information under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: Bureau of Export Administration (BXA).

Title: Exceptions to Reporting Requirement under the IC/DV Procedures.

Agency Form Number: Export Administration Regulations (EAR) Section 775.3(i)(3) and 775.10(g)(2).

OMB Approval Number: 0694-0001.

Burden: 16 hours.

Number of Respondents: 31.

Avg Hours Per Response: 30 minutes for reporting; 1 minute for recordkeeping.

Needs and Uses: This reporting requirement allows U.S. exporters to request an exception to the import certificate (or its equivalent) procedure. The requirement also covers requests for exceptions to the delivery verification procedure.

Affected Public: Businesses or other for-profit institutions, small businesses or organizations.

Frequency: On occasion.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Gary Waxman, (202) 395-7340.

Agency: Bureau of Export Administration (BXA).

Title: Procedures for Supporting Documentation.

Agency Form Number: Export Administration Regulations (EAR) Section 787.13, 775.10.

OMB Approval Number: 0694-0064.

Burden: 63 hours.

Number of Respondents: 3,558.

Avg Hours Per Response: One minute.

Needs and Uses: This collection of information is a recordkeeping requirement whereby exporters will retain in their files certain supporting documents for a period of five years.

Affected Public: Businesses or other for-profit institutions, small businesses or organizations.

Frequency: Recordkeeping and on occasion.

Respondent's Obligation: Required to obtain or retain a benefit.

OMB Desk Officer: Gary Waxman, (202) 395-7340.

Copies of the above information collection proposals can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 482-3271, Department of Commerce, Room 5312, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collections should be sent to Gary Waxman, OMB Desk Officer, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Dated: October 7, 1993.

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 93-25191 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-CW-F

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget (OMB) for clearance the following proposal for collection of information under the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: National Oceanic and Atmospheric Administration.

Title: Reporting Requirements for a Commercial Fisheries Exemption under Section 114 of the Marine Mammal Protection Act (MMPA).

Agency Form Number: None.

OMB Approval Number: 0648-0225.

Burden: 128,532.

Number of Respondents: 15,193.

Avg Hours Per Response: .042

(average number of responses per respondent is 198).

Needs and Uses: The MMPA mandates the protection of marine mammals and makes their killing, except under permit or exemption, a violation. Section 114 authorizes an exemption for commercial fishermen provided they register and report all takings. This specific collection obtains

information on the interactions between fishermen and marine mammals. Information is required by statute and needed by the National Marine Fisheries Service to determine impacts on marine mammals.

Affected Public: Individuals, businesses or other for-profit institutions, small businesses or organizations.

Frequency: On occasion, annually.

Respondent's Obligation: Mandatory
OMB Desk Officer: Don Arbuckle, (202) 395-7340.

Copies of the above information collection proposal can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 482-3271, Department of Commerce, Room 5327, 14th and Constitution Avenue, N.W., Washington, D.C. 20230.

Written comments and recommendations for the proposed information collection should be sent to Don Arbuckle, OMB Desk Officer, Room 3208, New Executive Office Building, Washington, D.C. 20503.

Dated: October 6, 1993.

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 93-25194 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-CW-F

Bureau of Export Administration

Agency Form Under Review by the Office of Management and Budget

DOC has submitted to the Office of Management and Budget for clearance the following proposal for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. chapter 35).

Agency: Bureau of Export Administration.

Title: Report of Requests for Restrictive Trade Practice or Boycott—Single or Multiple Transactions.

Agency Form Numbers: BXA-621P and BXA-6051P.

OMB Approval Number: 0694-0012.

Type of Request: Extension of the expiration date of a currently approved collection.

Burden: 14,771 reporting/recordkeeping hours.

Number of Respondents: 1,187.

Avg Hours Per Response: One hour for BXA-612P and 30 hours for BXA-6051P—1 minute for filing each record retained (14,529 records).

Needs and Uses: The Export Administration Regulations require U.S. persons to report any requests that they have received to take any action to comply with, further, or

support an unsanctioned foreign boycott against countries friendly to the U.S. The information provided by firms is used by BXA to monitor requests for participation in foreign boycotts, analyze changing trends for purposes of deciding U.S. policy of discouraging participation in restrictive trade practices, and to initiate boycott investigations.

Affected Public: Businesses or other for-profit institutions; small businesses or organizations.

Frequency: On occasion.

Respondent's Obligation: Mandatory.

OMB Desk Officer: Gary Waxman, (202) 395-7340.

Copies of the above information collection proposal can be obtained by calling or writing Edward Michals, DOC Forms Clearance Officer, (202) 482-3271, Department of Commerce, room 5327, 14th and Constitution Avenue, NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collection should be sent to Gary Waxman, OMB Desk Officer, room 3208, New Executive Office Building, Washington, DC 20503.

Dated: September 24, 1993.

Edward Michals,

Departmental Forms Clearance Officer, Office of Management and Organization.

[FR Doc. 93-25190 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-CW-M

COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

Amendment of an Import Limit for Certain Man-Made Fiber Textile Products Produced or Manufactured in Jamaica

October 8, 1993.

AGENCY: Committee for the Implementation of Textile Agreements (CITA).

ACTION: Issuing a directive to the Commissioner of Customs increasing a limit.

EFFECTIVE DATE: October 15, 1993.

FOR FURTHER INFORMATION CONTACT: Naomi Freeman, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, (202) 482-4212. For information on the quota status of this limit, refer to the Quota Status Reports posted on the bulletin boards of each Customs port or call (202) 927-5850. For information on embargoes and quota re-openings, call (202) 482-3715.

SUPPLEMENTARY INFORMATION:

Authority: Executive Order 11651 of March 3, 1972, as amended; section 204 of the Agricultural Act of 1956, as amended (7 U.S.C. 1854).

The Government of the United States has agreed to increase the 1993 Designated Consultation Level for Category 632. As a result, the limit for Category 632, which is currently filled, will re-open.

A description of the textile and apparel categories in terms of HTS numbers is available in the **CORRELATION:** Textile and Apparel Categories with the Harmonized Tariff Schedule of the United States (see **Federal Register** notice 57 FR 54976, published on November 23, 1992). Also see 57 FR 60512, published on December 21, 1992.

The letter to the Commissioner of Customs and the actions taken pursuant to it are not designed to implement all of the provisions of the bilateral agreement, but are designed to assist only in the implementation of certain of its provisions.

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

Committee for the Implementation of Textile Agreements

October 8, 1993.

Commissioner of Customs,

Department of the Treasury, Washington, DC 20229.

Dear Commissioner: This directive amends, but does not cancel, the directive issued to you on December 15, 1992, by the Chairman, Committee for the Implementation of Textile Agreements. That directive concerns imports of certain cotton, wool, man-made fiber and other vegetable fiber textiles and textile products, produced or manufactured in Jamaica and exported during the twelve-month period which began on January 1, 1993 and extends through December 31, 1993.

Effective on October 15, 1993, you are directed to amend the December 15, 1993 directive to increase the limit for Category 632 to 200,000 dozen pairs¹.

The Committee for the Implementation of Textile Agreements has determined that this action falls within the foreign affairs exception to the rulemaking provisions of 5 U.S.C. 553(a)(1).

Sincerely,

Ronald I. Levin,

Acting Chairman, Committee for the Implementation of Textile Agreements.

[FR Doc. 93-25264 Filed 10-13-93; 8:45 am]

BILLING CODE 3510-DR-F

¹ The limit has not been adjusted to account for any imports exported after December 31, 1992.

COMMODITY FUTURES TRADING COMMISSION

Agricultural Advisory Committee Meeting

This is to give notice, pursuant to section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. App. 2, Section 10(a) and 41 CFR 101-6.1015(b), that the Commodity Futures Trading Commission's Agricultural Advisory Committee will conduct a public meeting on November 10, 1993 in room 326 (Board Room) of the Stewart Center Building on the campus of Purdue University, State Street, West Lafayette, Indiana. The meeting will be held from 8:30 a.m. to 12:30 p.m. The agenda will consist of:

Agenda

- I. Introductory remarks, Commissioner Joseph B. Dial;
- II. Discussion of single regulator concept;
- III. Discussion of Arkansas Best;
- IV. Discussion of proposed changes in CME live cattle contract;
- V. Discussion of CFTC 4(c) exemptive authority;
- VI. Discussion of USDA's Options Pilot Program;
- VII. Discussion of dual trading;
- VIII. Discussion of 1994 Risk Management Summit for American Agribusiness;
- IX. Discussion of swaps, hybrids, and derivatives;
- X. Discussion of release times for USDA's market sensitive reports;
- XI. Discussion of CFTC paperwork and regulatory requirements;
- XII. Other Committee Business; and
- XIII. Closing Remarks by Commissioner Joseph B. Dial.

The purpose of this meeting is to solicit the views of the Committee on the above-listed agenda matters. The Advisory Committee was created by the Commodity Futures Trading Commission for the purpose of receiving advice and recommendations on agricultural issues. The purposes and objectives of the Advisory Committee are more fully set forth in the fifth renewal charter of the Advisory Committee.

The meeting is open to the public. The Chairman of the Advisory Committee, Commissioner Joseph B. Dial, is empowered to conduct the meeting in a fashion that will, in his judgment, facilitate the orderly conduct of business. Any member of the public who wishes to file a written statement with the Advisory Committee should mail a copy of the statement to the attention of: the Commodity Futures

Trading Commission Agricultural Advisory Committee c/o Kimberly N. Griles, Commodity Futures Trading Commission, 2033 K Street NW., Washington, DC 20581, before the meeting. Members of the public who wish to make oral statements should also inform Ms. Griles in writing at the foregoing address at least three business days before the meeting. Reasonable provision will be made, if time permits, for an oral presentation of no more than five minutes each in duration.

Issued by the Commission in Washington, DC, on October 7, 1993.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 93-25208 Filed 10-13-93; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF EDUCATION

National Assessment Governing Board; Vacancies

AGENCY: National Assessment Governing Board, Education.

ACTION: Recommendations for candidates to fill board vacancies.

SUMMARY: The National Assessment Governing Board is seeking recommendations for candidates to fill positions in its membership for four-year terms beginning October 1, 1994. The Nominations Committee of the National Assessment Governing Board is accepting nominations for individuals representing the following categories: Chief State School Officer, Eighth-Grade Classroom Teacher, Fourth-Grade Classroom Teacher, Elementary School Principal, Secondary School Principal, and General Public. There will be one vacancy in each category. Anyone wishing to nominate a candidate or candidates should submit a letter outlining the nominees' qualifications, along with a complete and current resume (including telephone number and address). The nomination period begins with the publication of this notice and closes December 20, 1993. Nominations should be mailed to Christine Johnson, Chair, Nominations Committee, National Assessment Governing Board, 800 North Capitol Street NW., Suite 825, Washington, DC 20002-4233, Attention: Dr. Daniel B. Taylor. Telephone inquiries should be made to Dr. Taylor at (202) 357-6938.

BACKGROUND INFORMATION:

The National Assessment Governing Board is established under section 406(i) of the General Education Provisions Act (GEPA) as amended by section 3403 of the National Assessment

of Educational Progress Improvement Act (NAEP Improvement Act), title III-C of the Augustus F. Hawkins—Robert T. Stafford Elementary and Secondary School Improvement Amendments of 1988 (Pub. L. 100-297), (20 U.S.C. 1221e-1).

The Board is established to formulate policy for the National Assessment of Educational Progress. Among other duties, it is responsible for developing specifications for test design and methodology, developing guidelines and standards for analysis plans, and reporting and disseminating results. The Board also has responsibility for selecting subject areas to be assessed, and for identifying achievement goals for each age and grade tested.

Dated: October 8, 1993.

Roy Truby,

Executive Director.

[FR Doc. 93-25235 Filed 10-13-93; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Acceptance of Unsolicited Proposal; Global Outpost, Inc.

September 16, 1993.

AGENCY: Department of Energy (DOE), San Francisco Operations Office.

ACTION: Notice of acceptance of unsolicited proposal.

SUMMARY: In accordance with 10 CFR 600.14, the Department of Energy (DOE) the Nuclear Energy Division announces the Financial Assistance Award to Global Outpost, Inc. for the project entitled "Evaluation of the rendezvous and docking interface of a generic reactor system to an orbital space platform". The proposal has been evaluated in accordance with the requirements of 10 CFR 600.14(e)(i) and (ii) and will provide valuable information needed in developing operational scenarios and the proposal also represents a unique approach in its objectives.

AWARD: It is anticipated that award to Global Outpost, Inc. will occur on or about September 30, 1993.

FOR FURTHER INFORMATION CONTACT:

Further information may be obtained by contacting the U.S. Department of Energy, San Francisco Operations Office, ATTN: Gerald R. Acock, Contract Specialist, Contracts and Assistance Management Division, 1301 Clay Street, room 700N, Oakland, California, 94612-

5208, Phone (510) 637-1867 (no collect calls please).

Joann P. van Guillory,

Acting Director, Contracts and Assistance Management Division.

[FR Doc. 93-25329 Filed 10-13-93; 8:45 am]

BILLING CODE 6450-01-M

Energy Information Administration

American Statistical Association Committee on Energy Statistics; Meeting

Pursuant to the provisions of the Federal Advisory Committee Act (Public Law 92-463, 86 Stat. 770), notice is hereby given of the following meeting:

Name: American Statistical Association's Committee on Energy Statistics, a utilized Federal Advisory Committee.

Date and time: Thursday, November 4, 9:30 a.m.-5:30 p.m.; Friday, November 5, 8:45 a.m.-12:15 p.m.

Place: Holiday Inn—Capitol, 550 C Street SW., Washington, DC.

Contact: Ms. Renee Miller, EIA Committee Liaison, U.S. Department of Energy, Energy Information Administration, EI-72, Washington, DC 20585, Telephone: (202) 254-5507.

Purpose of committee: To advise the Department of Energy, Energy Information Administration (EIA), on EIA technical statistical issues and to enable the EIA to benefit from the Committee's expertise concerning other energy statistical matters.

Tentative agenda:

Thursday, November 4, 1993

A. Opening Remarks

B. Major Topics

1. Status Report on the National Energy Modeling System
2. Panel Discussion on Energy Policy Act
3. Small Area Estimation

(Public Comment)

Friday, November 5, 1993

4. Survey Evaluation Techniques
5. Assessing the Quality of EIA Published Data on Imports and Exports
6. Performance Measurement

(Public Comment)

C. Topics for Future Meetings

Public participation: The meeting is open to the public. The chairperson of the committee is empowered to conduct the meeting in a fashion that will facilitate the orderly conduct of business. Written statements may be filed with the committee either before or after the meeting. If there are any questions, please contact Ms. Renee Miller, EIA Committee Liaison, at the address or telephone number listed above or Mrs. Antoinette Martin at (202) 254-5409.

Transcripts: Available for public review and copying at the Public Reading Room (room 1E-290), 1000 Independence Avenue, SW., Washington, DC 20585, (202) 586-6025,

between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Marcia Morris,
Deputy Advisory Committee Management
Officer.

[FR Doc. 93-25238 Filed 10-13-93; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. QF93-130-000]

BCH Energy, L.P.; Amendment to Filing

October 7, 1993.

On September 27, and October 5, 1993, BCH Energy, L.P. tendered for filing amendments to its initial filing in this docket.

The amendments pertain to the ownership structure and technical aspects of its small power production facility. No determination has been made that the submittal constitutes a complete filing.

Any person desiring to be heard or objecting to the granting of qualifying status should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed by October 26, 1993, and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25166 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. QF89-126-004]

Cedar Bay Generating Co. Limited Partnership; Amendments to Filing

October 7, 1993.

On August 31, 1993, and October 4, 1993, Cedar Bay Generating Company, Limited Partnership (Applicant) tendered for filing supplements to its filing in this docket.

The amendments provide additional information pertaining to the ownership and technical aspects of its cogeneration facility. No determination has been

made that the submittals constitute a complete filing.

Any person desiring to be heard or objecting to the granting of qualifying status should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests must be filed on or before October 27, 1993, and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25165 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. CP93-729-000, et al.]

The Montana Power Company, et al.; Natural Gas Certificate Filings

October 6, 1993.

Take notice that the following filings have been made with the Commission:

1. The Montana Power Company

[Docket No. CP93-729-000]

Take notice that on September 15, 1993, as supplemented September 23, 1993, the Montana Power Company (Montana Power), 40 E. Broadway, Butte, Montana 59701, filed an application in Docket No. CP93-729-000 pursuant to section 3 of the Natural Gas Act (NGA), as amended, 15 U.S.C. 717(b); and §§ 153.1 through 153.8 of the Commission's Regulations for an amendment to the Commission's "Order Designating Points of Entry" which will expire on December 31, 1993.¹ Montana Power seeks whatever authority deemed necessary under section 3 of the NGA in order to ensure continued operation and use of the Alberta/Del Bonita import point beyond December 31, 1993. Montana Power's request is more fully set forth in the application on file with the Commission and open to public inspection.

These facilities are operated by Montana Power at the Canadian-United States international border in the area of the Reagan Blackleaf Field in the Province of Alberta. In order to assure

¹ 17 FERC ¶ 61,178 (1981).

continued service through the import facilities to its retail markets, Montana Power requests expeditious treatment of its application. Montana Power requests any waivers of the Commission's regulations deemed necessary to effectuate the relief requested.

Concurrently with this application, Montana Power is filing an application with the Department of Energy (DOE) to extend the term of the import authorization to December 31, 2004, so as to coincide with the recently amended export authorization issued to Canadian Montana Pipe Line Company, the exporter in the transaction.

No construction of facilities or change of the point of entry are being proposed.

Comment date: October 27, 1993, in accordance with the first subparagraph of Standard Paragraph F at the end of this notice.

2. Paiute Pipeline Company

[Docket No. CP93-751-000]

Take notice that on September 30, 1993, Paiute Pipeline Company (Applicant), P.O. Box 94197, Las Vegas, Nevada 89193-4197, filed in Docket No. CP93-751-000 an applicant pursuant to section 7 of the Natural Gas Act and part 157 of the Commission's Regulations under the Natural Gas Act (18 CFR part 157) for an order granting a certificate of public convenience and necessity authorizing Applicant to construct and operate approximately 5.5 miles of new 16" loop pipeline along its Reno Lateral and approximately 2.3 miles of new 12" loop pipeline along its South Tahoe Lateral, in order to expand Applicant's existing transmission system capacity primarily to accommodate 4,553 Dth per day of new firm transportation contract entitlements under seven executed, long-term service agreements with seven members of the Northern Nevada Industrial Gas Users (NNIGU).

Further, Applicant requests that the Commission acknowledge, to the extent deemed necessary, that Applicant's total daily firm transportation service obligation during each period from April 1 through October 31, upon the in-service date of its proposed capacity expansion project, will be increased from 138,780 Dth to 142,783 Dth.

Applicant states that it proposes to achieve two objectives by its application. First, Applicant proposes to expand its system capacity to partially complement the system capacity expansion proposed by Northwest Pipeline Corporation (Northwest) in Docket No. CP93-673-000, in which proceeding, Applicant asserts, Northwest is seeking authorization to increase the quantity of gas that it can deliver to Applicant's system by 18,053

Dth per day. Of that quantity, Northwest is proposing to provide new firm transportation delivery capacity into Applicant's system of 4,553 Dth per day for the NNIGU shippers. Applicant indicates that it intends by its proposal to satisfy requests that it has received from the NNIGU shippers for a like quantity of additional firm transportation service on its system. Second, Applicant states that the new loop pipeline on its Reno Lateral will provide additional reliability of service and operational flexibility along the lateral, by which Applicant serves a significant portion of the load requirements on its system, including the Reno/Sparks population center.

Applicant states that it held an open season process which provided an equitable and nondiscriminatory method for potential customers to make long-term commitments for firm transportation service which subsequently would be made available by means of an appropriately designed system facility expansion that would complement Northwest's planned system expansion. That process resulted in the seven long-term firm transportation firm transportation service agreements with the NNIGU shippers for 4,553 Dth per day of new firm transportation contract entitlements.

The following table identifies the seven NNIGU shippers, each of which is a commercial or industrial end-user of natural gas, and sets forth the contract entitlement quantities contained in the seven new firm transportation service agreements under which Applicant will render service upon completion of the proposed system expansion:

Shipper	Daily reserved capacity (Dth)	Summer daily reserved capacity (Dth)
Caesars Tahoe	83	73
CYANCO	1,035	910
Eagle-Picher	1,220	1,073
Harrah's Tahoe	83	73
Harrah's Reno	435	382
R.R. Donnelley	455	400
Winnemucca Farms	1,242	1,092
Total	4,553	4,003

Applicant states that each of the seven firm transportation service agreements is for a primary term of fifteen years from the date of commencement of service.

Applicant requests that the Commission make a preliminary determination concerning the appropriate future rate treatment for Applicant's NNIGU expansion facilities

(i.e., rolled-in versus incremental). Applicant states that the NNIGU expansion service agreements provide each shipper with an option to terminate its agreement if an order issues within eight months after the filing of Applicant's application indicating that incremental rate treatment is appropriate for the NNIGU expansion facilities. Applicant asserts that rolled-in rate treatment for the NNIGU expansion project is appropriate, because the rate impact on Applicant's existing customers will be de minimis, and the relatively minor pipeline installations will provide benefits to many of Applicant's existing customers in the form of enhanced reliability and flexibility of operations.

If the Commission makes a preliminary determination supporting rolled-in treatment for this project, Applicant requests that the Commission establish its initial rates under the expansion service agreements as its maximum Rate Schedule FT-1 rates, including applicable surcharges, which are in effect at the time service commences under the agreements. In the alternatives, if the Commission makes a preliminary determination finding that incremental rate treatment is appropriate for the proposed NNIGU expansion project, Applicant states that it would submit an amendment to request approval for specific initial rates for service under the NNIGU expansion service agreements. These rates would be designed on an incremental basis to recover the costs of the NNIGU expansion facilities.

Applicant requests the use of expedited procedures leading to a preliminary determination on non-environmental issues, including the issues of future rate treatment and initial rates, by April 1, 1994, and a final certificate order by September 1, 1994 or earlier, so that the NNIGU expansion project can be completed and placed in service by November 1, 1995, concurrently with Northwest's proposed expansion project.

Applicant requests that the Commission convene a technical conference, if necessary, after expiration of the protest/intervention period to allow all active parties the opportunity to identify and address substantive, non-environmental issues raised by the application and the intervention.

Applicant estimates the total cost of its proposed construction activities to be \$3,516,580. Applicant states that it intends to finance its project costs through ongoing regular financing programs and internally generated funds.

Comment date: October 27, 1993, in accordance with Standard Paragraph F at the end of this notice.

3. Arkla Energy Resources Company

[Docket No. CP94-7-000]

Take notice that on October 4, 1993, Arkla Energy Resources Company (AER), P.O. Box 21734, Shreveport, Louisiana 71151, filed in Docket No. CP94-7-000 an application pursuant to section 7(b) of the Natural Gas Act for permission and approval to abandon an exchange of natural gas between AER and Natural Gas Pipeline Company of America (Natural), which was authorized in Docket No. CP75-123, all as more fully set forth in the application on file with the Commission and open to public inspection.

AER states that the exchange, which was carried out under an agreement on file with the Commission as AER's Rate Schedule XE-41, is no longer required. It is asserted that Natural has provided a written concurrence on the request to abandon. It is further asserted that the exchange agreement has been terminated by both parties and that the exchange has been inactive for several years. It is explained that the proposed abandonment will have no impact on AER's system or on any of its customers. It is further explained that cancellation of the rate schedule will allow AER's FERC Gas Tariff to more accurately reflect its current and active services.

Comment date: October 27, 1993, in accordance with Standard Paragraph F at the end of this notice.

4. Northwest Pipeline Corporation

[Docket No. CP93-752-000]

Take notice that on September 30, 1993, Northwest Pipeline Corporation (Northwest), 295 Chipeta Way, Salt Lake City, Utah 84158, filed in Docket No. CP93-752-000 a request pursuant to §§ 157.205, 157.211 and 157.216 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205, 157.211, 157.216) for authorization to replace certain metering facilities at its Kalama II Lake Meter Station (Kalama Station) in Cowlitz County, Washington, to enable Northwest to increase its maximum design delivery to Cascade Natural Gas Corporation (Cascade), under Northwest's blanket certificate issued in Docket No. CP82-433-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request that is on file with the Commission and open to public inspection.

Northwest states that it is presently contractually obligated to deliver up to 3,900 Dt per day of sales and

transportation gas to Cascade at the Kalama Station. Northwest further states that the maximum design delivery capacity of the Kalama Station is 3,370 Dt per day, at an operating pressure of 300 psig, which is less than Northwest's existing firm delivery obligations to Cascade at that point. Therefore, Northwest is proposing to upgrade the Kalama Station by replacing the existing three-inch meter with a new four-inch meter. It is stated that the construction and operation of the proposed four-inch meter will increase the maximum design delivery capacity of the Kalama Station to 4,526 MMBtu, at an operating pressure of 300 psig, thereby enabling Northwest to deliver its contractually obligated volume to Cascade. It is further stated that any volumes delivered to Cascade by way of the enlarged meter station will be within the authorized entitlement of Cascade or other shippers.

Northwest estimates the cost of upgrading the Kalama Station to be \$126,500, including a cost of \$1,500 for removing old facilities. It is stated that since the proposed facility upgrade is necessary to enable Northwest to deliver up to its current firm obligations to Cascade at the subject point, Northwest will not require any reimbursement cost from Cascade.

Comment date: November 22, 1993, in accordance with Standard Paragraph G at the end of this notice.

5. Ozark Gas Transmission System

[Docket No. CP94-9-000]

Take notice that on October 4, 1993, Ozark Gas Transmission System (Ozark), 1700 Pacific Ave., suite 2100, Dallas, Texas 75201, filed in Docket No. CP94-9-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to abandon certain lateral facilities under Ozark's blanket certificate issued in Docket No. CP85-134-000 pursuant to section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the Commission and open to public inspection.

Specifically, Ozark proposes to abandon 15.5 miles of lateral pipeline and related facilities by sale to Arkansas Oklahoma Gas Corporation. The lateral line is known as the Stephens-McBride lateral and is located in Sebastian County, Arkansas. Ozark asserts that it will maintain an interconnection with this lateral and that existing and future production along the lateral will have access to Ozark's transportation facilities.

Comment date: November 22, 1993, in accordance with Standard Paragraph F at the end of this notice.

Standard Paragraphs

F. Any person desiring to be heard or make any protest with reference to said filing should on or before the comment date file with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.211 and 385.214) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules.

Take further notice that, pursuant to the authority contained in and subject to jurisdiction conferred upon the Federal Energy Regulatory Commission by sections 7 and 15 of the Natural Gas Act and the Commission's Rules of Practice and Procedure, a hearing will be held without further notice before the Commission or its designee on this filing if no motion to intervene is filed within the time required herein, if the Commission on its own review of the matter finds that a grant of the certificate is required by the public convenience and necessity. If a motion for leave to intervene is timely filed, or if the Commission on its own motion believes that a formal hearing is required, further notice of such hearing will be duly given.

Under the procedure herein provided for, unless otherwise advised, it will be unnecessary for the applicant to appear or be represented at the hearing.

G. Any person or the Commission's staff may, within 45 days after the issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefore, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for

authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,
Secretary.

[FR Doc. 93-25157 Filed 10-13-93; 8:45 am]
BILLING CODE 6717-01-M

[Docket No. JD92-06705T Wyoming-28]

State of Wyoming; NGPA Amended Notice of Determination by Jurisdictional Agency Designating Tight Formation

October 7, 1993.

Take notice that on September 20, 1993, the Wyoming Oil and Gas Conservation Commission (Wyoming) amended its notice of determination that was filed in the above-referenced proceedings on May 20, 1992 pursuant to § 271.703(c)(3) of the Commission's regulations. The May 20, 1992 notice determined that the Dakota Formation underlying portions of Sweetwater, Lincoln and Uinta Counties, Wyoming, qualifies as a tight formation under section 107(b) of the Natural Gas Policy Act of 1978.

The amended notice of determination reduces the geographical area recommended for tight formation designation to approximately 440,400 acres, as described on the attached appendix.

The notice of determination also contains Wyoming's and the Bureau of Land Management's findings that the referenced portion of the Dakota Formation meets the requirements of the Commission's regulations set forth in 18 CFR part 271.

The application for determination is available for inspection, except for material which is confidential under 18 CFR 275.206, at the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426. Persons objecting to the determination may file a protest, in accordance with 18 CFR 275.203 and 275.204, within 20 days after the date this notice is issued by the Commission.

Lois D. Cashell,
Secretary.

Appendix

Sweetwater, Lincoln and Uinta Counties, Wyoming

Township 23 North, Range 113 West, 6th P.M.

All of Sections 1-36
Township 23 North, Range 112 West, 6th P.M.

All of Sections 1-28, N/2; N/2 of the S/2; and the SE/4 of the SE/4 of Section 29, N/2; SW/4; N/2 of the SE/4; and the SW/4 of the SE/4 of Section 30, W/2; SE/4; and the W/2 of the NE/4 of Section 31,

S/2 of the SW/4; E/2 of the NE/4; and the SE/4 of Section 32
 All of Sections 33-36
 Township 23 North, Range 111 West, 6th P.M.
 All of Sections 1-36
 Township 23 North, Range 110 West, 6th P.M.
 All of Sections 4-9, 16-21, and 28-23
 Township 22 North, Range 113 and 112 West, 6th P.M.
 All of Sections 1-36
 Township 22 North, Range 111 West, 6th P.M.
 All of Sections 1-24 and 26-34
 Township 22 North, Range 110 West, 6th P.M.
 All of Sections 4-9, 16-21, 28-29, and 31-33
 Township 21 North, Range 113 West, 6th P.M.
 All of Sections 1-36
 Township 21 North, Range 112 West, 6th P.M.
 All of Sections 1-35
 Township 21 North, Range 111 West, 6th P.M.
 All of Sections 2-30 and 32-36
 Township 21 North, Range 110 West, 6th P.M.
 All of Sections 4-9, 16-21, and 28-33
 Township 20 North, Range 114 West, 6th P.M.
 All of Sections 1-4, 9-16, 21-28 and 33-36
 Township 20 North, Range 113 West, 6th P.M.
 All of Sections 1-36
 Township 20 North, Range 112 West, 6th P.M.
 All of Sections 1-2, 5-8, 11-14, 18-19, and 30-31
 Township 20 North, Range 111 West, 6th P.M.
 All of Sections 1-36
 Township 19 North, Range 114 West, 6th P.M.
 All of Sections 1-4, 9-16, 21-28, and 33-36
 Township 19 North, Range 113 West, 6th P.M.
 All of Sections 1-36
 Township 19 North, Range 112 West, 6th P.M.
 All of Sections 1, 12-13, 19, 24, 25 and 30
 Township 19 North, Range 111 West, 6th P.M.
 All of Sections 1-36
 Township 18 North, Range 114 West, 6th P.M.
 All of Sections 1-4, 9-16, 21-28, and 33-36
 Township 18 North, Range 113 West, 6th P.M.
 All of Sections 1-23 and 25-36
 Township 18 North, Range 112 West, 6th P.M.
 All of Sections 6-7, 18, 24-25, 30-31, 34-36
 Township 18 North, Range 111 West, 6th P.M.
 All of Sections 1-36.

[FR Doc. 93-25158 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP72-144-000]

ANR Pipeline Co.; Cancellation of Rate Schedule

October 7, 1993.

Take notice that on October 4, 1993, ANR Pipeline Company (ANR) tendered for filing as part of its FERC Gas Tariff, Original Volume No. 2, the following tariff sheets to with a proposed effective date of November 1, 1993.

First Revised Sheet No. 206 Superseding Original Sheet Nos. 206 through 209

ANR states that the purpose of this filing is to cancel Rate Schedule X-23 which represents an exchange service among ANR (formerly Michigan Wisconsin Pipe Line Company), Florida Gas Transmission Company (Florida Gas) and Texas Eastern Transmission Corporation (Texas Eastern). The service expired by its own terms on December 1, 1972.

ANR respectfully requests that the revised tariff sheets be accepted for filing and made effective November 1, 1993, or the date assigned by the Federal Energy Regulatory Commission, whichever is later.

ANR states that it has provided Florida Gas and Texas Eastern with a copy of the filing.

Any person desiring to protest said filing should file a protest with the Federal Regulatory Commission, 825 North Capitol St., NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,
 Secretary.

[FR Doc. 93-25164 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP89-661-025]

Algonquin Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

October 7, 1993.

Take notice that on October 1, 1993, Algonquin Gas Transmission Company (Algonquin) tendered for filing a Service Agreement between Algonquin and New England Power (NEP) Rate Schedule constituting Rate Schedule X-38.

Algonquin states that the Commission issued a certificate of public

convenience and necessity, authorizing the new firm transportation service by order of October 9, 1991, as amended May 20, 1992, in Docket Nos. CP89-661-000 et al. Pursuant to § 154.51 of the Commission's regulations, Algonquin requests waiver of the notice requirements of § 154.22 to the extent necessary for the service agreements to become effective as of November 1, 1993, the date such service is scheduled to be made available to NEP.

Algonquin states that copies of the filing are being mailed to Algonquin's affected customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,
 Secretary.

[FR Doc. 93-25156 Filed 10-13-93; 8:45 am]
 BILLING CODE 6717-01-M

[Docket No. CP92-151-002]

Algonquin Gas Transmission Co.; Proposed Changes in FERC Gas Tariff

October 7, 1993.

Take notice that on October 1, 1993 Algonquin Gas Transmission Company (Algonquin) tendered for filing a Service Agreement between Algonquin and Southern Connecticut Gas Company (Southern Connecticut) constituting Rate Schedule X-39.

Algonquin states that the Commission issued a certificate of public convenience and necessity, authorizing the new firm transportation service by order of August 4, 1992 in Docket No. CP92-151-000. Pursuant to § 154.51 of the Commission's regulations, Algonquin requests waiver of the notice requirements of § 154.22 to the extent necessary for the service agreement to become effective as of November 1, 1993 the date such service is scheduled to be made available to Southern Connecticut.

Algonquin states that copies of the filing are being mailed to South Connecticut and the affected state commission.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission to determine the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of the filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25161 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-99-002]

Colorado Interstate Gas Co.; Motion To Place Rates Into Effect

October 7, 1993.

Take notice that on October 1, 1993, Colorado Interstate Gas Company (CIG) filed a Motion to Place Rates Into Effect. The Motion is accompanied by revised tariff sheets incorporating the new rates. On April 30, 1993, the Commission had accepted CIG's rate filing, and suspended its effectiveness until October 1, 1993. CIG's Motion places those higher rates into effect subject to refund.

CIG states that copies of this filing have been served on CIG's jurisdictional customers and public bodies, and the filing is available for public inspection at CIG's offices in Colorado Springs, Colorado.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington DC 20426, in accordance with Section 385.211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the Public Reference Room.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25170 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. TM94-1-16-002]

National Fuel Gas Supply Corp.; Proposed Changes in FERC Gas Tariff

October 7, 1993.

Take notice that on October 5, 1993, National Fuel Gas Supply Corporation (National) tendered for filing as part of its FERC Gas Tariff, Third Revised Volume No. 1, Sub Second Revised Sheet No. 222, with a proposed effective date of October 1, 1993.

National states that the foregoing tariff sheet is being filed in compliance with the Commission's order issued September 30, 1993, in Docket No. TM94-1-16-000 et al. Such order directed National to correct Texas Gas items 10 and 12 on Sheet No. 222 to reflect the proper amounts.

National states that copies of National's filing were served on National's jurisdictional customers and on the interested State Commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20436, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR 385.211). All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25172 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP94-3-000]

Northern Natural Gas Co.; Request Under Blanket Authorization

October 7, 1993.

Take notice that on October 1, 1993, Northern Natural Gas Company (Northern), 1111 South 103rd Street, Omaha, Nebraska 68124 filed in Docket No. CP94-3-000 a request pursuant to § 157.205 of the Commission's Regulations under the Natural Gas Act (18 CFR 157.205) for authorization to upgrade and existing delivery point to Peoples Natural Gas Company (Peoples), located in Goodhue County, Minnesota, under Northern's blanket certificate issued in Docket No. CP82-401-000 pursuant to Section 7 of the Natural Gas Act, all as more fully set forth in the request which is on file with the

Commission and open to public inspection.

Northern states that the Cannon Falls #1 town border station (TBS) would be upgraded to accommodate increased natural gas deliveries to Peoples. The increased peak day and annual volumes, it said, would be 868 MMBtu and 150,164 MMBtu, respectively.

Northern indicates that it has sufficient capacity to accommodate the changes proposed without detriment or disadvantage to Northern's other customers and that the increase would not exceed the total volumes authorized for Peoples.

Upgrading the delivery point, it is said, would cost \$22,000 and Peoples would pay for the installation of the facilities.

Any person or the Commission's staff may, within 45 days after issuance of the instant notice by the Commission, file pursuant to Rule 214 of the Commission's Procedural Rules (18 CFR 385.214) a motion to intervene or notice of intervention and pursuant to § 157.205 of the Regulations under the Natural Gas Act (18 CFR 157.205) a protest to the request. If no protest is filed within the time allowed therefor, the proposed activity shall be deemed to be authorized effective the day after the time allowed for filing a protest. If a protest is filed and not withdrawn within 30 days after the time allowed for filing a protest, the instant request shall be treated as an application for authorization pursuant to section 7 of the Natural Gas Act.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25163 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP92-74-010]

South Georgia Natural Gas Co.; Proposed Changes to FERC Gas Tariff

October 7, 1993.

Take notice that on October 1, 1993, South Georgia Natural Gas Company (South Georgia) tendered for filing as part of its FERC Gas Tariff, First Revised Volume No. 1, the following revised sheets:

Eighth Revised Sheet No. 4A

Eighth Revised Sheet No. 4B

South Georgia states that the proposed tariff sheets are being filed with a proposed effective date of October 1, 1993. These tariff sheets implement the prerrestructuring period interim rates provided for in the Stipulation and Agreement filed in South Georgia's Docket No. RP92-74-000 that was approved by the Federal Energy

Regulatory Commission's Order in Docket No. RP92-74-007, et al., issued August 23, 1993. These interim rates will be in effect until November 1, 1993, when South Georgia's restructuring rates approved in the August 23 Order will become effective.

South Georgia states that copies of South Georgia's filing will be served upon all of South Georgia's customers, interested state commissions and interested parties.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (§ 385.211). All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25167 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP91-203-034]

Tennessee Gas Pipeline Co.; Tariff Filing

October 7, 1993.

Take notice that on September 30, 1993, Tennessee Gas Pipeline Company (Tennessee) tendered for filing ten copies of the following tariff sheets to be effective November 1, 1993:

Primary Sheets

Fifth Revised Volume No. 1

First Revised Sheet No. 26

Original Sheet No. 26A

First Revised Sheet Nos. 176-181

First Revised Sheet Nos. 182-191

Original Volume No. 2

Sixteenth Revised Sheet No. 9

Eighth Revised Sheet No. 9A

Alternate Sheets

Fifth Revised Volume No. 1

Alternate First Revised Sheet No. 177

Alternate First Revised Sheet No. 180

Alternate First Revised Sheet No. 181

Original Volume No. 2

Alternate Sixteenth Revised Sheet No. 9

Alternate Eighth Revised Sheet No. 9A

Tennessee states that the purpose of this filing is to implement the settlement approved by the Commission in its order dated April 21, 1993, in the above-referenced dockets. In addition, this filing implements the Rate Schedule NET transportation service to

New England Power Company effective November 1, 1993

Any person desiring to protest this filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25169 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP92-184-004]

Texas Eastern Transmission Corp.; Amendment and Motion To Vacate

October 7, 1993.

Take notice that on October 1, 1993, Texas Eastern Transmission Corporation (Texas Eastern), 5400 Westheimer Court, Houston, Texas 77056-5310, filed in Docket No. CP92-184-003 pursuant to section 7(c) to amend and to partially vacate the Commission's order issued July 16, 1993, in Docket Nos. CP92-184-000 et al. in order to (1) revise initial rates approved in the July 16, 1993, order and (2) to reduce the scope of authorized facilities to reflect reduced service levels for underlying part 284 transportation, all as more fully set forth in the application, which is on file and open to public inspection.

It is indicated that on July 16, 1993, the Commission issued an order approving construction and operation of incremental facilities on Texas Eastern's mainline system which would permit Texas Eastern to render part 284 transportation service for specific shippers. Texas Eastern explains that the facilities and associated services were designated as the Integrated Transportation Project (ITP).

Texas Eastern states that it has been advised by the ITP shippers that current market conditions have necessitated revisions in the level of services required for the year 1994. As a result, the ITP shippers' aggregate service requirements for 1994 are now 181,164 Dekatherms per day (Dthd) rather than the 201,000 Dthd upon which the authorized facilities were based. To recognize this change, Texas Eastern requests authority to partially vacate the

July 16, 1993, order to reduce the facilities authorized to be constructed to provide Phase I ITP service to correspond with the ITP shippers aggregate service levels. Texas Eastern asserts that partial vacatur of some of the facilities is appropriate as Texas Eastern no longer has service requirements for a portion of the Phase I facilities.

As a result of the reduced level of facilities necessary to render aggregate ITP service levels and in light of current cost factors, primarily the federal corporate income tax rate of 35%, Texas Eastern also proposes to amend the July 16, 1993 certificate to modify the initial rate. Texas Eastern states that it has executed service agreements with UGI Utilities, Inc. (UGI) and Public Service Electric and Gas Company (PSE&G) under its open access Rate Schedule FT-1 with a primary term of twenty years for the service levels set forth below. Texas Eastern has also tendered similar service agreements to Delmarva Power and Light Company (Delmarva), Philadelphia Gas Works (PGW), and Yankee Gas Services Company (Yankee).

ITP shipper	11/01/93 Dthd vol- umes	11/01/94 Dthd vol- umes
UGI	20,000	10,000
PSE&G	13,000	97,000
Delmarva	0	20,000
PGW	0	6,000
Yankee	0	15,000
• Total	33,000	148,164

Texas Eastern asserts that because the rates authorized for ITP service are authorized on an incremental basis, all of the costs associated with the service will be borne by the recipients of the service. It is indicated that provision of this service will, therefore, have no effect on the rates or services of Texas Eastern's other customers.

Any person desiring to be heard or to make any protest with reference to said amendment and motion to vacate should on or before October 28, 1993, file with the Federal Energy Regulatory Commission, Washington, DC 20426, a motion to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 385.214 or 385.211) and the Regulations under the Natural Gas Act (18 CFR 157.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken but will not serve to make the protestants parties to the proceeding. Any person wishing to become a party to a proceeding or to

participate as a party in any hearing therein must file a motion to intervene in accordance with the Commission's Rules. Any person who has heretofore filed need not file again.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25159 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP92-165-003]

**Texas Eastern Transmission Corp.;
Proposed Changes in FERC Gas Tariff**

October 7, 1993.

Take notice that on October 1, 1993, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheets, with a proposed effective date of November 1, 1993:

Original Sheet No. 34B
Fourth Revised Sheet No. 211
Second Revised Sheet No. 212
Second Revised Sheet No. 431
Fourth Revised Sheet No. 463
Third Revised Sheet No. 631
Fourth Revised Sheet No. 633

Texas Eastern states that the above tariff sheets are being filed pursuant to and in compliance with the Commission's March 3, 1993 "Order Issuing Certificate" in Docket Nos. CP92-142-000 and CP92-165-000 ("March 3 Order") and the July 16, 1993 "Order Granting Rehearing, In Part, And Denying Rehearing, In Part" in Docket Nos. CP92-142-001 and CP92-165-001 ("July 16 Order"). These sheets reflect the implementation as of November 1, 1993 of new firm transportation service to CNG Transmission Corporation (CNG), which service is rendered by means of new facilities authorized by the March 3 Order and July 16 Order. Texas Eastern requests the Commission issue an order accepting such tariff sheets prior to November 1, 1993.

Texas Eastern is also proposing other limited revisions to its FERC Gas Tariff, Sixth Revised Volume No. 1, is necessary in order to incorporate the appropriate reference to Original Sheet No. 34B, Second Revised Sheet No. 431, Fourth Revised Sheet No. 463, Third Revised Sheet No. 631 and Fourth Revised Sheet No. 633 revise Sections 1, 3.14, 15.4 and 15.5 of the General Terms and Conditions, respectively.

Texas Eastern states that copies of this filing have been served on Texas Eastern's firm customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission,

825 North Capitol Street NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25160 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP92-164-003]

**Texas Eastern Transmission Corp.;
Proposed Changes in FERC Gas Tariff**

October 7, 1993.

Take notice that on October 1, 1993, Texas Eastern Transmission Corporation (Texas Eastern) tendered for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheets, with a proposed effective date of November 1, 1993.

Original Sheet No. 34A
Third Revised Sheet No. 211
First Revised Sheet No. 212
Original Sheet No. 212A
First Revised Sheet No. 431
Third Revised Sheet No. 463
Second Revised Sheet No. 625
Original Sheet No. 625A
Second Revised Sheet No. 627
Original Sheet No. 627A
First Revised Sheet No. 628
First Revised Sheet No. 628A
Second Revised Sheet No. 631
Third Revised Sheet No. 633

Texas Eastern states that the above tariff sheets are filed pursuant to and in compliance with the Commission's July 16, 1993, "Order Granting Rehearing in Part, Denying Rehearing in Part, and Issuing Certificate" in Docket Nos. CP92-184 and CP92-185 ("July 16 Order"). These tariff sheets reflect the implementation as of November 1, 1993, of new firm transportation service to certain ITP Customers which is rendered by means of new facilities authorized by the July 16 Order. Texas Eastern requests the Commission issue an order accepting such tariff sheets prior to November 1, 1993.

Texas Eastern states that copies of the filing were served on Texas Eastern's jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE.,

Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure. All such protests should be filed on or before October 15, 1993.

Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25162 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP94-18-000]

**Texas Eastern Transmission Corp.;
Proposed Changes in FERC Gas Tariff**

October 8, 1993.

Take notice that on October 6, 1993, Texas Eastern Transmission Corporation (Texas Eastern) submitted for filing as part of its FERC Gas Tariff, Sixth Revised Volume No. 1, the following tariff sheets:

First Revised Sheet No. 502
Original Sheet No. 502A

Texas Eastern states that these tariff sheets reflect the addition of a new operational flow order as set forth in Section 4.3(J). The OFO contemplated by Section 4.3(J) is one which Texas Eastern states its experience under Order No. 636 since implementation on June 1, 1993, has demonstrated to be critical to the provision of firm service to Texas Eastern's customers as contemplated by Order No. 636. Contrary to its expectations, Texas Eastern states its customers are not injecting gas into storage in quantities which will ensure continuity of reliable storage and no-notice service throughout the winter heating season. In light of the impending winter heating season, Texas Eastern proposes that Section 4.3(J) be made effective as of October 20, 1993. To that end, Texas Eastern requests a shortened comment period of October 13, 1993.

Texas Eastern requests that the Commission waive all necessary rules and regulations to permit the tariff sheets listed on herein to become effective on October 20, 1993. Texas Eastern requests a shortened comment period of October 13, 1993 in order that it may implement, if necessary, the OFO on October 20, 1993. To enable storage customers to comment within the shortened time period, Texas Eastern is faxing this filing to all firm storage customers under Rate Schedules SS, SS-1, FSS-1, and X-28.

Texas Eastern states that copies of the filing were also served on firm customers of Texas Eastern and interested state commissions. A copy of the filing has also been served on all parties in Docket No. RS92-11.

Any person desiring to be heard or to protest said filing should file a motion to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 211 and 214 of the Commission's Rules of Practice and Procedure. All such motions or protests should be filed on or before October 13, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a motion to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25204 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-109-007]

Williams Natural Gas Co.; Compliance Filing

October 7, 1993.

Take notice that on October 1, 1993, Williams Natural Gas Company (WNG), tendered for filing as part of its FERC Gas Tariff, the following revised tariff sheets, with a proposed effective date of November 1, 1993:

Second Revised Volume No. 1

First Revised Sheet Nos. 2, 5, 6, 6A, 200, 204, 205, 208, 280-285

Original Volume No. 2

Sixth Revised Sheet No. 144, Original Sheet No. 335A

WNG states that such revised sheets reflect the same general rate increase (less the cost of facilities not projected to be in service) and tariff changes originally filed in this docket, and are submitted pursuant to ordering paragraphs (A), (B) and (D) of the Commission's May 28, 1993, suspension order in this docket, to become effective, subject to refund, on November 1, 1993, in lieu of the tariff sheets as originally filed.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rule 211 of the Commission's Rules of Practice and Procedure (18 CFR

385.211). All such protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to this proceeding. Copies of this filing are on file with the Commission and are available for public inspection.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25168 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP93-109-008]

Williams Natural Gas Co.; Proposed Changes in FERC Gas Tariff

October 7, 1993.

Take notice that on October 4, 1993, Williams Natural Gas Company (WNG) tendered for filing as part of its FERC Gas Tariff, Second Revised Volume No. 1, Substitute First Revised Sheet No. 6, with proposed effective date of November 1, 1993.

WNG states that it submitted tariff changes on October 1, 1993, pursuant to ordering paragraphs (A), (B), and (D) of the Commission's May 28, 1993 suspension order in the above referenced docket. First Revised Sheet No. 6, submitted with that filing, inadvertently reflected the FTS-P Commodity rate of \$.0184 for the FTS-M Commodity rate of \$.0137. The instant filing is being made to correct this error.

WNG states that a copy of its filing was served on all participants listed on the Commission's official service list in this docket, as well as on all jurisdictional customers and interested state commissions.

Any person desiring to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with § 385.211 of the Commission's Rules and Regulations. All such motions or protests should be filed on or before October 15, 1993. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Copies of this filing are on file with the Commission and are available for public inspection in the public reference room.

Lois D. Cashell,

Secretary.

[FR Doc. 93-25171 Filed 10-13-93; 8:45 am]

BILLING CODE 6717-01-M

Office of Energy Research

Energy Research Financial Assistance 94-02; Medical Application Program

AGENCY: U.S. Department of Energy (DOE).

ACTION: Notice inviting grant applications.

SUMMARY: The Office of Health and Environmental Research (OHER) of the Office of Energy Research (ER), U.S. Department of Energy announces its interest in receiving applications for conducting a Project Definition Study for the National Biomedical Tracer Facility (NBTF).

The NBTF is a large proton accelerator, with supporting facilities, to be utilized for the production, processing, and distribution of radioisotopes used in medical and industrial applications. The NBTF may be either a new facility or a modification to an existing facility. The mission of the NBTF is to: (1) Produce radionuclides for the nuclear medicine community; (2) conduct research in radioisotope production; and, (3) provide opportunities for education and training in radioisotope production.

The goals of the Project Definition Study will be to: (1) Further refine the design, construction schedule, and cost estimates associated with the NBTF; (2) examine the radioactive waste management, disposal, and other environmental issues associated with the NBTF; (3) develop a business plan for commercial operation of the NBTF over its expected lifetime (including reimbursement to the Government for its construction); and (4) assist DOE in deciding whether or not construction and operation of the NBTF would satisfy current and future radioisotope needs for medical and industrial applications and whether or not such a facility could be operated by the private sector. It is anticipated that DOE will approve up to five applications for funding project definition studies at approximately \$300,000 each, contingent upon availability of Fiscal Year 1994 appropriated funds.

DATES: Formal applications submitted in response to this notice must be received by 4:30 p.m., E.S.T., February 1, 1994, in order to undergo a merit review, pursuant to 10 CFR part 600 and part 605, in March 1994 and to permit timely consideration for award in Fiscal Year 1994.

ADDRESSES: Formal applications referencing Program Notice 94-02 should be forwarded to: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance

Management Division, ER-64, room F-220, Washington, DC 20585. Attn: Program Notice 94-02. The following address must be used when submitting applications by U.S. Postal Service Express mail, any commercial mail delivery service, or when hand carried by the applicant: U.S. Department of Energy, Office of Energy Research, Acquisition and Assistance Management Division, ER-64, 19901 Germantown Road, Germantown, Maryland 20874.

FOR FURTHER INFORMATION CONTACT: Dr. Robert Wood, Office of Health and Environmental Research, ER-73, U.S. Department of Energy, GTN, Washington, DC 20585. Telephone: (301) 903-3213. Potential applicants are required to contact Dr. Wood for supplementary information by November 15, 1993.

SUPPLEMENTARY INFORMATION: Following the award, each recipient will have up to 9 months from the date of the award to complete the NBTF Project Definition Study and to provide a report to DOE. On the basis of the information contained in the studies, an independent National Academy of Sciences evaluation of the need for the NBTF, and DOE's own analyses of all relevant considerations, the Department will decide whether construction and operation of the NBTF is required to satisfy the current and future radioisotope needs for medical and industrial applications. If the data supports the need for an NBTF, as well as the fact that such a facility can be operated economically by the private sector, additional Congressional funding will be sought.

The project description portion of an application must not exceed twenty (20) double-spaced pages.

In completing the project description portion of the application, each applicant must address in detail the following categories:

- Experience in design, construction, and operation of a large proton accelerator;
- Experience with large scale production of radioisotopes including target chemistry, radioisotope processing, hot lab operation, waste disposal operations, or evidence that expertise can be obtained;
- Qualifications for establishing a radioisotope distribution network, packaging, and transportation;
- Experience in conducting research on radioisotope targetry, separations, purification, and in the development of improved production technology;
- Familiarity with Federal, State, and local regulations required for siting,

construction, and operation of the facility;

- Proven capability to provide an educational program in radiochemistry and a research program in nuclear medicine. Demonstrated capability in nuclear medicine research and in education and training, or evidence that such capabilities can be obtained. If a broad research and education component to the NBTF is recommended by the Institute of Medicine, such information will be requested later in the competition process.

More information about the development and submission of applications, eligibility, limitations, evaluation, selection process, and other policies and procedures may be found in 10 CFR part 605, the Energy Research Merit Review System (56 FR 10244) and the Application Guide for the Office of Energy Research Financial Assistance Program. The application guide is available from the Office of Health and Environmental Research, ER-73, Department of Energy, GTN, Washington, DC 20585. Telephone requests may be made by calling (301) 903-3213.

The Catalog of Federal Domestic Assistance Number for this program is 81.049.

Issued in Washington, DC, on October 8, 1993.

James F. Decker,

Acting Director, Office of Energy Research.

[FR Doc. 93-25240 Filed 10-13-93; 8:45 am]

BILLING CODE 6450-01-P

ENVIRONMENTAL PROTECTION AGENCY

[FRL-4788-9]

Proposed Settlement Agreement, Judicial Review of the National Emissions for Radon Emissions From Phosphogypsum Stacks

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed settlement agreement; opportunity for public comment.

SUMMARY: EPA hereby gives notice of a proposed settlement agreement in litigation involving review of a final rule amending the National Emission Standard for Hazardous Air Pollutants ("NESHAP") for Radon Emissions from Phosphogypsum Stacks, 40 CFR part 61, subpart R (57 FR 23305, June 3, 1992). EPA is providing an opportunity for public comment on the proposed settlement agreement pursuant to section 113(g) of the Clean Air Act.

DATES: Written comments on the proposed consent decree must be received by November 15, 1993.

ADDRESSES: Written comments should be sent to Timothy D. Backstrom, Air and Radiation Division (LE-132A), Office of General Counsel, U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460. Copies of the proposed settlement agreement may be obtained from Shermanita Isler-Simmons at the same address (telephone 202-260-7606).

FOR FURTHER INFORMATION CONTACT: Timothy D. Backstrom, Senior Attorney, Air and Radiation Division, EPA Office of General Counsel, telephone 202-260-7517.

SUPPLEMENTARY INFORMATION: In *The Fertilizer Institute v. Environmental Protection Agency*, No. 92-1320 (D.C. Cir.), and *ManoSota-88 v. Browner*, No. 92-1330 (D.C. Cir.), the petitioners sought judicial review of a final rule amending the NESHAP for Radon Emissions from Phosphogypsum Stacks, 40 CFR part 61 subpart R, issued by EPA on May 29, 1992 (57 FR 23305, June 3, 1992). The Fertilizer Institute ("TFI") also filed with the Administrator on August 3, 1992, a petition to reconsider certain aspects of the final rule amending the phosphogypsum NESHAP.

On July 2, 1993, EPA and petitioner The Fertilizer Institute ("TFI") in No. 92-1320 lodged with the U.S. Court of Appeals for the District of Columbia Circuit a proposed settlement agreement in that case. Based on that agreement, EPA and TFI jointly moved the Court to stay further proceedings in both No. 92-1320 and the consolidated case No. 92-1330 (the motion was supported by ManoSota-88, the petitioner in 92-1330). The Court granted the unopposed joint motion to stay the proceedings on July 9, 1993.

Under the proposed settlement agreement, EPA agrees that it will make a final determination as to whether it will grant or deny TFI's August 3, 1992, petition for reconsideration by January 31, 1994. If EPA fails to grant TFI's petition for reconsideration by January 31, 1994, TFI may move the Court to dissolve the stay of the proceedings in No. 92-1320. If EPA denies TFI's petition for reconsideration and TFI seeks judicial review of that denial, TFI agrees that it will move to consolidate such review with any remaining proceedings in No. 92-1320 and No. 92-1330.

Final approval and entry of the proposed settlement agreement are subject to section 113(g) of the Clean Air Act, which requires notice and

opportunity for comment on certain consent orders and settlement agreements to which the United States is a party. Accordingly, for a period of thirty (30) days following publication of this notice, EPA will receive written comments on the proposed settlement agreement. Under section 113(g), EPA or the Department of Justice may withdraw or withhold consent to the agreement if the comments disclose facts or circumstances indicating that such consent is inappropriate, improper, inadequate, or inconsistent with the requirements of the Act.

Dated: October 1, 1993.

Gerald H. Yamada,

Acting General Counsel.

[FR Doc. 93-25227 Filed 10-13-93; 8:45 am]

BILLING CODE 6560-50-M

[FRL-4788-7]

Solicitation for Research Grant Proposal—1994 Exploratory Research Grants

AGENCY: Environmental Protection Agency.

ACTION: General research grant solicitation.

SUMMARY: The U.S. Environmental Protection Agency (EPA), through its Office of Exploratory Research (OER) is seeking grant applications to conduct exploratory environmental research in biology, chemistry, physics, engineering, or socioeconomics. Investigations are sought in these research disciplines which focus on any aspect of pollution identification, characterization, abatement or control, or address the effects of pollutants on the environment. In addition, research is sought on environmental policy and its social and economic consequences.

This solicitation only concerns the research grants administered by EPA's Office of Exploratory Research, and outlines procedures for receiving grant assistance from that office.

The Office of Exploratory Research will not solicit for targeted grants through Requests for Applications in fiscal year 1994.

The main purpose of OER's Research Grants Program is to support advanced research in the environmental sciences, engineering and socioeconomics at U.S. academic institutions. The principal products sought are high quality scientific and technical articles in refereed technical journals.

The Application

Proposed projects must be investigative research which advances

the state of knowledge in the environmental sciences and technology. Applications will not be accepted for routine monitoring, state-of-the-art or market surveys, literature reviews, development or commercialization of proven concepts, or the preparation of materials and documents, including process designs or instruction manuals.

Application forms, instructions, and other pertinent information for assistance programs are available in the EPA Research Grants Application/Information Kit. Interested investigators should review the materials in this kit before preparing an application for assistance. The kits are available from: U.S. Environmental Protection Agency, Grants Operations Branch (3903F), 401 M Street SW., Washington, DC 20460, (202) 260-9266.

Each application will consist of the application for federal assistance form (Standard Forms 424 and 424A) and separate sheets providing the budget breakdown for each year of the project, resumes for the principal investigator and co-workers, abstract of the proposed project, and project narrative. All certification forms (drug-free workplace, etc.) must be signed and included with the application.

Application Submission/Closing Dates

Due to a heavy burden of pending applications in OER, the only closing date in fiscal year 1994 will be June 1, 1994.

To be considered, the original and eight copies of the application must be received by EPA's Grants Operations Branch no later than close of business on the closing date. Fully developed research grant applications, prepared in accordance with instructions in the Application for Federal Assistance Form SF-424, should be sent to the Grants Operations Branch. Informal, incomplete or unsigned proposals will not be considered. The application must be sent to: U.S. Environmental Protection Agency, Grants Operations Branch (3903F), 401 M Street SW., Washington, DC 20460.

For overnight express mail, the address is: U.S. Environmental Protection Agency, Grants Operation Branch, Fairchild Building, room 801, 499 South Capitol Street SW., Washington, DC 20460, (202) 260-9266.

Special Instructions

The following special instructions apply to all applicants responding to this solicitation:

- Applications must be unbound and clipped or stapled. The 424 form must be the first page of the application. Budget information should immediately

follow the 424 form. All certification forms should be placed at the end of the application.

- Applications must be identified by printing "OER-94" in the upper right hand corner or block 10 of Application Form SF-424. The absence of this identifier from an application may lead to delayed processing or misassignment of the application.

- A one-page abstract must be included with the application.

Well written abstracts contribute significantly to a proposal's chances of being selected for support.

- The project narrative section of the application must not exceed twenty-five 8½ x 11 inch, consecutively numbered pages of standard type (12 point, or 10 characters per inch), including tables, graphs and figures. For purposes of this limitation, the "project narrative section" of the application consists of the following items in the Application/Information/Kit:

- (1) Description of Project.
- (2) Objectives.
- (3) Results or Benefits expected.
- (4) Approach.
- (5) General Project Information.
- (6) Quality Assurance (If needed).

Attachments, appendices, and reference lists for the narrative section may be included but are within the 25 page limitation. Appendices will not be considered an integral part of the narrative.

Items not included under the 25 page limitation are the SF-424 and other forms, budgets, resumes, and the abstract.

Resumes must not exceed two consecutively numbered pages for each principal investigator and should focus on education, positions held and most recent or related publications.

Applications not meeting these requirements will be returned to the applicant without review.

Guidelines and Limitations

The typical grant issued by OER is for a total cost of approximately \$100,000 per year for two or three years. All budget costs and justifications, particularly requests for equipment, will be carefully reviewed. The maximum project period is three years; shorter periods are encouraged, as are modest funding requests. Subcontracts for research to be conducted under the grant should not exceed approximately 40% of the total direct cost of the grant for each year in which the subcontract is awarded.

Eligibility

The following eligibility requirements apply to both the general solicitation and targeted announcements (RFA's).

Academic and nonprofit institutions located in the U.S., and state or local governments are eligible under all existing authorizations. Profit-making firms are eligible only under certain laws, and then under restrictive conditions, including the absence of any profit from the project.

Potential applicants who are uncertain of their eligibility should study the restrictive language of the law governing the area of research interest or contact EPA's Grants Operations Branch at (202) 260-9266.

Federal agencies and federal employees are not eligible to participate in this program.

Review and Selection

All grant applications are initially reviewed by the Agency to determine their legal and administrative acceptability.

Acceptable applications are then reviewed by an appropriate technical review group. This review is designed to evaluate and rank each proposal according to its scientific merit and utility as a basis for recommending Agency approval or disapproval. Each review group is composed primarily of non-EPA scientists, engineers and economists who are experts in their respective disciplines. All reviewers are proficient in the technical areas that they are reviewing. The reviewers use the following criteria in their reviews:

- Quality of the research plan (including theoretical and/or experimental design, originality, and creativity).
- Qualifications of the principal investigator and staff including knowledge of relevant subject areas.
- Utility of the research, including potential contribution to scientific knowledge in the environmental area.
- Availability and adequacy of facilities and equipment.
- Budgetary justification—in particular justification and cost requests for equipment will be carefully reviewed.

A summary statement of the scientific review and recommendation of the panel is provided to each applicant.

Funding decisions are the sole responsibility of EPA. Grants are selected on the basis of technical merit, program balance and budget.

Proprietary Information

By submitting an application in response to this solicitation, the

applicant grants EPA permission to share the application with technical reviewers both within and outside of the Agency.

Applications containing proprietary or other types of confidential information will be immediately returned to the applicant without review.

Funding Mechanism

For all general and targeted grants, the funding mechanism will consist of a grant agreement between EPA and the recipient.

Federal grant regulation 40 CFR 30.307 requires that all recipients provide a minimum of 5% of the total project cost, which may not be taken from Federal sources. OER will not support a request for a deviation from this requirement for any grant supported by its Research Grants Program.

Contacts

For additional general information on the grants program, applicants may call (202) 260-7474. Applicants with additional questions may contact the appropriate individuals identified in Table I. Their address is: U.S. Environmental Protection Agency, Office of Exploratory Research (8703), 401 M Street, SW., Washington, DC 20460.

TABLE I.—CONTACTS FOR THE GENERAL SOLICITATION

Discipline	Contact	Phone number (Area code 202)
Biology	Clyde Bishop ...	260-5727
Chem/Physics of Air	Deran Pashayan.	260-2606
Chem/Physics of Water/Soil	Louis Swaby	260-7453
Engineering	Louis Swaby	260-7453
Socioeconomics	Robert Papetti ..	260-7473

Minority Institution Assistance

Preapplication assistance is available upon request for potential investigators representing institutions identified by the Secretary, Department of Education, as Historically Black Colleges and Universities (HBCUs) or the Hispanic Association of Colleges and Universities (HACUs).

The application Form SF-424, instructions, subject areas, and review procedures are the same as those for the general grants program.

For further information concerning Minority assistance, contact: Virginia Broadway, U.S. Environmental Protection Agency (8701), 401 M Street,

SW., Washington, DC 20460. (202) 260-7664.

Dated: October 5, 1993.

Robert A. Papetti,
Director, Research Grants Staff, Office of Exploratory Research.
[FR Doc. 93-25228 Filed 10-13-93; 8:45 am]
BILLING CODE 6560-50-M

[FRL-4789-1]

Proposed NPDES New Source General Permit for the Western Portion of the Outer Continental Shelf of the Gulf of Mexico (GMG390000)

AGENCY: Environmental Protection Agency (EPA).

ACTION: Notice of proposed NPDES general permit and availability of supplemental draft environmental impact statement.

SUMMARY: EPA Region 6 today proposes to issue a national pollutant discharge elimination system (NPDES) permit for the western portion of the outer continental shelf (OCS) of the Gulf of Mexico. If issued as proposed, the permit will regulate new sources in the Offshore Subcategory of the Oil and Gas Extraction Point Source Category located in and discharging pollutants to federal waters in lease blocks located seaward of the outer boundary of the territorial seas off Louisiana and Texas. The effluent limitations of the proposed permit are based on new source performance standards (NSPS), ocean discharge criteria, and, for waste streams not subject to the NSPS, EPA's best professional judgment (BPJ) on the best available control technology economically achievable (BAT) and best conventional technology (BCT). EPA has prepared a supplemental draft environmental impact statement (SDEIS) on proposed issuance of this permit. EPA Region 6 solicits comments on its proposal and the SDEIS.

DATES: Written comments must be received by November 29, 1993. The Lafayette, Louisiana public meeting and hearing will be held starting at 6 p.m. on November 16, 1993. The Houston, Texas public meeting and hearing will be held starting at 6 p.m. on November 17, 1993.

ADDRESSES: Written comments should be sent to:

Regional Administrator, EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733.

Verbal comments may be submitted at public meetings/hearings EPA Region 6 will hold at:

Holiday Inn Holidome, 2032 NE., Evangeline Thruway, Lafayette, Louisiana; and

Holiday Inn near Greenway Plaza, 2712
Southwest Freeway (US 59) Houston,
Texas.

FOR FURTHER INFORMATION, CONTACT: Ms. Ellen Caldwell (6W-PI), EPA Region 6, 1445 Ross Avenue, Dallas, Texas 75202-2733, Telephone (214) 655-7513. A copy of the draft permit, an explanatory fact sheet and/or the SDEIS may be obtained from Ms. Caldwell. In addition, the current administrative record on the proposal is available for examination at the Region's Dallas offices during normal working hours after providing Ms. Caldwell 24 hours advance notice. If only minor changes to the SDEIS are necessary, the final supplemental environmental impact statement (FSEIS) will incorporate the SDEIS by reference and include: (1) A revised and updated summary; (2) revisions and additions to the SDEIS; (3) EPA's responses to comments; and (4) EPA's preferred alternative. Interested parties should thus retain a copy of the SDEIS for possible use in combination with the FSEIS.

SUPPLEMENTARY INFORMATION: Pursuant to section 301(a) of the Clean Water Act (CWA), 33 U.S.C. 1311(a), discharges of pollutants to waters of the United States, the territorial seas, and the contiguous zone are unlawful, except as authorized by an NPDES permit issued by EPA (or an EPA-approved state) in accordance with CWA section 402, 33 U.S.C. 1342. Although EPA frequently authorizes such discharges through NPDES permits issued to individual facilities, it may, as here, choose to authorize them through promulgation of a general permit. The Agency's use of general NPDES permits is described at 40 CFR 122.28.

NPDES permits typically include technology-based effluent limitations regulating the quality of discharged pollutants and conditions, e.g., requiring recordkeeping and reporting, necessary for enforcement of the permit. Those limitations and conditions are derived from EPA promulgated effluent limitations guidelines including NSPS, and, prior to promulgation of such guidelines, the best professional judgment (BPJ) of the Agency's technical staff. Permits also contain limitations assuring compliance with state water quality standards or, as in this case, to avoid degradation of the marine environment.

At 57 FR 54642 (November 19, 1992), EPA Region 6 issued NPDES general permit GMG290000 authorizing discharges from existing sources in the Offshore Subcategory of the Oil and Gas Extraction Point Source Category to the OCS of the Western Gulf. Because EPA

had then published no BAT or BCT effluent limitations guidelines, the technology-based limits of that permit were established through BPJ. Subsequently, the Agency promulgated BAT guidelines, BCT guidelines, and NSPS for the Offshore Subcategory at 58 FR 12504 (January 15, 1993). On August 4, 1993, EPA Region 6 proposed modifications to NPDES permit GMG290000 at 58 FR 41474, in part to render it consistent with those new BAT and BCT guidelines. Today, the Region proposes a separate general permit regulating discharges from "new sources" in the Offshore Subcategory.

The OCS of the Western Gulf consists of those federal waters seaward of the outer boundary of the territorial seas (i.e., three mile limit) off Louisiana and Texas. The inner boundary of the OCS area is based on CWA, not property ownership. Hence, some oil and gas operators with leases from the State of Texas, which claims ownership of the sea bottom in part of the OCS area, will be required to obtain coverage under the new source permit after its issuance.

"New sources" in the Offshore Subcategory include oil and gas development and production facilities on which significant site preparation has commenced since publication of the NSPS, but does not include exploratory activities. To resolve problems which might result from the lag between promulgation of the NSPS and new source NPDES permits, the NSPS temporarily excludes from the definition of "new source" new development and production facilities that would otherwise be new sources if, on the effective date of the NSPS, those facilities were already subject to an existing NPDES permit, e.g., GMG290000. See 58 FR 12456-12458. When the proposed new source permit is issued, such facilities will become new sources and should apply for coverage thereunder.

The draft permit includes technology based effluent limitations derived from the NSPS for wastestreams subject thereto and BAT and BCT limitations based on BPJ for wastestreams not covered by NSPS. As required by CWA section 403(c) and implementing criteria at 40 CFR part 125, subpart M, the draft permit also includes water quality based limitations protecting the marine environment from degradation. Proposed limitations for each covered waste stream are summarized below:

Drilling Fluids

In accordance with the NSPS, the draft permit prohibits the discharge of drilling fluids containing free oil (monitored using the static sheen

method), containing stock barite with more than 3 mg/kg of cadmium or 1 mg/kg of mercury, containing diesel oil, or having an LC50 aquatic toxicity value of less than 30,000 ppm. For compliance with CWA section 403(c), the draft permit limits the discharge rate to a maximum of 1000 bbl/hr and less near areas of biological concern.

Since 1986, Region 6 has included BPJ technology-based limitations in its OCS general permits prohibiting the discharge of oil based drilling fluids, inverse emulsion drilling fluids, oil contaminated drilling fluids, and drilling fluids to which mineral oil has been added (except as a carrier fluid, lubricity additive, or pill). With promulgation of the NSPS, Region 6 lost its authority, under CWA section 402(a)(1), to impose these limitations on a BPJ basis. It is nevertheless proposing to include them in the new source OCS permit on two different grounds. First, the Region believes these conditions may be necessary to assure compliance with the "no free oil" NSPS limitation and thus proposes them as best management practices authorized by CWA section 402(a)(2). Second, the Region lacks assurance the discharges authorized by the permit would not degrade the marine environment in the absence of these time-honored permit conditions. Accordingly, it is also basing its proposal to include them in the permit on CWA section 403(c).

Drill Cuttings

The draft permit contains the same limits for drill cuttings as for drilling fluids, proposed on the same regulatory bases. Independent toxicity testing of drill cuttings is not required because the Agency presumes the cuttings will have the same toxic characteristics as the drilling fluids adhering to them. If a specific drilling fluid cannot be discharged in compliance with the permit, cuttings removed from that fluid may not be discharged.

Produced Water

Based on the NSPS, the draft permit imposes a monthly limit of 29 mg/l and a maximum limit of 42 mg/l on oil and grease in discharged produced water.

To implement CWA section 403(c), the draft permit also imposes a toxicity limit on produced water discharges, essentially requiring that they exhibit no toxic effects 100 meters from the outfall and establishes critical dilution values for toxicity testing of produced water. EPA derived those critical dilution values using the CORMIX1 model, adjusted to more accurately reflect the conditions under which Offshore

Subcategory facilities may discharge produced water.

After issuance of the existing source OCS permit, Industry representatives requested that EPA Region 6 establish permit limits accommodating the use of diffusers to achieve greater dilution, thus allowing discharges of produced water which would otherwise not comply with the proposed toxicity limits. When it proposed modification of that permit, Region 6 solicited comments on the need for diffuser use and suggestions for permit provisions which might accommodate that use at 58 FR 41474 (August 14, 1993). EPA has not concluded its review of the comments it received and solicits similar comments in connection with today's proposal.

To obtain data for potential use in future regulatory actions, the draft permit also requires monitoring of radium 226 and 228 in produced water discharges.

Well Treatment, Completion, and Workover Fluids

As required by the NSPS, the draft permit limits the oil and grease content of well treatment, completion, and workover fluids to a monthly average of 29 mg/l and a maximum of 42 mg/l. Additionally, the draft permit prohibits the discharge of free oil as measured by the static sheen test. This limit is based on BCT guidelines.

As in the case of several of the proposed conditions on drilling fluid discharges, the Region also proposes to include other conditions which are somewhat similar to limitations it has formerly included in OCS general permits on BPJ technology bases. EPA proposes to prohibit the discharge of well treatment, completion, and workover fluids containing priority pollutants in other than trace amounts, in effect prohibiting the addition of priority pollutants to such fluids. This condition is proposed both as a BMP authorized by CWA section 402(a)(2) and to assure compliance with the requirements of CWA section 403(c).

Produced Sand, Deck Drainage, Sanitary Waste, and Domestic Waste

The draft permit prohibits the discharge of produced sand, the discharge of deck drainage containing free oil (as monitored by the visual sheen test), and the discharge of sanitary waste containing floating solids or foam. It also prohibits the discharge of sanitary waste with a chlorine concentration less than 1 mg/l from platforms manned by ten or more persons. Each of these proposed limits is based on the NSPS.

Rubbish, Trash, and Other Refuse

Consistent with interim final Coast Guard regulations implementing Annex V of MARPOL 73/78, 54 FR 18384 (April 28, 1989), the draft permit allows the discharge of comminuted food waste, incinerator ash, and non-plastic clinkers able to pass through a 25mm mesh more than 3 nautical miles from the nearest land. Incinerator ash and non-plastic clinkers unable to pass through a 25mm mesh may only be discharged more than 12 nautical miles from nearest land.

Miscellaneous Discharges

The draft permit prohibits miscellaneous discharges containing free oil (as monitored by visual sheen test) and prohibits miscellaneous discharges containing floating solids or visible foam. These limits apply to discharges of diatomaceous earth filter media, blowout preventer fluids, uncontaminated ballast water, uncontaminated bilge water, uncontaminated freshwater, uncontaminated seawater, muds and cuttings at the sea floor, excess cement slurry, source water, source sand, boiler blowdown, and discharges from desalinization units. The proposed permit also prohibits miscellaneous discharges which contain floating solids or visible foam. The NSPS did not cover these discharges and the proposed limitations are BCT or BAT based on BPJ. Those limitations are moreover consistent with the limits of the existing source permit GMG290000.

All Discharges

To assure compliance with CWA section 403(c) and various proposed effluent limits, the proposed permit also prohibits all discharges which contain halogenated phenolic compounds, and requires that operators minimize the discharge of surfactants, dispersants, and detergents.

EPA now solicits comments on the draft permit and draft EIS. Limitations in the final permit may vary from the proposed limits of the draft permit as a result of comments.

Other Legal Requirements

Oil Spills

CWA section 311, 33 U.S.C. 1321, prohibits the discharge of oil and hazardous materials in harmful quantities, but discharges authorized by NPDES permits are excluded from that prohibition. Permittees should note, however, that the permit does not preclude the institution of legal action or relieve permittees from any responsibilities, liabilities, or penalties

for other unauthorized discharges of oil and hazardous materials which are covered by CWA section 311.

Coastal Zone Management Act

Discharges authorized by the proposed permit will be to waters outside Louisiana's Coastal Zone and the effluent limitations imposed on those discharges will prevent them from affecting coastal waters. Accordingly, the primary effect issuance of this permit will have on Louisiana's coastal zone will be increased demand for onshore disposal of wastes which cannot be discharged under its terms. In promulgating the NSPS, EPA considered the issue of onshore disposal capacity for such wastes and tailored its final rule to assure sufficient capacity would be available. Moreover, to the extent it will occur in Louisiana's coastal zone, such disposal will be regulated by the State, assuring consistency with its Coastal Zone Management Plan. EPA thus finds issuance of the proposed permit will be consistent with that plan. The proposed new source permit and this determination will be submitted to the State of Louisiana with a request for a consistency certification for compliance with 16 U.S.C. 1456(c).

Marine Protection, Research, and Sanctuaries Act

The Marine Protection, Research, and Sanctuaries Act of 1972 (MPRSA), 33 U.S.C. 1401, *et seq.*, establishes the Marine Sanctuaries Program implemented by the National Oceanographic and Atmospheric Administration (NOAA). Under MPRSA, NOAA designates certain ocean waters as marine sanctuaries for preserving or restoring their conservation, recreational, ecological, or aesthetic values. NOAA has designated the Flower Garden Banks, which is within the area covered by the proposed permit, a marine sanctuary. As proposed, the permit prohibits discharges in areas of biological concern, including marine sanctuaries.

State Water Quality Standards and Certification

Because no state waters are included in the area covered by the draft permit, none will be affected if it is issued as proposed. Hence, the certification provisions of CWA section 401, 33 U.S.C. 1341, do not apply to EPA's proposed action.

Executive Order 12291

The Office of Management and Budget (OMB) has exempted this action from the review requirements of Executive Order 12292 pursuant to section 8(b) of

that Order. It should be noted, however, that EPA in fact obtained OMB review of a regulatory impact analysis prepared in connection with its promulgation of the NSPS. Incremental compliance costs associated with the new limitations the proposed permit imposes on Offshore Subcategory oil and gas operators were considered in that review.

Paperwork Reduction Act

The information collection requirements of the proposed permit have been approved by OMB under the provisions of the Paperwork Reduction Act, 44 U.S.C. 3501, *et seq.*, and assigned OMB control numbers 2040-0086 (NPDES permit application) and 2040-0004 (discharge monitoring reports). EPA estimates it will take an affected facility three hours to prepare a request for coverage under the proposed permit and 38 hours per year to prepare discharge monitoring reports in compliance with its terms.

National Environmental Policy Act

In accordance with the National Environmental Policy Act of 1969, 42 U.S.C. 4331, *et seq.*, and EPA's implementing regulations at 40 CFR part 6, subpart F, and 40 CFR 122.19(c), EPA has determined issuance of the proposed permit will be a major federal action which may significantly affect the quality of the human environment. The environmental impacts of the oil and gas exploration activities from which the discharges regulated by the general permit arise have been previously considered in a November 1992 Final EIS prepared by the Minerals Management Service of the Department of the Interior in connection with Lease Sales 142 and 143. EPA has adopted that Final EIS and prepared a supplement thereto (the SDEIS) to provide additional information and evaluation on its proposed general permit decision. As noted above, the SDEIS is available for review and comment.

Endangered Species Act

In a 1987 biological opinion rendered under section 7 of the Endangered Species Act, 16 U.S.C. 1536, the National Marine Fisheries Service (NMFS) determined that OCS oil and gas development and production operations were unlikely to jeopardize the continued existence of any listed species under its jurisdiction. MMS reaffirmed that opinion in connection with Lease Sales 142/143 in 1992. The United States Fish & Wildlife Service (FWS) similarly issued no jeopardy opinions for OCS oil and gas operations in 1987 and 1992. Accordingly, the

effects of actions interrelated to today's permit proposal, e.g., rig construction, have already been considered under section 7 and are considered part of the "environmental baseline" in accordance with 50 CFR 402.02.

Because the effluent limitations of the proposed permit are protective of sensitive marine organisms, as required by EPA's ocean discharge criteria at 40 CFR part 125, subpart M, the discharge authorization EPA proposes will be unlikely to adversely affect listed threatened or endangered species or designated critical habitat. EPA Region 6 will seek written concurrence of the U.S. Fish and Wildlife Service and National Marine Fisheries Service in this determination. The Services provided similar concurrences in connection with EPA's issuance of the less stringent November 14, 1992 existing source permit (GMG290000).

Regulatory Flexibility Act

The Regulatory Flexibility Act, 5 U.S.C. 601, *et seq.*, requires that EPA prepare a regulatory flexibility analysis for regulations that have a significant impact on a substantial number of small entities. In promulgating the NSPS, EPA prepared an economic analysis showing they would directly impact no small entities. See 58 FR 12492. Based on those findings, EPA Region 6 certifies, pursuant to 5 U.S.C. 605(b), that the permit proposed today will not have a significant impact on a substantial number of small entities.

Myron O. Knudson,

Director, Water Management Division, EPA Region 6.

[FR Doc. 93-25229 Filed 10-13-93; 8:45 am]

BILLING CODE: 6560-50-P

FEDERAL COMMUNICATIONS COMMISSION

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

October 6, 1993.

The Federal Communications Commission has submitted the following information collection requirement to OMB for review and clearance under the Paperwork Reduction Act of 1980 (44 U.S.C. 3507).

Copies of this submission may be purchased from the Commission's copy contractor, International Transcription Service, Inc., 2100 M Street, NW., suite 140, Washington, DC 20037, (202) 857-3800. For further information on this submission contact Judy Boley, Federal Communications Commission, (202) 632-0276. Persons wishing to comment

on this information collection should contact Jonas Neihardt, Office of Management and Budget, room 3235 NEOB, Washington, DC 20503, (202) 395-4814.

OMB Number: 3060-0461

Title: Section 90.173, Policies governing the assignment of

Action: Revision of a currently approved collection

Respondents: State or local governments and businesses or other for-profit (including small businesses)

Frequency of Response: On Occasion reporting requirement

Estimated Annual Burden: 200 responses; 4.5 hours average burden per response; 900 hours total annual burden.

Needs and Uses: Private land mobile channels are becoming scarce in many areas, making it difficult for eligible applicants to be licensed on frequencies that are available on an exclusive basis. The Commission proposes to address this spectrum scarcity by recycling channels that are not being used effectively by the existing licenses. To identify these channels, the Commission proposes to enlist the assistance of persons who wish to be licensed. Under the proposal, individuals who provide the Commission with information that a current licensee is violating certain Rules would be granted a licensing preference for any channels recovered as a result of that information. The Commission will use the information to determine whether the channels of the existing licensee should be recovered due to violations of our Rules and whether any recovered channels should be reassigned to the applicant. Without this information, the FCC might not learn of rule violations and, due to the existence of a current licensee, would deny applications for frequencies that are licensed on an exclusive basis. The spectrum would, therefore, continue to be used inefficiently. In some cases, the Commission might learn of violations but, under current rules, would be required to reassign any channels recovered on a first-come, first-served basis without giving a preference to persons who brought violations to the Commission's attention.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93-25135 Filed 10-13-93; 8:45 am]

BILLING CODE 6712-01-M

**Public Information Collection
Approved by Office of Management
and Budget**

The Federal Communications Commission (FCC) has received Office of Management and Budget (OMB) approval for the following public information collection pursuant to the Paperwork Reduction Act of 1980, Public Law 96-511. For further information contact Shoko B. Hair, Federal Communications Commission, (202) 632-6934.

Federal Communications Commission

OMB Control No.: 3060-0577

Title: Expanded Interconnection with Local Telephone Company, Facilities, CC Docket No. 91-141.

Expiration Date: 09/30/96

Estimated Annual Burden: 16

responses, 15 hours average burden per response; plus occasional fresh look public notice filings, with de minimus burden per response.

Description: In the Second Memorandum Opinion and Order on Reconsideration in CC Docket No. 91-141 (released September 2, 1993), the Commission reconsidered de novo, and adopted a modified version of, the "fresh look" policy adopted in the Special Access Order, 7 FCC Rcd 7369 (1992), in that docket. The September 2 Order also clarified and expanded earlier Commission requirements concerning the neutral application of nonrecurring charges, modified the requirements for tariffing virtual collocation arrangements, and specified certain standards that must be met for a carrier's connection charge rate structure to be considered reasonable. The Order requires local exchange carriers (LECs) to make tariff filings to provide public notice of the start of the "fresh look" period at each of their offices where expanded interconnection is implemented. LECs must also file tariff revisions to implement the modified fresh look rules. LECs must make tariff revisions to bring their tariffs into compliance with the requirements concerning nonrecurring charges no later than October 18, 1993. LECs must revise their connection charge tariffs if they do not satisfy the standards set forth in the Order. Finally, LECs may choose to revise their virtual collocation tariffs to reflect the less extensive tariffing requirements adopted on reconsideration.

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93-25183 Filed 10-13-93; 8:45 am]

BILLING CODE 6712-01-M

[Report No. 1977]

**Petition for Reconsideration of Action
in Rulemaking Proceeding**

October 7, 1993.

Petition for reconsideration has been filed in the Commission rulemaking proceeding listed in this Public Notice and published pursuant to 47 CFR 1.429(e). The full text of this document is available for viewing and copying in room 239, 1919 M Street, NW., Washington, DC or may be purchased from the Commission's copy contractor ITS, Inc. (202) 857-3800. Opposition to this petition must be filed October 29, 1993. See § 1.4(b)(1) of the Commission's rules (47 CFR 1.4(b)(1)). Replies to an opposition must be filed within 10 days after the time for filing oppositions has expired.

Subject: Tariff Filing Requirements for Nondominant Common Carriers (CC Docket No. 93-36).

Number of Petitions Filed: 1

Federal Communications Commission.

William F. Caton,

Acting Secretary.

[FR Doc. 93-25136 Filed 10-13-93; 8:45 am]

BILLING CODE 6712-01-M

**FEDERAL EMERGENCY
MANAGEMENT AGENCY**

**Public Information Collection
Requirements Submitted to OMB for
Review**

ACTION: Notice.

SUMMARY: The Federal Emergency Management Agency (FEMA) has submitted to the Office of Management and Budget the following public information collection requirements for review and clearance in accordance with the Paperwork Reduction Act of 1980, 44 U.S.C. chapter 35.

DATES: Comments on this information collection must be submitted on or before December 13, 1993.

ADDRESSES: Direct comments regarding the burden estimate or any aspect of this information collection, including suggestions for reducing this burden, to: the FEMA Information Collections Clearance Officer at the address below; and to Gary Waxman, Office of Management and Budget, 3235 New Executive Office Building, Washington, DC 20503, (202) 395-7340, within 60 days of this notice.

FOR FURTHER INFORMATION CONTACT: Copies of the above information collection request and supporting documentation can be obtained by calling or writing Linda Borrer, FEMA

Information Collections Clearance Officer, Federal Emergency Management Agency, 500 C Street, SW., Washington, DC 20472, (202) 646-2624.

Type: Revision of 3067-0142.

Title: Capability and Hazard Identification Program (CHIP).

Abstract: The Federal Emergency Management Agency (FEMA) requires consistent information on the status of State and local emergency management capabilities, and the impact of FEMA funding on improving those capabilities. CHIP data is a nationwide baseline on State and local hazards, current capabilities, and resource requirements. FEMA uses the data to set program priorities, prepare FEMA budgets, allocate funds and provide reports to Congress.

Type of Respondents: State and local governments.

Estimate of Total Annual Reporting and Recordkeeping Burden: 34,600.

Number of Respondents: States—56; Locals—2,900.

Estimated Average Burden Time per Response: State—100 hours; Locals—10 hours.

Frequency of Response: Annually.

Dated: October 5, 1993.

Wesley C. Moore,

Director, Office of Administrative Support.

[FR Doc. 93-25243 Filed 10-13-93; 8:45 am]

BILLING CODE 6718-01-M

[FEMA-995-DR]

**Missouri; Amendment to Notice of a
Major Disaster Declaration**

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Missouri, (FEMA-995-DR), dated July 9, 1993, and related determinations.

EFFECTIVE DATE: October 6, 1993.

FOR FURTHER INFORMATION CONTACT: Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: The notice of a major disaster for the State of Missouri, dated July 9, 1993, is hereby amended to include the following area among those areas determined to have been adversely affected by the catastrophe declared a major disaster by the President in his declaration of July 9, 1993:

Dade County for Individual Assistance.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance)

Richard W. Krimm,

Deputy Associate Director, State and Local Programs and Support.

[FR Doc. 93-25244 Filed 10-13-93; 8:45 am]

BILLING CODE 6718-02-M

[FEMA-998-DR]

Nebraska; Amendment to Notice of a Major Disaster Declaration

AGENCY: Federal Emergency Management Agency (FEMA).

ACTION: Notice.

SUMMARY: This notice amends the notice of a major disaster for the State of Nebraska, (FEMA-998-DR), dated July 19, 1993, and related determinations.

EFFECTIVE DATE: September 27, 1993.

FOR FURTHER INFORMATION CONTACT:

Pauline C. Campbell, Disaster Assistance Programs, Federal Emergency Management Agency, Washington, DC 20472, (202) 646-3606.

SUPPLEMENTARY INFORMATION: Notice is hereby given that, in a letter dated September 27, 1993, the President amended the cost-sharing arrangements concerning Federal funds provided under the authority of the Robert T. Stafford Disaster Relief and Emergency Assistance Act (42 U.S.C. 5121 *et seq.*), in a letter to James L. Witt, Director of the Federal Emergency Management Agency, as follows:

I have determined that the damage in certain areas of the State of Nebraska, resulting from severe storms and flooding on June 23, 1993, through and including August 5, 1993, is of sufficient severity and magnitude that special conditions are warranted regarding the cost-sharing arrangements concerning Federal funds provided under the Robert T. Stafford Disaster Relief and Emergency Assistance Act ("the Stafford Act") for the Public Assistance program.

Therefore, I amend my previous declaration to authorize Federal funds for Public Assistance at 90 percent of total eligible costs, except for direct Federal assistance costs for emergency work authorized at 100 percent Federal funding. This 90 percent reimbursement applies to all authorized Public Assistance costs, including debris removal to eliminate immediate threats to public health and safety, emergency work to save lives and protect public health and safety, and repair or reconstruction of uninsured public and private non-profit facilities.

This adjustment to State and local cost sharing applies only to Public

Assistance costs eligible for such adjustment under the law. The law specifically prohibits a similar adjustment for funds provided to States for the Individual and Family Grant program. These funds will continue to be reimbursed at 75 percent of total eligible costs.

Please notify the Governor of the State of Nebraska and the Federal Coordinating Officer of this amendment to my major disaster declaration.

(Catalog of Federal Domestic Assistance No. 83.516, Disaster Assistance.)

James L. Witt,

Director.

[FR Doc. 93-25242 Filed 10-13-93; 8:45 am]

BILLING CODE 6718-02-M

FEDERAL MARITIME COMMISSION

[Docket No. 93-21]

Mr. Stanley Hecht v. Puerto Rico Maritime Shipping Authority; Filing of Complaint and Assignment

Notice is given that a complaint filed by Stanley Hecht ("Complainant") against Puerto Rico Maritime Shipping Authority ("Respondent") was served October 7, 1993. Complainant alleges that Respondent has violated sections 17 and 18 of the Shipping Act, 1916, 46 U.S.C. app. 816 and 817, by publishing and enforcing tariff and bill of lading provisions that impose liability for costs and expenses incurred in collecting charges due Respondent.

This proceeding has been assigned to the office of Administrative Law Judges. Hearing in this matter, if any is held, shall commence within the time limitations prescribed in 46 CFR 502.61, and only after consideration has been given by the parties and the presiding officer to the use of alternative forms of dispute resolution. The hearing shall include oral testimony and cross-examination in the discretion of the presiding officer only upon proper showing that there are genuine issues of material fact that cannot be resolved on the basis of sworn statements, affidavits, depositions, or other documents or that the nature of the matter in issue is such that an oral hearing and cross-examination are necessary for the development of an adequate record. Pursuant to the further terms of 46 CFR 502.61, the initial decision of the presiding officer in this proceeding shall be issued by October 7, 1994, and the

final decision of the Commission shall be issued by February 6, 1995.

Joseph C. Polking,

Secretary.

[FR Doc. 93-25205 Filed 10-13-93; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

T. Brent Ballinger, et al.; Change in Bank Control Notices; Acquisitions of Shares of Banks or Bank Holding Companies

The notificants listed below have applied under the Change in Bank Control Act (12 U.S.C. 1817(j)) and § 225.41 of the Board's Regulation Y (12 CFR 225.41) to acquire a bank or bank holding company. The factors that are considered in acting on the notices are set forth in paragraph 7 of the Act (12 U.S.C. 1817(j)(7)).

The notices are available for immediate inspection at the Federal Reserve Bank indicated. Once the notices have been accepted for processing, they will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank indicated for that notice or to the offices of the Board of Governors. Comments must be received not later than November 2, 1993.

A. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *T. Brent Ballinger*, Pawhuska, Oklahoma; to acquire an additional 8.44 percent of the voting shares of N.B.C. Bancshares of Pawhuska, Inc., Pawhuska, Oklahoma, for a total of 31.95 percent, and thereby indirectly acquire NBC Bank, Pawhuska, Oklahoma.

2. *Whitman T. Eastman*, Gunnison, Colorado; to acquire an additional 22.1 percent of the voting shares of First National Bankshares of Gunnison, Inc., Gunnison, Colorado, for a total of 36.4 percent, and thereby indirectly acquire The First National Bank of Gunnison, Gunnison, Colorado.

3. *Buford J. and Anna Van Loenen*, Prairie View, Kansas; to acquire an additional 43.3 percent of the voting shares of Phillips Holdings, Inc., Stuttgart, Kansas, and thereby indirectly acquire Farmers State Bank, Stuttgart, Kansas.

Board of Governors of the Federal Reserve System, October 6, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-25139 Filed 10-13-93; 8:45 am]

BILLING CODE 6210-01-F

**Fairbank Bancshares, Inc., et al.;
Notice of Applications to Engage de
novo in Permissible Nonbanking
Activities**

The companies listed in this notice have filed an application under § 225.23(a)(1) of the Board's Regulation Y (12 CFR 225.23(a)(1)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to commence or to engage *de novo*, either directly or through a subsidiary, in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Unless otherwise noted, comments regarding the applications must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than November 2, 1993.

A. Federal Reserve Bank of Chicago (James A. Bluemle, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Fairbank Bancshares, Inc.*, Fairbank, Iowa; to engage *de novo* in making and servicing loans pursuant to § 225.25(b)(1) of the Board's Regulation Y. These activities will be conducted in the geographic area surrounding Fairbank, Iowa.

2. *First of America Bank Corporation*, Kalamazoo, Michigan; to engage *de novo* through its subsidiary, *First of America Mortgage Company*, Kalamazoo,

Michigan, in performing appraisals of real estate pursuant to § 225.25(b)(13) of the Board's Regulation Y.

3. *Whitewater Bancorp, Inc.*, Whitewater, Wisconsin; to engage *de novo* through its subsidiary, *CRA Development Corporation*, Whitewater, Wisconsin, in forming a community development corporation to invest in limited partnerships involved in community development efforts including affordable housing, job creation and other economic development projects pursuant to § 225.25(b)(6) of the Board's Regulation Y. These activities will be conducted in Walworth, Jefferson, and Rock Counties in the State of Wisconsin.

Board of Governors of the Federal Reserve System, October 6, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-25140 Filed 10-13-93; 8:45 am]

BILLING CODE 6210-01-F

**Keystone Financial, Inc., et al.;
Formations of; Acquisitions by; and
Mergers of Bank Holding Companies**

The companies listed in this notice have applied for the Board's approval under section 3 of the Bank Holding Company Act (12 U.S.C. 1842) and § 225.14 of the Board's Regulation Y (12 CFR 225.14) to become a bank holding company or to acquire a bank or bank holding company. The factors that are considered in acting on the applications are set forth in section 3(c) of the Act (12 U.S.C. 1842(c)).

Each application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing to the Reserve Bank or to the offices of the Board of Governors. Any comment on an application that requests a hearing must include a statement of why a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute and summarizing the evidence that would be presented at a hearing.

Unless otherwise noted, comments regarding each of these applications must be received not later than November 5, 1993.

A. Federal Reserve Bank of Philadelphia (Thomas K. Desch, Vice President) 100 North 6th Street, Philadelphia, Pennsylvania 19105:

1. *Keystone Financial, Inc.*, Harrisburg, Pennsylvania; merge with

WM Bancorp, Cumberland, Maryland, and thereby acquire *American Trust Bank*, Cumberland, Maryland, and *American Trust Bank of West Virginia*, N.A., Keyser, West Virginia.

B. Federal Reserve Bank of Cleveland (John J. Wixted, Jr., Vice President) 1455 East Sixth Street, Cleveland, Ohio 44101:

1. *First Commonwealth Financial Corporation*, Indiana, Pennsylvania; to acquire 100 percent of the voting shares of *Peoples Bank of Western Pennsylvania*, New Castle, Pennsylvania.

C. Federal Reserve Bank of Richmond (Lloyd W. Bostian, Jr., Senior Vice President) 701 East Byrd Street, Richmond, Virginia 23261:

1. *First Savings Bancorp, Inc.*, Southern Pines, North Carolina; to become a bank holding company by acquiring 100 percent of the voting shares of *First Savings Bank of Moore County, Inc.*, SSB, Southern Pines, North Carolina.

D. Federal Reserve Bank of Atlanta (Zane R. Kelley, Vice President) 104 Marietta Street, N.W., Atlanta, Georgia 30303:

1. *Southland Bank Corporation*, Butler, Georgia; to become a bank holding company by acquiring 100 percent of the voting shares of *United Bank of Crawford*, Roberta, Georgia.

2. *SouthTrust Corporation*, Birmingham, Alabama; and *SouthTrust of Florida, Inc.*, Jacksonville, Florida; to merge with *Cypress Banks, Inc.*, Wesley Chapel, Florida, and thereby indirectly acquire *First National Bank of the South*, Wesley Chapel, Florida.

E. Federal Reserve Bank of Kansas City (John E. Yorke, Senior Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *First National of Hoxie Employee Stock Ownership Plan*, Hoxie, Kansas; to become a bank holding company by acquiring 54.8 percent of the voting shares of *First Bancshares of Hoxie, Inc.*, Hoxie, Kansas, and thereby indirectly acquire *First National Bank*, Hoxie, Kansas.

2. *Myers BancShares, Inc.*, Alva, Oklahoma; to become a bank holding company by acquiring 96 percent of the voting shares of *The Central National Bank*, Alva, Oklahoma.

3. *Plaza Bancshares, Inc.*, Bartlesville, Oklahoma; to become a bank holding company by acquiring 94.4 percent of the voting shares of *Plaza National Bank of Bartlesville*, Bartlesville, Oklahoma.

Board of Governors of the Federal Reserve System, October 6, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-25141 Filed 10-13-93; 8:45 am]

BILLING CODE 6210-01-F

Norwest Corporation; Acquisition of Company Engaged in Permissible Nonbanking Activities

The organization listed in this notice has applied under § 225.23(a)(2) or (f) of the Board's Regulation Y (12 CFR 225.23(a)(2) or (f)) for the Board's approval under section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.21(a) of Regulation Y (12 CFR 225.21(a)) to acquire or control voting securities or assets of a company engaged in a nonbanking activity that is listed in § 225.25 of Regulation Y as closely related to banking and permissible for bank holding companies. Unless otherwise noted, such activities will be conducted throughout the United States.

The application is available for immediate inspection at the Federal Reserve Bank indicated. Once the application has been accepted for processing, it will also be available for inspection at the offices of the Board of Governors. Interested persons may express their views in writing on the question whether consummation of the proposal can "reasonably be expected to produce benefits to the public, such as greater convenience, increased competition, or gains in efficiency, that outweigh possible adverse effects, such as undue concentration of resources, decreased or unfair competition, conflicts of interests, or unsound banking practices." Any request for a hearing on this question must be accompanied by a statement of the reasons a written presentation would not suffice in lieu of a hearing, identifying specifically any questions of fact that are in dispute, summarizing the evidence that would be presented at a hearing, and indicating how the party commenting would be aggrieved by approval of the proposal.

Comments regarding the application must be received at the Reserve Bank indicated or the offices of the Board of Governors not later than October 20, 1993.

A. Federal Reserve Bank of Minneapolis (James M. Lyon, Vice President) 250 Marquette Avenue, Minneapolis, Minnesota 55480;

1. Norwest Corporation, Minneapolis, Minnesota; to acquire the mortgage origination and servicing business conducted by St. Cloud National Bank

& Trust Co., St. Cloud, Minnesota, and thereby engage in making, acquiring, or servicing loans or other extensions of credit such as would be made by a mortgage company pursuant to § 225.25(b)(1) of the Board's Regulation Y. These activities will be conducted in the Chicago, Illinois area

Board of Governors of the Federal Reserve System, October 6, 1993.

Jennifer J. Johnson,

Associate Secretary of the Board.

[FR Doc. 93-25142 Filed 10-13-93; 8:45 am]

BILLING CODE 6210-01-F

FEDERAL RETIREMENT THRIFT INVESTMENT BOARD

Employee Thrift Advisory Council; Open Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), a notice is hereby given of the following committee meeting:

Name: Employee Thrift Advisory Council.

Time: 10 a.m.

Date: October 27, 1993.

Place: Fourth Floor, Conference Room, Federal Retirement Thrift Investment Board, 1250 H Street NW., Washington, DC.

Status: Open.

Matters to be considered: Approval of the minutes of the May 19, 1993, meeting; report of the Executive Director on the status of the Thrift Savings Plan; Thrift Savings Plan open season activities; Analysis of additional Thrift Savings Plan investment funds; legislation; and new business.

Any interested person may attend, appear before, or file statements with the Council. For further information contact John J. O'Meara, Committee Management Officer, on (202) 942-1662.

Dated: October 7, 1993.

Francis X. Cavanaugh,

Executive Director, Federal Retirement Thrift Investment Board.

[FR Doc. 93-25152 Filed 10-13-93; 8:45 am]

BILLING CODE 6780-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Office of the Secretary

Interest Rate on Overdue Debts

Section 30.13 of the Department of Health and Human Services' claims collection regulations (45 CFR part 30) provides that the Secretary shall charge an annual rate of interest as fixed by the

Secretary of the Treasury after taking into consideration private consumer rates of interest prevailing on the date that HHS becomes entitled to recovery. The rate generally cannot be lower than the Department of Treasury's current value of funds rate or the applicable rate determined from the "Schedule of Certified Interest Rates with Range of Maturities." This rate may be revised quarterly by the Secretary of the Treasury and shall be published quarterly by the Department of Health and Human Services in the Federal Register.

The Secretary of the Treasury has certified a rate of 13.5% for the quarter ended September 30, 1993. This interest rate will remain in effect until such time as the Secretary of the Treasury notifies HHS of any change.

Dated: October 6, 1993.

George H. Strader,

Deputy Assistant Secretary, Finance.

[FR Doc. 93-25233 Filed 10-13-93; 8:45 am]

BILLING CODE 4150-04-M

Centers for Disease Control and Prevention

Advisory Council for the Elimination of Tuberculosis; Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the following council meeting.

Name: Advisory Council for the Elimination of Tuberculosis (ACET).

Times and Dates: 8:30 a.m.-5 p.m., November 8, 1993. 8:30 a.m.-11:45 a.m., November 9, 1993.

Place: Corporate Square Office Park, Corporate Square Boulevard, Building 11, Room 1413, Atlanta, Georgia 30329.

Status: Open to the public, limited only by the space available.

Purpose: This council advises and makes recommendations to the Secretary of Health and Human Services, the Assistant Secretary for Health, and the Director, CDC, regarding the elimination of tuberculosis. Specifically, the council makes recommendations regarding policies, strategies, objectives, and priorities; addresses the development and application of new technologies; and reviews the extent to which progress has been made toward eliminating tuberculosis.

Matters To Be Discussed: General update on governmental actions on tuberculosis; update on new training and educational activities; legislative/funding update; update on tuberculosis

model centers; revision of BCG recommendations; revision of model tuberculosis program recommendations; update on 1992 surveillance data and outbreaks; tuberculosis management data; MDR-TB outbreak follow-up investigations; tuberculosis hospital surveys; upgrading laboratory capabilities for diagnosis and epidemiology support; tuberculin skin testing and screening guidelines; and review of corrections statement.

Agenda items are subject to change as priorities dictate.

Contact Person for more Information:
Dixie E. Snider, Jr., M.D., Acting Associate Director for Science, CDC, and Executive Secretary, ACET, 1600 Clifton Road, NE., Mailstop D-39, Atlanta, Georgia 30333, telephone 404/639-3701.

Dated: October 6, 1993.

Elvin Hilyer,

Associate Director for Policy Coordination,
Centers for Disease Control and Prevention
(CDC).

[FR Doc. 93-25188 Filed 10-13-93; 8:45 am]

BILLING CODE 4180-18-M

Food and Drug Administration

[GN# 2140]

Statement of Organization, Functions, and Delegations of Authority

Part H, Chapter HF (Food and Drug Administration) of the Statement of Organization, Functions, and Delegations of Authority for the Department of Health and Human Services (35 FR 3685, February 25, 1970, and 56 FR 29484, June 27, 1991, as amended most recently in pertinent part 58 FR 14214, March 16, 1993) is amended to reflect a reorganization of the National Center for Toxicological Research (NCTR), Office of Operations, Food and Drug Administration (FDA). As NCTR continues to integrate its research efforts into the regulatory mission of the FDA, re-focusing of NCTR's research capabilities has emphasized the necessity to have all research functions at NCTR located in one organization, the Office of Research. In order to place stronger emphasis on the importance of the planning functions of the Center, the title of the Office of Management has been changed to the Office of Planning and Resource Management. All research support functions have been centralized into the Office of Research Services which has been retitled as the Office of Research Support.

FDA believes the new NCTR structure will provide a more efficient span-of-

control for all organizational units. Under Section HF-B, Organization:

1. Delete subparagraph (q-1) Office of the Center Director in its entirety and insert a new subparagraph reading as follows:

(q-1) *Office of the Center Director (HFT1)*. Provides leadership and direction to assure the efficient and effective planning, performance, and evaluation of Center activities.

Staffs and supports the operation of the Center's Science Advisory Board.

Advises and assists top Agency management on research and research strategies that have impact on the development and execution of long-range program goals of the Agency.

Provides leadership and direction to all Office of the Director office functions.

Provides executive secretariat support for the Immediate Office of the Director, including maintaining and controlling the Director's working files.

Plans and coordinates the Center's Equal Employment Opportunity Program.

2. Delete subparagraphs (q-3 through q-5) in their entirety and insert the following new subparagraphs:

(q-3) *Office of Planning and Resource Management (HFT1D)*. Advises the Director on the strategic and operational planning and resource utilization decisions necessary to accomplish the mission and goals of the Center.

Organizes, plans, directs, and develops strategic and operational planning systems to allow Center's management to define and monitor the Center goals and objectives.

Supports and directs program/project evaluations of the Center's activities. Performs special management analyses of Center program and administrative operations. Maintains the Center systems of policies and procedures.

Provides and directs the formulation, execution, and accounting functions for the Center's budget. Operates and maintains accounting system.

(q-4) *Office of Research (HFTD)*. Organizes, plans, and directs Center research programs in accordance with Centerwide strategic direction.

Directs studies on the kinetics and metabolism of chemicals prerequisite to the implementation of carcinogenic, teratogenic, and mutagenic experiments; directs the development of protocols for safety evaluation of toxic chemicals.

Directs the development of experimental methods used to extrapolate test results from animals to humans.

Directs the development of in vitro models to serve as links in the assessment of toxic manifestations

expected in mammals in general and in humans in particular.

Directs research to expand comparative physiology and biochemistry to primates and other potentially applicable experimental species.

Coordinates research in Center program areas with leading scientists in other segments of FDA and the scientific community at large.

Coordinates with other Center and Agency components and top level officials of other agencies to provide input for long-term research planning in responsible program areas. Ensures implementation of programs responsive to the Center's portion of the Agency's integrated research plan.

Responsible for the scientific oversight of Center research contracts and agreements in Center programs.

(q-5) *Office of Research Support (HFTE)*. Organizes, plans, and directs Center research support in the areas of pathology, diet preparation, animal husbandry, engineering, facilities and equipment maintenance, automated data processing, and administrative services.

Plans and coordinates the implementation of research support in response to the Office of Research.

Responsible for the management and activity monitoring of on site Center service contracts in responsible program areas.

Provides advice and guidance to Center employees on and coordinates conflict of interest, outside activities, ethics reviews, incentive awards and employee suggestion programs, and international travel.

Prior Delegation of Authority. Pending further delegations, directives, or orders by the Commissioner of Food and Drugs, all delegations of authority to officers or employees of the Center in effect prior to the date of this order shall continue in effect in them or their successors.

Dated: September 23, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 93-25145 Filed 10-13-93; 8:45 am]

BILLING CODE 4160-01-M

National Institutes of Health

Division of Research Grants; Meetings

Pursuant to Public Law 92-463, notice is hereby given of meetings of the Division of Research Grants Behavioral and Neurosciences Special Emphasis Panel.

The meetings will be closed in accordance with the provisions set forth

in section 552b(c)(4) and 552b(c)(6), title 5, U.S.C. and section 10(d) of Public Law 92-463, for the review, discussion and evaluation of individual grant applications and Small Business Innovation Research Program Applications in the various areas and disciplines related to behavior and neuroscience. These applications and the discussions could reveal confidential trade secrets or commercial property such as patentable material and personal information concerning individuals associated with the applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

The Office of Committee Management, Division of Research Grants, Westwood Building, National Institutes of Health, Bethesda, Maryland 20892, telephone 301-594-7265, will furnish summaries of the meetings and rosters of panel members.

Meetings to Review Individual Grant Applications

Scientific Review Administrator: Dr. Teresa Levitin (301) 594-7141.

Date of Meeting: October 29, 1993.

Place of Meeting: Westwood Bldg.,

Room 303, NIH, Bethesda, MD.

(Telephone Conference).

Time of Meeting: 9 a.m.

Meetings to Review Small Business Innovation Research Program Applications

Scientific Review Administrator: Dr. Jane Hu (301) 594-7269.

Date of Meeting: November 5, 1993.

Place of Meeting: Holiday Inn, Chevy Chase, MD.

Time of Meeting: 8:30 a.m.

(Catalog of Federal Domestic Assistance Program Nos. 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: October 1, 1993.

Susan K. Feldman,

Committee Management Officer, NIH.

[FR Doc. 93-25187 Filed 10-13-93; 8:45 am]

BILLING CODE 4140-01-M

of the Interior, will meet in formal session Friday, November 19, 1993, from 8 a.m. to 5 p.m., and Saturday, November 20, 1993, from 8 a.m. to 10:15 a.m., at the La Casa Del Zorro Hotel in Borrego Springs, California.

Agenda items for the meetings will include:

- An update on mineral issues.
- A report on range policy reform.
- Desert tortoise critical habitat and livestock grazing.
- A briefing on National Biological Survey.
- An update on the Southern California Association of Governments (SCAG) open space planning effort.
- A status report on District environmental assessments and environmental impact statements.
- A progress report on the Motor Vehicle Access California Desert Conservation Area Plan.
- An update on the West Mojave Coordinated Management Plan.

On Thursday, November 18, from 7:30 a.m. to 5 p.m., Council members will participate in a field tour of portions of the El Centro Resource Area, with scheduled stops at the San Felipe Area of Critical Environmental Concern, Sacatone Overlook, and Cottonwood Campground. Tentative stops may include the Jacumba Mountains Wilderness Study Area, Yuha Geoglyph site, and Crucifixion Thorn Natural Area. The tour will focus on the management programs for each area.

The public is welcome to participate in the field tour, but should plan on providing their own transportation, drinks, and lunch. Anyone interested in participating should contact BLM at (909) 697-5215 for more information. The tour will assemble at the La Casa Del Zorro Hotel at 7:15 a.m.

All Desert District Advisory Council meetings are open to the public. Time for public comment may be made available by the Council Chairman during the presentation of various agenda items, and is scheduled at the end of the meeting for topics not on the agenda.

Written comments may be filed in advance of the meeting with the California Desert District Advisory Council Chairman, Mr. David Fisher, c/o Bureau of Land Management, Public Affairs Office, 6221 Box Springs Boulevard, Riverside, California 92507-0714. Written comments are also accepted at the time of the meeting and, if copies are provided to the recorder, will be incorporated into the minutes.

FOR FURTHER INFORMATION AND MEETING CONFIRMATION: Contact the Bureau of Land Management, California Desert

District, Public Affairs Office, 6221 Box Springs Boulevard, Riverside, California 92507; (909) 697-5215.

Dated: October 7, 1993.

Henri R. Bisson,

District Manager.

[FR Doc. 93-25255 Filed 10-13-93; 8:45 am]

BILLING CODE 4310-40-M

[AZ-040-4210-03-03; AZA 28166]

Realty Action; Recreation and Public Purposes Act Classification; Arizona

AGENCY: Bureau of Land Management, Safford District, Arizona, Interior.

ACTION: Notice.

SUMMARY: The following public land in Pima County, Arizona has been examined and found suitable for classification for lease or conveyance to the Helmet Peak Volunteer Fire Department under the provisions of the Recreation and Public Purposes Act, as amended (43 U.S.C. 869 *et seq.*).

Gila and Salt River Meridian, Arizona

T. 17 S., R. 12 E.,

Sec. 11, lots 5 and 6, SE $\frac{1}{4}$ NW $\frac{1}{4}$ (within).

Containing 4.66 acres, more or less.

The land is not needed for Federal purposes. Lease or conveyance is consistent with current BLM land use planning, and would be in the public interest.

When issued, the lease/patent will be subject to the following terms, conditions and reservations:

1. Provisions of the Recreation and Public Purposes Act and to all applicable regulations of the Secretary of the Interior.

2. A right-of-way for ditches and canals constructed by the authority of the United States.

3. All minerals shall be reserved to the United States, together with the right to prospect for, mine, and remove the minerals.

Detailed information concerning these actions is available for review at the Office of the Bureau of Land Management, Tucson Resource Area Office, 12661 East Broadway Boulevard, Tucson, Arizona.

Upon publication of this notice in the Federal Register, the lands will be segregated from all other forms of appropriation under the public land laws, including the general mining laws, except for lease or conveyance under the Recreation and Public Purposes Act and leasing under the mineral leasing laws.

For a period of 45 days from the date of publication of this notice in the Federal Register, interested parties may

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[CA-060-01-4410-04-ADVB]

Meeting of the California Desert District Advisory Council

SUMMARY: Notice is hereby given, in accordance with Public Laws 92-463 and 94-579, that the California Desert District Advisory Council to the Bureau of Land Management, U.S. Department

submit comments regarding the proposed lease/conveyance or classification of the land to the District Manager, Safford District Office, 711 14th Avenue, Safford, Arizona 85546.

CLASSIFICATION COMMENTS: Interested parties may submit comments involving the suitability of the land for a fire station. Comments on the classification are restricted to whether the land is physically suited for the proposal, whether the use will maximize the future use or uses of the land, whether the use is consistent with local planning and zoning, or if the use is consistent with State and Federal programs.

APPLICATION COMMENTS: Interested parties may submit comments regarding the specific use proposed in the application and plan of development, whether the BLM followed proper administrative procedure in reaching the decision or any other factor not directly related to the suitability of the land for a fire station.

Any adverse comments will be reviewed by the State Director. In the absence of any adverse comments, the classification will become effective 60 days from the date of publication of this notice in the *Federal Register*.

Dated: October 4, 1993.

William T. Civish,
District Manager.

[FR Doc. 93-25134 Filed 10-13-93; 8:45 am]
BILLING CODE 4310-32-M

[NV-930-4210-05; N-56458]

Land Exchange; Clark County, NV

October 1, 1993.

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice; issuance of land exchange conveyance document, Nevada.

SUMMARY: This notice identifies Federal and non-Federal lands involved in a recently completed exchange transaction. With the exception of oil, gas, sodium and potassium, the mineral estate in the Federal lands was conveyed with the surface estate. As to the non-Federal lands, the United States acquired only those minerals owned by the proponent.

FOR FURTHER INFORMATION CONTACT: Mary Clark, Nevada State Office, Bureau of Land Management, P.O. Box 12000, Reno, NV 89520, (702) 785-6530.

SUPPLEMENTARY INFORMATION: The following described lands were conveyed out of Federal ownership pursuant to sec. 206 of the Act of October 21, 1976 (43 U.S.C. 1716):

Mount Diablo Meridian, Nevada

T. 20 S., R. 60 E.,

Sec. 7, E $\frac{1}{2}$ NE $\frac{1}{4}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$,
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SE $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$,
N $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$,
SE $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$,
SW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$,
NW $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$,
S $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$;

Sec. 28, W $\frac{1}{2}$ NE $\frac{1}{4}$, NE $\frac{1}{4}$ NW $\frac{1}{4}$,
E $\frac{1}{2}$ SE $\frac{1}{4}$ NW $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$.

The area described contains 591.88 acres in Clark County, Nevada. Four patents were issued on March 30, 1993, as follows: Patent No. 27-93-0011 to Olympic National Joint Venture Patent No. 27-93-0012 to Olympic Hobbie Joint Venture Patent No. 27-93-0013 to Olympic Nevada Inc. Patent No. 27-93-0014 to Olympic GKB Joint Venture. The first phase of the exchange was

completed on April 1, 1993, when Patent No. 27-93-0015 was issued to Olympic Nevada Inc. The second and final phase of the exchange was completed on August 5, 1993, at which time five patents were issued as follows:

Patent No. 27-93-0030 to Olympic Apache Joint Venture
Patent No. 27-93-0031 to Olympic GKB Joint Venture
Patent No. 27-93-0032 to Olympic Falcon Joint Venture
Patent No. 27-93-0033 to Olympic Lands Inc.
Patent No. 27-93-0034 to Olympic Nevada Inc.

The non-Federal lands acquired by the United States in this exchange are described as follows:

Mount Diablo Meridian, Nevada

T. 22 S., R. 58 E.,

Sec. 1, SW $\frac{1}{4}$, excepting therefrom the interest in and to those portions of said land deeded to the State of Nevada (for State Route 159—Blue Diamond Road) by a Deed recorded November 15, 1984 as Document No. 1981385 in Book 2022 of Official Records, Clark County, Nevada, being a parcel or strip of land one hundred fifty (150) feet in width, being seventy five (75) feet wide on each side of the surveyed highway centerline of State Route 159 (Blue Diamond Road) (Project RS-159(2)), which centerline is more fully described as follows, to wit:

Beginning at the intersection of the centerline of State Route 159 (Blue Diamond Road) (Project RS-159(2)), at Highway Engineer's Station "E" 245+84.13 P.O.T. and the north-south quarter section line of Section 1, T. 22 S., R. 58 E., M.D.M.; said point of beginning more fully described as bearing N. 5°33'24" W. a distance of 1709.81 feet from the south quarter corner of said Section 1; thence N. 54°07'24" W. along said centerline a distance of 667.72 feet to a point; thence from a tangent which bears the last described course curving to the right along said centerline with a radius of 9000 feet, through an angle of 7°23'25" an arc distance of 1160.86 feet to an intersection with the east-west quarter section line of said Section 1, the point of ending at Highway Engineer's Station "E" 264+12.71 P.O.C.; said point more fully described as bearing S. 88°28'29" E. a distance of 1418.12 feet from the west quarter corner of said Section 1, said parcel contains an area of 6.3 acres, more or less. The sidelines of said parcel are to be lengthened or shortened to intersect with the north-south quarter section line and the east-west quarter section line of said Section 1.

Sec. 1, SW $\frac{1}{4}$ SE $\frac{1}{4}$, excluding a parcel or strip of land one hundred fifty (150) feet in width, being seventy five (75) feet wide on each side of the surveyed highway centerline of State Route 159 (Blue Diamond Road) (Project RS-159(2)), which centerline is more fully described as follows, to wit:

Beginning at the intersection of the centerline of State Route 159 (Blue Diamond

Road) (Project RS-159(2)), at Highway Engineer's Station "E" 228+52.24 P.O.T. and the east one-sixteenth line of Section 1, T. 22 S., R. 58 E., M.D.M.; said point of beginning more fully described as bearing N. 60°58'30" E. a distance of 1415.54 feet from the south quarter corner of said Section 1; thence N. 54°07'24" W. along said centerline a distance of 1192.03 feet to an intersection with the south one-sixteenth line of said Section 1, the point of ending at Highway Engineer's Station "E" 240+44.27 P.O.T.; said point more fully described as bearing N. 11°06'11" a distance of 1411.82 feet from the south quarter corner of said Section 1, said parcel contains an area of 4.10 acres, more or less. The sidelines of said parcel are to be lengthened or shortened to intersect with the east one-sixteenth line and the south one-sixteenth line of said Section 1.

Sec. 2, E $\frac{1}{2}$ SE $\frac{1}{4}$, excluding Parcel A (which contains 9.6 acres);
Sec. 12, NW $\frac{1}{4}$ NW $\frac{1}{4}$.

The area described contains 300.06 acres in Clark County, Nevada. Title to the non-Federal land in Phase 1 of the exchange was accepted on March 30, 1993, and title was accepted on August 5, 1993, to the non-Federal lands involved in Phase 2 of the exchange.

In both phases of the exchange the value of the Federal lands exceeded the value of non-Federal lands. Equalization payments totaling \$925,000.00 were made by the exchange proponent. The purpose of this exchange was to acquire private inholdings within the Red Rock Canyon National Conservation Area (RRCNCA).

In accordance with Public Law 101-621, dated November 16, 1990, the RRCNCA lands are withdrawn from all forms of entry, appropriation, or disposal under the public land laws, from location, entry and patent under the mining laws, and from operation under the mineral leasing and geothermal leasing laws, and all amendments thereto.

Marla B. Bohl,

Acting Deputy State Director, Operations.

[FR Doc. 93-25133 Filed 10-13-93; 8:45 am]

BILLING CODE 4310-HC-P

[OR-020-00-4370-04; G3-439]

Oregon; Wild Horse Gathering Schedule Meeting

AGENCY: Bureau of Land Management, (BLM), DOI.

ACTION: Burns District Office: Statewide wild horse gathering schedule public meeting.

SUMMARY: In accordance with Public Law 92-195, this notice sets forth the public meeting date to discuss the use of helicopters in gathering wild horses and the proposed gathering schedule in Oregon for FY 94.

EFFECTIVE DATE: (October 20, 1993, 3 p.m. to 4:30 p.m.).

ADDRESSES: The meeting will take place at the BLM Burns District Office in Hines, Oregon.

FOR FURTHER INFORMATION CONTACT: E. Ron Harding, Wild Horse Management Specialist, Burns District, Bureau of Land Management, HC 74-12533 Hwy. 20 West, Hines, Oregon 97738—Telephone (503) 573-5241.

SUPPLEMENTARY INFORMATION: The use of helicopters to gather wild horses throughout Oregon in Fiscal Year 1994 will be discussed along with other aspects of the program and adoption process. Information concerning the gathering of all Oregon wild horse herds will be presented at the meeting. The total number of horses expected to be gathered will be between 500 to 600 depending on the availability of funds and the capability of the Burns District to process and adopt out the horses gathered.

This meeting is open to the public. Persons interested in making an oral statement at this meeting are asked to notify the District Manager, Burns District Office, HC 74-12533 Hwy. 20 West, Hines, Oregon 97738 by October 20, 1993. Written statements must be received by this date.

Summary minutes of the meeting will be available for public inspection and duplication within 30 days following the meeting.

Dated: October 6, 1993.

Craig M. Hansen,

Three Rivers Resource Area Manager.

[FR Doc. 93-25256 Filed 10-13-93; 8:45 am]

BILLING CODE 4370-04-M

[CA-940-4210-06; CACA 33164]

Proposed Withdrawal; California

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Reclamation proposes to withdraw 6,737 acres of public lands, 1,361 acres of Federal reserved mineral estates, and 397 acres of National Forest System lands to protect the lands for the proposed Auburn Dam and Reservoir and its facilities (Auburn-Folsom South Unit, Central Valley Project) near Auburn, California. This notice closes the public lands from surface entry and mining and the Federal reserved mineral estates and National Forest System lands from location and entry under the United States mining laws for 2 years. The lands will remain open to mineral leasing.

FOR FURTHER INFORMATION CONTACT: Viola Andrade, BLM California State Office, 2800 Cottage Way, room E-2845, Sacramento, California 95825, 916-978-4820.

SUPPLEMENTARY INFORMATION: On October 7, 1993 a petition was approved allowing the Bureau of Reclamation to file an application to withdraw the following described public lands from settlement, sale, location, or entry under the general land laws, including the mining laws, and to withdraw the following described Federal reserved mineral estates and National Forest System lands from location and entry under the United States mining laws, subject to valid existing rights:

Public Lands

Mount Diablo Meridian

- T. 12 N., R. 8 E.,
Sec. 12, S $\frac{1}{2}$ SW $\frac{1}{4}$.
- T. 12 N., R. 9 E.,
Sec. 1, lots 10 and 11;
Sec. 4, S $\frac{1}{2}$ N $\frac{1}{2}$ (excluding Mineral Survey 5431);
Sec. 5, lot 48;
Sec. 18, lot 1.
- T. 13 N., R. 9 E.,
Sec. 1, Mineral Survey 2653;
Sec. 2, lots 1, 2, and 7, N $\frac{1}{2}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ SW $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$, and SW $\frac{1}{4}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 11, lot 2, SE $\frac{1}{4}$ SW $\frac{1}{4}$ and SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 13, S $\frac{1}{2}$ SE $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 22, NE $\frac{1}{4}$ SW $\frac{1}{4}$ and W $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 23, Mineral Survey U-3 (formerly lot 41), excluding patented land;
Sec. 24, lot 2 (excluding Mineral Surveys 2516, 5487, 5488, 4962, and 5209), SE $\frac{1}{4}$ NE $\frac{1}{4}$, N $\frac{1}{2}$ NE $\frac{1}{4}$, NE $\frac{1}{4}$ NW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$ (excluding Mineral Survey 5488);
Sec. 25, SE $\frac{1}{4}$ NE $\frac{1}{4}$, W $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$, and W $\frac{1}{2}$ W $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 28, NE $\frac{1}{4}$ NE $\frac{1}{4}$, S $\frac{1}{2}$ NW $\frac{1}{4}$ NE $\frac{1}{4}$, SE $\frac{1}{4}$ NW $\frac{1}{4}$, NW $\frac{1}{4}$ SW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, E $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$, and W $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$;
Sec. 30, NW $\frac{1}{4}$ SE $\frac{1}{4}$;
Sec. 32, lot 5;
Sec. 34, lots 4, 11, 19, and 20;
Sec. 36, lots 1, 2, and 3.
- T. 14 N., R. 9 E.,
Sec. 1, lot 5, NE $\frac{1}{4}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$, NW $\frac{1}{4}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$, S $\frac{1}{2}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$, SE $\frac{1}{4}$ NW $\frac{1}{4}$, and unpatented land in the W $\frac{1}{2}$ SW $\frac{1}{4}$ embraced in the Gitaway and Blue Rock quartz mining claims;
Sec. 12, NW $\frac{1}{4}$, NE $\frac{1}{4}$, and SE $\frac{1}{4}$;
Sec. 13, NE $\frac{1}{4}$;
Sec. 24, SE $\frac{1}{4}$ and E $\frac{1}{2}$ E $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 25, lots 1, 2, and 7 (excluding Mineral Survey 5816), lot 8, NE $\frac{1}{4}$ SE $\frac{1}{4}$, W $\frac{1}{2}$ SE $\frac{1}{4}$, NE $\frac{1}{4}$ SW $\frac{1}{4}$ (excluding Mineral Survey 5816), and S $\frac{1}{2}$ SW $\frac{1}{4}$;
Sec. 35, lots 1, 3, and 4, NE $\frac{1}{4}$, E $\frac{1}{2}$ NW $\frac{1}{4}$, SW $\frac{1}{4}$ SW $\frac{1}{4}$, and E $\frac{1}{2}$ SE $\frac{1}{4}$;
Sec. 36, lots 2, 3, 7, 8, 9, 14, and 22, and NW $\frac{1}{4}$.
- T. 15 N., R. 9 E.,
Sec. 36, SE $\frac{1}{4}$ SW $\frac{1}{4}$.
- T. 13 N., R. 10 E.,

- Sec. 2, lot 1 and lots 3 to 15, inclusive;
 Sec. 9, lots 8, 12, and 13, and SW $\frac{1}{4}$ NE $\frac{1}{4}$;
 Sec. 10;
 Sec. 11, E $\frac{1}{2}$ SE $\frac{1}{4}$;
 Sec. 14, lots 1, 4, 5, and 6, and SW $\frac{1}{4}$ SE $\frac{1}{4}$;
 Sec. 18, lots 3, 4, 11, and 13, S $\frac{1}{2}$ lot 5, and
 S $\frac{1}{2}$ lot 8;
 Sec. 19, lot 24;
 Sec. 20, lots 1, 2, and 8, N $\frac{1}{2}$ NE $\frac{1}{4}$, and
 SE $\frac{1}{4}$ NE $\frac{1}{4}$;
 Sec. 22, lots 1, 2, 7, and 8;
 Sec. 28, NE $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$, N $\frac{1}{2}$ SE $\frac{1}{4}$ NE $\frac{1}{4}$,
 and N $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$;
 Sec. 30, lot 1 (excluding Mineral Survey
 4709), lots 5 and 5, S $\frac{1}{2}$ NE $\frac{1}{4}$, and
 NE $\frac{1}{4}$ SE $\frac{1}{4}$.
- T. 14 N., R. 10 E.,
 Sec. 7, lot 6;
 Sec. 18, lots 2 to 7, inclusive, and lots 10,
 11, 13, and 15;
 Sec. 30, lots 4, 8, 9, 10, 15, 16, 17, and N $\frac{1}{2}$
 lot 178, E $\frac{1}{2}$ NW $\frac{1}{4}$, and W $\frac{1}{2}$ SW $\frac{1}{4}$ NW $\frac{1}{4}$.

Federal Reserved Mineral Estates

Mount Diablo Meridian

- T. 12 N., R. 9 E.,
 Sec. 4, lots 5 to 9, inclusive;
 Sec. 6, lots 4 to 9, inclusive, and
 SE $\frac{1}{4}$ NE $\frac{1}{4}$.
- T. 13 N., R. 9 E.,
 Sec. 26, lots 3 and 4, W $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ NE $\frac{1}{4}$,
 NE $\frac{1}{4}$ NW $\frac{1}{4}$, N $\frac{1}{2}$ SW $\frac{1}{4}$, SW $\frac{1}{4}$ SW $\frac{1}{4}$, and
 W $\frac{1}{2}$ NW $\frac{1}{4}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$;
 Sec. 28, W $\frac{1}{2}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ and
 E $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$;
 Sec. 32, lots 2 and 3, NE $\frac{1}{4}$, NE $\frac{1}{4}$ NW $\frac{1}{4}$,
 W $\frac{1}{2}$ NW $\frac{1}{4}$, and N $\frac{1}{2}$ SE $\frac{1}{4}$;
 Sec. 34, lots 3, 5, 6, 8, 14, and 15.
- T. 14 N., R. 10 E.,
 Sec. 6, lots 8 and 9, N $\frac{1}{2}$ lot 15, SW $\frac{1}{4}$ lot
 15, lots 17 and 18, N $\frac{1}{2}$ lot 19, SW $\frac{1}{4}$ lot
 19, and lot 33.

National Forest System Lands

Mount Diablo Meridian

Tahoe National Forest

- T. 13 N., R. 11 E.,
 Sec. 4, lot (excluding Mineral Survey
 5300);
- T. 14 N., R. 11 E.,
 Sec. 31, S $\frac{1}{2}$ SE $\frac{1}{4}$ SW $\frac{1}{4}$ and
 SW $\frac{1}{4}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$;
 Sec. 32, SE $\frac{1}{4}$ SW $\frac{1}{4}$ SW $\frac{1}{4}$ and S $\frac{1}{2}$ N $\frac{1}{2}$ SE $\frac{1}{4}$,
 and N $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$;
 Sec. 33, S $\frac{1}{2}$ N $\frac{1}{2}$ SW $\frac{1}{4}$, S $\frac{1}{2}$ N $\frac{1}{2}$ SE $\frac{1}{4}$, and
 N $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$;
 Sec. 34, N $\frac{1}{2}$ SW $\frac{1}{4}$, SE $\frac{1}{4}$ SW $\frac{1}{4}$, and
 W $\frac{1}{2}$ NW $\frac{1}{4}$ SE $\frac{1}{4}$.

Tahoe and Eldora National Forests

- T. 13 N., R. 11 E.,
 Sec. 4, lot 3 (excluding mineral Survey
 5300).
- T. 14 N., R. 11 E.,
 Sec. 33, S $\frac{1}{2}$ SW $\frac{1}{4}$ SE $\frac{1}{4}$ (excluding Mineral
 Survey 5300) and SE $\frac{1}{4}$ SE $\frac{1}{4}$.

The areas described aggregate approximately 6,737 acres of public land, 1,361 acres of Federal served mineral estates, and 397 acres of National Forest System lands in Placer and El Dorado counties.

The purpose of the proposed withdrawal is to protect the lands for

the proposed Auburn Dam and Reservoir. Until an application is filed, no further action will be taken on this proposal.

For a period of 2 years from the date of publication of this notice in the **Federal Register**, the lands will be segregated as specified above unless the application is denied or canceled or the withdrawal is approved prior to that date. The temporary uses which may be permitted during this segregative period are licenses, permits, rights-of-way, cooperative agreements or other discretionary land use authorizations of a temporary nature.

The temporary segregation of the lands in connection with a withdrawal application or proposal shall not affect administrative jurisdiction over the land, and the segregation not have the effect of authorizing any use of the land by the Bureau of Reclamation.

Dated: October 7, 1993.

Nancy J. Alex,

Chief, Lands Section.

[FR Doc. 93-25189 Filed 10-13-93; 8:45 am]

BILLING CODE 4310-40-M

Fish and Wildlife Service

Aquatic Nuisance Species Task Force Meeting

AGENCY: U.S. Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Aquatic Nuisance Species (ANS) Task Force. A number of subjects will be discussed during the meeting including: The Aquatic Nuisance Species Program, the proposed Ruffe Control Program, ballast water management activities/initiatives, the Intentional Introductions Policy Review Report to Congress, and upcoming events.

DATES: The ANS Task Force will meet from 9 a.m. to 3 p.m. on Tuesday, November 9, 1993.

ADDRESSES: The ANS Task Force meeting will be held at the U.S. Fish and Wildlife Service Building, room 200A&B, 4401 N. Fairfax Drive, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Sharon Gross, ANS Task Force Coordinator, U.S. Fish and Wildlife Service, 4401 N. Fairfax Drive, Arlington, VA 22203 at (703) 358-1718.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the ANS Task Force established under

the authority of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (Pub. L. 101-646, 104 Stat. 4761, 16 U.S.C. 4701 *et seq.*, November 29, 1990). Minutes of the meetings will be maintained by the Coordinator, ANS Task Force, room 840, 4401 N. Fairfax Drive, Arlington, Virginia 22203 and will be available for public inspection during regular business hours, Monday through Friday within 30 days following the meeting.

Dated: October 7, 1993.

Gary Edwards,

Assistant Director, Fisheries, Co-Chair, Aquatic Nuisance Species Task Force.

[FR Doc. 93-25219 Filed 10-13-93; 8:45 am]

BILLING CODE 4310-55-M

Aquatic Nuisance Species Task Force Monitoring Committee Meeting

AGENCY: U.S. Fish and Wildlife Service, Department of the Interior.

ACTION: Notice of meeting.

SUMMARY: This notice announces a meeting of the Monitoring Committee (Committee), a committee of the Aquatic Nuisance Species Task Force. A number of subjects will be discussed during the Committee meeting including: review of monitoring programs collecting data concerning nonindigenous species, and development of a pilot program to obtain information from existing monitoring programs.

DATES: The Monitoring Committee will meet from 9:30 a.m. to 3:30 p.m. on Tuesday, November 2, 1993.

ADDRESSES: The Monitoring Committee meeting will be held at the U.S. Fish and Wildlife Service Building, room 700, 4401 N. Fairfax Drive, Arlington, Virginia 22203.

FOR FURTHER INFORMATION CONTACT: Dr. James Weaver, National Fisheries Research Center, 7920 NW. 71st Street, Gainesville, Florida 32606 at (904) 378-8181.

SUPPLEMENTARY INFORMATION: Pursuant to section 10(a)(2) of the Federal Advisory Committee Act (5 U.S.C. App. I), this notice announces a meeting of the Aquatic Nuisance Species Task Force Monitoring Committee established under the authority of the Nonindigenous Aquatic Nuisance Prevention and Control Act of 1990 (Pub. L. 101-646, 104 Stat. 4761, 16 U.S.C. 4701 *et seq.*, November 29, 1990). Minutes of the meetings will be maintained by the Coordinator, Aquatic Nuisance Species Task Force, room 840, 4401 N. Fairfax Drive, Arlington, Virginia 22203 and the Monitoring Committee Chairman, National

Fisheries Research Center, 7920 NW. 71st Street, Gainesville, Florida 32606 and will be available for public inspection during regular business hours, Monday through Friday within 30 days following the meeting.

Dated: October 7, 1993.

Gary Edwards,

Co-Chair, Aquatic Nuisance Species Task Force.

[FR Doc. 93-25220 Filed 10-13-93; 8:45 am]

BILLING CODE 4310-55-M

Geological Survey

Earth Observing System (EOS) Land Processes Distributed Active Archive Center (DAAC) Science Advisory Panel; Meeting

AGENCY: U.S. Geological Survey, Interior.

ACTION: Notice of meeting.

SUMMARY: Pursuant to Public Law 92-463, the Land Processes DAAC Science Advisory Panel will meet at the U.S. Geological Survey Earth Resources Observation Systems (EROS) Data Center near Sioux Falls, South Dakota. The Panel, comprised of scientists from academic and government institutions, will provide Land Processes DAAC management with advice and consultation on a broad range of scientific and technical topics relevant to the development and operation of DAAC systems and capabilities.

Topics to be reviewed and discussed by the Panel include Land Processes DAAC FY 1993 accomplishments and FY 1994 planned activities; the role and activities of the EOS core system (ECS) contractor in Land Processes DAAC development; EOS test site data set development; digital elevation model (DEM) and ground control point (GCP) issues; data product quality control and validation; Advanced Spaceborne Thermal Emission and Reflection Radiometer (ASTER) requirements for global assimilation model (GAM) weather data; information management system (IMS) development status; and others.

DATES: October 26-28, 1993, commencing at 8:30 a.m. on October 26 and adjourning at 3:30 p.m. on October 28.

FOR FURTHER INFORMATION CONTACT: Dr. Bryan Bailey, Land Processes DAAC Project Scientist, U.S. Geological Survey, EROS Data Center, Sioux Falls, South Dakota 57198 at (605) 594-6001.

SUPPLEMENTARY INFORMATION: Meetings of the Land Processes DAAC Science Advisory Panel are open to the public.

Dated: October 4, 1993.

Robert M. Hirsch,

Acting Director, U.S. Geological Survey.

[FR Doc. 93-25132 Filed 10-13-93; 8:45 am]

BILLING CODE 4310-31-M

National Park Service

Yosemite Valley Housing Plan, Yosemite National Park; Intent To Prepare a Supplement to the Draft Plan and Supplemental Environmental Impact Statement

SUMMARY: The National Park Service will prepare a supplementary environmental impact statement, for the Draft Yosemite Valley Housing Plan and Draft Supplement to the Environmental Impact Statement (SEIS) for the General Management Plan for Yosemite National Park, in order to introduce and analyze two additional alternatives to those presented in the prior document. This action is in accordance with the regulations promulgated by the Council on Environmental Quality at 40 CFR 1502.9(c).

BACKGROUND: The Draft Yosemite Valley Housing Plan and Draft Supplement to the Environmental Impact Statement (SEIS) for the General Management Plan for Yosemite National Park was issued in July, 1992 (57 FR 34146) with the public comment period ending September 30, 1992. This plan and SEIS examined the effects of a proposal and four alternatives for housing National Park Service and concession employees who work in Yosemite Valley. The proposed action would provide housing for 952 employees at a new development site at Foresta. Alternative A would provide housing for 1395 employees at Foresta. Alternative B would provide housing for 934 employees at El Portal with the housing located on both sides of the Merced River. Alternative C would provide housing for 491 employees at El Portal, confined to the north bank of the river, and improve existing housing in Yosemite Valley. Alternative D, no-action, would continue to house 1359 employees in Yosemite Valley. The administrative offices for NPS and the primary concessioner would be located in Foresta under the proposed action and Alternative A, in El Portal under Alternatives B and C, and remain in Yosemite Valley under Alternative D. The proposed action and the alternatives were analyzed for impacts on biotic communities, sensitive species, the Merced River, air quality, scenic quality, cultural resources, socio-economic concerns, Yosemite Valley

visitors, park and concession operations, and energy consumption.

After reviewing public comments on the plan and SEIS, the National Park Service intends to evaluate two additional alternatives that were not analyzed in the earlier draft. The first, Alternative E, relocates the same facilities and provides the same amount of housing as Alternative C in the draft plan/SEIS; but the housing would be located on both sides of the Merced River. The second, Alternative F, would relocate both of the administrative offices to Wawona and house approximately 200 additional employees in Wawona. Wawona is a small community in the extreme southern portion of the park.

SUPPLEMENTARY INFORMATION: Persons wishing to provide input to this expanded scope of the project and associated supplemental environmental impact statement should send those comments to the Superintendent, Yosemite National Park, P.O. Box 577, Yosemite National Park, California 95389 by November 30, 1993. Requests for further information should be directed to this address or telephone number (209) 372-0200.

The responsible official is Stanley Albright, Regional Director, Western Regional Office. The supplement to the draft plan and supplemental environmental impact statement is expected to be completed and available for public review by July, 1994. Comments received on the document will be considered and incorporated as appropriate, along with comments received on the previously circulated Draft Yosemite Valley Housing Plan and Draft Supplement to the Environmental Impact Statement (SEIS) for the General Management Plan for Yosemite National Park, in the preparation of a final Yosemite Housing Plan/supplemental environmental impact statement. This document and subsequent Record of Decision are expected about a year later.

Dated: September 27, 1993.

Patricia L. Neubaehner,

Acting Regional Director, Western Region.

[FR Doc. 93-25186 Filed 10-13-93; 8:45 am]

BILLING CODE 4310-70-P

INTERNATIONAL TRADE COMMISSION

[Investigation No. 337-TA-348]

Commission Determination To Vacate as Moot an Initial Determination Granting a Motion To Amend the Notice of Investigation To Allow Discovery on Public Interest and Remedy

In the matter of certain in-line roller skates with ventilated boots and in-line roller skates with axle aperture plugs and component parts thereof.

AGENCY: U.S. International Trade Commission.

ACTION: Notice.

SUMMARY: Notice is hereby given that the U.S. International Trade Commission has determined to vacate as moot the initial determination (ID) (Order No. 20) of the presiding administrative law judge (ALJ) in the above-captioned investigation granting a motion to amend the notice of investigation and allow discovery to be taken on the issues of public interest and remedy.

ADDRESSES: Copies of the ID and all other nonconfidential documents filed in connection with this investigation are available for public inspection during official business hours (8:45 a.m. to 5:15 p.m.) in the Office of the Secretary, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-2000.

FOR FURTHER INFORMATION CONTACT: Anjali K. Singh, Esq., Office of the General Counsel, U.S. International Trade Commission, 500 E Street SW., Washington, DC 20436, telephone 202-205-3117. Hearing-impaired individuals are advised that information about this matter can be obtained by contacting the Commission's TDD terminal, 202-205-1810.

SUPPLEMENTARY INFORMATION: On February 18, 1993, Rollerblade, Inc. filed a complaint with the Commission alleging unfair acts in violation of section 337 of the Tariff Act of 1930 (19 U.S.C. 1337). The unfair acts alleged in the complaint are the unauthorized importation into the United States, the sale for importation, and the sale within the United States after importation of certain in-line roller skates with ventilated boots, and in-line roller skates with axle aperture plugs and component parts thereof, that allegedly infringe claims 1, 2, 3, 4, 5, 6, 7, or 8 of U.S. Letters Patent 5,171,033, and/or claim 5 of U.S. Letters Patent 5,048,848. On March 18, 1993, the Commission voted to institute an investigation of the

complaint and published notice of its investigation in the *Federal Register* (58 FR 16204 (March 25, 1993)).

On July 23, 1993, respondent Rocas SRL filed a motion (Motion No. 348-29) to amend the notice of investigation to authorize discovery and evidence to be taken relating to the issues of public interest and remedy. The Commission investigative attorney supported the motion. Complainant Rollerblade filed a response in opposition to the motion to amend the notice of investigation. On July 28, 1993, the ALJ issued an ID granting the motion in part to allow discovery on the issues of public interest and remedy. On August 30, 1993, the Commission determined to review the ID because on the same date it had determined to review and remand a subsequent ID (Order No. 21) granting complainant's motion for summary judgment on the issue of domestic industry. The latter ID was remanded to the ALJ with instructions to allow discovery and evidence to be taken on the domestic industry issue. The information that would be obtained on the public interest issues, i.e., information regarding complainant Rollerblade's alleged plans to move its domestic operations abroad, is the same information that the Commission has authorized the parties to obtain with respect to the domestic industry issue. Therefore, the Commission determined to vacate the ALJ's ID (Order No. 20) as moot.

This action is taken pursuant to section 337 of the Tariff Act of 1930, as amended (19 U.S.C. 1337), and Commission interim rule 210.56(c) (19 CFR 210.56(c)).

By order of the Commission.

Issued: October 7, 1993.

Donna R. Koehnke,
Secretary.

[FR Doc. 93-25246 Filed 10-13-93; 8:45 am]

BILLING CODE 7020-02-P-M

DEPARTMENT OF JUSTICE

Lodging of Consent Decree in *United States v. Core Craft, Inc., et al.*, Pursuant to the Comprehensive Environmental Response, Compensation and Liability Act

In accordance with section 122(d)(2) of the Comprehensive Environmental Response, Compensation and Liability Act ("CERCLA"), 42 U.S.C. 9622(d)(2), and the policy of the Department of Justice, 28 CFR 50.7, notice is hereby given that on September 10, 1993, a proposed Consent Decree in *United States of America v. Core Craft, Inc., et*

al., Civil Action No. 3-93-603, was lodged with the United States District Court for the District of Minnesota. This action was brought pursuant to CERCLA section 107(a), 42 U.S.C. 9607(a), to recover costs expended by the United States at the Kummer Sanitary Landfill Site in Bemidji, Minnesota. The Site is listed on the National Priorities List set forth at 40 CFR part 300, appendix B.

The Kummer Sanitary Landfill comprises 40-acres situated in Northern Township, Minnesota, approximately one-half mile north of the City of Bemidji and one mile west of Lake Bemidji. The landfill's operators were licensed to accept mixed municipal waste from 1971 to 1984 under a permit issued by the Minnesota Pollution Control Agency. Based on the results of several studies of conditions at the landfill, the Minnesota Pollution Control Agency and the United States Environmental Protection Agency have determined that the ground water contained elevated levels of various substances designated as hazardous under CERCLA, including but not limited to vinyl chloride, trans-1,2-dichloroethene, ethylene glycol monoethyl ether, polyester resin (styrene anhydrides), methylene chloride and xylene.

Under the proposed Consent Decree, the settling defendants will reimburse \$5 million of the approximately \$10 million in past and projected response costs associated with the Site, as well as pay \$22,000 in resolution of a natural resource damage claim.

The Department of Justice will receive comments on the proposed Consent Decree for a period of 30 days from the date of publication of this Notice. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, Washington, DC 20530. All comments should refer to *United States v. Core Craft, Inc., et al.*, D.J. Ref. No. 90-11-2-604.

The proposed Consent Decree may be examined at the Region V Office of the U.S. Environmental Protection Agency, 111 West Jackson Street, Third Floor, Chicago, Illinois 60604 (312-886-0556); the Office of the United States Attorney for the District of Minnesota, 234 U.S. Courthouse, 110 South Fourth St., Minneapolis, MN 55401 (612) 348-1500; and the U.S. Department of Justice, Consent Decree Library, 1120 G Street, NW., 4th Floor, Washington, DC 20005 (202-624-0892). A copy of the proposed Consent Decree may be obtained in person or by mail from the Consent Decree Library. In requesting a copy, please specify the document

sought, together with a check payable to the "Consent Decree Library" for \$8.00 (Consent Decree only) or \$57.50 (Consent Decree and appendices thereto) (\$.25 per page reproduction costs).

John C. Cruden,

Environment and Natural Resources Division,
Chief, Environmental Enforcement Section.

[FR Doc. 93-25131 Filed 10-13-93; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to the Resource Conservation and Recovery Act; United States v. Donald A. Johnson

In accordance with Department policy, 28 CFR 50.7, notice is hereby given that on September 9, 1993, a proposed Consent Decree in *United States v. Donald A. Johnson* Civil Action No. 1:91-CV-639, was lodged in the United States District Court for the Western District of Michigan. The Complaint filed by the United States alleged violations of the Resource Conservation and Recovery Act. The Consent Decree requires the defendant to pay a civil penalty of \$5,000 in settlement of the claims set forth in the Complaint filed by the United States.

The Department of Justice will receive for a period of thirty (30) days from the date of this publication comments concerning the proposed Consent Decree. Comments should be addressed to the Assistant Attorney General, Environment and Natural Resources Division, U.S. Department of Justice, P.O. Box 7611, Ben Franklin Station, Washington, DC 20044, and should refer to *United States v. Donald A. Johnson*, DOJ Ref. No. 90-7-1-635.

The proposed Consent Decree may be examined at any of the following offices: (1) The United States Attorney for the Western District of Michigan, 110 Michigan Street NW., room 399, Grand Rapids, Michigan 49503 (contact Assistant United States Attorney W. Francesca Ferguson); (2) The U.S. Environmental Protection Agency, Region 5, 77 West Jackson Boulevard, Chicago, Illinois 60604-3590 (contact Assistant Regional Counsel Thomas Krueger); and (3) the Environmental Enforcement Section, Environment & Natural Resources Division, U.S. Department of Justice, room 1541, 10th & Pennsylvania Avenue NW., Washington, DC. Copies of the proposed Consent Decree may be obtained in

person or by mail from the Environmental Enforcement Section Document Center, 1120 G Street, NW., Washington, DC 20005, telephone (202) 624-0892. For a copy of the Consent Decree please enclose a check in the amount of \$3.00 (25 cents per page reproduction charge) payable to Consent Decree Library.

John C. Cruden,

Chief, Environmental Enforcement Section,
Environment & Natural Resources Division.

[FR Doc. 93-25129 Filed 10-13-93; 8:45 am]

BILLING CODE 4410-01-M

Lodging of Consent Decree Pursuant to the Clean Water Act; In Re: Oriental Republic of Uruguay

In accordance with Departmental policy, 28 CFR 50.7, notice is hereby given that a proposed consent decree in *In Re: Oriental Republic of Uruguay* (M/V Presidente Rivera), Civil Action No. 90-404-SLR, was lodged on September 29, 1993 with the United States Court for the District of Delaware. The proposed consent decree will, if approved, settle an action brought under section 311 of the Clean Water Act, 33 U.S.C. 1321, seeking recovery for natural resource damages caused by, and response costs incident to, a June 24, 1989 oil spill into the Delaware River from the Uruguayan oil tanker *Presidente Rivera*.

The Department of Justice will receive, for a period of thirty (30) days from the date of this publication, comments relating to the proposed consent decree. Comments should be addressed to the Assistant Attorney General for the Environment and Natural Resources Division, Department of Justice, Washington, DC 20530, and should refer to *In Re: Oriental Republic of Uruguay* (M/V Presidente Rivera), DOJ Ref. #90-5-1-1-3609.

The proposed consent decree may be examined at the office of the United States Attorney, District of Delaware, 1201 Market Street, suite 1100, Wilmington, DE 19899-2046, and at the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005, (202) 624-0892. A copy of the proposed consent decree may be obtained in person or by mail from the Consent Decree Library, 1120 G Street NW., 4th Floor, Washington, DC 20005. In requesting a copy please refer to the referenced case and enclose a check in the amount of \$5.50 (25 cents per page

reproduction costs), payable to the Consent Decree Library.

Myles E. Flint,

Acting Assistant Attorney General,
Environment and Natural Resources Division.

[FR Doc. 93-25130 Filed 10-13-93; 8:45 am]

BILLING CODE 4410-01-M

DEPARTMENT OF LABOR

Employment and Training Administration

Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance

Petitions have been filed with the Secretary of Labor under section 221(a) of the Trade Act of 1974 ("the Act") and are identified in the appendix to this notice. Upon receipt of these petitions, the Director of the Office of Trade Adjustment Assistance, Employment and Training Administration, has instituted investigations pursuant to section 221(a) of the Act.

The purpose of each of the investigations is to determine whether the workers are eligible to apply for adjustment assistance under title II, chapter 2, of the Act. The investigations will further relate, as appropriate, to the determination of the date on which total or partial separations began or threatened to begin and the subdivision of the firm involved.

The petitioners or any other persons showing a substantial interest in the subject matter of the investigations may request a public hearing, provided such request is filed in writing with the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than October 25, 1993.

Interested persons are invited to submit written comments regarding the subject matter of the investigations to the Director, Office of Trade Adjustment Assistance, at the address shown below, not later than October 25, 1993.

The petitions filed in this case are available for inspection at the Office of the Director, Office of Trade Adjustment Assistance, Employment and Training Administration, U.S. Department of Labor, 200 Constitution Avenue NW., Washington, DC 20210.

Signed at Washington, DC, this 27th day of September, 1993.

Marvin M. Fooks,

Director, Office of Trade Adjustment Assistance.

APPENDIX

Petitioner: Union/workers/firm—	Location	Date received	Date of petition	Petition	Articles produced
Briggs & Stratton Corp (AIW)	Wauwatosa, WI ...	09/27/93	09/16/93	29,058	Gasoline engines.
Briggs & Stratton Corp (AIW)	West Allis, WI	09/27/93	09/16/93	29,059	Gasoline engines.
Briggs & Stratton Corp (AIW)	Menomonee Falls, WI.	09/27/93	09/16/93	29,060	Gasoline engines.
Allied Signal (Wkrs)	Rumford, RI	09/27/93	09/03/93	29,061	Vehicles filters.
SPS Technologies (Wkrs)	Santa Ana, CA ...	09/27/93	09/16/93	29,062	Aerospace fasteners.
Virginia Apparel Corp (Wkrs)	Blackstone, VA ...	09/27/93	09/14/93	29,063	Ladies' and mens' pants.
Penn Footwear Co (UFCW)	Nanticoke, PA	09/27/93	09/13/93	29,064	Footwear.
Penetrators, Inc (Wkrs)	Midland, TX	09/27/93	09/16/93	29,065	Oil and gas.
Penetrators, Inc (Wkrs)	Houston, TX	09/27/93	09/16/93	29,066	Oil and Gas.
Olympic Plating Industries, Inc (UPIU).	Canton, OH	09/27/93	09/19/93	29,067	Chrome plating service.
Northern Shipping Co (Wkrs)	Philadelphia, PA .	09/27/93	09/15/93	29,068	Provides terminal services.
Northland (IBEW)	Watertown, NY ...	09/27/93	09/14/93	29,069	Electric motors.
Muelhens, Inc (Wkrs)	Orange, CT	09/27/93	09/08/93	29,070	Perfumes and toiletries.
Midcon Cables Co (Wkrs)	Joplin, MO	09/27/93	09/13/93	29,071	Electric wire harness.
Jockey International (Wkrs)	Maysville, KY	09/27/93	09/06/93	29,072	Underwear.
Energy Data Services, Inc (Co/Wkrs).	Englewood, CO ...	09/27/93	09/01/93	29,073	Oil and gas.
Coal Street Mfg (ILGWU)	Wilkes Barre, PA	09/27/93	09/14/93	29,074	Dresses.
Chess King (Wkrs)	Worcester, MA ...	09/27/93	09/14/93	29,075	Men's clothing.
CertainTeed Corp (IBT)	Kansas City, KS ..	09/27/93	09/07/93	29,076	Fiberglass insulation products.
Carter Mining Co (Wkrs)	Gillette, WY	09/27/93	09/14/93	29,077	Bituminous coal.
Brush Fuses, Inc (Wkrs)	Glendale Heights, IL.	09/27/93	09/09/93	29,078	Electrical fuses.
Brush Fuses, Inc (Wkrs)	Nogales, AZ	09/27/93	09/09/93	29,079	Electrical fuses.
Andmore Sportswear Corp (ILGWU).	Port Jervis, NY ...	09/27/93	09/16/93	29,080	Men's and Womens' bathing suits.
Airshield Corp (Wkrs)	Bridgeport, CT ...	09/27/93	09/15/93	29,081	Fairings and wind deflectors for trucks.
Advanced Machine Technology (IAMAW).	Portland, OR	09/27/93	09/13/93	29,082	Industrial printing presses.
Darrah Fashions, BR3 (Wkrs)	Bridsboro, PA	09/27/93	09/15/93	29,083	Ladies' Dresses.
Darrah Fashions, BR2 (Wkrs)	Tower City, PA ...	09/27/93	09/15/93	29,084	Ladies' dresses.
Darrah Fashions, BR1 (Wkrs)	Wisconsin, PA ...	09/27/93	09/15/93	29,085	Ladies' dresses.

[FR Doc. 93-25221 Filed 10-13-93; 8:45 am]
BILLING CODE 4510-30-M

Signed in Washington, DC, this October 7, 1993.

Marvin M. Fooks,
Director, Office of Trade Adjustment Assistance.

[FR Doc. 93-25225 Filed 10-13-93; 8:45 am]
BILLING CODE 4510-30-M

[TA-W-28,927]

Eastern Associated Coal Corp.
Kopperston No. 1 Mine, Charleston, WV; Investigations Regarding Certifications of Eligibility To Apply for Worker Adjustment Assistance; Correction

This notice corrects the notice for petition TA-W-28,927 which was published in the Federal Register on August 24, 1993 (58 FR 44699) in FR Document 93-20416. A printing error concerning the location of Eastern Associated Coal Corporation's Kopperston No. 1 mine appears in the 3rd line of the second column in the appendix table on page 44699. The location should read "Charleston, West Virginia" instead of Kopperston, West Virginia.

[TA-W-28,858]

Magnetek Century Electric, Inc., El Paso, Texas; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18 an application for administrative reconsideration was filed with the Director of the Office of Trade Adjustment Assistance for workers at Magnetek Century Electric, Incorporated, El Paso, Texas. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA-W-28,858; Magnetek Century Electric, Incorporated, El Paso, Texas (September 30, 1993)

Signed at Washington, DC, this 5th day of October, 1993.

Marvin M. Fooks,
Director, Office of Adjustment Assistance.

[FR Doc. 93-25222 Filed 10-13-93; 8:45 am]
BILLING CODE 4510-30-M

[TA-W-28,717]

Oberdorfer High Tex, Sandpoint, ID; Dismissal of Application for Reconsideration

Pursuant to 29 CFR 90.18 an application for administrative reconsideration was filed with the Director of the Office of Trade Adjustment Assistance for workers at Oberdorfer High Tex, Sandpoint, Idaho. The review indicated that the application contained no new substantial information which would bear importantly on the Department's determination. Therefore, dismissal of the application was issued.

TA-W-28,717; Oberdorfer High Tex Sandpoint, ID (October 5, 1993)

Signed at Washington, DC, this 5th day of October, 1993.

Marvin M. Fooks,

Director, Office of Adjustment Assistance.

[FR Doc. 93-25223 Filed 10-13-93; 8:45 am]

BILLING CODE 4510-30-M

[TA-W-28,686 and TA-W-28,686A]

Smarte Carte, Inc., White Bear Lake, MN and Chicago, IL; Negative Determination Regarding Application for Reconsideration

By an application dated September 19, 1993, one of the petitioners requested administrative reconsideration of the subject petition for trade adjustment assistance. The denial notice was signed on September 9, 1993 and published in the *Federal Register* on September 22, 1993 (58 FR 49321).

Pursuant to 29 CFR 90.18(c) reconsideration may be granted under the following circumstances:

(1) If it appears on the basis of facts not previously considered that the determination complained of was erroneous;

(2) If it appears that the determination complained of was based on a mistake in the determination of facts not previously considered; or

(3) If in the opinion of the Certifying Officer, a mis-interpretation of facts or of the law justified reconsideration of the decision.

Investigation findings show that the workers produce baggage carts at White Bear Lake and provide rental baggage cart concession services at the Chicago O'Hare airport. The findings show that the product is marketed through competitive bidding.

The petitioner states that although the foreign awardee of the O'Hare baggage cart bid had its carts made domestically, it produced its vending systems in Australia.

The Department's denial was based on the fact that the "contributed importantly" test of the Group Eligibility Requirements of the Trade Act was not met. The "contributed importantly" test is generally demonstrated through a survey of the workers' firm's customers. The Department's survey of unsuccessful bids for baggage cart concessions in 1993 showed that Smarte Carte's unsuccessful bid for continued concessions at the Chicago O'Hare airport went to an Illinois firm with a foreign parent company.

The findings show that the Illinois firm had the carts manufactured domestically; however, the Illinois firm

had vending systems for the baggage carts assembled at the O'Hare airport. Some of the components for the vending systems came from Australia but most were produced domestically including the validators (coin and bill acceptors), coin boxes and bags.

Foreign ownership of a domestic firm and lost domestic bids would not, in themselves, provide a basis for a worker group certification.

Conclusion

After review of the application and investigative findings, I conclude that there has been no error or misinterpretation of the law or of the facts which would justify reconsideration of the Department of Labor's prior decision. Accordingly, the application is denied.

Signed at Washington, DC, this day of October 6, 1993.

Stephen A. Wandner,

Deputy Director, Office of Legislation & Actuarial Service, Unemployment Insurance Service.

[FR Doc. 93-25224 Filed 10-13-93; 8:45 am]

BILLING CODE 4510-30-M

NATIONAL SCIENCE FOUNDATION

Advisory Panel for Anthropological and Geographic Sciences; Meetings

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463, as amended), the National Science Foundation (NSF) announces the following Five meetings.

Name: Advisory Panel for Anthropological and Geographic Sciences #1757.

Dates & Time: November 8-9, 1993; 9 a.m.-5 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, Room 310, Arlington, VA 22230.

Contact Person: John E. Yellen, Program Director for Archaeology National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (202) 357-7804.

Agenda: To review and evaluate Archaeology proposals as a part of the selection process for awards.

Date & Time: October 26-27, 1993; 9 a.m.-5 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, Room 11 Arlington, VA 22230.

Contact Person: Dr. Jonathan Friedlaender, Program Director for Physical Anthropology, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (202) 357-7804.

Agenda: To review and evaluate physical anthropology proposals as part of the selection process for awards.

Date & Time: November 4-5, 1993; 9 a.m.-5 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, Room 5, Arlington, VA 22230.

Contact Person: Dr. Stuart Plattner, Program Director for Cultural Anthropology, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (202) 357-7804.

Agenda: To review and evaluate cultural anthropology proposals as part of the selection process for awards.

Date & Time: November 1-2, 1993; 8 a.m.-5 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, Room 310.02 Arlington, VA 22230.

Contact Person: Dr. David C. Hodge, or Thomas J. Baerwald, Program Directors for Geography, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (202) 357-7326.

Agenda: To review and evaluate geography proposals as part of the selection process for awards.

Date & Time: December 13-14, 1993; 8:30 a.m.-5 p.m.

Place: National Science Foundation, Stafford Place, 4201 Wilson Boulevard, room 360, Arlington, VA 22230.

Contact Person: Dr. Robin Cantor or Dr. Thomas J. Baerwald, Coordinators for Human Dimensions/Economics of Global Change, National Science Foundation, 4201 Wilson Boulevard, Arlington, VA 22230. Telephone: (202) 357-7417.

Agenda: To review and evaluate human dimension and global change proposals as part of the selection process for awards.

Type of Meetings: Closed.

Purpose of Meetings: To provide advice and recommendations concerning support for research proposals submitted to the NSF for financial support.

Reason for Closing: The proposals being reviewed include information of a proprietary or confidential nature, including technical information, financial data, such as salaries; and personal information concerning individuals associated with the proposals. These matters are exempt under 5 U.S.C. 552(b)(4) and (6) of the Government in the Sunshine Act.

Dated: October 8, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93-25251 Filed 10-13-93; 8:45 am]

BILLING CODE 7555-01-M

Committee on Equal Opportunities in Science and Engineering; Meeting

In accordance with the Federal Advisory Committee Act (Pub. L. 92-463), as amended, the National Science Foundation announces the following meeting:

Name: Committee on Equal Opportunities in Science and Engineering (CEOSE) (1173).

Date and time: November 4, 1993; 8:30 a.m.-5 p.m. (Open). November 5, 1993; 8:30 a.m.-12 Noon (Open).

Place: Room 340, National Science Foundation, 4102 Wilson Boulevard, Arlington, VA 22230.

Type of Meeting: Open.

Contact Person: Wanda E. Ward, Executive Secretary, CEOSE, National Science Foundation, 4102 Wilson Boulevard, Room 814, Arlington, VA 22230. Telephone: (703) 306-1633.

Summary Minutes: May be obtained from the Executive Secretary at the above address.

Purpose of Meeting: To review the Report to Congress and to review assessments of participation rates of all segments of society in science and engineering.

Agenda: November 4: 8:30 a.m. to 5 p.m.—Presentations/discussions of Report to Congress; review of assessments of participation rates of all segments of society in science and engineering; 5 p.m.—Reception. November 5: 8:30 a.m. to 12 Noon—Discussion of CEOSE Report to Congress, NSF education programs and NSF future directions.

Dated: October 8, 1993.

M. Rebecca Winkler,

Committee Management Officer.

[FR Doc. 93-25252 Filed 10-13-93; 8:45 am]

BILLING CODE 7555-01-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 72-3 (50-261)]

Carolina Power and Light Co.; Issuance of Exemption and Amendment to Materials License No. SNM-2502

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 9 to Materials License No. SNM-2502 held by the Carolina Power and Light Company for the receipt and storage of spent fuel at the H.B. Robinson Independent Spent Fuel Storage Installation (ISFSI), located on the H.B. Robinson Steam Electric Plant Unit 2 site, Darlington County, South Carolina. The amendment is effective as of the date of issuance.

The amendment issues the following exemption from the provisions of 10 CFR 72.122(i) with respect to providing instrumentation and control systems to monitor systems that are important to safety over anticipated ranges for normal and off-normal operations for the Carolina Power and Light Company's H.B. Robinson ISFSI. The Commission, on its own initiative, has determined that, due to the passive design and inherent safety of the NUHOMS-7P cask, no instrumentation and control systems are required for the dry shielded canister and the horizontal storage module (DSC and HSM) system during storage operations.

Pursuant to 10 CFR 72.7, the Commission has determined that the

granting of the exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest.

The exemption and amendment comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the exemption and license amendment. Prior public notice of the amendment was not required since the amendment does not involve a significant hazards consideration and does not present a genuine issue as to whether the health and safety of the public will be significantly affected.

For further details with respect to this action, see (1) Amendment No. 9 to Materials License No. SNM-2502, and (2) the Commission's letter to the licensee dated October 6, 1993. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the Local Public Document Room at the Oconee County Public Library, 501 W. Southbroad Street, Walhalla, South Carolina 29691.

Exemption

I

Carolina Power and Light Company (CP&L or the licensee) holds materials license (SNM-2502) for receipt and storage of spent fuel from its H.B. Robinson Steam Electric Plant Unit No. 2 at an independent spent fuel storage installation (ISFSI) located on the H.B. Robinson Steam Electric Plant Unit No. 2 site.

Section 72.122(i) of 10 CFR part 72 requires each licensee to provide instrumentation and control systems to monitor systems that are important to safety over anticipated ranges for normal and off-normal operations. Those instruments and control systems that must remain operational under accident conditions must be identified in the Safety Analysis Report.

II

The NRC staff, while reviewing a materials license application for dry concrete module storage of spent fuel from Baltimore Gas and Electric Company's Calvert Cliffs Nuclear Power Plant, concluded, in its November 1992, "Safety Evaluation Report for the Baltimore Gas and Electric Company's Safety Analysis Report for an

Independent Spent Fuel Storage Installation," that " * * * given the passive design and inherent safety, there is no technical reason to require instrumentation and control systems for monitoring the NUHOMS-24P (DSC and HSM) system during storage operations at the Calvert Cliffs ISFSI. Therefore, pursuant to 10 CFR 72.7, the Commission has determined to grant an exemption from the requirements of 10 CFR 72.122(i) with respect to the DSC and HSM for storage operations, and, in support thereof, has further determined that the granting of such exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest." Since there is similarly no technical reason to require instrumentation and control systems for monitoring the NUHOMS-7P DSC and HSM system during storage operations at the H.B. Robinson ISFSI, a comparable exemption is warranted in this docket as well.

The proposed exemption from 10 CFR 72.122(i) will not result in a significant offsite release of radioactive material and will not result in any significant increase in individual or occupational dose. The proposed exemption from 10 CFR 72.122(i) will not involve a significant increase in the probability or consequences of an accident, will not involve a significant decrease in a safety margin, and, therefore, will not involve a significant hazards consideration and does not present a genuine issue as to whether the health and safety of the public will be significantly affected. Accordingly, the NRC staff concludes that the proposed exemption would not be inimical to the common defense and security or to the health and safety of the public.

III

Accordingly, the Commission in accordance with 10 CFR 72.7 has determined that the exemption is authorized by law, will not present undue risk to the public health and safety, and is consistent with the common defense and security.

Accordingly, the Commission hereby grants the licensee an exemption from the requirements of 10 CFR 72.122(i) with respect to the NUHOMS-7P DSC and HSM for storage operations.

Pursuant to 10 CFR 51.22(c)(11), the Commission has determined that the granting of this exemption is identified as an action eligible for categorical exclusion from the requirements of 10 CFR part 51.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 6th day of October 1993.

For the Nuclear Regulatory Commission,
Carl J. Paperiello,

Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93-25207 Filed 10-13-93; 8:45 am]

BILLING CODE 7590-01-P

[Docket No. 72-4 (50-269/270/287)]

Duke Power Co.; Issuance of Exemption and Amendment to Materials License No. SNM-2503

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 3 to Materials License No. SNM-2503 held by the Duke Power Company for the receipt and storage of spent fuel at the Oconee Independent Spent Fuel Storage Installation, located on the Oconee Nuclear Station site, Oconee County, South Carolina. The amendment is effective as of the date of issuance.

The amendment issues the following exemption from the provisions of 10 CFR 72.122(i) with respect to providing instrumentation and control systems to monitor systems that are important to safety over anticipated ranges for normal and off-normal operations for the Duke Power Company's Oconee independent spent fuel storage installation. The Commission, on its own initiative, has determined that, due to the passive design and inherent safety of the NUHOMS-24P cask, no instrumentation and control systems are required for the dry shielded canister and the horizontal storage module (DSC and HSM) system during storage operations.

Pursuant to 10 CFR 72.7, the Commission has determined that the granting of the exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest.

The exemption and amendment comply with the standards and requirements of the Atomic Energy Act of 1954, as amended (the Act), and the Commission's rules and regulations. The Commission has made appropriate findings as required by the Act and the Commission's rules and regulations in 10 CFR chapter I, which are set forth in the exemption and license amendment. Prior public notice of the amendment was not required since the amendment does not involve a significant hazards consideration and does not present a genuine issue as to whether the health and safety of the public will be significantly affected.

For further details with respect to this action, see (1) Amendment No. 3 to Materials License No. SNM-2503, and (2) the Commission's letter to the licensee dated October 6, 1993. All of these items are available for public inspection at the Commission's Public Document Room, the Gelman Building, 2120 L Street, NW., Washington, DC, and at the Local Public Document Room at the Oconee County Public Library, 501 W. Southbroad Street, Walhalla, South Carolina 29691.

Exemption

I

Duke Power Company (DPC or the licensee) holds materials license (SNM-2503) for receipt and storage of spent fuel from its Oconee Nuclear Station at an independent spent fuel storage installation (ISFSI) located on the Oconee Nuclear Station site.

Section 72.122(i) of 10 CFR part 72 requires each licensee to provide instrumentation and control systems to monitor systems that are important to safety over anticipated ranges for normal and off-normal operations. Those instruments and control systems that must remain operational under accident conditions must be identified in the Safety Analysis Report.

II

The NRC staff, while reviewing a materials license application for dry concrete module storage of spent fuel from Baltimore Gas and Electric Company's Calvert Cliffs Nuclear Power Plant, concluded, in its November 1992, "Safety Evaluation Report for the Baltimore Gas and Electric Company's Safety Analysis Report for an Independent Spent Fuel Storage Installation," that " * * * given the passive design and inherent safety, there is no technical reason to require instrumentation and control systems for monitoring the HUHOMS-24P (DSC and HSM) system during storage operations at the Calvert Cliffs ISFSI. Therefore, pursuant to 10 CFR 72.7, the Commission has determined to grant an exemption from the requirements of 10 CFR 72.122(i) with respect to the DSC and HSM for storage operations, and, in support thereof, has further determined that the granting of such exemption is authorized by law and will not endanger life or property or the common defense and security and is otherwise in the public interest." Since there is similarly no technical reason to require instrumentation and control systems for monitoring the NUHOMS-24P DSC and HSM system during storage operations at the Oconee ISFSI, a comparable

exemption is warranted in this docket as well.

The proposed exemption from 10 CFR 72.122(i) will not result in a significant offsite release of radioactive material and will not result in any significant increase in individual or occupational dose. The proposed exemption from 10 CFR 72.122(i) will not involve a significant increase in the probability or consequences of an accident will not involve a significant decrease in a safety margin, and, therefore, will not involve a significant hazards consideration and does not present a genuine issue as to whether the health and safety of the public will be significantly affected. Accordingly, the NRC staff concludes that the proposed exemption would not be inimical to the common defense and security or to the health and safety of the public.

III

Accordingly, the Commission in accordance with 10 CFR 72.7 has determined that the exemption is authorized by law, will not present undue risk to the public health and safety, and is consistent with the common defense and security.

Accordingly, the Commission hereby grants the licensee an exemption from the requirements of 10 CFR 72.122(i) with respect to the NUHOMS-24P DSC and HSM for storage operations.

Pursuant to 10 CFR 51.22(c)(11), the Commission has determined that the granting of this exemption is identified as an action eligible for categorical exclusion from the requirements of 10 CFR part 51.

This exemption is effective upon issuance.

Dated at Rockville, Maryland, this 6th day of October 1993.

For the Nuclear Regulatory Commission,
Carl J. Paperiello,

Director, Division of Industrial and Medical Nuclear Safety, Office of Nuclear Material Safety and Safeguards.

[FR Doc. 93-25206 Filed 10-13-93; 8:45 am]

BILLING CODE 7590-01-P

OFFICE OF THE UNITED STATES TRADE REPRESENTATIVE

Request for Public Comment With Respect to the Annual National Trade Estimate Report on Foreign Trade Barriers

AGENCY: Office of the United States Trade Representative (USTR).

ACTION: Pursuant to Section 303 of the Trade and Tariff Act of 1984, as amended, USTR is required to publish annually the National Trade Estimate

Report on Foreign Trade Barriers (NTE). In this regard, the Trade Policy Staff Committee (TPSC) is calling on interested parties to assist it in identifying significant barriers to U.S. exports of goods, services and overseas direct investment for inclusion in the NTE. Particularly important are impediments materially affecting the actual and potential financial performance of an industry sector.

REQUIREMENTS, DATES AND ADDRESSES:

Submissions should contain descriptions of any or all of the following eight categories of foreign trade barriers: (1) import policies (e.g. tariffs, quantitative restrictions, import licensing, customs barriers); (2) standards, testing, labeling, and certification; (3) discriminatory government procurement practices (e.g. "buy national" policies and closed bidding); (4) export subsidies (e.g. export financing on preferential terms and agricultural export subsidies that displace U.S. exports in third country markets); (5) lack of intellectual property protection (e.g. inadequate patent, copyright, and trademark regimes); (6) services barriers (e.g. constraints on port access and commercial shipping, regulation of international data flows, and restrictions on the use of data processing); (7) investment barriers (e.g. limitations on foreign equity participation, local content and export requirements, and restrictions on repatriation of earnings and capital); and (8) other barriers (e.g. barriers that encompass more than one category listed above or that affect a single sector).

Submissions also should contain estimates of the potential increase in exports that result from the removal of the barrier, as well as a clear discussion of the method(s) by which the estimates were computed. Estimates should fall within the following value ranges: less than \$5 million; \$5 to \$25 million; \$25 to \$50 million; \$50 to \$100 million; \$100 to \$500 million; or over \$500 million.

Interested parties should submit, not later than noon, Friday, November 12, 1993, thirty double-sided copies of comments to the Executive Secretary, Trade Policy Staff Committee, Office of the United States Trade Representative, 600 17th Street NW., room 414, Washington, DC 20506. Please note that interested parties discussing barriers in more than one country should provide a separate submission for each country.

Submissions will be available for public inspection by appointment with the staff of the USTR Public Reading Room, except for information granted

"business confidential" status pursuant to 15 CFR 2003.6. Any business confidential material must be clearly marked as such on the cover page and succeeding pages. Such submissions must be accomplished by a nonconfidential summary thereof.

FOR FURTHER INFORMATION CONTACT:
John Panulas, Assistant Director for Policy Coordination, USTR (202-395-7210).

Frederick L. Montgomery,
Chairman, Trade Policy Staff Committee,
[FR Doc. 93-25335 Filed 10-12-93; 1:50 pm]
BILLING CODE 3190-01-M

SECURITIES AND EXCHANGE COMMISSION

[Release Nos. 33-7021; 34-33022;
International Series Release No. 588]

October 6, 1993.

Exemptions From Rules 10b-6, 10b-7, and 10b-8 During Distributions of Certain German Securities

Pursuant to delegated authority, the Division of Market Regulation issued the following letter granting class exemptions ("Exemptions") from Rules 10b-6, 10b-7, and 10b-8 ("Trading Rules") under the Securities Exchange Act of 1934 to facilitate distributions in the United States of securities of certain highly capitalized German issuers. The Exemptions permit distribution participants and their affiliated purchasers to effect transactions in Germany otherwise prohibited by the Trading Rules, subject to certain disclosure, recordkeeping, record production, and notice requirements.

The Exemptions have been issued in the context of a continuing review of the Trading Rules, and are published to provide notice of their availability.

Margaret H. McFarland,
Deputy Secretary.

October 6, 1993.

Edward F. Greene, Esq.
Cleary, Gottlieb, Steen & Hamilton,
Level 2, City Tower, 40 Basinghall
Street, London EC2V 5DE, United
Kingdom,

Re: Distributions of Certain German Securities File No. TP 93-327

Dear Mr. Greene: In your letter dated September 29, 1993, as supplemented by conversations with the staff, you request on behalf of Deutsche Bank AG ("Deutsche Bank") exemptions from Rules 10b-6, 10b-7, and 10b-8 under the Securities Exchange Act of 1934 ("Exchange Act") with respect to market activities by distribution participants and their affiliated purchasers during

distributions in the United States of equity securities of certain highly capitalized German issuers, as more fully described below.

We understand the facts to be as follows:

Offerings by German Issuers

You indicate that, for purposes of your request, the term "equity securities" includes equity-related securities, such as convertible or exchangeable bonds and warrants. Such equity-related securities may be issued by the issuer of the equity securities itself, or by a subsidiary of such issuer. However, you do not request any relief with respect to offerings of nonconvertible debt.

The structure of an offering of equity securities of a German company varies depending on whether it is a primary or a secondary offering. As a result of the principle of equal treatment of all shareholders contained in the German Stock Corporation Act (para. 53(a), and a provision of that act (para. 186(1)) granting shareholders pre-emptive rights to subscribe pro rata to any capital increase, primary offerings of shares in German companies generally are made by means of offerings of rights to existing shareholders to subscribe for additional shares. Similar provisions apply to the issuance of convertible bonds, participation certificates and other equity-related securities. As described in your letter, pre-emptive rights may be excluded, in whole or in part, only in very limited circumstances. Accordingly, offerings of such securities, whether by the issuer of the underlying security or by a subsidiary of such issuer, generally will be conducted as rights offerings.

Your letter sets forth a timetable of the steps involved in a rights offering by a German issuer. In practice, the lead underwriter normally will have settled all major points (apart from price) with the issuer at least two or three weeks in advance of the decision by the issuer to proceed with a rights offering, and in some cases longer. The lead underwriter also normally will give advice to the issuer with regard to the strategy and execution of the capital increase, in particular with respect to timing and size, and will assist the issuer in obtaining listings of the new shares. Although the lead underwriter thus will know about the general capital raising plans well in advance, this knowledge typically is kept confidential by the underwriter's corporate finance division, subject to confidential consultation with a limited number of senior personnel in the trading and sales

areas, and is not communicated generally to the trading or sales desks.

The new shares are usually offered at a substantial discount (20-30%) from the market price of the outstanding shares at the time the rights offering is priced. A syndicate of underwriters typically agrees (in exchange for underwriters' compensation, the terms of which vary from offering to offering) to subscribe for the shares and in turn to offer them on behalf of the company to all shareholders on a pro rata basis. Any shares not taken up by holders of rights, normally are disposed of by the syndicate in the market pursuant to the directions of the issuer. However, this activity typically is minimal because, owing to the substantial discount at which new shares are offered, most rights are exercised by the then holders of the rights.

In a secondary offering, the underwriting syndicate generally agrees to purchase the shares from the selling shareholder at an agreed offering price less the underwriting commissions. The shares are then distributed by the underwriters at the agreed offering price. Shares that cannot otherwise be disposed of are either sold on the market or held for investment. The offering price is set just prior to the beginning of the offering period, and is based on the then prevailing market conditions.

In certain rights offerings, one or more of the existing substantial shareholders may wish not to take up some or all of their rights, in which event a separate syndicate of underwriters may be organized to purchase from such shareholders and to sell to the public either the rights or the shares such shareholders are entitled to buy through the exercise of those rights ("special secondary offerings"). For shares, the price generally is fixed at the end of the subscription period based on a formula (e.g., the issue price of the shares plus the average market price of the rights during the last five trading days of the subscription period).

Market Activities During Offerings

In Germany, the underwriters of an offering generally will be the major commercial banks, which, in the tradition of universal banking, provide a full range of banking and securities services to clients. The activities of German banks include, in addition to the deposit and credit business, securities activities (such as brokerage, underwriting and custodial services) and investment advisory services, including managing on a discretionary basis the portfolios of bank customers and, through affiliates, managing mutual

funds. Most trading in German securities and derivatives is conducted by banks (or their affiliates) either for their own accounts or for the accounts of their customers.

With limited exceptions and subject to applicable antitrust laws, German banks are free to engage, sometimes indirectly through subsidiaries, in any business, whether of a financial or non-financial nature. It is not uncommon for German banks to have shareholdings in industrial or commercial companies and for officers of German banks to sit on the Supervisory Boards (as discussed below) of industrial companies, whether or not the banks in question are shareholders. German stock corporations have a dual board system: the "Vorstand" (Managing Board), like a U.S. board of directors, is responsible for the overall management of the company; the "Aufsichtsrat" (Supervisory Board) is generally limited to overseeing the Managing Board and appointing its members.

The German banks acting as underwriters typically continue to engage in a wide range of activities during an offering. In particular, the underwriters continue to trade in the ordinary course during the period immediately prior to the announcement of the rights offering and for the period during which rights are traded. German underwriters manage their underwriting risks, and the lead underwriter manages the risks associated with maintaining an orderly market, in two principal ways: by buying rights and selling shares short, and by hedging through the Deutsche Terminbörse ("DTB") (the listed options market) and over-the-counter derivative markets.

The underwriters may be active in trading all kinds of securities of the issuer, or derivative instruments related to such securities, in the cash market (i.e., rights, common shares, preferred shares, participation certificates, bonds with equity warrants, convertible bonds, and straight bonds) and in the options and futures market (i.e., equity options, futures, index options, and index futures). In these markets, the underwriters would both execute orders for customers and trade securities and derivatives for their own account. Other activities involve arbitrage trading between the various national and international exchanges where the securities are listed, index-arbitrage, basket-trading, and buying and selling in order to provide liquidity to the markets.

German banks, themselves and through their affiliates, provide investment advisory services to private and institutional clients both in

Germany and elsewhere. Investment advisory services include portfolio management of individual and institutional clients' segregated accounts and the management of mutual funds. Any investment advisor is required to act in the interests of its clients, pursuant to general provisions of German Law. German mutual fund management companies must be separate legal entities (but generally are owned by banks) and are regulated by the Federal Banking Supervisory Authority. They are required by the Act on Mutual Fund Management Companies to have special banking licenses limited to the conduct of this type of business. Pursuant to that act, and under general legal principles, fund managers are obliged to manage the funds exclusively in the interests of the investors. While the officers of a universal bank generally are not also officers of the management companies owned by such bank, it is not unusual for officers of a bank to be on the Supervisory Board or advisory board of the management companies owned by that bank.

In addition, German banks (including the underwriters) acting as custodians for customers are obliged to furnish information to their customers about any rights offering pursuant to the General Business Conditions applicable to banks. Such information contains all the necessary details of the offer and a request to instruct the custodian how to respond. If customers fail to instruct their custodians by the day prior to the last trading day of the rights offering, the custodians will sell the rights on the last trading day. In their capacity as custodians, German banks do not give advice to their customers on how they should respond to the rights offering; however, the customers may otherwise be in contact with their banks, including banks that may be acting as underwriters, for investment advice.

In addition, German law prohibits German stock corporations and their subsidiaries from purchasing shares in the corporation except in limited circumstances. These circumstances are set forth in the German Stock Corporation Act (para. 71) and include, *inter alia*, purchases necessary to avert serious impending damage to the corporation (in such case, the Managing Board has to report to the shareholders at the next general meeting the reasons for and the purpose of the purchase, the number of and the nominal amount of the shares purchased, the percentage of the share capital purchased, and the consideration for the shares); purchases made for the purpose of offering shares to employees of the corporation or of a

subsidiary (which offer must be made within one year of the purchase); and purchases to indemnify shareholders of affiliates (subject to certain conditions). In all cases, purchases are limited to 10 percent of the share capital of the corporation and are dependent upon a special reserve having been created therefor in the balance sheet. Moreover, the German Stock Corporation Act (para. 56) prohibits a German stock corporation and its subsidiaries from subscribing to shares of the corporation in connection with a capital increase.

The German Securities Market

Equity securities are traded both on the German stock exchanges and in the over-the-counter market. The General Business Conditions applicable to banks provide that, unless the customer otherwise directs, equity orders are to be executed on one of the stock exchanges.

Germany has eight stock exchanges, located in Berlin, Bremen, Düsseldorf, Frankfurt, Hamburg, Hanover, Munich, and Stuttgart (collectively, "German Stock Exchanges"). The Frankfurt Stock Exchange accounts for 70 percent of total turnover. With regard to institutional trading, there is also a screen-based electronic trading system, IBIS (Integrated Stock Exchange Trading and Information System), which is administratively part of the Frankfurt Stock Exchange. Most equity trades are carried out through an exchange, *i.e.*, either on the floor or through IBIS. Exceptions are cross-border trades and transactions involving significant holdings.

Standardized options and futures contracts are traded on the DTB, a fully electronic options exchange operating throughout Germany. On the DTB, market makers are admitted with the obligation to quote firm bid and ask prices in a reasonable number of options contracts. In contrast, German banks are not obliged by German Stock Exchange rules or otherwise to act as market makers in the cash market.

Each German Stock Exchange, as well as the DTB, is subject to the statutory supervision of the government of the Federal State (Land) in which it is located. The DTB is considered located in Frankfurt and is therefore subject to the supervision of the government of the State of Hessen. The Stock Exchange Act provides that a state-appointed "Staatskommissar" be appointed for each stock exchange. Subject to directions given by the State government, the Staatskommissar is responsible for monitoring trading on the exchange and for ensuring compliance with the Stock Exchange Act and the rules and regulations of the

exchange. Each State government also appoints specialists ("Amtlicher Kursmakler") for the securities that trade on the exchange supervised by that government.

For a bank or state-appointed specialist and its personnel to trade on a German Stock Exchange, the permission of the Managing Board of the exchange is required. Permission will be granted only if the applicant is a fit and proper person (this normally involves an examination requirement) to carry on such business.

Floor trading on the German Stock Exchanges takes place on a continuous basis, with round lots representing 50 shares or an integral multiple thereof, during stock exchange hours (between 10:30 a.m. and 1:30 p.m.). Opening and closing prices are determined by the state-appointed specialist by balancing the then available supply and demand. There is an additional fixing by the state-appointed specialist around mid-session for all listed shares. Floor trading of liquid shares between the setting of the opening, mid-session, and closing prices takes place on an auction basis; floor trading in less liquid shares, odd-lots, and rights takes place only at the mid-session fixing.

About 40 shares with liquid markets are also traded through the screen-based, quote-driven IBIS system from 8:30 a.m. to 5:00 p.m. Minimum trading size in IBIS is in general 500 shares. Details of all floor and IBIS trades, including the identities of counterparties and price and volume data, are available to the Staatskommissar. Price and volume data are also reported publicly by the relevant German Stock Exchange (including IBIS).

The state-appointed specialist is not involved in establishing prices on the DTB. An opening price is determined by the DTB as the level at which the most registered buy and sell orders could be carried out at a certain time. After fixing the opening price, continuous trading commences at which buy and sell orders are matched automatically in the computer system. Trading in equity products on the DTB is between 9:30 a.m. and 4:00 p.m.

The Stock Exchange Act (para. 29, subpara. 3) provides that only a price that reflects the actual market situation can be determined as an exchange quoted price. This requirement is subject to the stock exchange supervisory system. Further, the Federal Banking Supervisory Authority in its Requirements for Security Trading at Banks of December 30, 1980 requires, *inter alia*, that trading and settlement be strictly separated and that all securities

and derivative transactions be recorded in writing without delay, and restricts the conclusion of transactions not reflecting market conditions: such transactions are the exception to the rule, and must be reported to senior management if they do not reflect market conditions; each bank's books are subject to audit by the Supervisory Authority.

Request for Exemptions

You note that because transactions outside the United States could affect the prices of rights or shares being distributed in the United States, a question arises as to the potential applicability of Rules 10b-6, 10b-7, and 10b-8 to trading outside the United States of securities that are the subject of the distribution, any securities of the same class and series, or any right to purchase any such securities (collectively, "related securities") by distribution participants and their affiliated purchasers during the distribution. Assuming the existence of a "distribution" in the United States, as defined in paragraph (c)(5) of Rule 10b-6, distribution participants and their affiliated purchasers would be subject to the restrictions of Rule 10b-6 from a period of time prior to the commencement of offers or sales and continuing until the end of the distribution in the United States. You believe that the application of Rules 10b-6, 10b-7, and 10b-8 to the activities of distribution participants and their affiliated purchasers outside the United States during U.S. distributions of securities of certain German issuers could seriously jeopardize the success of any distribution of securities of such issuers.

For example, the application of Rules 10b-6, 10b-7, and 10b-8 would prevent German underwriters from conducting their normal proprietary trading, including arbitrage between securities markets and fulfilling their market making obligations in options listed for trading on the DTB, during distributions in the United States. You note that the underwriters, particularly the lead underwriter, are expected to maintain an orderly market in the security being distributed and related securities by buying and selling as principal, and with respect to options listed for trading on the DTB, are required to trade to fulfill their market making obligations. You advise that, although the underwriters would not engage in formal stabilizing activities, their activities outside the United States to maintain an orderly market in the rights and/or shares may be considered the "placing of any bid, or the effecting of

any purchase, for the purpose of pegging, fixing, or stabilizing the price" of the offered securities. With respect to underwritten rights offerings, the application of Rule 10b-8 would limit the customary risk management activities of German distribution participants with respect to the purchasing of rights and offsetting sales of shares or other hedging transactions in derivative securities, other than in compliance with Rule 10b-8.

Given the high proportion of trading in the securities of German issuers that is conducted by the larger German banks and the likelihood that most (if not all) of such banks would be participants in any such distribution of a "blue-chip" German issuer, you indicate that the market for such securities in Germany could collapse if such German distribution participants were restricted from trading by the application of Rule 10b-6. You state that withdrawal from proprietary trading in such securities also could affect the calculation of the value of Deutscher Aktienindex ("DAX"), a continuously updated, market capitalization-weighted performance index of 30 German "blue-chip" issuers. You note that these consequences are particularly onerous in the context of a rights offering because of the exceptionally long distribution period involved in such offerings.

In your view, the application of Rules 10b-6, 10b-7, and 10b-8 also would restrict normal activities by German distribution participants in their dealing with their customers by restricting the ability of German distribution participants to solicit their customers to purchase the security being distributed and related securities (which in a rights offering would restrict their ability to solicit other customers to purchase rights from shareholders who choose not to exercise their rights) and to offer investment advice to their customers. You advise that the application of these rules also may restrict transactional and advisory activities with respect to discretionary accounts managed by German distribution participants or their affiliated purchasers and investment funds managed by affiliated purchasers of German distribution participants.

Accordingly, you request that the Commission grant exemptions from Rules 10b-6, 10b-7, and 10b-8 to permit distribution participants and their affiliated purchasers to effect transactions in the securities of highly capitalized German issuers during a distribution in the United States of such issuer's securities, pursuant to the

terms, conditions, and limitations set forth in your letter.

Response

On the basis of your representations and the facts presented, the Commission hereby grants exemptions from Rules 10b-6, 10b-7, and 10b-8 to distribution participants, as defined in Rule 10b-6(c)(6)(ii), and their affiliated purchasers, as defined in Rule 10b-6(c)(6)(i) (collectively, "Relevant Parties"), in connection with transactions in Relevant Securities (as defined below) outside the United States during distributions of Qualified German Securities (as defined below) subject to the following terms, conditions, and limitations:

I. Securities

A. The security being distributed ("Qualified German Security") must:

1. Be issued by (i) a "foreign private issuer" within the meaning of Rule 3b-4 under the Exchange Act incorporated under the laws of Germany, which issuer ("German Issuer") has outstanding a component security of the DAX;¹ or (ii) a subsidiary of a German Issuer; and

2. Satisfy one of the following:

- Be a DAX component security; or
- Be an equity security of a German Issuer having an average daily trading volume that equals or exceeds the equivalent of DM8 million (which exceeded US\$5 million as of September 10, 1993), as published by foreign financial regulatory authorities ("FFRAs")² and any U.S. securities

¹ References to the DAX refer to the composition of the index on the date of this letter; *provided, however*, that any security added to the DAX after the date of this letter also will be treated as a Qualified German Security if its issuer satisfies the requirements in paragraph I.A.1. and such security has an aggregate market value that equals or exceeds the equivalent of DM1.6 billion (which exceeded US\$1 billion as of September 10, 1993) and an average daily trading volume that equals or exceeds the equivalent of DM8 million (which exceeded US\$5 million as of September 10, 1993) as published by "foreign financial regulatory authorities" (as defined below) and any U.S. securities exchanges or automated inter-dealer quotation systems, during a period ("Reference Period") that is 20 consecutive business days in Frankfurt within 60 consecutive calendar days prior to the commencement of the Covered Period as defined in paragraph III.A. below.

² An FFRA is defined in Section 3(a)(51) of the Exchange Act, 5 U.S.C. 78(c)(51), as any (A) foreign securities authority; (B) other governmental body or foreign equivalent of a self-regulatory organization empowered by a foreign government to administer or enforce its laws relating to the regulation of fiduciaries, trusts, commercial lending, insurance, trading in contracts of sale of a commodity for future delivery, or other instruments traded on or subject to the rules of a contract market, board of trade, or foreign equivalent, or other financial activities; or (C) membership organization a function of which is to regulate participation of its

exchanges or automated inter-dealer quotation systems during the Reference Period; or

iii. Be a security that is convertible into, exchangeable for, or a right to acquire a security of a German Issuer described in paragraph I.A.2. (i) or (ii) above.

B. "Relevant Security" means:

- A Qualified German Security; or
- A security of the same class and series as, or a right to purchase, a Qualified German Security.

II. Transactions Effected in the United States

All transactions in Relevant Securities effected in the United States shall comply with Rules 10b-6, 10b-7, and 10b-8.

III. Transactions Effected in Germany

A. All transactions during the Covered Period (as defined below) in Relevant Securities effected in Germany shall be conducted in compliance with German law. For purposes of these exemptions, "Covered Period" means: (i) in the case of a rights distribution, the period commencing when the subscription price is determined and continuing until the completion of the distribution in the United States, and (ii) in the case of any other distribution, the period commencing three business days in Frankfurt before the price is determined and continuing until the completion of the distribution in the United States; *provided, however*, that the Covered Period shall not commence with respect to any Relevant Party until such person becomes a distribution participant.

B. All transactions in Relevant Securities during the Covered Period effected in Germany on a principal basis shall be effected or reported on the trading facilities of a German Stock Exchange (including IBIS), or the DTB.

C. Disclosure of Trading Activities³

1. The inside front cover page of the offering materials used in the offer and sale in the United States of a Qualified German Security shall prominently display a statement in substantially the following form, subject to appropriate modification where circumstances require. Such statement shall be in capital letters, printed in bold-face roman type at least as large as ten-point modern type and at least two points leaded:

members in activities listed above. The German Stock Exchanges, which include IBIS, are considered to be FFRAs.

³ Unless subsequently modified by the Commission, this disclosure requirement shall not apply to distributions effected solely pursuant to Rule 144A under the Securities Act of 1933 ("Securities Act").

In connection with this offering, certain persons may engage in transactions for their own accounts or for the accounts of others in (identify relevant securities) pursuant to exemptions from rules 10b-6, 10b-7, and 10b-8 under the Securities Exchange Act of 1934. See "[Identify Section of Offering Materials That Describes the Transactions to be Effected]."

2. In addition, there shall be included in the identified section of the offering materials a comprehensive description of the activities that may be undertaken by the Relevant Parties in the Relevant Securities during the distribution. ⁴

D. Recordkeeping and Reporting.

1. Each Relevant Party shall provide to an Independent Entity acceptable to the Director, Division of Market Regulation ("Independent Entity"),⁵ the information described in paragraph III.D.2. below with respect to its transactions in Relevant Securities in Germany; *provided, however*, that in the case of a distribution made pursuant to rights, such information is only required to be reported to the Independent Entity during the period or periods commencing at any time during the Covered Period that the rights exercise price does not represent a discount of at least 10 percent from the then current market price of the security underlying the rights and continuing until (a) the end of the Covered Period or (b) until the rights exercise price represents a discount of at least 12 percent from the then current market price of the security underlying the rights. ⁶

2. When required pursuant to paragraph III.D.1. above, the Relevant Parties will provide the following information to the Independent Entity, in a Comma Delimited ASCII (American Standard Code for Information Interchange) format including a common record layout acceptable to the Independent Entity and the Division, with respect to transactions during the Covered Period in Relevant Securities:

a. Name of the security, date, time (of execution and reporting, where available to the Relevant Party), price, and volume of each transaction;

⁴ The staff of the Division of Market Regulation ("Division") and the Division of Corporation Finance have reviewed Exhibit A attached to your request letter and believe that the disclosure contained therein would satisfy the requirement of this subparagraph.

⁵ The Division expects that the Independent Entity will be the Frankfurt Stock Exchange ("FSE"). Alternatively if the FSE is not available to act as the Independent Entity, the Independent Entity may be the independent accountant of the lead German underwriter; however, for each distribution there can be only one Independent Entity to which transaction information is reported.

⁶ For purposes of this exemption, unless stated otherwise, the market price for a security shall be the closing price on the floor of the FSE.

provided, however, that no information regarding a customer transaction need be provided unless such transaction has a value of DM500,000 or more;

b. The exchange or inter-dealer quotation system on which the transaction was effected, if any;

c. An indication whether such transaction was for a proprietary account or the account of a customer, *provided that* any transaction effected by an underwriter for a customer account for which it has exercised discretionary authority shall be reported as a proprietary trade; and

d. The identity of a counterparty only where such counterparty is an underwriter or a selling group member.

3. The Independent Entity and the Relevant Parties shall keep all documents produced or prepared pursuant to paragraph III.D.2. for a period of not less than two years.

4. Upon the request of the Division, the Independent Entity shall transmit the information provided by the Relevant Parties pursuant to paragraph III.D.2. above to the Division within 30 days of the request.

5. If the information required to be produced in paragraph III.D.2. above is not available from the Independent Entity, upon the request of the Division such information shall be provided by the Relevant Party and be made available to the Division at its office in Washington, D.C.

6. Representatives of a Relevant Party will be made available (in person at the office of the Division or by telephone) to respond to inquiries of the Division relating to its records.

IV. Transactions Effected in Significant Markets

A. All transactions in Relevant Securities in a "Significant Market," as defined below, shall be effected in accordance with the requirements of Rules 10b-6, 10b-7, and 10b-8, except as permitted by paragraph IV.B. below or by other available exemptions. For purposes of these exemptions, "Significant Market" means: (i) SEAQ International or any other dealer market outside the United States and Germany for which price and volume information is published by an FFRA or (ii) any other securities market(s) in a single country other than the United States or Germany to which a German Issuer has applied for listing the German Qualified Security and been accepted, if during the Reference Period the volume in either (i) or (ii) in such Qualified German Security, as published by the relevant FFRA(s) in such securities market is 10 percent or more of the aggregate worldwide trading volume in

that security published by all FFRAs in (i) and (ii), FFRAs in Germany, and U.S. securities markets to which such German Issuer has applied for listing such Qualified German Security and been accepted.

B. In the case of a distribution of Qualified German Securities made pursuant to rights ("rights distribution"), the Relevant Parties located in the United Kingdom ("U.K. Relevant Parties"): (a) in connection with the rights distribution, may purchase or solicit the purchase of Relevant Securities in transactions solely in response to orders for the accounts of their customers in the ordinary course of their business in the United Kingdom ("customer facilitation activities"); and (b) may bid for or purchase Relevant Securities as principal in market making transactions through SEAQ International during the rights distribution, in each case subject to the following conditions:

1. During the period from five business days prior to the expiration date of the rights distribution and until the expiration date, inclusive, at any time at which the difference between the rights exercise price and the market price of the security underlying the rights (which for this purpose will be taken to mean the mid-price between the highest bid and lowest offer quoted on SEAQ International during the rights distribution) does not represent a discount of at least 10 percent from the then current market price of the security underlying the rights, the U.K. Relevant Parties will effect "passive market making" transactions in the Relevant Securities subject to the terms and conditions of *Letter regarding Distributions of SEAQ and SEAQ International Securities* (July 12, 1993) ("LSE Letter");

2. The U.K. Relevant Parties, in accordance with Item 502(d)(1) of Regulation S-K under the Securities Act, shall include a statement regarding transactions which stabilize or maintain the market price of the Relevant Securities with appropriate modification, to reflect the possibility that the U.K. Relevant Parties may engage in market making, including passive market making, and customer facilitation activities that otherwise would be prohibited by Rule 10b-6, and shall include pursuant to Rule 408 under the Securities Act in the "Plan of Distribution" or similar section of the prospectus, a brief description of such proposed market making and customer facilitation activities in the Relevant Securities; and

3. The recordkeeping and production requirements set forth by the

Commission in the LSE Letter shall apply to all of the activities engaged in by the U.K. Relevant Parties during the rights distribution.

V General Conditions

A. For purposes of these exemptions, a two business day cooling-off period shall apply under Rule 10b-6(a)(4) (xi) and (xii) in the United States and each Significant Market, provided that trading in Relevant Securities in Significant Markets shall be subject to the exemptive relief then available in such market, if any, or the record maintenance and record production requirements contained in *Letter regarding Application of Cooling-Off Periods Under Rule 10b-6 to Distributions of Foreign Securities* (March 4, 1993) (or any modifications thereto) are satisfied by Relevant Parties in such Significant Market, except that with respect to the identity of customers, Relevant Parties may agree to use their best efforts to provide the Commission, upon its request, with the identity of customers to the extent permitted by applicable law.

B. The lead underwriter or the global coordinator shall promptly, but in any event before the commencement of the Covered Period, provide a written notice ("Notice") to the Division containing the following information: (i) the name of the issuer and the Qualified German Security; (ii) whether the Qualified German Security is a DAX component security or information with respect to the market capitalization and the average daily trading volume of the Qualified German Security to be distributed; (iii) the identity of the Significant Markets where the Qualified German Security trades; (iv) if the Notice is for more than one entity, the identity of all underwriters and selling group members relying on these exemptions; and (v) a statement that the Relevant Parties are aware of the terms and conditions of these exemptions.

C. Any person who fails to comply with the conditions of the exemptions, including a failure to provide requested information, would not be permitted to rely on the exemptions in future distributions. Upon a showing of good cause, however, the Commission or the Division may determine that it is not necessary under the circumstances that the exemptions be denied.

The foregoing exemptions from Rules 10b-6, 10b-7, and 10b-8 are based solely on your representations and the

facts presented, and are strictly limited to the application of those rules to the proposed transactions. Any different facts or representations might require a different response. Responsibility for compliance with any other applicable provisions of the federal securities laws must rest with the Relevant Parties. The Division expresses no view with respect to any other questions that the proposed transactions may raise, including, but not limited to, the adequacy of disclosure concerning, and the applicability of any other federal or state laws to, the proposed transactions.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority,

Brandon Becker

Director

Clearly, Gottlieb, Steen & Hamilton,
Level 2, City Tower, 40 Basinghall
Street, London EC2V 5DE.

1934 Act—Section 10(b)
Rules 10b-6, 10b-7 and 10b-8
September 29, 1993

Securities and Exchange Commission,
450 Fifth Street NW., Judiciary Plaza,
Washington, DC 20549

Attention: Division of Market
Regulation—Office of Trading
Practices

Re: Exemptions From Rules 10b-6, 10b-7 and 10b-8 for Rights Offerings and Secondary Offerings of Certain German Companies

Ladies and Gentlemen: We are acting as counsel to Deutsche Bank AG ("Deutsche Bank") in connection with possible offerings of equity securities of certain German companies involving a distribution of some or all of the securities in the United States.¹ The offerings may be either primary or secondary offerings, and the securities being distributed in the United States may be offered publicly or on a private basis (under Rule 144A or otherwise).² On behalf of Deutsche Bank, we hereby submit the following application to the Securities and Exchange Commission (the "Commission") for exemptions from Rules 10b-6, 10b-7 and 10b-8 under the Securities Exchange Act of 1934 (the "Exchange Act") to the extent

¹ The term equity securities shall include equity-related securities, such as convertible or exchangeable bonds and warrants. Such equity-related securities may be issued by the issuer of the equity securities itself, or by a subsidiary of such issuer. Offerings of straight debt securities are outside the scope of this letter.

² In the case of private placements and primary offerings made through rights, it is assumed for purposes of this application, and only for such purposes, that the marketing efforts in the United States would constitute a "distribution" for purposes of Rule 10b-6. See note 15 below.

and for the reasons set forth in Part III below.

I. Offerings by German Companies

The structure of an offering of equity securities in a German company varies depending on whether it is a primary or a secondary offering.

A. Primary Offerings.

As a result of the principle of equal treatment of all shareholders enshrined in German corporate law,³ and pursuant to a statutory provision granting shareholders pre-emptive rights to subscribe pro rata to any capital increase,⁴ primary offerings of shares in German companies are generally made by means of offerings of rights to existing shareholders to subscribe for additional shares.⁵ The new shares are usually offered at a substantial discount (20-30%) from the market price of the outstanding shares at the time the issue is priced.

In a rights offering, a syndicate of underwriters typically agrees (in exchange for underwriters' compensation the terms of which vary from offering to offering) to subscribe for the shares and in turn to offer them on behalf of the company to all shareholders on a pro rata basis. The following table sets forth the minimum timing of the various steps involved in a rights offering:

Trading Day and Step

X—acceptance by the issuer of the offer by the underwriters/subscription by the underwriters, including, normally, payment of 25% of the par value of the shares

³ See para. 53(a) of the German Stock Corporation Act.

⁴ See para. 186(1) of the German Stock Corporation Act. Similar provisions apply to the issue of convertible bonds, participation certificates and other equity-related securities. Accordingly, offerings of such securities, whether by the issuer of the underlying equity security or by a subsidiary of such issuer, will generally be conducted as rights offerings.

⁵ Pre-emptive rights may be excluded, in whole or in part, only through the shareholders' resolution approving the capital increase, which must be adopted with a 75% majority of the capital stock represented at the shareholders' meeting. Moreover, the Managing Board of the company (see note 9 below) must report in writing to the shareholders' meeting on the reasons for the exclusion of pre-emptive rights. See para. 186(4)(2) of the German Stock Corporation Act. Furthermore, decisions of the shareholders' meeting excluding pre-emptive rights may be challenged in the German courts by any shareholder whose objection was recorded at the meeting. See para. 245 of the German Stock Corporation Act. Finally, pursuant to German court decisions, an issuer may exclude pre-emptive rights in only limited circumstances, such as (subject to certain requirements) a new listing on a foreign stock exchange, an offer to employees or a reorganization. For these reasons, among others, it is rare for German companies to raise capital otherwise than through rights offerings.

⁷ Supplemental Notices shall be provided for underwriters and selling group members identified after a Notice has been filed.

- X+3—entry of the capital increase into the Commercial Register
 X+7—pricing—*i.e.*, determination of the subscription price
 X+8—approval of the listing on the German stock exchanges
 X+9—publication of the rights offering
 X+13—first day of subscription period for existing shareholders/trading in the rights commences
 X+20—trading in the rights ends
 X+22—last day of subscription period for holders of rights/settlement, including, normally, payment of the remaining 75% of the par value of the shares plus premium.
 X+24—listing on the German stock exchanges/trading in the new shares commences.

In practice, the lead underwriter will normally have settled all major points (apart from price) with the issuer at least two or three weeks in advance of the decision by the issuer to proceed with a rights offering, and in some cases longer.⁶

Any shares not taken up by holders of rights are normally disposed of by the syndicate in the market pursuant to the directions of the issuer.⁷

B. Secondary Offerings.

In a secondary offering, the underwriting syndicate generally agrees to purchase the shares from the selling shareholder at an agreed offering price less the underwriting commissions. The shares are then distributed by the underwriters at the agreed offering price. Shares that cannot otherwise be disposed of are either sold on the market or held for investment. The offering price is set just prior to the beginning of the offering period, and is based on the then prevailing market conditions.

C. Special Secondary Offerings.

In certain rights offerings, one or more of the existing substantial shareholders may wish not to take up some or all of their rights, in which event a separate syndicate of underwriters may be organized to purchase from such shareholders and to sell to the public

⁶ The lead underwriter also will normally give advice to the issuer with regard to the strategy and execution of the capital increase, in particular with respect to timing and size, and will assist the issuer in obtaining listings of the new shares. Although the lead underwriter thus will normally know of the general capital raising plans well in advance, this knowledge is typically kept confidential by the underwriter's corporate finance division, subject to confidential consultation with a limited number of senior personnel in the trading and sales areas, and is not communicated generally to the trading or sales desks.

⁷ It should, however, be noted that this is normally of minimal significance because, due to the substantial discount at which new shares are offered, most rights are exercised by the then holders of the rights.

either the rights or the shares such shareholders are entitled to buy through the exercise of those rights. For shares, the price is generally fixed at the end of the subscription period based on a formula (*e.g.*, the issue price of the shares plus the average market price of the rights during the last five Trading Days of the subscription period).

D. Market Activities of Underwriters during Offerings.

In Germany, the banks are the underwriters of securities. In contrast to the United States, the vast majority of German banks are universal banks (the distinction between commercial and investment banking being historically largely unknown) providing a full range of banking and securities services under one roof. The activities of banks include, in addition to the deposit and credit business, securities activities (such as brokerage, underwriting and custodial services) and investment advisory services—including managing on a discretionary basis the portfolios of bank customers and, through affiliates, managing mutual funds.⁸ Most trading in German securities and derivatives is conducted by banks (or their affiliates) either for their own accounts or for the accounts of their customers.

With limited exceptions and subject to applicable antitrust laws, German banks are free to engage, sometimes indirectly through subsidiaries, in any business, whether of a financial or non-financial nature. It is not uncommon for German banks to have shareholdings in industrial or commercial companies and for officers of German banks to sit on the Supervisory Boards⁹ of industrial

⁸ German banks, themselves and through their affiliates, provide investment advisory services to private and institutional clients both in Germany and elsewhere. Investment advisory services include portfolio management of individual and institutional clients' segregated accounts and the management of mutual funds. Any investment advisor is required, pursuant to general provisions of German Law, to act in the interests of its clients. See paras. 662 ff. and 675 of the German Civil Code and paras. 383 ff. of the German Commercial Code; see also para. 8(2) of the Annex to the Provisions for Securities Deposit Audits of the Federal Banking Supervisory Authority of December 1970. German mutual fund management companies must be separate legal entities (but are generally owned by banks) and are regulated by the Federal Banking Supervisory Authority. They are required by the Act on Mutual Fund Management Companies to have special banking licenses limited to the conduct of this type of business. Pursuant to para. 10 of that act, and under general legal principles, fund managers are obliged to manage the funds exclusively in the interests of the investors. While the officers of a universal bank are generally not also officers of the management companies owned by such bank, it is not unusual for officers of a bank to be on the Supervisory Board (see note 9 below) or Advisory Board of the management companies owned by that bank.

⁹ German stock corporations have a dual board system: the Vorstand (Managing Board), like a U.S.

company, whether or not the banks in question are shareholders.

The German banks acting as underwriters typically continue to engage in a wide range of trading activities during an offering. In particular, the underwriters continue to trade in the ordinary course during the period immediately prior to the announcement of the rights offering and for the period during which rights are traded. Accordingly, the underwriters may be active in trading all kinds of securities of the issuer, or derivative instruments related to such securities, both in the cash market (*i.e.*, rights, common shares, preferred shares, participation certificates, bonds with equity warrants, convertible bonds and straight bonds) and in the options and futures market (*i.e.*, equity options, futures, index options and index futures). In these markets, the underwriters would both execute orders for customers¹⁰ and trade securities and derivatives in the ordinary course for their own accounts. Other activities involve proprietary arbitrage trading between the various national and international exchanges where the securities are listed, index-arbitrage and basket-trading. In addition, the underwriters continue to make investment decisions for the accounts they manage, and their mutual fund management company affiliates continue to make investment decisions on behalf of the mutual funds they manage.

In the cash market, German banks are not obliged by stock exchange rules or otherwise to act as "market-makers."¹¹ Nonetheless, the issuer and the market expect the underwriters to maintain an

Board of Directors, is responsible for the overall management of the company; the Aufsichtsrat (Supervisory Board) is generally limited to overseeing the Managing Board and appointing its members.

¹⁰ In addition, German banks (including the underwriters) acting as custodians for customers are obliged pursuant to their General Business Conditions (No. 39) to furnish information to their customers about any rights offering. Such information contains all the necessary details of the offer and a request to instruct the custodian how to respond. If customers fail to instruct their custodians by the day prior to the last Trading Day of the rights offering, the custodians will sell the rights on the last Trading Day. In their capacities as custodians, German banks do not give advice to their customers on how they should respond to the rights offering; this is not to say, however, that the customers are not otherwise in contact with their banks, including banks that may be acting as underwriters, for investment advice (see note 8 above).

¹¹ This is in contrast to the listed options market on the Deutsche Terminbörse (the "DTB"), a fully electronic options exchange operating throughout Germany, where market-makers are admitted with the obligation to quote firm bid and ask prices in a reasonable number of option contracts.

orderly market during the rights offering period, both in rights and in shares. Accordingly, the lead underwriter in particular both buys and sells rights and shares as principal for its own account and on behalf of its customers to provide liquidity to the market and to create a stable market environment during the offering.

German underwriters manage their underwriting risks, and the lead underwriter manages the risks associated with maintaining an orderly market, in two principal ways: by buying rights and selling shares short, and by hedging through the DTB and over-the-counter derivative markets.

II. The German Market

Equity securities are traded both on the German stock exchanges and in the over-the-counter market. The General Business Conditions (No. 29) applicable to banks provide that, unless the customer otherwise directs, equity orders are to be executed on one of the stock exchanges.

Germany has eight stock exchanges, located in Berlin, Bremen, Düsseldorf, Frankfurt, Hamburg, Hanover, Munich and Stuttgart (collectively, the "German Stock Exchanges"). The Frankfurt Stock Exchange accounts for 70% of total turnover. With regard to institutional trading, there is also a screen-based electronic trading system, IBIS, which is administratively part of the Frankfurt Stock Exchange. Most equity trades are carried out through an exchange—i.e., either on the floor or through IBIS. Exceptions are cross-border trades and transactions involving significant holdings. Standardized options and futures contracts are traded on the DTB.

Each German Stock Exchange, as well as the DTB, is subject to the statutory supervision of the government of the Federal State (*Land*) in which it is located. The DTB is considered located in Frankfurt and is therefore subject to the supervision of the government of the State of Hessen. The Stock Exchange Act provides that a state-appointed "Staatskommissar" be appointed for each stock exchange. Subject to directions given by the State government, the *Staatskommissar* is responsible for monitoring trading on the exchange and for ensuring compliance with the Stock Exchange Act and the rules and regulations of the exchange. Each State government also appoints specialists (*Amtlicher Kursmakler*) for the securities that trade on the exchange supervised by that government.

For a bank or state-appointed specialist and its personnel to trade on a German Stock Exchange, the

permission of the Managing Board of the exchange is required. Permission will be granted only if the applicant is a fit and proper person (this normally involves an examination requirement) to carry on such business.

Floor trading on the German Stock Exchanges takes place on a continuous basis, with round lots representing 50 shares or an integral multiple thereof, during stock exchange hours (between 10:30 a.m. and 1:30 p.m.). Opening and closing prices are determined by the state-appointed specialist by balancing the then available supply and demand. There is an additional fixing by the state-appointed specialist around mid-session for all listed shares. Floor trading of liquid shares between the setting of the opening, mid-session and closing prices takes place on an auction basis; floor trading in less liquid shares, odd lots and rights takes place only at the mid-session fixing.

About 40 shares with liquid markets are also traded through the screen-based, quote-driven IBIS system from 8:30 a.m. to 5:00 p.m. Minimum trading size in IBIS is in general 500 shares.

Details of all floor and IBIS trades, including the identities of the counterparties and price and volume data, are available to the *Staatskommissar*. Price and volume data are also reported publicly by the relevant German Stock Exchange (including IBIS).

The state-appointed specialist is not involved in establishing prices on the DTB. An opening price is determined by the DTB as the level at which the most registered buy and sell orders could be carried out at a certain time. After fixing the opening price, continuous trading commences at which buy and sell orders are matched automatically in the computer system. Trading in equity products on the DTB is between 9:30 a.m. and 4:00 p.m.

Legislation and rules and regulations concerning the securities markets in Germany contain a variety of provisions relating to market manipulation. In particular, para. 29, subpara. 3 of the Stock Exchange Act provides that only a price which reflects the actual market situation can be determined as an exchange quoted price. This procedure is subject to the stock exchange supervisory system. Further, the Federal Banking Supervisory Authority in its Requirements for Security Trading at Banks of December 30, 1980 requires, *inter alia*, that trading and settlement be strictly separated and that all securities and derivative transactions be recorded in writing without delay, and restricts the conclusion of transactions not reflecting market conditions: such

transactions have to be the exception to the rule, and have to be reported to senior management if they do not reflect market conditions; each bank's books are subject to audit by the Supervisory Authority.

In addition, German law prohibits German stock corporations and their subsidiaries from purchasing shares in the corporation except in limited circumstances. These circumstances are set forth in para. 71 of the German Stock Corporation Act and include, *inter alia*, purchases necessary to avert serious impending damage to the corporation,¹² purchases made for the purpose of offering shares to employees of the corporation or of a subsidiary (which offer must be made within one year of the purchase) and purchases to indemnify shareholders of affiliates (subject to certain conditions). In these cases, purchases are limited to 10% of the share capital of the corporation and are dependent upon a special reserve having been created therefor in the balance sheet. Moreover, para. 56 of the German Stock Corporation Act prohibits a German stock corporation and its subsidiaries from subscribing to shares of the corporation in connection with a capital increase.

III. Proposed Exemption From Rules 10b-6, 10b-7 and 10b-8

Because trading outside the United States could affect the prices of rights and/or shares being offered in the United States, a question arises as to the potential applicability of Rules 10b-6, 10b-7 and 10b-8 under the Exchange Act to trading outside the United States of Affected Securities¹³ by distribution participants (as defined in Rule 10b-6(c)(6)(ii)) and their affiliates during the offering. Assuming the existence of a jurisdictional predicate for the application of Rules 10b-6, 10b-7 and 10b-8, we hereby apply for exemptions from the provisions of such rules pursuant to Rules 10b-6(i), 10b-7(o) and 10b-8(f), to the extent and for the reasons set forth below.¹⁴

Assuming the existence of a U.S. "distribution" for purposes of Rule 10b-

¹² In this case, the Managing Board has to report to the shareholders at the next general meeting the reasons for and the purpose of the purchase, the number of and the nominal amount of the shares purchased, the percentage of the share capital purchased and the consideration for the shares.

¹³ As used in this letter, the term "Affected Securities" means the securities that are the subject of the distribution, any securities of the same class and series and any right to purchase any such securities.

¹⁴ Seeking or taking advantage of any such exemptions does not involve a concession by Deutsche Bank or any other person that Rules 10b-6, 10b-7 or 10b-8 apply to activities outside the United States.

6,¹⁵ distribution participants and their affiliates would be subject to the restrictions of Rule 10b-6 from some time before the pricing¹⁶ until the end of the distribution in the United States. Rule 10b-6 generally makes it unlawful, in connection with a distribution of securities, for any person engaged in such distribution to "bid for or purchase for any account in which he has a beneficial interest, any security which is the subject of such distribution, or any security of the same class and series, or any right to purchase any such security, or to attempt to induce any person to purchase any security or right * * *."

Distribution participants and their affiliates will not engage in conventional U.S.-style stabilization in connection with a rights offering, secondary offering or special secondary offering of the kind described above. In the absence of such activities, the restrictions contained in Rule 10b-7 may be inapplicable. Nevertheless, to the extent that the activities of distribution participants or their affiliates outside the United States in furtherance of efforts to maintain an orderly market in rights and/or shares may be deemed to constitute the "placing of any bid, or the effecting of any purchase, for the purpose of pegging, fixing or stabilizing the price," and assuming that the requisite jurisdictional predicate exists, the restrictions contained in Rule 10b-7 may be deemed to apply.

Finally, the restrictions contained in Rule 10b-8 may be deemed to apply to the conduct of the underwriters' risk-management activities outside the United States.

A. Reasons for Relief.

The application of Rules 10b-6, 10b-7 and 10b-8 to the activities of distribution participants and their affiliates outside the United States could seriously jeopardize the success of any rights offering, secondary offering or

special secondary offering. In particular, the application of Rules 10b-6, 10b-7 and 10b-8 outside the United States would have, *inter alia*, the following consequences:

1. Distribution participants, including the underwriters and in particular the lead underwriter, would be unable to maintain an orderly market by buying and selling Affected Securities as principals during the offering. Moreover, distribution participants would be precluded from fulfilling their formal market-making obligations on the DTB with respect to listed options that are Affected Securities. Finally, and what is perhaps most important, the market in Germany for the shares of the company in question could simply collapse (with corresponding effects on the Deutscher Aktienindex (the "DAX"))¹⁷ as a consequence of the application of Rules 10b-6, 10b-7 and 10b-8, given the high proportion of trading in the shares of German companies that is conducted by the larger German banks, and the likelihood that most (if not all) of such banks would act as distribution participants in an offering by a blue-chip German company.

2. Distribution participants would be restricted in their dealings with customers, who may wish to trade rights, shares or other Affected Securities during the offering. For example, the underwriters could be prohibited from encouraging customers to purchase rights that existing shareholders did not wish to exercise, from encouraging customers to purchase outstanding shares, and from buying rights or shares to facilitate such purchases. Moreover, the underwriters might not be able to continue certain of their regular contacts with customers, such as discussions regarding investment strategies with respect to the rights and shares, and might not be permitted to buy and sell Affected Securities, as either principal or agent, in connection with their customers' trading activities.

3. Distribution participants' risk management activities would be restricted to those permitted by Rule 10b-8. This would place limits on their ability to buy rights and sell shares short, and they would be precluded by Rule 10b-6 from hedging in derivatives or other Affected Securities.

4. Distribution participants' customary proprietary trading activities, involving arbitrage and other trading strategies, would be curtailed.

5. Accounts managed by distribution participants and their affiliates on a discretionary basis, investment funds for which affiliates of underwriters act as investment advisors (see note 8 above) and other entities (e.g., industrial companies) that may be viewed under U.S. law as affiliates of a distribution participant could be considered "affiliated purchasers" under Rule 10b-6(c)(6)(i). Such affiliated purchasers would be subject to the same restrictions under Rule 10b-6 as the relevant distribution participant and thus would not be permitted to bid for or purchase any Affected Security.

These consequences are particularly harsh in the context of a rights offering, with its exceptionally long distribution period. They are, however, also problematic in the context of a secondary offering or special secondary offering, even if directed solely to the United States, because any halt in share trading in Germany could jeopardize the functioning of the market.

B. Scope and Conditions of Exemption.

We propose that the Commission grant exemptions to the effect that Rules 10b-6, 10b-7 and 10b-8 shall not apply to distribution participants and their affiliated purchasers in connection with transactions in Relevant Securities (as defined below) outside the United States during distributions in the United States of Qualified German Securities (as defined below), subject to the following terms, conditions and limitations:

1. Securities.

a. The security being distributed (a "Qualified German Security") must:

- Be issued by (aa) a "foreign private issuer" within the meaning of Rule 3b-4 under the Exchange Act incorporated under the laws of Germany, which issuer (a "German Issuer") has outstanding a component security of the DAX¹⁸ or (bb) a subsidiary of a German Issuer; and

¹⁸ References to the DAX refer to the composition of the index on the date of this letter; provided, however, that any security added to the DAX after the date of this letter also will be treated as a Qualified German Security if its issuer satisfies the requirements in 1.a.i. and such security has an aggregate market value that equals or exceeds the equivalent of DM 1.6 billion (which exceeded U.S. \$1 billion at September 10, 1993) and an average daily trading volume that equals or exceeds the equivalent of DM 8.0 million (which exceeded U.S. \$5 million at September 10, 1993) as published by FFRA (as defined in note 19 below) and any U.S. securities exchanges or automated inter-dealer quotation systems during a period (the "Reference Period") that is 20 consecutive business days in

¹⁵ We note that many U.S. private placements (under Rule 144A or otherwise) will not be distributions. Moreover, a number of registered rights offerings also may not be distributions; as the Commission stated in its release regarding cross-border rights offerings, "[i]t is likely that many of the rights offerings using proposed Rule 801 on Form F-11 will not be 'distributions' as defined in Rule 10b-6, and the persons participating in such offerings will not be affected by the rule * * *." See Cross-Border Rights Offers; Amendments to Form F-3, Securities Act Release Nos. 33-6896; 34-29274, 48 SEC Docket 1617, 1631 (June 5, 1991).

¹⁶ Under current Commission interpretations, neither the two-day nor the nine-day "cooling-off period" could be available in Germany, because German bank-secrecy laws prohibit the disclosure by banks of the identities of their customers. See Exemption Regarding Application of Cooling-Off Periods Under Rule 10b-6 to Distributions of Foreign Securities, Exchange Act Release No. 34-31943, 53 SEC Docket 1583 (March 4, 1993).

¹⁷ The DAX is a continuously updated, market-capitalization-weighted performance index of 30 German blue-chip companies; the shares included in the DAX are selected on the basis of their trading volume and their market capitalization. Adjustments are made to the DAX for capital changes, subscription rights and dividends.

ii. Satisfy one of the following:

(aa) Be a DAX component security; or
 (bb) Be an equity security of a German Issuer having an average daily trading volume that equals or exceeds the equivalent of DM 8.0 million (which exceeded U.S. \$5 million at September 10, 1993), as published by foreign financial regulatory authorities ("FFRAs")¹⁹ and any U.S. securities exchanges or automated inter-dealer quotation systems during the Reference Period; or

(cc) Be a security that is convertible into, exchangeable for, or is a right to acquire a security of a German Issuer described in subparagraph ii.(aa) or (bb) above.

b. "Relevant Security" means:

i. A Qualified German Security; or
 ii. A security of the same class and series as, or a right to purchase, a Qualified German Security.

2. Transactions Effected in the United States.

All transactions in Relevant Securities effected in the United States shall comply with Rules 10b-6, 10b-7 and 10b-8.

3. Transactions Effected in Germany.

a. All transactions during the Covered Period (as defined below) in Relevant Securities effected in Germany shall be conducted in compliance with German law. For purposes of this exemption, "Covered Period" means (i) in the case of a rights offering, the period commencing when the subscription price is determined and continuing until the completion of the distribution in the United States, and (ii) in the case of any other offering, the period commencing three business days in Frankfurt before the price is determined and continuing until the completion of the distribution in the United States; *provided, however*, that the Covered Period shall not commence with respect to any Relevant Party until such person becomes a distribution participant.

b. All transactions in Relevant Securities during the Covered Period

Frankfurt within 60 consecutive calendar days prior to the commencement of the Covered Period (as defined in 3.a. below).

¹⁹ An FFRA is defined in Section 3(a)(51) of the Exchange Act, 5 U.S.C. 78(c)(51), as any (A) foreign securities authority; (B) other governmental body or foreign equivalent of a self-regulatory organization empowered by a foreign government to administer or enforce its laws relating to the regulation of fiduciaries, trusts, commercial lending, insurance, trading in contracts of sale of a commodity for future delivery, or other instruments traded on or subject to the rules of a contract market, board of trade, or foreign equivalent, or other financial activities, or (C) membership organization a function of which is to regulate participation of its members in activities listed above. For purposes of this letter, the German Stock Exchanges (including IBIS) are considered to be FFRAs.

effected in Germany on a principal basis shall be effected or reported on the trading facilities of a German Stock Exchange (including IBIS) or the DTB.

c. Disclosure of Trading Activities²⁰

i. The inside front cover page of the offering materials used in the offer and sale in the United States of a Qualified German Security shall prominently display a statement in substantially the following form, subject to appropriate modification where circumstances require. Such statement shall be in capital letters, printed in bold-face roman type at least as large as ten-point modern type and at least two points leaded:

In connection with this offering, certain persons may engage in transactions for their own accounts or for the Accounts of Others in (Identify Relevant Securities) pursuant to exemptions from rules 10b-6, 10b-7 and 10b-8 under the Securities Exchange Act of 1934. See "[Identify Section of Offering Materials That Describes the Transactions To Be Effected]."

ii. In addition, there shall be included in the identified section of the offering materials a description of the activities that may be undertaken by the underwriters (and their affiliates) in the Relevant Securities during the distribution in substantially the form of Exhibit A.

d. Recordkeeping and Reporting.

i. Each Relevant Party shall provide to the Frankfurt Stock Exchange or the independent accountant of the lead underwriter (the "Independent Entity"), but only one of them in connection with any offering, the information described in paragraph 3.d.ii. below with respect to its transactions in Relevant Securities in Germany; *provided, however*, that in the case of a distribution made pursuant to a rights offering, such information is only required to be reported to the Independent Entity during the period or periods (aa) commencing at any time during the Covered Period that the rights exercise price does not represent a discount of at least 10% from the then current market price of the security underlying the rights and (bb) continuing (x) until the end of the Covered Period or (y) until the rights exercise price represents a discount of at least 12 percent from the then current market price of the security underlying the rights.²¹

²⁰ Unless subsequently modified by the Commission, this disclosure requirement shall not apply to distributions effected solely pursuant to Rule 144A under the Securities Act of 1933 (the "Securities Act").

²¹ For purposes of this exemption, unless stated otherwise the market price for a security shall be the closing price on the floor of the Frankfurt Stock Exchange.

ii. When required pursuant to paragraph 3.d.i. above, the Relevant Parties will provide the following information to the Independent Entity, in a Comma Delimited ASCII (American Standard Code for Information Interchange) format including a common record layout acceptable to the Independent Entity and the Commission's Division of Market Regulation (the "Division"), with respect to transactions during the Covered Period in Relevant Securities:

(aa) name of the security, date, time (of execution or reporting, where available to the Relevant Party), price and volume of each transaction; *provided, however*, that no information regarding a customer transaction need be provided unless such transaction has a value of DM 500,000 or more.

(bb) the exchange or inter-dealer quotation system on which the transaction was effected, if any;

(cc) an indication whether such transaction was for a proprietary account or the account of a customer, *provided, however*, that any transaction effected by an underwriter for a customer account for which it has exercised discretionary authority shall be reported as a proprietary trade; and
 (dd) the identity of the counterparty only where the counterparty is an underwriter or a selling group member.²²

iii. The Independent Entity and the Relevant Parties shall keep all documents produced or prepared pursuant to paragraph 3.d.ii. for a period of not less than two years.

iv. Upon the request of the Division, the Independent Entity shall transmit the information provided by the Relevant Parties pursuant to paragraph 3.d.ii. above to the Division within 30 days of the request.

v. If the information required to be produced in paragraph 3.d.ii. above is not available from the Independent Entity, upon the request of the Division such information shall be provided by the Relevant Party and be made available to the Division at its office in Washington, D.C.

vi. Representatives of the affected Relevant Party will be made available (in person at the office of the Division in Washington, D.C., or by telephone) to respond to inquiries of the Division relating to the records provided by such Relevant Party.

4. Transactions Effected in Significant Markets.

²² The underwriting papers for the offering will contain provisions whereby each underwriter and selling group member gives any consent that may be required for the release of its identity to the Independent Entity and the Division.

a. All transactions in Relevant Securities in a "Significant Market," as defined below, shall be effected in accordance with the requirements of Rules 10b-6, 10b-7 and 10b-8, except as permitted by paragraph 4.b. below or by other available exemptions. A "Significant Market" shall mean (i) (aa) SEAQ International or (bb) any other dealer market outside Germany and the United States for which price and volume information is published by an FFRA or (ii) any other securities markets in a single country other than Germany or the United States to which a German Issuer has applied for listing the relevant Qualified German Security described in 1.a.ii.aa. or bb above and been accepted, if the volume in either (i) (aa) or (bb) or (ii) in such relevant Qualified German Security, as published by SEAQ International, such other dealer market or such other relevant securities markets (as the case may be), is 10% or more of the aggregate worldwide trading volume in that security published by SEAQ International all such other dealer markets and all other securities markets to which such German Issuer has applied for listing such relevant Qualified German Security and been accepted, during the Reference Period.

b. In the case of a distribution of Qualified German Securities made pursuant to rights (a "rights offering"), the Relevant Parties located in the United Kingdom ("U.K. Relevant Parties"): (a) in connection with the rights offering, may purchase or solicit the purchase of Relevant Securities in transactions solely in response to orders for the accounts of their customers in the ordinary course of their business in the United Kingdom ("customer facilitation activities"); and (b) may bid for or purchase Relevant Securities as principal in market making transactions through SEAQ International during the rights offering, in each case subject to the following conditions:

i. During the period from five business days prior to the expiration date of the rights offering and until the expiration date, inclusive, at any time at which the difference between the rights exercise price and the market price of the security underlying the rights (which for this purpose will be taken to mean the mid-price between the highest bid and lowest offer quoted on SEAQ International for the security underlying the rights) does not represent a discount of at least 10 percent from the then current market price of the security underlying the rights, the U.K. Relevant Parties will effect "passive market making" transactions in the Relevant Securities subject to the terms and

conditions of Letter regarding Distributions of SEAQ and SEAQ International Securities (July 12, 1993) (the "LSE Letter");

ii. The U.K. Relevant Parties, in accordance with Item 502(d)(1) of Regulation S-K under the Securities Act, shall include a statement regarding transactions which stabilize or maintain the market price of the Relevant Securities with appropriate modification, to reflect the possibility that the U.K. Relevant Parties may engage in market making, including passive market making, and customer facilitation activities that otherwise would be prohibited by Rule 10b-6, and shall include pursuant to Rule 408 under the Securities Act in the "Plan of Distribution" or similar section of the prospectus, a brief description of such proposed market making and customer facilitation activities in the Relevant Securities; and

iii. The recordkeeping and production requirements set forth by the Commission in the LSE Letter shall apply to all of the activities engaged in by the U.K. Relevant Parties during the rights offering.

5. General Conditions.

a. For purposes of this exemption, a two business day cooling-off period shall apply under Rule 10b-6(a)(4) (xi) and (xii) in the United States and in each Significant Market, provided that trading in Relevant Securities in any Significant Market shall be subject to the exemptive relief then available in such markets, if any, or the record maintenance and record production requirements contained in Exemption Regarding Application of Cooling-Off Periods Under Rule 10b-6 to Distributions of Foreign Securities, Exchange Act Release No. 34-31943, 53 SEC Docket 1583 (March 4, 1993) are satisfied by Relevant Parties in such Significant Market (subject to applicable bank secrecy laws).

b. The lead underwriter or the global coordinator shall promptly, but in any event before the commencement of the Covered Period, provide a written notice ("Notice") to the Division of the following information: (i) the name of the issuer and the Qualified German Security; (ii) whether the Qualified German Security is a DAX component security or information with respect to the market capitalization and the average daily trading volume of the Qualified German Securities to be distributed; (iii) the identity of the Significant Markets where the Qualified German Security trades; (iv) if the Notice is for more than one entity, the identity of all underwriters and selling group members relying on these

exemptions;²³ and (v) a statement that the Relevant Parties are aware of the terms and conditions of these exemptions.

c. Any person who fails to comply with the conditions of the exemption, including a failure to provide requested information, would not be permitted to rely on the exemption in future distributions. Upon a showing of good cause, however, the Commission or the Division may determine that it is not necessary under the circumstances that the exemption be denied.

* * * * *

We believe this proposed exemption would make it possible to maintain liquidity for shares of German companies throughout a public offering or private placement in the United States, while minimizing the risk of abuses of the kind at which Rules 10b-6, 10b-7 and 10b-8 are aimed.

Please do not hesitate to call me at 011-44-71-638-5291, or my colleague Daniel A. Braverman at 212-225-2182, if we may be of any assistance in connection with this application.

Very truly yours,

Edward F. Greene.

cc: Brandon Becker, Esq., Director, Division of Market Regulation, Securities and Exchange Commission

Michael D. Mann, Esq., Director, Office of International Affairs, Securities and Exchange Commission

Linda C. Quinn, Esq., Director, Division of Corporation Finance, Securities and Exchange Commission

Dr. Jur. Klaus Köhler, Deputy General Counsel and Senior Vice President, Deutsche Bank AG

Exhibit A

The German Underwriters (and their affiliates) will, and the other Underwriters (and their affiliates) may, continue to engage in the transactions and other activities described below, in Germany and elsewhere outside the United States, in respect of the securities being distributed, securities of the same class and series as the securities being distributed, and securities convertible into, exchangeable for, or giving a right to acquire, the foregoing securities, and derivatives thereof (collectively, the "Relevant Securities"), during the distribution period, in accordance with exemptions obtained from the Securities and Exchange Commission (the "Commission") from the application outside the United States of Rules 10b-6, 10b-7 and 10b-8 under the U.S.

²³ Supplemental notices shall be provided for underwriters and selling group members identified after a notice has been filed.

Securities Exchange Act of 1934. Such exemptions are subject to certain exceptions, limitations and conditions set out in the Commission's exemptive order, including compliance with German law.

The activities referred to above are (a) buying and selling Relevant Securities for the accounts of such Underwriters (or their affiliates), whether for purposes of risk management in connection with the offering, arbitrage or otherwise, (b) buying and selling Relevant Securities on behalf of customers, (c) advising customers as to the purchase or sale of Relevant Securities, including publication of specific company and industry research reports, (d) engaging in securities lending transactions in Relevant Securities and (e) stabilizing the market (as described below). As a result of these activities, the Underwriters may at any time be short or long Relevant Securities.

It is general market practice in Germany for the Underwriters, and the lead Underwriter in particular, to maintain an orderly market in subscription rights and existing shares, and it is expected that the lead Underwriter will take measures to avoid extreme price fluctuations during the distribution period. *[Add in the case of rights offerings:* In addition, the lead Underwriter will endeavor to ensure, through the entry of buy or sell orders on the various German stock exchanges, that the same price for the subscription rights is set on each day on all German stock exchanges. In general, the price for subscription rights is set by each German stock exchange at mid-session, and trading in the rights on such exchange takes place at that price.]

The activities referred to above may result in the market prices of the Relevant Securities being different from those that might otherwise have prevailed in the open market if Rules 10b-6, 10b-7 and 10b-8 had applied in Germany and elsewhere outside the United States.

[FR Doc. 93-25091 Filed 10-13-93; 8:45 am]

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[Release No. 34-33011; File Nos. SR-OCC-92-05, SR-NSCC-91-07, SR-SCCP-92-01, and SR-MCC-92-02]

Self-Regulatory Organization; The Options Clearing Corp., National Securities Clearing Corp., Stock Clearing Corp. of Philadelphia, and Midwest Clearing Corp.; Filing of Proposed Rule Changes Relating to Revised Options Exercise Settlement Agreements

October 4, 1993.

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"),¹ notice is hereby given that The Options Clearing Corporation ("OCC") on January 27, 1992, the National Securities Clearing Corporation ("NSCC") on October 21, 1991, the Stock Clearing Corporation of Philadelphia ("SCCP") on February 27, 1992, and the Midwest Clearing Corporation ("MCC") on March 5, 1992, filed with the Securities and Exchange Commission the proposed rule changes as described in Items I, II, and III below, which Items have been prepared primarily by the self-regulatory organizations. Notices of the proposed rule changes were published previously.² Since that time, the self-regulatory organizations have amended their original filings.³ The Commission is publishing this notice to solicit comments on the proposed rule changes from interested persons.

I. Self-Regulatory Organizations' Statement of the Terms of Substance of the Proposed Rule Changes

The proposed rule changes will permit OCC, NSCC, SCCC, and MCC to put into effect amended and restated agreements providing for the settlement of exercises and assignments of equity options. In addition, OCC's proposed rule change will make related changes to OCC's By-Laws, Rules, and certain form agreements used by OCC's clearing members.

¹ 15 U.S.C. 78s(b)(1) (1988).

² Securities Exchange Act Release Nos. 30488 (March 17, 1992), 57 FR 10201 [File No. SR-OCC-92-05]; 30489 (March 17, 1992), 57 FR 10197 [File No. SR-NSCC-91-07]; 30490 (March 17, 1992), 57 FR 10205 [File No. SR-SCCP-92-01]; 30491 (March 17, 1992) 57 FR 10197 [File No. SR-MCC-92-02].

³ OCC filed Amendment No. 1 to File No. SR-OCC-92-05 with the Commission on February 27, 1992, and Amendment No. 2 on June 4, 1993. SCCC filed Amendment No. 1 to File No. SR-SCCP-92-01 with the Commission on May 26, 1992, and Amendment No. 2 on July 1, 1993. MCC filed Amendment No. 1 to file No. SR-MCC-92-02 with the Commission on January 7, 1993, and Amendment No. 2 on July 6, 1993. NSCC filed Amendment No. 1 to File No. SR-NSCC-91-07 on May 19, 1993.

II. Self-Regulatory Organizations' Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

In its filing with the Commission, the self-regulatory organizations included statements concerning the purpose of and basis for the proposed rule changes. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organizations have prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organizations' Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Changes

1. Background

The purpose of the proposed rule changes is to revise the Options Exercise Settlement Agreements between OCC and NSCC, SCCC, and MCC (hereinafter collectively referred to as the "correspondent clearing corporations" or "CCC's"). In its filing OCC also proposes to revise its procedures for effecting settlement of exercises and assignments of equity options through the CCCs, to make related changes to its By-Laws and Rules, and to implement revised forms for use by its clearing members in establishing the arrangements by which they effect settlements of exercises and assignments of equity options through the facilities of the CCCs.

In the original filings, OCC, NSCC, SCCC, and MCC proposed to make effective Amended and Restated Options Exercise Settlement Agreements (hereinafter collectively referred to as the "First Restated Agreements"). OCC, NSCC, SCCC and MCC have amended the First Restated Agreements (hereinafter collectively referred to as the "Second Restated Agreements") and are proposing to make the three Second Restated Agreements, which are the subjects of these amended rule filings, effective in place of the three First Restated Agreements.⁴ The Second Restated Agreements will replace the options exercise settlement agreements that are currently in effect between OCC and each CCC (hereinafter sometimes collectively referred to as the "Original

⁴ Each Second Restated Agreement provides that it will become effective on the later of the effective date set forth in the Second Restated Agreement or the date of approval by the Commission of both parties' proposed rule changes that include the Second Restated Agreement as an Exhibit. Each Second Restated Agreement provides that it shall become effective in lieu of the respective First Restated Agreement.

Agreements"). The MCC and SCCP Second Restated Agreements are substantially identical in form. The NSCC Second Restated Agreement is substantially in the same form with variations reflecting that NSCC will provide OCC with a daily report identifying all securities which are eligible for settlement through NSCC's continuous net settlement ("CNS") system.

2. The Original Agreements and the Changes Made by the Second Restated Agreements

(a) *Operation and continuing use of broker-to-broker settlement procedures.* Prior to implementing the Original Agreements, exercises of equity options were settled broker-to-broker. In broker-to-broker settlement, upon receipt of an equity option exercise notice, OCC would issue a delivery advice to the delivering clearing member (i.e., the assigned clearing member in the case of a call or the exercising clearing member in the case of a put) and to the receiving clearing member (i.e., the exercising clearing member in the case of a call or the assigned clearing member in the case of a put). The delivery advice would instruct the delivering clearing member to make delivery of the security underlying the exercised option directly to the receiving clearing member and would specify the address at which delivery was to be made and the exercise settlement amount to be paid. OCC continues to have rules governing broker-to-broker settlement.⁵ However, broker-to-broker settlement has been largely replaced by settlement through the facilities of the CCCs. Under the Second Restated Agreements, OCC will use broker-to-broker settlement only for exercises and assignments of equity options overlying securities which are not eligible for settlement in NSCC's continuous net settlement system ("CNS Securities").⁶

⁵ OCC Rules 901-912.

⁶ "CNS Securities" are defined only in the terms of NSCC's CNS System and not in terms of the securities that are eligible for each individual CCC's continuous net settlement system. The definition is new in the Second Restated Agreements as is the exclusion of non-CNS Securities. Both of these changes are made necessary by changes to OCC's margin system which changes were designed to improve the margin system's ability to evaluate and neutralize OCC's risk during the five business day period between the exercise and settlement of an equity option. (OCC's margin system as it is related to these filings is discussed in detail below in the section on OCC rule 601.) Because all securities underlying equity options issued by OCC are ordinarily CNS Securities, all exercise settlements will continue to be settled through the CCCs. However, in unusual circumstances in which an underlying security ceases to be a CNS Security or in which the owners of an underlying security become entitled to an additional security as a result

(b) *Operations of the original options exercise settlement agreements.* After OCC entered into the Original Agreements with the CCCs, OCC began to settle the great majority of equity option exercises through the facilities of the CCCs.⁷ Each clearing member was required to designate a CCC as its designated clearing corporation ("DCC") for purposes of effecting settlements of exercises of equity options. Rather than delivering an underlying security broker-to-broker, in the revised system a delivering clearing member delivers the security to and receives payment of the exercise settlement amount from its DCC. A receiving clearing member makes payment to and receives the security from its DCC. If the delivering clearing member and the receiving clearing member have designated the same CCC as their DCCs, all deliveries and receipts of securities and all payments and receipts of settlement monies will take place at that DCC in accordance with its settlement procedures. If the delivering clearing member and receiving clearing member have designated different CCCs as their respective DCCs, the DCC for the delivering clearing member delivers the security to and receives payment from the DCC for the receiving clearing member in accordance with the interface arrangements between the two DCCs.

The Original Agreements provide for a five-day settlement period for settlement of exercises of equity options. The date of the exercise and the settlement period are analogous to the trade date ("T") and settlement period for ordinary, regular-way stock trades effected on a stock exchange. OCC reports the exercises and assignments of clearing members to their respective DCCs during the night of T. The DCCs effect settlement on the fifth business day after T ("T+5").

(c) *Changes made by the second restated agreements.* The Second Restated Agreements alter and supplement the provisions of the Original Agreements in several ways. The most important modifications are set forth below.

(i) *Timing of the effectiveness of the guarantees of the correspondent*

of a rights offering or other extraordinary transaction and that additional security is not a CNS Security, exercise settlement may be effected entirely or partly through OCC's broker-to-broker settlement system. A new Interpretation .02 to Rule 913 reflects that ordinarily only CNS Securities will be delivered in settlement of stock options through the facilities of the CCCs.

⁷ OCC first executed Options Exercise Settlement Agreements with each of Stock Clearing Corporation (NSCC's predecessor), SCCP, and MCC in 1976.

clearing corporations. Section 4 of each Original Agreement provides that if the CCC does not notify OCC prior to 12 Noon Central Time (1 p.m. Eastern Time) on T+4 that the CCC has ceased to act for an OCC clearing member which had designated the CCC as its DCC, the CCC is unconditionally obligated as of that time to complete the settlement of the exercise. These provisions were in accordance with the provisions of the rules of the CCCs as in effect in 1976. However, each CCC has subsequently amended its rules to provide that the CCC will be unconditionally obligated to complete settlement of any "locked-in" trade⁸ in any security eligible for settlement through the CCC's continuous net settlement system. The CCC's guarantees commence at midnight, or in the case of MCC at 11:59 p.m., of the day the trade is reported to its participants, which is usually T+1.

Section 4(a) of each Second Restated Agreement provides that the CCC will become unconditionally obligated to effect settlement or to close out each exercise and assignment of equity options overlying CNS Securities commencing at the time specified by the CCC's rules applicable to locked-in trades in securities eligible for settlement through the CCC's continuous net settlement system. This revised provision has the effect of causing options exercises and assignments reported by OCC to the CCCs during the night of T to become guaranteed as of the time at which the CCCs generally become obligated to effect settlement (i.e., usually midnight at the end of T+1).⁹ OCC Rule 913 is amended to state expressly that OCC's direct guarantee to the clearing member acting on behalf of the holder of the option terminates at the time that the clearing member's DCC becomes unconditionally obligated to effect settlement of the transaction.¹⁰

⁸ Locked-in trades are trades executed through automated order routing and trade execution systems. Each of the Second Restated Agreements provides that exercises and assignments of options reported by OCC to the CCC will be deemed to be locked-in trades.

⁹ The trade guarantee rules of the CCCs described in the text have been approved by the Commission on a temporary basis. Securities Exchange Act Release No. 32547 (June 29, 1993), 58 FR 26491, [File Nos. SR-NSCC-93-04, SR-SCCP-93-02, SR-MCC-93-02] (order granting approval until June 30, 1994). If the Commission should in the future decline to approve these rules, OCC and the CCCs will need to revisit the question of the point in time at which the CCCs guarantee options exercise settlements, and OCC will need to revisit its procedures for settling stock option exercises and, in particular, make adjustments to its margin system.

¹⁰ Section 4(a) of each First Restated Agreement permitted the CCC to eliminate an exercise

(ii) *Guarantee by OCC to each Correspondent Clearing Corporation.* Each Second Restated Agreement provides that OCC will compensate the CCC for losses incurred by it in closing out the exercises and assignments of a defaulting participating member. The amount of the compensation will be the smallest of the "net options loss," the "net overall loss," or the "maximum guarantee amount." The net options loss is essentially the actual net loss incurred by the CCC in closing out exercises and assignments of options to which the CCC is unconditionally obligated at the time of the default. The net overall loss is essentially the actual net loss incurred by the CCC in closing out all transactions of the defaulting participating member to which the CCC is unconditionally obligated at the time of the default. The maximum guarantee amount is essentially the sum of the mark-to-market amounts,¹¹ positive and negative, for all options exercises and assignments to which the CCC is

transaction from its system in accordance with its rules even after its guarantee had attached to the transaction. Although this could have occurred only in the extremely unlikely event that a security were to cease to be eligible for settlement through the continuous net settlement system of the CCC during the time remaining until actual settlement of the transaction, OCC has concluded that it cannot efficiently develop a margin system that reflects and neutralizes OCC's risk exposure if a CCC's guarantee can be revoked after attaching to an exercise transaction. Accordingly, each Second Restated Agreement provides that the CCC will not eliminate any exercise transaction of options overlying CNS Securities from its system after its guarantee attaches.

Section 4(b) of each First Restated Agreement provided that in the event of a default by a participating member for which it is the DCC, the CCC could voluntarily determine to complete settlement of transactions with respect to which it had not yet become obligated at the time of the default. (In general, a participating member is an entity that is an OCC clearing member and is a member of the CCC that it has designated as its DCC. The definition is discussed further below in subsection 2(c)(iii).) OCC has concluded that it cannot efficiently develop a margin system that reflects and neutralizes OCC's risk exposure if the CCCs have the right to make this voluntary determination. Accordingly, each Second Restated Agreement expressly provides that the CCC will not effect settlement of transactions which have been reported to it but to which it has not yet become obligated at the time of a default of a participating member.

¹¹ The term mark-to-market amount is defined to mean the difference between the exercise price of an option and the closing price of the underlying stock on the trading day immediately preceding the then most recently completed regular morning settlement of the participating member with OCC.

For example, if a participating member defaults prior to the opening of business on T+4 and if the participating member has not made regular morning settlement with OCC on T+4 but had made regular morning settlement with OCC on T+3, the mark-to-market amount for the stock underlying the option will be determined as of the close of trading on T+2.

unconditionally obligated at the time of the default.¹²

OCC's guarantee in each Second Restated Agreement does not cover the exposure of the CCC to losses from exercise and assignment settlements that can result if a participating member transfers settlements from its account at the CCC to the account of any other member of the CCC, including another participating member or another member that is an affiliate of the participating member, and the transferee member defaults on its obligations to the CCC with respect to those settlements. This occurs for several reasons. First, OCC will not be a party to the transfer and accordingly will not have the ability to review the impact of the transfer on the financial condition of the transferee member. Second, the three prongs of the computation of OCC's guarantee obligation are all premised on the assumption that the negative values arising from short positions of a participating member may be offset against the positive values arising from the long positions of the participating member. This assumption may not hold true if, for example, a participating member transfers its short positions but not its offsetting long positions to the account of another member and that member fails to make settlement.

(iii) *Permissible arrangements for effecting settlement through a Correspondent Clearing Corporation.* Each Original Agreement contemplated that settlements of exercises and assignments would be effected by participating members (*i.e.*, entities that are OCC clearing members and also participants in the relevant CCC). The Original Agreement between OCC and NSCC was amended in 1987 to include Canadian clearing members.¹³ Each Second Restated Agreement retains the basic participating member settlement concept and contains expanded provisions addressing situations particular to the Canadian clearing member settlement concept.

In addition, each Second Restated Agreement contains provisions addressing the alternative settlement arrangement that is currently described

¹² The effect of the maximum guarantee amount prong is to cap OCC's exposure at an amount that should be covered by the margin deposits collected by OCC and that should at least be equal to the net of the in-the-money amounts for all exercises and assignments being settled through a CCC as of the close of trading on the day or days on which the exercises were effected.

¹³ Canadian clearing members are clearing members that are organized in Canada and that settle exercises and assignments of equity options through the facilities of the Canadian Depository for Securities ("CDS").

in OCC's rules in which a clearing member appoints another clearing member to effect settlement on its behalf at the appointed clearing member's DCC. Each Second Restated Agreement also contains provisions addressing a new alternative settlement arrangement under which an OCC clearing member nominates an entity that is not an OCC clearing member but that is a participant in a CCC to effect settlement on its behalf.

3. Revised Agreements for Appointing Clearing Members and Appointed Clearing Members

In connection with implementing the Second Restated Agreements, OCC is revising the form of agreement that OCC requires from each clearing member that appoints another clearing member to act for it for purposes of settling exercises and assignments of equity options. The most important purpose of the revisions is to cause the appointing clearing member to acknowledge expressly that its obligations to OCC with respect to settlements of exercises and assignments are not satisfied until its appointed clearing member has satisfied its obligations to its DCC arising from those exercises and assignments and, accordingly, that the uses that OCC may make of the appointing clearing member's margin deposits and other assets include the satisfaction of any obligation to the DCC incurred by OCC as a result of the DCC's settlement of the appointing clearing member's exercises and assignments.

4. New Agreement for Canadian Clearing Members That Settle Through CDS

In connection with implementing the Second Restated Agreements, OCC also will require each Canadian clearing member that settles through CDS to execute a new agreement. The primary purpose of the new agreement is to cause each such clearing member to acknowledge expressly that the obligations of the Canadian clearing member to OCC with respect to settlement of exercises and assignments are not satisfied until CDS has satisfied its obligations arising from those exercises and assignments to the DCC of the clearing member, and, accordingly, that the uses that OCC may make of the Canadian clearing member's margin deposits and other assets include the satisfaction of any obligation to the DCC incurred by OCC as a result of the DCC's settlement of the Canadian clearing member's exercises and assignments through CDS. The agreement also causes the Canadian clearing member to acknowledge that it will be deemed not

to have designated a DCC for purposes of OCC's rules if CDS at any time should cease to be a participant in good standing of a CCC. The new agreement is designed to make it as parallel as possible in form and content to the appointing clearing member agreement and the nominating clearing member agreement.¹⁴

5. New Agreement for Nominating Clearing Members and Nominated Correspondents

The new agreement to be used by a nominating clearing member that appoints a nominated correspondent parallels the existing agreement that is used by an appointing clearing member that appoints an appointed clearing member but differs in two respects to accommodate the differences in the nominated correspondent settlement arrangement. First, the new agreement requires the nominating clearing member to not only appoint its nominated correspondent but also to designate the CCC through which its settlements are to be made.¹⁵ Second, the new agreement requires that the DCC of the nominating clearing member acknowledge the appointment of the nominated correspondent. This additional acknowledgement is appropriate because OCC will report exercises and assignments of each nominating clearing member to the DCC of the nominating clearing member using the OCC clearing member number of the nominating clearing member.¹⁶ Therefore, OCC needs to be assured by the DCC that the DCC is aware of the appointment of the nominated correspondent and is prepared to recognize that settlements reported to it under the OCC clearing member number of the nominating clearing member are to be processed for the account of the nominated correspondent.

The need to accommodate the nominating clearing member alternative

¹⁴ NSCC is the only CCC of which CDS is currently a participant. Accordingly, Canadian clearing members that wish to settle through CDS will be required to select NSCC as their DCC. However, provisions relating to Canadian clearing members that settle through CDS also are included in the MCC Second Restated Agreement and the SCCP Second Restated Agreement in order to preserve the similarity of the three Second Restated Agreements as far as possible and in order to accommodate the possibility that MCC or SCCP may enter into a relationship with CDS at some time in the future.

¹⁵ In contrast, an appointing clearing member is not required to designate a DCC because settlement is effected through the DCC of the appointed clearing member.

¹⁶ In contrast, OCC reports exercises and assignments of each appointing clearing member to the DCC of the appointed clearing member using the OCC clearing member number of the appointed clearing member.

settlement arrangement came to OCC's attention as a result of a review of the records of OCC and NSCC relating to settlements of options exercises and assignments. In the course of that review, it was determined that NSCC's procedures permitted an NSCC participant that is not an OCC clearing member but that is affiliated with two OCC clearing members, neither of which is an NSCC participant, to effect settlement of options exercises and assignments on behalf of the two OCC clearing members. After considering the arrangement, OCC has determined that it does not create any unusual risk for OCC or for the system for settling options exercises and assignments. OCC also has determined that such an arrangement will not involve any additional risk to OCC or to the system even if the entities involved are not affiliated. Accordingly, OCC has concluded that such arrangements should be expressly described in and permitted by its By-Laws and Rules.

Structurally, the nominated correspondent settlement arrangement is more similar to the CDS settlement arrangement than to the appointed clearing member settlement arrangement. As in the CDS arrangement, the nominating clearing member (the counterpart to the Canadian clearing member in the CDS settlement arrangement) must designate a CCC as its designated clearing corporation, but the nominating clearing member does not have to be a participant in good standing of the CCC that it designates. As in the CDS arrangement, the nominated correspondent (the counterpart to CDS in the CDS settling arrangement) must be a participant in good standing of the CCC designated by the nominating clearing member. In addition, as in the CDS arrangement, the nominating clearing member is deemed to be the delivering or receiving clearing member, as the case may be, for purposes of Rule 913, and accordingly, it is the recipient of delivery advices made available by OCC.¹⁷

In the nominated correspondent settlement arrangement, OCC will collect margin throughout the settlement period from the nominating clearing member. In the event that a nominated correspondent were to default on its obligations to the CCC designated by the nominating clearing member, OCC will use the margin

¹⁷ In contrast, Rule 913(f) provides that the appointed clearing member is deemed to be the delivering or receiving clearing member, as the case may be, and accordingly, the appointed clearing member is the recipient of delivery advices made available by OCC.

deposits and other assets of the nominating clearing member to satisfy any resulting obligation to the CCC incurred by OCC in accordance with the applicable Second Restated Agreement.

6. Changes in OCC's By-Laws and Rules

In connection with implementing the Second Restated Agreements, OCC is making various changes, many of which are technical in nature, to its By-Laws and Rules. The substantive changes consist of the following.

Paragraphs 1(a) and 5(a) of Article VIII of the By-Laws are amended primarily to make clear that OCC may apply the clearing fund deposit of a clearing member to satisfy any obligation incurred by OCC to a CCC as a result of the failure of the clearing member, its appointed clearing member, its nominated correspondent, or CDS in the case of a Canadian clearing member to perform an obligation to the CCC arising from exercise and assignment settlements. Amendments are also made to make clear that the order in which clearing fund deposits will be applied is the same as in other circumstances in which OCC is forced to draw on the clearing fund.

Rule 212 is amended to state expressly that any Canadian clearing member that settles through CDS does not need to be a participant in a CCC. Rule 212 is also amended to accommodate the nominated correspondent settlement concept.

Rule 305(b) is amended to state expressly that OCC's Chairman and President have the same authority to impose restrictions with respect to a clearing member's activities as an appointed clearing member as those officials have with respect to a clearing member's other activities. A new Interpretation .10 is added to Rule 305 to state expressly that the difficulty of a clearing member, its appointed clearing member, its nominated correspondent, or CDS in meeting its obligations to the DCC as designated by the clearing member or its appointing clearing member will be grounds for OCC's Chairman or President to impose restrictions pursuant to the rule.

Rule 601, which sets forth OCC's margin requirements for equity options, is being amended to provide that for margin purposes equity options will be treated as being in one of two product groups. One product group, the DCC-guaranteed product group, will consist of all exercised equity options for which the DCC's have guaranteed to deliver and receive the underlying CNS Securities in settlement of the exercise

and assignments.¹⁸ The other product group, the non-DCC-guaranteed product group, will include all other equity options (i.e., all open positions, all exercised and assigned options that overlie CNS Securities where delivery and receipt of the CNS Securities has not yet been guaranteed by the DCCs, and all exercised and assigned options that overlie non-CNS Securities. The non-DCC-guaranteed product group also will include all stock loan and borrow positions.

Rule 601 also is being amended to state that any margin requirement for the non-DCC-guaranteed product group in firm accounts and in market-makers' and specialists' accounts will not be reduced by the value of any margin credit arising from the DCC-guaranteed product group. The purpose of this change is to assure that OCC gives no margin credit for value which will be controlled by a CCC and which OCC might be unable to recover in the event that it suspends a clearing member. Rule 601 does continue to permit OCC to use any margin credit arising from a clearing member's non-DCC-guaranteed options positions in firm accounts and market-makers' and specialists' accounts to reduce the clearing member's margin requirement arising from the DCC-guaranteed product group.¹⁹

Rule 601 is also being amended to permit OCC to hold a clearing member's margin for an extra day if OCC receives

a notice from the clearing member's DCC that the clearing member or its appointed clearing member, its nominated correspondent, or CDS, in the case of a Canadian clearing member, has not performed an obligation to the DCC. This change is necessary to enable OCC to comply with the Second Restated Agreements which provide that if (1) the DCC notifies OCC prior to 6 a.m. Central Time (7 a.m. Eastern Time) on T+6 that a participating member, appointed clearing member, nominated correspondent, or CDS has not fulfilled its settlement obligations with the DCC and (2) the DCC notifies OCC prior to 4 p.m. Central Time (5 p.m. Eastern Time) on T+6 that it has ceased to act with respect to the entity, the DCC may still call on OCC's guarantee.

OCC Rule 608, which describes when margin may be withdrawn, is being amended to state expressly that the Chairman or President of OCC may refuse to authorize the withdrawal of margin for any of the same reasons that would cause such officials to require the deposit of intra-day margin pursuant to OCC's Rule 609. The purpose of the change is to eliminate a possible misreading of Rules 608 and 609 as requiring OCC to permit a withdrawal of margin deposits before OCC can require the deposit of intra-day margin pursuant to Rule 609.

OCC Rule 913, which governs settlements through the CCCs, is being revised. Paragraph (a) is being amended to state expressly that each Canadian clearing member that appoints CDS and each nominating clearing member that appoints a nominated correspondent must designate a DCC, but neither need be a participant in good standing of the DCC.

Paragraph (c) is being amended to state that OCC shall be deemed to have made full settlement with respect to the exercise and assignment of an equity option at the time when the DCCs for the concerned clearing members are unconditionally obligated to complete the transaction and that thereafter OCC will have no obligation with respect to the transaction except for any obligation OCC may have to the DCCs under their respective Second Restated Agreements. Paragraph (c) continues to provide that the rights and obligations of the two clearing members will be governed by the rules of their respective DCCs after the guarantees of the DCCs become effective.

Paragraph (f) is being amended to expressly state that after notice of revocation is received by OCC, the appointment of an appointed clearing member remains effective with respect to each exercise and assignment

occurring prior to the effective date of revocation until the settlement of all such exercises and assignments are completed. Language also is being added which states that reports made available to an appointed clearing member will be deemed to have been made available to the appointing clearing member at the same time they are made available to an appointed clearing member for purposes of OCC's Rule 208.²⁰

New paragraph (g) is being added to Rule 913 to describe the nominated correspondent settlement arrangement. New paragraph (h) is being added to describe the CDS settlement arrangement.

New paragraph (j) is being added to Rule 913 to state expressly that:

(1) The obligations of a clearing member with respect to the settlement of any securities contract arising out of an exercised and assigned option contract being settled through a DCC will not be deemed to be completed until settlement is completed with the DCC and until OCC has no further responsibility to the DCC with respect to such securities contract;

(2) OCC's guarantee to a DCC of the performance obligation of a clearing member with respect to the securities contract arising out of an exercised and assigned option contract is part of the securities contract; and

(3) That any clearing member that fails (or whose appointed clearing member of nominated correspondent fails or on behalf of which CDS fails) to complete performance of its obligations under any such securities contract is obligated to reimburse OCC for any resulting payments made by OCC to the DCC.

An essential purpose of paragraph (j) is to make clear that any payment made by OCC pursuant its guarantee to a DCC will be pursuant to and for the purpose of liquidating securities contracts arising out of exercised option contracts. Accordingly, under the special provisions of the Bankruptcy Code that protect the close-out activities of securities clearing agencies, such payments by OCC should not be subject to attack by the trustee for a bankrupt clearing member. A second purpose of the paragraph is to make clear that a clearing member that causes OCC to make a guarantee payment to the clearing member's DCC will have a continuing obligation to OCC to reimburse OCC for the payment. This

²⁰ Rule 208 states that the failure of a clearing member to advise OCC on the business day on which a report is made available of any item requiring change constitutes a waiver of the clearing member's right to have the report changed.

¹⁸ In circumstances in which the security originally underlying an exercised option is a CNS Security and owners of that security have become entitled to receive an additional security which is not a CNS Security, OCC's margin system will treat the option as being in the DCC-guaranteed product group after the delivery and receipt of the CNS Security has been guaranteed by the DCCs for the two clearing members. This margin treatment does not precisely reflect the actual settlement of the exercise of such an option because ordinarily the CNS Security will be delivered through the facilities of the CCCs while the additional non-CNS Security will be delivered through OCC's broker-to-broker settlement system. However, this margin treatment is dictated by the constraints of OCC's margin system which without extensive and expensive modification cannot decompose an options exercise into two components and treat one component as being in the DCC-guaranteed class group and the other component as being in the non-DCC-guaranteed class group. OCC has concluded that this discrepancy between its margin system and its settlement system is unlikely in any reasonably foreseeable circumstances to result in a risk to OCC that is inadequately covered by clearing members' margin deposits and by the other elements of OCC's risk reduction systems.

¹⁹ OCC's initial filing proposed amending Rule 601 to separate stock options into two product groups, but the separation was between open positions and exercised positions. The separation as revised in OCC Amendment No. 2 more accurately isolates those exercised stock options which OCC might be unable to recover the value in the event of a clearing member suspension and, therefore, allows OCC to better neutralize its risk exposure to exercised assigned stock options.

provision in conjunction with the section of OCC's By-Laws that describes OCC's lien on clearing member assets makes it clear that OCC may satisfy the clearing member's obligation out of assets that are subject to OCC's lien which are maintained in either the clearing member's firm account or in the account where the obligation originated. A new Interpretation 102 is being added to Rule 913 to state that OCC ordinarily will effect settlement of exercised stock options overlying CNS Securities through the facilities of the CCCs.

Rule 1102 is being amended to state that OCC may suspend a clearing member if its appointed clearing member, its nominated correspondent, or CDS, in the case of a Canadian clearing member that settles through CDS, is in default of any delivery of funds or securities to its DCC. The phrase in Rule 1102 that currently states that OCC may suspend a clearing member if the suspension is necessary for the protection of OCC, other clearing members, creditors, or investors is being modified to refer to OCC, other clearing members, or the general public in order to conform this language to the language used elsewhere in OCC's rules.

Rule 1107 is being amended to state that following the default of a clearing member, OCC will deliver the clearing member's securities that have been deposited in specific deposits and in escrow deposits to the clearing member's DCC. This change is required to enable OCC to comply with the provisions of the Second Restated Agreements which require OCC to deliver such deposits to the DCC of a suspended clearing member against payment by the DCC of the appropriate exercise settlement amounts.

A new paragraph (c) is being added to Rule 1107. Paragraph (c) states that if OCC incurs an obligation to a DCC as a result of exercised and assigned option contracts of a suspended member, OCC may use the funds of the suspended clearing member that are subject to OCC's control to satisfy the obligation.

7. Statutory Basis for the Proposed Rule Changes

OCC believes the proposed rule change is consistent with the purposes and requirements of section 17A of the Act²¹ because it enhances the system used by OCC to effect settlement of exercises and assignments of equity options. In particular, the proposed rule change provides that the CCCs will guarantee settlements of exercises of equity options overlying CNS Securities at an earlier time in the settlement cycle

and provides that OCC will provide the CCCs with a back-up guarantee of performance of exercised and assigned options. The effect is to reduce the need for the CCCs to hold security deposits covering settlements that are also covered by margin deposited with OCC and to improve the efficiency of the equity option exercise settlement system without increasing the risk to OCC and the CCCs. In addition, the proposed rule change improves the description in OCC's rules of the alternatives currently available for effecting settlement of stock options and makes the nominated correspondent alternative available.

B. Self-Regulatory Organizations' Statement on Burden on Competition

OCC, NSCC, SCCC, and MCC do not believe that the proposed rule changes will impose any burden on competition.

C. Self-Regulatory Organizations' Statement on Comments on the Proposed Rule Changes Received From Members, Participants or Others

Written comments were not and are not intended to be solicited by OCC, NSCC, SCCC, or MCC with respect to the proposed rule changes, and none have been received.

III. Date of Effectiveness of the Proposed Rule Changes and Timing for Commission Action

Within thirty-five 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 ninety 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 self-regulatory organization 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. Persons making written submissions should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the submission, all subsequent amendments, all written statements with respect to the proposed rule change that are filed with the Commission, and all written communications relating to the proposed rule change between the Commission and any person, other than

those that may be withheld from the public in accordance with the provisions of 5 U.S.C. 552, will be available for inspection and copying in the Commission's Public Reference Section, 450 Fifth Street, NW., Washington, DC 20549. Copies of such filing will also be available for inspection and copying at the principal offices of OCC, NSCC, SCCC, and MCC. All submissions should refer File Nos. SR-OCC-92-05, SR-NSCC-91-07, SR-SCCP-92-01, and SR-MCC-92-02 and should be submitted by November 4, 1993.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.²²

Margaret H. McFarland,
Deputy Secretary.

[FR Doc. 93-25151 Filed 10-13-93; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

[Public Notice 1876]

Shipping Coordinating Committee, Subcommittee on Safety of Life at Sea Working Group on Radiocommunications; Meeting

The Working Group on Radiocommunications of the Subcommittee on Safety of Life at Sea will conduct open meetings at 9:30 a.m. on December 15, 1993. These meetings will be held in the Department of Transportation Headquarters Building, 400 Seventh Street, SW., Washington, DC 20950.

The purpose of this meeting is to discuss the outcome of the 39th Session of the International Maritime Organization (IMO) Subcommittee on Radiocommunications which is scheduled for November 29 through December 3, 1993, at the IMO headquarters in London, England.

Agenda items include decisions of the 39th Session, primarily related to the implementation of the Global Maritime Distress and Safety System (GMDSS).

Members of the public may attend this meeting up to the seating capacity of the room.

For further information and meeting room number, contact Mr. Ronald J. Grandmason, U.S. Coast Guard Headquarters (G-TTM), 2100 Second Street, SW., Washington, DC 20593-0001. Telephone: (202) 267-1389.

²¹ 15 U.S.C. 78q-1 (1988).

²² 17 CFR 200.30-3(a)(12) (1992).

Dated: September 27, 1993.

Marie Murray,

Executive Secretary, Shipping Coordinating Committee.

[FR Doc. 93-25127 Filed 10-13-93; 8:45 am]

BILLING CODE 4710-07-M

[Public Notice 1882]

Shipping Coordinating Committee, Subcommittee on Ocean Dumping; Meeting

The Subcommittee on Ocean Dumping of the Shipping Coordinating Committee will hold an open meeting on October 29, 1993 from 1 p.m. to 3 p.m. to obtain public comment on the issues to be addressed November 8-12, 1993 at the Sixteenth Consultative Meeting of the Contracting Parties to the London Convention of 1972, which regulates ocean dumping.

The meeting will be held at the Environmental Protection Agency, Waterside Mall, 401 M Street, SW., Washington, DC 20460, in Conference Room 17 of the Washington Information Center. Interested members of the public are invited to attend, up to the capacity of the room.

For further information, please contact Mr. John Lishman, Oceans and Coastal Protection Division, telephone (202) 260-8448.

Dated: October 4, 1993.

Geoffrey Ogden,

Chairman, Shipping Coordinating Committee.

[FR Doc. 93-25195 Filed 10-13-93; 8:45 am]

BILLING CODE 4710-09-M

DEPARTMENT OF TRANSPORTATION

National Highway Traffic Safety Administration

Announcing the Third Meeting of the Motor Vehicle Titling, Registration, and Salvage Advisory Committee

AGENCY: National Highway Traffic Safety Administration (NHTSA), Department of Transportation (DOT).

ACTION: Meeting announcement.

SUMMARY: This notice announces the third meeting of the Motor Vehicle Titling, Registration, and Salvage Advisory Committee. The Committee was established as required by section 140 of the Anti Car Theft Act of 1992, Public Law 102-519, and in accordance with the Federal Advisory Committee Act, for the purpose of studying problems related to motor vehicle titling, registration, and controls over motor vehicle salvage which may affect the motor vehicle theft problem. The

Committee will develop and submit a report to the President, the Congress, and the chief executive of each State concerning the results of this study, which will include recommendations to solve these problems. At this meeting the Committee will discuss uniform state titling procedures necessary to ensure that titles for damaged motor vehicles are properly branded; flood damaged vehicles; and the need for enforcement mechanisms.

DATE AND TIME: The meeting is scheduled to begin at 10 a.m. on Monday, October 25, 1993, and conclude at 4 p.m. on Tuesday, October 26, 1993.

ADDRESS: The meeting on Monday, October 25, 1993, will be held in room 2230, and the meeting on Tuesday, October 26, 1993, will be held in rooms 4436-4438 of the Department of Transportation Building, which is located at 400 Seventh Street, SW., Washington, DC.

SUPPLEMENTARY INFORMATION: In April 1993, the Motor Vehicle Titling, Registration, and Salvage Advisory Committee was established as required by section 140 of the Anti Car Theft Act of 1992, Public Law 102-519. The purpose of the Committee is to study problems which relate to motor vehicle titling, registration, and vehicle salvage controls, including the lack of uniformity in State laws, which may contribute to motor vehicle theft and fraud problems.

The Committee will prepare a report containing the results of the study, including appropriate recommendations to solve the problems identified. The report shall be submitted to the President, the Congress, and to the chief executive officer of each State not later than April 1994.

This meeting is open to the public; however, participation will be determined by the Committee Chairperson.

A public reference file (P.F. 93-001) has been established to contain products of the Committee and will be open to the public during the hours of 9:30 a.m. to 4 p.m. at the National Highway Traffic Safety Administration's Technical Reference Division in room 5108 at 400 Seventh Street, SW., Washington, DC 20590, telephone (202) 366-2678.

FOR FURTHER INFORMATION CONTACT: Richard C. Morse, Odometer Fraud Staff, Office of the Associate Administrator for Enforcement, National Highway Traffic Safety Administration, NEF-20, room 5321, 400 Seventh Street, SW., Washington, DC 20590, phone: 202-366-4761.

Issued on: October 8, 1993.

William A. Boshly,

Associate Administrator for Enforcement.

[FR Doc. 93-25217 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-69-M

Research and Special Programs Administration

Applications for Modification of Exemptions or Applications To Become a Party to an Exemption

AGENCY: Research and Special Programs Administration, DOT.

ACTION: List of applications for modification of exemptions or applications to become a party to an exemption.

SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. This notice is abbreviated to expedite docketing and public notice. Because the sections affected, modes of transportation, and the nature of application have been shown in earlier Federal Register publications, they are not repeated here. Requests for modifications of exemptions (e.g., to provide for additional hazardous materials, packaging design changes, additional mode of transportation, etc.) are described in footnotes to the application number. Application numbers with the suffix "X" denote a modification request. Application numbers with the suffix "P" denote a party to request. These applications have been separated from the new applications for exemptions to facilitate processing.

DATES: Comments must be received on or before October 29, 1993.

ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs, Administration, U.S. Department of Transportation, Washington, DC 20590.

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption number.

FOR FURTHER INFORMATION:

Copies of the applications are available for inspection in the Dockets Unit, room 8426, Nassif Building, 400 7th Street SW., Washington, DC.

Application No.	Applicant	Modification of exemption	Application No.	Applicant	Parties to exemption	Applications for Exemptions
7954-X	Air Products and Chemicals, Inc., Allentown, PA (See Footnote 1).	7954	7991-P	Atlanta & Saint Andrews Bay Railway Company, Panama City, FL.	7991	AGENCY: Research and Special Programs Administration, DOT. ACTION: List of applicants for exemptions.
9723-X	Heritage Transport, Inc., Indianapolis, IN (See Footnote 2).	9723	8451-P	SCB Technologies, Inc., Albuquerque, NM.	8451	SUMMARY: In accordance with the procedures governing the application for, and the processing of, exemptions from the Department of Transportation's Hazardous Materials Regulations (49 CFR part 107, subpart B), notice is hereby given that the Office of Hazardous Materials Safety has received the applications described herein. Each mode of transportation for which a particular exemption is requested is indicated by a number in the "Nature of Application" portion of the table below as follows: 1—Motor vehicle, 2—Rail freight, 3—Cargo vessel, 4—Cargo aircraft only, 5—Passenger-carrying aircraft. DATES: Comments must be received on or before November 15, 1993. ADDRESS COMMENTS TO: Dockets Unit, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590.
11041-X	Aerojet Propulsion Division (APD), Sacramento, CA (See Footnote 3).	11041	8554-P	Boren-Ireco Co., Inc., Parrish, AL.	8554	
11119-X	U.S. Chemical and Plastics Co., Inc., Canton, OH (See Footnote 4).	11119	8554-P	Conex, Inc., Derby, IN	8554	
			8556-P	Air Products Helium, Inc. (APHI), Allentown, PA.	8556	
			8556-P	Linde Puerto Rico, Inc., Gurabo, PR.	8556	
			8723-P	W.H. Burt Explosives, Inc., Moab, UT.	8723	
			8915-P	Epichem Limited, Merseyside, UK.	8915	
			9275-P	Emery Worldwide, Newark, NJ.	9275	
			9623-P	Piedmont Explosives, Inc., Statesville, NC.	9623	
			10307-P	Georgia Gulf Corporation, Plaquemine, LA.	10307	
			10845-P	Public Service Electric and Gas Company (PSE&G), Newark, NJ.	10845	

(1) To modify exemption to provide for nitrogen trifluoride, classed as Division 2.2, as an additional commodity to be transported in DOT specification cylinders.

(2) To modify exemption to provide for rail as an additional mode of transportation for use in transporting lab packs.

(3) To reissue exemption originally issued on an emergency basis to authorize certain Class 9 material to be shipped in cargo tanks.

(4) To reissue exemption originally issued on an emergency basis to authorize certain organic peroxides to be shipped as limited quantities/consumer commodities when the inside containers do not exceed 125 ml for liquids and 500 grams for solids.

Application No.	Applicant	Parties to exemption
4453-P	Winchester Building Supply Co., Inc., Winchester, VA.	4453
6611-P	Air Products Helium, Inc. (APHI), Allentown, PA.	6611
6626-P	Auto Gas Light Welding Supply Co., Inc., Clifton, NJ.	6626
6765-P	Air Products Helium, Inc. (APHI), Allentown, PA.	6765

This notice of receipt of applications for modification of exemption and for party to an exemption is published in accordance with part 107 of the Hazardous Materials Transportation Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on October 8, 1993.

J. Suzanne Hedgepeth,
Chief, Exemption Programs, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 93-25216 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-80-M

Comments should refer to the application number and be submitted in triplicate. If confirmation of receipt of comments is desired, include a self-addressed stamped postcard showing the exemption application number.

FOR FURTHER INFORMATION: Copies of the applications are available for inspection in the Dockets Unit, Room 8426, Nassif Building, 400 7th Street SW., Washington, DC.

NEW EXEMPTIONS

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
11115-N	U.S. Department of Energy, Washington, DC.	49 CFR 173.416	To authorize a one-time shipment of a Nordion International Gammacell 220 High Dose Rate Irradiator in a foreign approved Type B(U) package, radioactive material, special form, n.o.s., Cobalt-60, Class 7 consisting of a cylindrical steel-encased lead radiation shield with a plywood overpack. (Mode 1.)
11117-N	Champion International Corporation, Hamilton, OH.	49 CFR 174.67(i)&(j)	To authorize rail cars containing various commodities, classed as Division 2.3, 5.1 and Class 8, to remain connected during unloading without the physical presence of an unloader. (Mode 2.)
11130-N	Clean Harbors Environmental Services, Inc Quincy, MA.	49 CFR 173.12(b), 177.848	To load, transport and store Division 6.1 liquids in Packing Group 1, Zone A packed in "lab-pack" drums on the same transport vehicle carrying packages containing various classes of hazardous materials. (Mode 1.)

NEW EXEMPTIONS—Continued

Application No.	Applicant	Regulation(s) affected	Nature of exemption thereof
11131-N	Interstate Navigation Company, New London, CT.	49 CFR 107.101	To authorize the transport of LPG propane gas, classed as Division 2.1, contained in cylinders on passenger ferries. (Mode 3.)
11132-N	Uniroyal Chemical Company, Inc., Middlebury, CT.	49 CFR 173.224, 49 CFR	To authorize the transport of Division 4.1, flammable solid, in a specially designed composite type packaging in quantities not to exceed 55 pounds. (Mode 1.)
11134-N	ETSS of Ohio, Inc., Tipp City, OH.	49 CFR 177.848(c)(d), 49 CFR ...	To authorize the shipment of limited quantities of Class 3, 8, and Division 5.1, 6.1 waste chemicals in lab packs on the same vehicle. (Mode 1.)
11135-N	Enron Clean Fuels Marketing Company, Houston, TX.	49 CFR 173.29(b)(ii)	To authorize the one-time shipment of a DOT Specification 111A100W1 rail car, containing methyl alcohol residue, Class 3. (Mode 2.)
11136-N	American Pyrotechnics Association, Chestertown, MD.	49 CFR 172.101, 172.204(c)(3), 173.27, 175.30(a)(1), 175.320.	To authorize the transport of fireworks, 1.3G explosives which are forbidden for shipment by cargo-only aircraft. (Mode 4.)
11137-N	BioSurface Technology, Inc., Cambridge, MA.	49 CFR 172.101(j), 172.101(k), 173.196(a)(b)(e) and (f), 173.24(e), 173.24(f), 173.24(i), 173.24a(a), 173.27(b), 173.27(c), 173.29(a), 178.609, 49 CFR.	To authorize the transport by courier of human skin grafts classed as infectious substances, Division 6.2 in specially designed containers in quantities greater than those authorized by CFR. (Modes 1, 3, 5.)
11138-N	Nippon Riku-Un Sangyo Co., Ltd., Tokyo, Japan.	49 CFR 173.315(a)	To authorize the transport of refrigerant gases, n.o.s., classed as Division 2.2 in non-DOT specification portable tank comparable DOT-51 specification. (Modes 1, 2, 3.)
11142-N	Air Products and Chemicals, Inc., Allentown, PA.	49 CFR 173.302(2)(3)&(4), 173.34(e)(1)(3)(4)(6), CFR.	To authorize ultrasonic retesting of DOT-Specification 3AA and 3AAX cylinders used for shipment of material classed as Division 2.1 and 2.2. (Mode 1.)
11144-N	Sam Nally Shop, Inc., Bardstow, KY.	49 CFR 173.63	To manufacture, mark and sell non-DOT specification containers similar to an IME container for use in transporting detonators, classed as Division 1.1 and 1.4 explosives in open body pickup trucks. (Mode 1.)

NOTE: Exemption 10866-P McClure Industries, Inc. that appeared on page 48931 of the FEDERAL REGISTER on September 20, 1993, should have appeared as 11141-N "To manufacture, mark and sell a specially designed fiberglass container, Sani-Trux 30, to be used as outer packaging in transporting medical waste classed as Division 6.2.

This notice of receipt of applications for new exemptions is published in accordance with Part 107 of the Hazardous Materials Transportation Act (49 U.S.C. 1806; 49 CFR 1.53(e)).

Issued in Washington, DC, on October 8, 1993.

J. Suzanne Hedgepeth,

Chief, Exemption Programs, Office of Hazardous Materials Exemptions and Approvals.

[FR Doc. 93-25215 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-60-M

[Docket Nos. PDA-7(R), PDA-9(R), PDA-10(R), PDA-11(R)]

Applications by HASA, Inc. and the Swimming Pool Chemical Manufacturers' Association for Preemption Determinations Regarding Certain California State and Local Requirements

AGENCY: Research and Special Programs Administration (RSPA), DOT.

ACTION: Public notice reopening comment period.

SUMMARY: HASA, Inc. (HASA) and the Swimming Pool Chemical Manufacturers' Association (SPCMA) have applied to the Department for a determination that certain California and Los Angeles County requirements are preempted by the Hazardous Materials Transportation Act (HMTA). These provisions relate to the transportation of hazardous materials on private property. This Notice reopens the comment period on HASA's and SPCMA's applications. RSPA is reopening the comment period in all four preemption determination applications (PDAs) because each relates to Los Angeles County regulations or a California statute applicable to the "on-site" handling of hazardous materials.

DATES: Comments received on or before November 15, 1993, will be considered before an administrative ruling is issued in each of the four PDAs by RSPA's Associate Administrator for Hazardous Materials Safety. These additional comments may address only the three specific matters discussed below; commenters may not raise or discuss other issues.

ADDRESSES: HASA's and SPCMA's applications and any comments received may be reviewed in the Dockets Unit, Research and Special Programs Administration, room 8421, Nassif Building, 400 Seventh Street, SW., Washington, DC 20590-0001. Further comments on the three matters discussed below may be submitted to the Dockets Unit at the above address, and should include the Docket Number (PDA-7(R), PDA-9(R), PDA-10(R), or PDA-11(R)). Three copies should be submitted. A copy of each comment must also be sent to Ms. Mary Flynn, Director, Government Relations and Public Affairs, HASA, Inc. and Co-Chairman, Hazardous Materials Transportation and Storage Committee, SPCMA, 23119 Drayton Street, Saugus, CA 91350; Mr. Larry J. Monteilh, Executive Officer, Board of Supervisors for the County of Los Angeles, 500 West Temple Street, Room 383, Los Angeles, CA 90012; and, Dr. Richard Andrews, Director, Governor's Office of Emergency Services, State of California, 2800 Meadowview Road, Sacramento, CA 95832. A certification that a copy has been sent to these persons must also

be included with the comment. (The following format is suggested: "I hereby certify that copies of this comment have been sent to Ms. Flynn and Messrs. Monteilh and Andrews at the addresses specified in the Federal Register.")

FOR FURTHER INFORMATION CONTACT: Nancy E. Machado, Office of the Chief Counsel, Research and Special Programs Administration, U.S. Department of Transportation, Washington, DC 20590-0001 (Tel. No. 202-366-4400).

SUPPLEMENTARY INFORMATION:

I. Background

On December 22, 1992, HASA applied for a determination that the HMTA preempts certain provisions of Titles 2 and 32 of the Los Angeles County Code applicable to the transportation of hazardous materials on private property (PDA-7(R)). HASA, a California corporation, manufactures, packages, warehouses, and transports chemical compounds for use in, among other things, potable waste water treatment, and swimming pool and spa disinfection.

On January 26, 1993, RSPA published a Public Notice and Invitation to Comment on HASA's application (58 FR 6176). That Notice set forth the text of HASA's application, and asked that comments be filed with RSPA on or before March 31, 1993, and that rebuttal comments be filed on or before June 4, 1993.

Between December 30, 1992, and January 20, 1993, SPCMA a non-profit organization with members involved in the transportation of hazardous materials, submitted three separate applications seeking determinations that the HMTA preempts certain provisions of:

(a) Chapter 6.95 of the California Health and Safety Code as they apply to the storage and handling of hazardous materials (PDA-9(R));

(b) Title 32 of the Los Angeles County Code which it asserts are applicable to the transportation of cryogenic liquids, including loading, unloading, and storage incidental thereto, and the construction of containers used for transporting cryogenic liquids (PDA-10(R)); and

(c) Title 32 of the Los Angeles County Code as they apply to the on-site transportation of compressed gases (PDA-11(R)).

SPCMA is a non-profit organization composed of individual member companies with manufacturing and distribution facilities located across the United States, including California. SPCMA members manufacture, package, warehouse, and transport chemical

compounds for use in potable and waste water treatment, and swimming pool and spa disinfection.

On February 12, 1993, RSPA published a Public Notice and Invitation to Comment on each of SPCMA's applications (58 FR 8494, 8480, 8488). Those Notices set forth the text of SPCMA's applications and asked that comments be filed with RSPA on or before April 9, 1993, and that rebuttal comments be filed on or before June 4, 1993.

II. Matters on Which Additional Comments May Be Submitted

(1) *Correspondence to Secretary Peña*—On April 27, 1993, Congressman George Miller (D-CA), Chairman of the House Committee on Natural Resources, wrote to Secretary of Transportation Federico Peña stating his opposition to SPCMA's request for a preemption determination in PDA-9(R). That letter was placed in the public docket. (The letter is reproduced in appendix A to this notice.) After the period for rebuttal comments had ended, Congressman Miller made additional remarks concerning PDA-9(R) in a letter to Secretary Peña dated September 10, 1993. (The letter is reproduced in appendix B to this notice.) Congressman Miller cites a recent hazardous materials accident in Contra Costa County, California, as evidence that stronger State and local regulation of hazardous materials is needed.

In a letter to Secretary Peña dated September 13, 1993, California State Assemblyman Robert J. Campbell, and 23 other State legislators, requested that the Department deny SPCMA's request for a preemption determination in PDA-9(R). (The letter is reproduced in appendix C to this notice.) This letter was also received outside the rebuttal comment period in PDA-9(R). Assemblyman Campbell's letter also cites the Contra Costa County spill as proof that State regulation of hazardous materials is necessary to minimize the risk of hazardous materials accidents at fixed facilities.

RSPA is extending the comment period in PDA-7(R), PDA-9(R), PDA-10(R), and PDA-11(R) to allow interested parties to respond to Congressman Miller's September 10, 1993 letter and Assemblyman Campbell's September 13, 1993 letter.

In accordance with 49 CFR 107.207, all interested persons are invited to submit comments on Congressman Miller's September 10, 1993 letter and Assemblyman Campbell's September 13, 1993 letter.

(2) *The Requirements as Applied and Enforced*—

There is little information in the record as to how the California and Los Angeles County regulations at issue in PDA-7(R), PDA-9(R), PDA-10(R), and PDA-11(R) are actually applied and enforced. RSPA is interested in receiving comments and examples regarding: (1) The specific activities covered by the requirements, as enforced, and the point during those activities when the respective enforcing agencies consider that the requirements become applicable; (2) who the requirements are applicable to and actually enforced against (e.g., shippers, carriers, consignees); and (3) the penalties for non-compliance, as applied and enforced.

In accordance with 49 CFR 107.207, all interested persons are invited to submit further comments on these issues.

(3) *Revisions to Title 32 of the Los Angeles County Code*—

The applicants in PDA-7(R), PDA-10(R) and PDA-11(R) each ask for preemption of several requirements contained in title 32 of the 1990 Los Angeles County Code. Title 32 of the 1990 Los Angeles County Code adopted by reference the 1988 Uniform Fire Code. On May 20, 1993, the Los Angeles County Board of Supervisors adopted Los Angeles County Ordinance No. 93-0044, which amended title 32 to incorporate, with amendments, additions and deletions, the 1991 edition of the Uniform Fire Code.

In accordance with 49 CFR 107.207, RSPA directs the applicants to supplement their applications, if necessary, to make them consistent with title 32, as amended. For example, the applicants should ensure that the amendment of title 32 has not affected their substantive arguments, or the accuracy of their citations to particular provisions of title 32.

Issued in Washington, DC, on October 6, 1993.

Alan I. Roberts,
Associate Administrator for Hazardous Materials Safety.

Appendix A

U.S. House of Representatives, Committee on Natural Resources, Washington, DC 20015-6201

April 27, 1993.

The Honorable Federico Peña,
Secretary of Transportation, 400 Seventh Street SW., Washington, DC 20590.

Dear Mr. Secretary:

Re: "Application for an Administrative Determination Pursuant to 49 U.S.C. 1811(c) and 49 C.F.R. 107.23 et seq.,"
Swimming Pool Manufacturers Association.

I wish to express my opposition to the above application filed with the Department of Transportation (DOT) by the Swimming Pool Chemical Manufacturers' Association (SPCMA). The SPCMA application has requested that DOT's Hazardous Materials Safety Research and Special Programs Administration exempt member facilities from the State of California regulations found in Chapter 6.95 of the California Health and Safety Code. These state regulations protect the public and the environment from hazardous materials through effective emergency response planning and responsible hazardous materials management.

The SPCMA argues that the California Health and Safety Code is pre-empted by the federal Hazardous Materials Transportation Act (HMTA). The SPCMA claims that the HMTA applies not only to transportation, but also to the storage of hazardous materials. However, it is clear that the HMTA was not intended to apply to the storage of hazardous materials and that the HMTA and the California Health and Safety Code are, in fact, compatible.

I am particularly concerned about the effect that this pre-emption, if approved, would have on the Risk Management and Prevention Program (RMPP) found in Article 2 of Chapter 6.95 of the California Health and Safety Code. The RMPP was established by the California legislature in 1986 following the Bhopal disaster. It is intended to prevent the accidental release of acutely hazardous materials and to provide information useful for emergency response planning in the event of a release. The SPCMA's member facilities handle chlorine, a highly toxic and volatile material. It is critical that these facilities comply with the RMPP to minimize adverse health and environmental effects should an accident occur.

Furthermore, if DOT approves the exemption requested by the SPCMA, it would encourage other industries handling acutely hazardous materials to apply for similar exemptions. There are more than 130 such business in Contra Costa County alone. An accident at any one of these facilities could affect many people in the San Francisco Bay area. It is critical that these businesses have adequate emergency response planning and notification, which can only be achieved through compliance with the RMPP.

If you have any questions, please contact Celia Boddington of my staff at 202-226-0200.

Thank you for your attention to this matter.

Sincerely,

George Miller,
Chairman.

Appendix B

U.S. House of Representatives, Committee on Natural Resources, Washington, DC 20515-6201

September 10, 1993.

The Honorable Federico Peña,
Secretary of Transportation, 400 Seventh Street SW, Washington, DC 20590.

Dear Mr. Secretary:

Re: "Application for an Administrative Determination Pursuant to 49 U.S.C. 1811(c) and 49 C.F.R. 107.23 et seq.," Swimming Pool Manufacturers Association.

Since I wrote to you on April 27, in opposition to the above application, a major chemical accident in Contra Costa County, California has underscored the importance of denying this exemption request submitted by the Swimming Pool Chemical Manufacturers' Association (SPCMA).

On July 26, the escape valve on a tank car carrying oleum ruptured during unloading at the General Chemical facility in Richmond, California. Thousands of Contra Costa County residents sought medical treatment following exposure to the toxic cloud resulting from the spill. Following the Richmond accident, the Subcommittee on Oversight and Investigations of the Committee on Natural Resources held a hearing on August 10 to explore how people can live safely with the hazardous materials industry.

State and local witnesses emphasized the importance of California's Risk Management Prevention Program (RMPP) in preventing accidents and in ensuring adequate emergency response when a leak occurs. Witnesses also testified that the tank car involved in the General Chemical leak was not regulated by state law because reporting of tank cars storing hazardous materials is not required if storage is for 30-days or less. It is clear that state regulation must be strengthened, not reduced.

Communities such as Contra Costa County are currently covered by the states' RMPP, which requires responsible management of hazardous materials. However, Department of Transportation approval of the SPCMA exemption request would deny this protection to communities throughout California.

DOT approval of the SPCMA application would set a policy precedent that could render the RMPP useless. It is vital that the hazardous materials handlers in the state comply with the RMPP to minimize the risk of accidents. I therefore urge you to deny the exemption application by SPCMA.

Thank you for your consideration. If you have any questions, please contact Celia Boddington of my staff at 202-226-0200.

Sincerely,

George Miller,
Chairman.

Appendix C

Assembly, California Legislature, Robert J. Campbell, Assemblyman, Eleventh District, Chairman, Ways & Means Subcommittee on School Finance

September 13, 1993.

Mr. Federico Peña,
Secretary of Transportation, Department of Transportation, 400 7th Street, SW., Washington, DC 20590.

Re: Application for an Administrative Determination Pursuant to 49 USC 1811(c) and 49 CFR 107.203 et seq by the Swimming Pool Chemical Manufacturers Association.

Dear Secretary Peña: We are writing about an issue of deep concern to us. Last year, the Swimming Pool Chemical Manufacturers Association (SPCMA) requested that the Department of Transportation determine whether federal law, specifically the Hazardous Materials Transportation Act, preempts Chapter 6.95 of the California Health and Safety Code. In essence, SPCMA is asking to exempt its member organizations from California laws designed to reduce the risk of chemical accidents and to plan for emergency response in the event of such an accident. We hope you will take whatever action necessary to immediately lay this issue to rest. Without any doubt the state has every responsibility for regulating hazardous materials that are on-site at a fixed facility. To argue that the storage of a hazardous material is a transportation issue simply because the material is being held on-site in a railcar is dangerously fraudulent.

As you may be aware, on July 27, 1993 a major chemical spill occurred at General Chemical Company in Richmond, California. Sulphuric acid was spewed over Contra Costa and Solano counties, sending residents to hospitals and closing freeways. This resulted from a leaky railroad tank valve which leaked oleum, a concentrated form of sulphuric acid, for more than three hours. As you may be aware, Richmond is located in Contra Costa, a county with a heavy industrial base, many facilities that handle acutely hazardous materials, and a long history of hazardous material spills.

The state has worked diligently to put in place legislation and regulatory programs to minimize the risk of chemical accidents. In particular, the state has implemented Chapter 6.95 of the California Health and Safety Code. These codes cover hazardous materials business plans, emergency response planning and notification, and risk management and prevention programs. All of these statutes are geared toward reducing the risk of accidents and assisting in emergency response in the event an accident occurs.

The General Chemical accident has focused debate on both the need to improve state regulations and to clarify potential grey areas between federal and state responsibilities, specifically the regulation of rail cars that are on-site and used for "temporary" storage of hazardous materials.

We are especially concerned that the SPCMA petition, if granted, would set a very dangerous precedent throughout the manufacturing industries in the state. According to a recent survey conducted by Congressman Miller, there are over 500 rail tank cars carrying over 80 million gallons of hazardous chemicals stored on tracks in Contra Costa County alone. There is the strong possibility that if SPCMA's petition is granted, many more industry groups will file similar petitions.

We fully recognize and respect the responsibility the Department of Transportation has in ensuring the safe transportation of hazardous materials. However, we firmly believe that the regulations that have been implemented under Chapter 6.95 of the California Health and Safety Code are not in conflict with the Hazardous Materials Transportation Act.

Furthermore, in the wake of the General Chemical accident and a series of other accidents that have occurred in Contra Costa over the last couple of years, the state is attempting to review and improve its risk management and prevention laws. The SPCMA petition only creates confusion and serves to slow California's efforts to provide adequate protection for its citizens in relation to the prevention of hazardous materials accidents at fixed facilities.

For all of the reasons above, we strongly urge you to expeditiously deny SPCMA's petition. If you have any questions regarding this request, please feel free to contact us.

Sincerely,

Assemblemember Tom Bates

Assemblemember Robert Campbell

Assemblemember Burt Margolin

Assemblemember Tom Umberg

Assemblemember Thomas M. Hannigan

Assemblemember Mike Gotch

Assemblemember Valerie Brown

Assemblemember Willie L. Brown, Jr.

Assemblemember Marguerite Archie-Hudson

Senator Gary Hart

Senator Bill Lockyer

Senator Nicholas C. Petris

Senator Art Torres

Senator Herschel Rosenthal

Senator Milton Marks

Assemblemember Byron Sher

Assemblemember Phil Isenberg

Assemblemember Dan Hauser

Assemblemember Delaine Eastin

Assemblemember Deirdre Alpert

Assemblemember Hilda Solis

Senator Henry J. Mello

Senator Tom Hayden

Senator A. E. Alquist

[FR Doc. 93-25146 Filed 10-13-93; 8:45 am]

BILLING CODE 4910-60-P

DEPARTMENT OF VETERANS AFFAIRS

Veterans' Advisory Committee on Environmental Hazards; Meeting

The Department of Veterans Affairs (VA) gives notice under Public Law 92-

463 that a meeting of the Veterans' Advisory Committee on Environmental Hazards will be held on Thursday, October 28, 1993, in room 401, and on October 29, 1993, in room 855, 801 I Street, NW., Washington, DC 20004. The meeting will convene at 9 a.m. and adjourn at 5 p.m.

The purpose of the meeting is to review information relating to the health effects of exposure to ionizing radiation.

The meeting is open to the public to the capacity of the room. For those wishing to attend, contact Mrs. Leney Holohan, Department of Veterans Affairs Central Office (026B), 810 Vermont Avenue, NW., Washington, DC 20420, phone (202) 523-3911, prior to October 22, 1993.

Members of the public may direct questions or submit prepared statements for review by the Committee in advance of the meeting, in writing only, to Mr. Frederic L. Conway, Deputy Assistant General Counsel, (026B), Department of Veterans Affairs Central Office, 810 Vermont Avenue, NW., Washington, DC 20420. Submitted material must be received at least five days prior to the meeting. Such members of the public may be asked to clarify submitted material prior to consideration by the Committee.

Dated: October 1, 1993.

Heyward Bannister,
Committee Management Officer.

[FR Doc. 93-25197 Filed 10-13-93; 8:45 am]

BILLING CODE 6320-01-M

Sunshine Act Meetings

Federal Register

Vol. 58, No. 197

Thursday, October 14, 1993

This section of the FEDERAL REGISTER contains notices of meetings published under the "Government in the Sunshine Act" (Pub. L. 94-409) 5 U.S.C. 552b(e)(3).

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 the Federal Deposit Insurance Corporation's Board of Directors will meet in open session at 10:00 a.m. on Tuesday, October 19, 1993, to consider the following matters:

Summary Agenda: No substantive discussion of the following items is anticipated. These matters will be resolved with a single vote unless a member of the Board of Directors requests that an item be moved to the discussion agenda.

Disposition of minutes of previous meetings.

Reports of actions approved by the standing committees of the Corporation and by officers of the Corporation pursuant to authority delegated by the Board of Directors.

Discussion Agenda:

Memorandum and resolution re: Proposed amendments to Part 360 of the Corporation's rules and regulations, entitled "Receivership Rules," which would comply with the statutory requirement of prescribing regulations on the prohibition against increasing losses to the insurance funds by protecting uninsured depositors and non-depositor creditors of insured depository institutions.

Memorandum and resolution re: Final amendments to Part 337 of the Corporation's rules and regulations, entitled "Unsafe and Unsound Banking Practices," which revise the capital category definitions used in the Corporation's regulations governing the acceptance of brokered deposits so that those definitions conform to the definitions used in regulations implementing section 38 of the Federal Deposit Insurance Act.

The meeting will be held in the Board Room on the sixth floor of the FDIC Building located at 550 17th Street NW., Washington, DC

The FDIC will provide attendees with auxiliary aids (e.g., sign language interpretation) required for this meeting. Those attendees needing such assistance should call (202) 942-3111 (Voice); (202) 942-3132 (TTY), to make necessary arrangements.

Requests for further information concerning the meeting may be directed to Mr. Hoyle L. Robinson, Executive Secretary of the Corporation, at (202) 898-6757.

Dated: October 12, 1993.
Federal Deposit Insurance Corporation.
Hoyle L. Robinson,
Executive Secretary.
[FR Doc. 93-25397 Filed 10-12-93; 3:04 pm]
BILLING CODE 6714-01-M

FEDERAL ELECTION COMMISSION

DATE AND TIME: Tuesday, October 19, 1993 at 10:00 a.m.
PLACE: 999 E Street, NW., Washington, DC.
STATUS: This meeting will be closed to the public.

ITEMS TO BE DISCUSSED:

Compliance matters pursuant to 2 U.S.C. § 437g.

Audits conducted pursuant to 2 U.S.C. § 437g, § 438(b), and Title 26, U.S.C.

Matters concerning participation in civil actions or proceedings or arbitration.

Internal personnel rules and procedures or matters affecting a particular employee.

DATE AND TIME: Wednesday, October 20, 1993 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This oral hearing will be open to the public.

MATTER BEFORE THE COMMISSION:

Compliance Procedures Regulations (11 CFR Parts 4, 5, 7, 102 and 111).

DATE AND TIME: Thursday, October 21, 1993 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington, DC (Ninth Floor).

STATUS: This meeting will be open to the public.

ITEMS TO BE DISCUSSED:

Correction and Approval of Minutes.
Advisory Opinion 1993-17: Ms. Maureen E. Garde on behalf of the Massachusetts Democratic Party (continued from meeting of October 7, 1993).

Best Efforts Rulemaking (11 CFR § 104.7(b))—Final Rules and Explanation and Justification (continued from meeting of October 7, 1993).

AO Procedure Revisions Regarding Public Comments on OGC draft AOs.

Briefing on REGO.
Administrative Matters.

DATE AND TIME: Wednesday, October 27, 1993 at 10:00 a.m.

PLACE: 999 E Street, NW., Washington DC (Ninth Floor).

STATUS: This oral hearing will be open to the public.

MATTER BEFORE THE COMMISSION:

Convention Regulations (11 CFR Parts 107, 114, and 9008).

PERSON TO CONTACT FOR INFORMATION:

Mr. Fred Eiland, Press Officer,
Telephone: (202) 219-4155.

Delores Hardy,

Administrative Assistant.

[FR Doc. 93-25398 Filed 10-12-93; 3:08 pm]

BILLING CODE 6715-01-M

DEPARTMENT OF JUSTICE

Parole Commission

Record of Vote of meeting Closure
(Public Law 94-409) (5 U.S.C. Sec. 552b)

I, Edward F. Reilly, Jr., Chairman of the United States Parole Commission, presided at a meeting of said Commission which started at approximately nine-thirty a.m. on Thursday, October 7, 1993 at the Commission's Central Office, 5550 Friendship Boulevard, Chevy Chase, Maryland 20815. The purpose of the meeting was to decide four appeals from National Commissioners' decisions pursuant to 28 CFR Section 2.27. Five Commissioners were present, constituting a quorum when the vote to close the meeting was submitted.

Public announcement further describing the subject matter of the meeting and certifications of General Counsel that this meeting may be closed by vote of the Commissioners present were submitted to the Commissioners prior to the conduct of any other business. Upon motion duly made, seconded, and carried, the following Commissioners voted that the meeting be closed: Edward F. Reilly, Jr., Carol Pavilack Getty, Jasper Clay, Jr., Vincent Fichtel, Jr., and John R. Simpson.

IN WITNESS WHEREOF, I make this official record of the vote taken to close this meeting and authorize this record to be made available to the public.

Dated: October 7, 1993,

Edward F. Reilly, Jr.,

Chairman, U.S. Parole Commission.

[FR Doc. 93-25396 Filed 10-12-93; 3:01 pm]

BILLING CODE 4410-01-M

POSTAL RATE COMMISSION

TIME AND DATES: 2:18 p.m., October 8, 1993.

PLACE: Conference Room, 1333 H Street, NW, Suite 300, Washington, DC 20268.
STATUS: Closed.

MATTERS TO BE CONSIDERED: Personnel Matters.

CONTACT PERSON FOR MORE INFORMATION: Charles L. Clapp, Secretary, Postal Rate Commission, Suite 300, 1333 H Street, NW, Washington, DC 20268-0001, Telephone (202) 789-6840.

Charles L. Clapp,
Secretary.

[FR Doc. 93-25394 Filed 10-12-93; 2:58 pm]

BILLING CODE 7710-FW-P

POSTAL RATE COMMISSION

TIME AND DATES: 2:07 p.m., October 8, 1993.

PLACE: Conference Room, 1333 H Street, NW, Suite 300, Washington, DC 20268.
STATUS: Open.

MATTERS TO BE CONSIDERED: Election of Vice Chairman.

CONTACT PERSON FOR MORE INFORMATION: Charles L. Clapp, Secretary, Postal Rate Commission, Suite 300, 1333 H Street, NW., Washington, DC 20268-0001, Telephone (202) 789-6840.

Charles L. Clapp,
Secretary.

[FR Doc. 93-25395 Filed 10-12-93; 3:00 pm]

BILLING CODE 7710-FW-P

U.S. RAILROAD RETIREMENT BOARD

Notice of Public Meeting

Notice is hereby given that the Railroad Retirement Board will hold a meeting on October 19, 1993, 9:00 a.m., at the Board's meeting room on the 8th floor of its headquarters building, 844 North Rush Street, Chicago, Illinois, 60611. The agenda for this meeting follows:

Portion open to the public

- (1) Plan to Improve the Quality and Timeliness of Claims Processing
- (2) Debt Prevention Task Force Report
- (3) Pre-Recovery Waiver Debt
- (4) Request for Waiver of Interest and/or Penalty Assessments
- (5) Division of Audit and Compliance Fiscal Year 1993 Audit Plan
- (6) Announcement No. 93-17A GM-13 Audit Manager
- (7) 1993 Railroad Retirement Board Award for Excellence Program
- (8) Performance Awards for General Schedule Employees
- (9) RRB Physical Examination Program
- (10) Updated Energy Conservation Program
- (11) Coverage Determination—Livingston Rebuild Center
- (12) Coverage Determination—Parker LaFarge, Inc.
- (13) Coverage Determination—Kokomo Rail Company, Inc.
- (14) Coverage Determination—VWV Enterprises, Inc.
- (15) Coverage Determination—Rio Grande Industries, Inc.
- (16) Coverage Determination—Illinois Central Corporation
- (17) Coverage Determination—Rail Link, Inc.
- (18) Coverage Determination—Albany Bridge Company, Inc.

- (19) Coverage Determination—Tulare Valley Railroad Company
- (20) Coverage Determination—Reading and Northern Service Company
- (21) Coverage Determination—Santa Cruz, Big Trees & Pacific Ry. Co.
- (22) Regulations—Parts 202 and 301, Employers Under the Railroad Retirement Act and Railroad Unemployment Insurance Act
- (23) Regulations—Part 203, Employees Under the Railroad Retirement Act
- (24) Regulations—Part 226, Computing Employee Spouse and Divorced Spouse Annuities
- (25) Regulations—Part 230, Reduction and Non—Payment of Annuities by Reason of Work
- (26) Regulations—Part 266, Representative Payee
- (27) Regulations—Part 328, Voluntary Leaving of Work
- (28) Regulations—Part 345, Contribution and Contribution Reports

Portion closed to the public

- (A) Draft Fiscal Year 1994 Performance Appraisal Plans
- (B) Appeal of Nonwaiver of Overpayment, Willard H. Triplett

The person to contact for more information is Beatrice Ezerski, Secretary of the Board, COM No. 312-751-4920, FTS No. 386-4920.

Dated: October 8, 1993.

Beatrice Ezerski,
Secretary to the Board.

[FR Doc. 93-25307 Filed 10-12-93; 9:48 am]

BILLING CODE 7905-01-M

Corrections

Federal Register

Vol. 58, No. 197

Thursday, October 14, 1993

This section of the FEDERAL REGISTER contains editorial corrections of previously published Presidential, Rule, Proposed Rule, and Notice documents. These corrections are prepared by the Office of the Federal Register. Agency prepared corrections are issued as signed documents and appear in the appropriate document categories elsewhere in the issue.

**FEDERAL COMMUNICATIONS
COMMISSION****47 CFR Part 90**

[PR Docket No. 90-481; FCC 93-411]

**Construction, Licensing and Operation
of Private Land Mobile Radio Stations***Correction*

In rule document 93-23785, beginning on page 51251 in the issue of Friday, October 1, 1993, make the following correction:

On page 51251, in the second column, in the **EFFECTIVE DATE:**, in the first line, "October 1, 1993." should read "November 1, 1993."

BILLING CODE 1505-01-D

**DEPARTMENT OF HEALTH AND
HUMAN SERVICES****Food and Drug Administration****21 CFR Part 812**

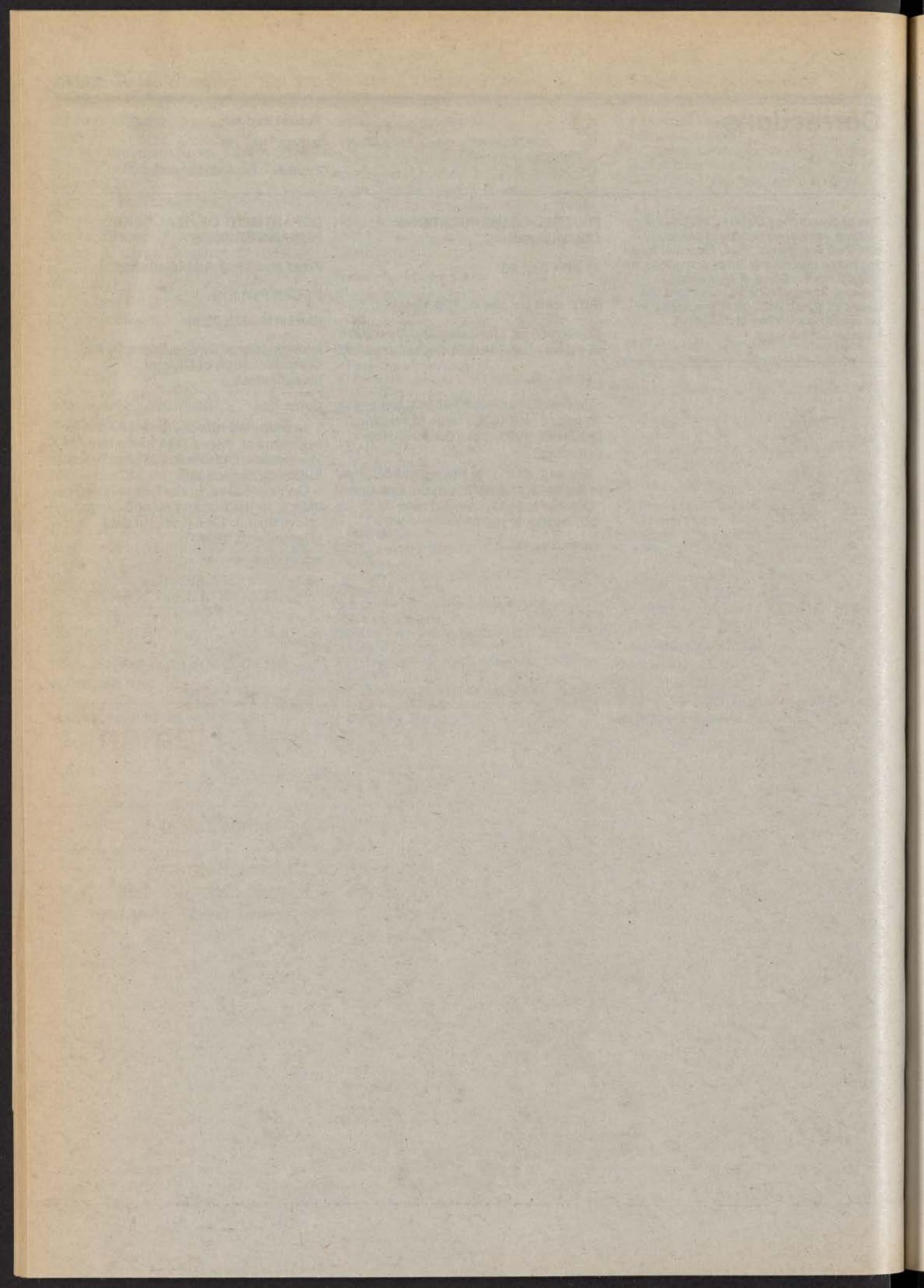
[Docket No. 92N-0308]

**Investigational Device Exemptions;
Disqualification of Clinical
Investigators***Correction*

In proposed rule document 93-24475 beginning on page 52144 in the issue of Wednesday, October 6, 1993, make the following correction:

On page 52144, in the first column, in **DATES:**, in the first and second lines, "November 5, 1993." should read "December 6, 1993."

BILLING CODE 1505-01-D



federal register

Thursday
October 14, 1993

Part II

**Department of
Health and Human
Services**

Food and Drug Administration

**Application of Current Statutory
Authorities to Human Somatic Cell
Therapy Products and Gene Therapy
Products; Notice**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration**

[Docket No. 93N-0173]

Application of Current Statutory Authorities to Human Somatic Cell Therapy Products and Gene Therapy Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is making available, through this document, a statement of the manner in which FDA's current statutory authorities governing therapeutic products apply to human somatic cell therapy products and gene therapy products. FDA is publishing this statement in response to requests that the agency clarify its regulatory approach and provide guidance to manufacturers of products intended to be used in somatic cell therapy or gene therapy. As scientific knowledge in the area of somatic cell and gene therapy continues to accumulate and evolve, the agency's approach may also evolve.

DATES: Submit written comments on the document by December 13, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857. Submit investigational new drug applications (IND's) for somatic cell therapy and gene therapy products to the Division of Application Review and Policy (HFM-585), Office of Therapeutics Research and Review, Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448. Submit written requests for single copies of the document entitled "Points to Consider in Human Somatic Cell Therapy and Gene Therapy" to the Congressional and Consumer Affairs Branch (HFM-12), Center for Biologics Evaluation and Research, Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-295-9000. Send two self-addressed adhesive labels to assist that office in processing requests.

FOR FURTHER INFORMATION CONTACT: Ann Reed Gaines, Center for Biologics Evaluation and Research (HFM-635), Food and Drug Administration, 1401 Rockville Pike, Rockville, MD 20852-1448, 301-594-3074.

SUPPLEMENTARY INFORMATION:

I. Introduction

As a consequence of scientific and biotechnological progress during the past decade, new therapies involving somatic cells and genetic material are being investigated, and commercial development of products for use in somatic cell therapies and gene therapies is occurring. Existing FDA statutory authorities, although enacted prior to the advent of somatic cell and gene therapies, are sufficiently broad in scope to encompass these new products and require that areas such as quality control, safety, potency, and efficacy be thoroughly addressed prior to marketing. Manufacturers and other interested parties have questioned FDA regarding how such products will be regulated. This statement outlines the current regulatory approach to products intended for use in somatic cell and gene therapies.

II. Background**A. Legal Authorities**

FDA regulates numerous kinds of products intended to prevent, treat, or diagnose diseases or injuries under legal authorities established in the Public Health Service Act (the PHS Act) and the Federal Food, Drug, and Cosmetic Act (the act). Section 351(a) of the PHS Act (42 U.S.C. 262(a)) identifies a biological product as "any virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, or analogous product, or arsphenamine or its derivatives (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of diseases or injuries of man." Section 201(g)(1) of the act (21 U.S.C. 321(g)(1)) defines the term "drug," in part, as "articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals." The term "device" is defined in section 201(h) of the act, in part, as:

*** "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article *** intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, *** which does not achieve its primary intended purposes through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes." Both the "drug" definition and the "device" definition also include articles "intended to affect the structure or any function of the body."

Section 351(a) of the PHS Act requires premarket approval for biological

products. Licenses are to be issued upon a showing that the establishments and products "meet standards, designed to insure the continued safety, purity, and potency of such products * * *." (42 U.S.C. 262(d)). A biological product's effectiveness for its intended uses must be shown as part of the statutory requirement for potency (21 CFR 600.3(s)). At the investigational stages, when the products are being studied in clinical trials to gather safety and effectiveness data, biological products must meet the requirements of part 312 (21 CFR part 312). FDA's biologics regulations require the submission of both product license applications (PLA's) and establishment license applications (ELA's) (21 CFR 601.1 through 601.10). Biologics establishments and products must satisfy detailed standards set forth in the regulations (21 CFR parts 600 through 680).

Section 351(b) of the PHS Act prohibits falsely labeling or marking a biological product. Under section 361 of the PHS Act (42 U.S.C. 264), the agency may promulgate regulations to prevent the introduction, transmission, or spread of communicable diseases.

Products considered to be biological products subject to the provisions of section 351 of the PHS Act are simultaneously also drugs or devices subject to the applicable provisions under the act. For example, the adulteration, misbranding, and registration provisions of the act would apply to the product as a drug or device.

Under section 501 of the act (21 U.S.C. 351), both drugs and devices are considered adulterated for any of a number of specified reasons. Included among these adulteration provisions is the requirement that the methods and facilities and controls used for manufacture, processing, packing, and holding or installation conform with current good manufacturing practice (CGMP) regulations (21 U.S.C. 351(a)(2)(B) and (h)). FDA's implementing regulations codified at 21 CFR parts 211 and 820 specify the drug and device CGMP requirements.

Section 502 of the act (21 U.S.C. 352) sets forth misbranding provisions that apply to drugs and devices. Among other circumstances, a drug or device is considered misbranded if the labeling is false or misleading or if the labeling fails to bear adequate directions for use or adequate warnings against unsafe use (21 U.S.C. 352(a) and (f)). Any drug or device is also misbranded if it is dangerous to health when used in the manner or with the frequency suggested in the labeling (21 U.S.C. 352(j)). For prescription drugs and restricted

devices, section 502 of the act describes certain information that must be included in all advertisements or other printed material (21 U.S.C. 352(n) and (r)). FDA's regulations also establish labeling and advertising requirements in more detail (21 CFR parts 201, 202, and 801).

Section 510 of the act (21 U.S.C. 360) requires persons who own or operate establishments for the manufacture, preparation, propagation, compounding, or processing of drugs or devices (with certain exceptions) to register those establishments with FDA. Individuals who must register their establishments under section 510 of the act must also file a list of all the drugs and devices being made or processed at the establishment. FDA's registration regulations are codified at 21 CFR parts 207 and 807.

Although products regulated by FDA as biological products must also meet drug or device requirements, the agency does not require duplicate premarket approvals. For example, if FDA requires a PLA to be submitted for the product as a biologic, the agency does not also require submission of a new drug application (NDA) or a device premarket approval application (PMA).

The interstate commerce nexus needed to require premarket approval under the statutory provisions governing biologics and drugs may be created in various ways in addition to shipment of the finished product by the manufacturer. For example, even if a biological drug product is manufactured entirely with materials that have not crossed State lines, transport of the product into another State by an individual patient creates the interstate commerce nexus. If a component used in the manufacture of the product moves interstate, the interstate commerce prerequisite for the prohibition against drug misbranding is also satisfied even when the finished product stays within the State. Products that do not carry labeling approved in a PLA (or NDA) are misbranded under section 502(f)(1) of the act (21 U.S.C. 352(f)(1); 21 CFR 201.5, 201.100(c)(2)). Moreover, falsely labeling a biological product is prohibited under section 351(b) of the PHS Act without regard to any interstate commerce nexus (42 U.S.C. 262(b)). The act contains a presumption of interstate commerce for devices (section 709 of the act (21 U.S.C. 379a)).

Both the PHS Act and the act provide authority for enforcement of the various statutory requirements. FDA is authorized to conduct inspections to determine compliance with regulatory requirements (42 U.S.C. 262(c) and 21

U.S.C. 360(h) and 374). Approved PMA's may be suspended or revoked (42 U.S.C. 262(a) and 21 U.S.C. 355(e) and 360e(e)). Biological products and devices may be recalled under certain circumstances (42 U.S.C. 262(d)(2) and 21 U.S.C. 360h). Judicial actions, including seizures, injunctions, and criminal prosecutions, may also be initiated (42 U.S.C. 262(f) and 21 U.S.C. 332, 333, and 334).

Some products may contain a combination of biological products and drugs or devices. Under a provision of the Safe Medical Devices Act of 1990, FDA determines the primary mode of action of the combination products (21 U.S.C. 353(g)), then assigns the primary jurisdiction for review of the product within the agency based on that determination. FDA has established procedures for designating the organization within FDA (i.e., the Center for Biologics Evaluation and Research (CBER), the Center for Drug Evaluation and Research (CDER), or the Center for Devices and Radiological Health (CDRH)) to review combination products or any other products where the agency center with primary jurisdiction is unclear (21 CFR 3.1 through 3.10). CBER, CDER, and CDRH have also entered into intercenter agreements to clarify the centers' responsibilities for reviewing various kinds of products.

B. Regulation of Somatic Cell and Gene Therapy Products

This statement is intended to present the agency's current approach to regulating somatic cell and gene therapy products. For the purpose of this statement, somatic cell therapy products are defined as autologous (i.e., self), allogeneic (i.e., intra-species), or xenogeneic (i.e., inter-species) cells that have been propagated, expanded, selected, pharmacologically treated, or otherwise altered in biological characteristics *ex vivo* to be administered to humans and applicable to the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries. Cellular products intended for use as somatic cell therapy are biological products subject to regulation pursuant to the PHS Act (42 U.S.C. 262) and also fall within the definition of drugs in the act (21 U.S.C. 321(g)). As biological products, somatic cell therapy products are subject to establishment and product licensure to ensure product safety, purity, and potency. At the investigational stage, these products must be in compliance with part 312. Clinical trials are, therefore, to be conducted under IND's. As drugs, somatic cell therapy products are also

subject to drug requirements such as conformity with CGMP regulations.

FDA has not required premarketing approval for many types of transplantation, including bone marrow transplants. However, recent scientific and biotechnological developments now enable bone marrow to be manufactured into a somatic cell therapy product. Such products are subject to FDA regulation consistent with the approach to other somatic cell therapies described in this statement. In addition, other forms of transplantation, such as the transfer of whole organs and tissues, have been, or are currently being reassessed and addressed by FDA or other Federal agencies in light of current knowledge and technological advances.

Gene therapy products are defined for the purpose of this statement as products containing genetic material administered to modify or manipulate the expression of genetic material or to alter the biological properties of living cells. Some gene therapy products (e.g., those containing viral vectors) to be administered to humans fall within the definition of biological products and are subject to the licensing provisions of the PHS Act, as well as to the drug provisions of the act. Other gene therapy products, such as chemically synthesized products, meet the drug definition but not the biological product definition and are regulated under the relevant provisions of the act only.

Biological products intended for use as source materials for further manufacture into licensed somatic cell therapy products or gene therapy products require premarketing approval as biological products intended for further manufacture when they are shipped from one legal entity to another. Such products would be considered part of a shared manufacturing arrangement in which: (1) Two or more manufacturers perform different aspects of the manufacture of a product, (2) neither performs nor is licensed to perform all aspects of the manufacture, and (3) each manufacturer holds product and establishment license applications. In a shared manufacturing arrangement, FDA accepts only license applications for biological products intended for further manufacture that specify the licensed manufacturer or manufacturers to which the intermediate product will be shipped and approves such applications only after demonstration of safety and efficacy of the end product. For example, biological gene therapy products intended for use *ex vivo* in the manufacture of genetically altered cells for somatic cell therapies will require premarketing approval as biological

products intended for further manufacture when shipped from one legal entity to another and will be approved only when the final somatic cell therapy product is approved. For further discussion regarding shared manufacturing, refer to FDA's policy statement concerning cooperative manufacturing arrangements for licensed biological products, which was published in the **Federal Register** on November 25, 1992 (57 FR 55544).

In accordance with the statutory provisions governing biological products and drugs, a somatic cell therapy product or gene therapy product must be the subject of an IND in compliance with part 312 or of an approved PLA regardless of whether the finished product is shipped across State lines.

The manufacture of somatic cell therapy products or gene therapy products will involve many ancillary products used as part of the manufacturing process. The ancillary products are not intended to be present in final products but may have an impact on the safety, purity, or potency of the products under manufacture. Such ancillary products meet the definition of devices and, if marketed, will be regulated under the act device authorities, with the appropriate type of regulatory control being determined according to codified procedures (e.g., investigational device exemption (IDE)—21 CFR part 812; premarket approval (PMA)—21 CFR part 814; premarket notification (510(k))—21 CFR 870.81 through 807.97). When these ancillary products are used in the manufacturing of somatic cell or gene therapy products, they become subject to drug CGMP's, in particular for components and containers (21 CFR 211.80 through 211.94 and 211.101(b) and (c)).

Some of the ancillary products will already be marketed as medical devices, drugs, or biological products. When an ancillary product used as a component of the manufacturing process is marketed but not labeled for the specific use, such use may initially be described under the IND for the final somatic cell or gene therapy product. Such use of ancillary products by manufacturers of investigational somatic cell therapy or gene therapy products is contingent upon the submission of complete descriptions of the use of the ancillary product in the manufacturing process.

If the ancillary product used as a component of the manufacturing process does not have marketing approval, manufacturers of the somatic cell or gene therapy product must submit or provide cross-reference to a

complete description of the manufacturing process, specifications, qualification, and acceptance criteria of the ancillary product. This information may be filed by the sponsor of the IND for the somatic cell or gene therapy product, may be filed in an IND or IDE by the manufacturer of an ancillary product, or may be made available by the manufacturer of the ancillary product in a master file format, as defined in 21 CFR 814.3(d) and discussed in 21 CFR 814.20(c).

Manufacturers who wish to market ancillary products for use in the manufacturing of somatic cell or gene therapy products must file either: (1) A 510(k), (2) a PMA, (3) an amendment to an existing 510(k), PMA, NDA, or PLA.

The manufacture of somatic cell therapy products or gene therapy products may involve components of manufacture intentionally present as part of the final products. Products containing both a somatic cell component and another drug or device component in the final product will be handled as combination products.

The following statement succinctly describes FDA's current approach to regulating somatic cell therapy and gene therapy products with primary emphasis on premarket approval issues. As previously discussed, products that meet the biologic, drug, or device definition must also comply with other relevant provisions of the PHS Act and the act. Manufacturers may also find useful information in FDA's document entitled "Points to Consider in Human Somatic Cell Therapy and Gene Therapy," Docket No. 91N-0428, available from CBER's Congressional and Consumer Affairs Branch (address above).

III. Statement

A. Somatic Cell Therapy

1. Definition

Somatic cell therapy is the prevention, treatment, cure, diagnosis, or mitigation of disease or injuries in humans by the administration of autologous, allogeneic, or xenogeneic cells that have been manipulated or altered ex vivo. Manufacture of products for somatic cell therapy involves the ex vivo propagation, expansion, selection, or pharmacologic treatment of cells, or other alteration of their biological characteristics.

2. Cells Subject To Licensure as Final Products When Intended for Use as Somatic Cell Therapy

Cells subject to licensure as final biological products when intended for use as somatic cell therapy include cells

manipulated in a way that changes the biological characteristics of the cell population (e.g., by expansion, selection, encapsulation, activation, or genetic modification as a part of gene therapy as defined in section III.B.1. of this document).

Examples include the following: (1) Autologous or allogeneic lymphocytes activated and expanded ex vivo (e.g., lymphokine-activated killer cells (LAK), tumor infiltrating lymphocytes (TIL cells), antigen specific clones); (2) encapsulated autologous, allogeneic, or xenogeneic cells or cultured cell lines intended to secrete a bioactive factor or factors (e.g., insulin, growth hormone, a neurotransmitter); (3) autologous or allogeneic somatic cells (e.g., hepatocytes, myocytes, fibroblasts, bone marrow- or blood-derived hematopoietic stem cells, lymphocytes) that have been genetically modified; (4) cultured cell lines; and (5) autologous or allogeneic bone marrow transplants using expanded or activated bone marrow cells. (For bone marrow products whose status is not clear, consult CBER.)

3. Cells and Tissues Subject to Licensure as Source Material

Cells and tissues subject to biological product licensure as source material include allogeneic or xenogeneic cells harvested by other than the final product license holder and intended for manufacture into a somatic cell product. Examples include the following: (1) Muscle cells removed from donors and shipped to a manufacturer for expansion into a muscle cell therapy, (2) animal cells harvested at an animal care facility and shipped to a manufacturer for encapsulation or other manufacturing steps into a somatic cell therapy, and (3) other human tissue harvested from donors and shipped to another legal entity for manufacture into a somatic cell therapy.

4. Cells for Which Applications for Approval Prior to Marketing are not Presently Required

Cells for which applications for approval prior to marketing are not required at the present time include the following: (1) Cell transplants not having the characteristics described in sections III.A.2. and III.A.3. of this document, and (2) minimally manipulated or purged bone marrow transplants. Examples include the following: (1) Allogeneic bone marrow transplantation employing ex vivo T cell purging with a monoclonal antibody approved for such purging, (2) autologous bone marrow transplantation employing ex vivo tumor cell purging by an approved agent, and (3)

autologous bone marrow transplantation employing bone marrow enriched for stem cells by immunoadherence. (However, extensive manipulation of bone marrow for the purpose of obtaining purified stem cell populations would result in a somatic cell therapy subject to licensure.)

B. Gene Therapy

1. Definition

Gene therapy is a medical intervention based on modification of the genetic material of living cells. Cells may be modified *ex vivo* for subsequent administration or may be altered *in vivo* by gene therapy products given directly to the subject. When the genetic manipulation is performed *ex vivo* on cells that are then administered to the patient, this is also a type of somatic cell therapy. The genetic manipulation may be intended to prevent, treat, cure, diagnose, or mitigate disease or injuries in humans.

2. Final Products Containing the Genetic Material Intended for Gene Therapy

Final products containing the genetic material intended for gene therapy are regulated as biological products requiring PLA's (e.g., viral vectors containing genetic material to be transferred, *ex vivo* transduced cells and analogous products) or as drugs requiring NDA's (e.g., synthetic products) regardless of whether they are intended for use *in vivo* or *ex vivo*. Gene therapy products that are licensed biological products will be approved as biological products intended for further manufacture if they are intended to be used *ex vivo* during the manufacture of genetically altered cells.

Examples include the following: (1) A synthetic polynucleotide sequence intended to alter a specific genetic sequence in human somatic cells after systemic administration is regulated as a drug requiring an NDA; (2) a retroviral vector containing the adenosine deaminase (ADA) gene, intended to be administered intravenously to the patient, is regulated as a biological product requiring a PLA; and (3) a

retroviral vector containing the ADA gene and intended to modify cells *ex vivo* is regulated as a biological product intended for further manufacture requiring a PLA.

3. Viral Vector Systems Intended for Further Manufacture Into Final Products

The manufacture and quality control of viral vector systems (i.e., not containing the complete genetic material) that are designed to serve as the starting point for further manufacture into final products (i.e., insertion of additional genetic material into the vector) may be described in a drug master file.

C. Ancillary Products Used during Production of Somatic Cell Therapies

Numerous products will be used during production of somatic cell therapy. Examples include the following: (1) Bioreactors and cell culturing systems, (2) components of culture media, (3) drug- or biologic-like components used to activate or otherwise change the biological characteristics of the cells, (4) certain antisense polynucleotides, and (5) agents used to purge or select or stimulate specific cell populations. A common characteristic of these products is that they are intended to act on the cells, rather than to have an independent effect on the patient. Additionally, the intended action of these products is not dependent upon incorporation into the somatic cell with maintenance of the products' structural or functional integrity.

These products meet the definition of medical devices. They are regulated as devices, with the type of regulatory control being determined according to codified procedures. In contrast, products administered directly to patients or products whose function requires incorporation into the somatic cells with maintenance to some degree of structural or functional integrity (e.g., viral or other vectors containing genetic material to be used in gene therapy) are not considered ancillary products; rather, they are regulated as drugs or biological products.

The center primarily responsible for regulating a particular device will be designated according to the current intercenter agreements. For example, according to the current agreement, CDER will regulate the synthetic antisense compounds, CBER will be responsible for monoclonal antibody-based purging agents, and CDRH will oversee the approval of bioreactors.

D. Combination Products

Many somatic cell products administered to patients will be combinations of a biological product and a device or of a drug, a biological product, and a device. Examples include the following: (1) Encapsulated pancreatic islet cells secreting insulin, and (2) a device containing encapsulated cells secreting a neurotransmitter. The combination products for which the primary mechanism of action is that of the somatic cell therapy component will be regulated as biological products.

IV. Comments

FDA recognizes that somatic cell and gene therapy products constitute a new and emerging scientific area. The agency will review and consider written comments on the regulatory approach set forth in this notice. Any comments received will be considered in determining whether amendments to, or revisions of, the approach are warranted. Two copies of any comments should be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Comments received are available for public examination in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

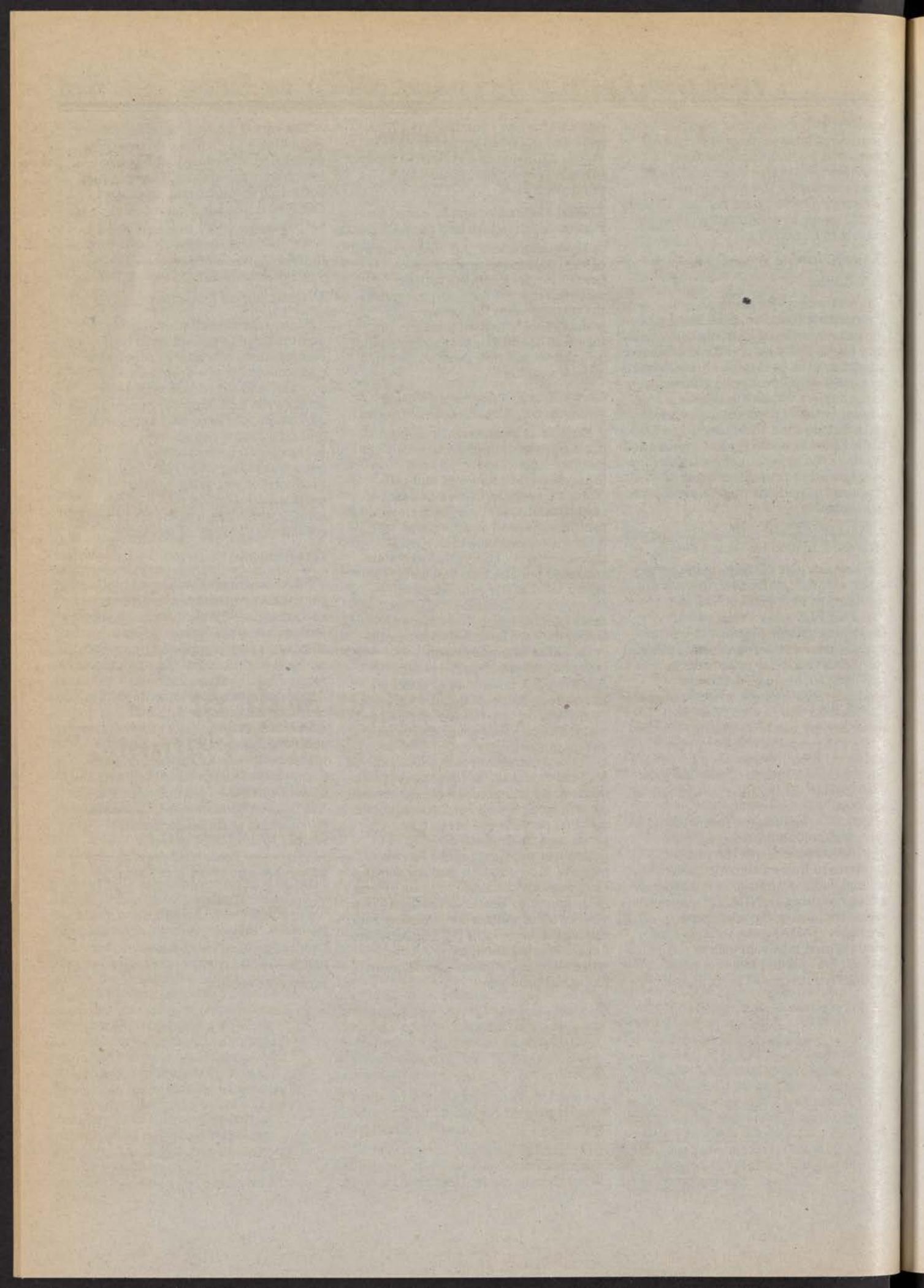
Dated: September 24, 1993.

Michael R. Taylor,

Deputy Commissioner for Policy

[FR Doc. 93-24938 Filed 10-13-93; 8:45 am]

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Federal Register

Thursday
October 14, 1993

Part III

**Department of
Health and Human
Services**

Food and Drug Administration

**21 CFR Part 101, et al.
Folic Acid; Proposed Rules**

DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 101**

[Docket No. 91N-100H]

RIN 0905-AB67

Food Labeling: Health Claims and Label Statements; Folate and Neural Tube Defects

AGENCY: Food and Drug Administration, DHHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to revise its food labeling regulations to authorize the use of a health claim about the relationship between folate and the risk of neural tube birth defects on labels or in labeling of foods in conventional food form or dietary supplements. This rule is being proposed in response to provisions of the Nutrition Labeling and Education Act of 1990 (the 1990 amendments) and the Dietary Supplement Act of 1992 (the DS Act) that bear on health claims. FDA has reviewed the scientific data in conformity with the requirements of the 1990 amendments and has considered recommendations provided by the Folic Acid Subcommittee of its Food Advisory Committee (the Folic Acid Subcommittee) as well as comments received. The agency has tentatively decided to authorize a health claim for folate and neural tube defects (NTD's) and to provide for safe use of folic acid in foods by amending several of its regulations that permit use of folic acid in foods.

DATES: Written comments by December 13, 1993. The agency is proposing that any final rule that may issue based upon this proposal become effective 30 days after the date of publication, except that for foods that are fortified with folic acid to ensure that the folic acid is safely used, any final rule authorizing a health claim will not be effective until the effective date of the amendment to the food additive regulation for folic acid proposed elsewhere in this issue of the *Federal Register*.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Jeanne I. Rader, Center for Food Safety and Applied Nutrition (HFS-175), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5375.

SUPPLEMENTARY INFORMATION:**I. Background****A. The 1990 Amendments**

The 1990 amendments to the Federal Food, Drug, and Cosmetic Act (the act) provided for extensive changes in the way foods are labeled. With respect to health claims, the 1990 amendments amended the act by adding a provision (section 403(r)(1)(B) of the act (21 U.S.C. 343(r)(1)(B))) that provides that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under the act. Congress enacted the health claims provisions of the 1990 amendments to help U.S. consumers maintain healthy dietary practices and to protect consumers from unfounded health claims. The 1990 amendments required that FDA evaluate 10 nutrient-disease relationships with respect to their appropriateness for health claims. The topic of folic acid and NTD's was among those 10 topics.

In the *Federal Register* of November 27, 1991 (56 FR 60537), the agency proposed to establish general requirements in conformity with the requirements of the 1990 amendments that would govern the appropriateness and validity of health claims. On January 6, 1993, FDA published a final rule on the general requirements for health claims (58 FR 2478). The regulation that FDA adopted provides that the agency will promulgate regulations authorizing health claims only when it determines, based on the totality of publicly available scientific evidence (including evidence from well-designed studies conducted in a manner that is consistent with generally recognized scientific procedures and principles), that there is significant agreement, among experts qualified by training or experience to evaluate such claims, that the claim is supported by the scientific evidence.

The regulation also requires, among other things, that all label and labeling statements about the substance-disease relationship be based on and be consistent with the conclusions set forth in the regulation (§ 101.14(d)(2)(i)(21 CFR 101.14(d)(2)(i)); that the claim be limited to describing the value that ingestion of the substance, as part of a total dietary pattern, may have on a particular disease or health-related condition (§ 101.14(d)(2)(ii)); that the claim be complete, truthful, and not misleading, and, where factors other than dietary intakes of the substance

affect the relationship between the substance and the disease or health-related condition, such factors may be required to be addressed in the claim (§ 101.14(d)(2)(iii)); that all information required to be in the claim appear in one place without other intervening material (§ 101.14(d)(2)(iv)); that the claim enable the public to comprehend the information provided and to understand the relative significance of such information in the context of a total daily diet (§ 101.14(d)(2)(v)); and that the level of the substance be sufficiently high and in an appropriate form to justify the claim (§ 101.14(d)(2)(vii)). Foods bearing health claims must also bear nutrition labeling including information on the substance that is the subject of the health claim (§ 101.14(d)(3)).

The health claim provisions of the 1990 amendments do not alter the requirements of the act that foods be safe, and that information on food labels and labeling be truthful and not misleading. Sections added by the 1990 amendments cannot be implemented independently of the remaining portions of the act. The act must be considered as a whole, and FDA's responsibility for ensuring that foods are safe, and that labeling is not misleading, is explicitly provided for in sections 402 (21 U.S.C. 342) and 403 of the act. Further, a health claim cannot be authorized for a substance if its use would increase the risk of another disease or health-related condition, and disqualifying levels for sodium, total fat, saturated fat, and cholesterol cannot be exceeded in foods bearing health claims. Additional disqualifying provisions could be specified as appropriate.

B. The DS Act

The agency notes that the final rule on general requirements for health claims that it published January 6, 1993 (58 FR 2478), did not include general requirements for health claims on dietary supplements. In October 1992, Congress passed the DS Act (Pub. L. 102-571), which imposed a moratorium until December 15, 1993, on FDA implementation of the 1990 amendments with respect to dietary supplements not in conventional food form. The DS Act directed FDA to issue, by June 15, 1993, proposed rules to implement the 1990 amendments with respect to dietary supplements and to issue final rules based on these proposals by December 31, 1993. Accordingly, FDA published (58 FR 33700, June 18, 1993) a proposed rule on general requirements for health claims on dietary supplements. FDA proposed to revise its food labeling

regulations to make dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances subject to the general requirements that apply to all other types of food with respect to health claims.

The DS Act also amended the so-called "hammer" provision of the 1990 amendments to provide that if the agency does not meet the established December 31, 1993, timeframe for issuance of final rules, the proposed regulations are to be considered final regulations.

With respect to the 10 nutrient-disease relationships that the 1990 amendments directed FDA to consider, in the *Federal Register* of January 6, 1993 (58 FR 2537 through 2849), the agency issued regulations announcing its decisions with respect to foods in conventional food form on each of these relationships. However, under section 202(a)(1) and (b) of the DS Act, while FDA could provide that the health claims that it authorized for food in conventional food form could also appear on dietary supplements that qualified to bear those claims, the agency could not act before December 15, 1993, to deny claims on dietary supplements on any of the 10 relationships.

In the wake of the January 6, 1993, final rules, six nutrient-disease relationships remain unresolved for dietary supplements. In this document, FDA is proposing to authorize a health claim on the relationship between folate and NTD's. This proposal pertains to all food, whether in conventional food form or a dietary supplement. Elsewhere in this issue of the *Federal Register*, FDA is addressing the remaining five nutrient-disease relationships for dietary supplements.

C. Chronology of Regulatory and Other Activities Related to Folate and NTD's

Since the passage of the 1990 amendments in November 1990, the rapidly evolving nature of the science relative to folate and NTD's and a number of Public Health Service (PHS) activities have intertwined with the regulatory process relative to a health claim for this topic. To facilitate an understanding of FDA's evolving activities on this matter, these events are described briefly in chronological order below and in greater detail later in this document.

1. The Proposed Rule

In response to the 1990 amendments, the agency proposed (56 FR 60610, November 27, 1991) not to authorize the use on the label or in labeling of foods, including dietary supplements, of

health claims relating to an association between folic acid and NTD's.

a. *Summary of data.* In reaching this tentative decision, the agency reviewed all of the available human studies. These studies consisted of four intervention trials with women at high risk of recurrence of an NTD pregnancy because of a personal history of such a pregnancy (Refs. 1, 2, 3, and 4; Table 1) and four observational studies of women at risk of occurrence of an NTD pregnancy (Refs. 5, 6, 7, 8, and 9; Table 2). FDA also reviewed a number of studies in which levels of various vitamins were measured in blood samples obtained from women during or following the periconceptional interval (i.e., around the time of conception) and a number of animal studies to determine whether vitamin status was associated with risk for an NTD pregnancy (see 56 FR 60610). With the exception of the Medical Research Council of the United Kingdom (MRC) trial (Ref. 4) the results of these studies were not conclusive relative to a specific effect of folate intake on reduction in risk of pregnancies affected by NTD's.

In July 1991, the MRC (Ref. 4) published the results of a well-conducted clinical trial in which women at high risk of an NTD-affected pregnancy, because of a personal history of such a pregnancy, were given supplements containing 4 milligrams (mg) (4,000 micrograms (μ g)) of folic acid daily (i.e., 10 times the Reference Daily Intake (RDI)), and the outcomes of their pregnancies were compared with those of women who had not received folic acid in their supplements. This study clearly demonstrated, for the first time, a significant reduction in recurrence of NTD's with high levels of folic acid but not with supplementation with other vitamins. This study established a specific role for folic acid in reducing the risk of recurrence of NTD pregnancies in women with a previous history of this defect, but extrapolation of these results to women in the general population at much lower risk of occurrence of NTD-affected pregnancies, and extrapolation of the results to lower levels of folate (e.g., 400 μ g folic acid daily, or 100 percent of the RDI), were problematic.

b. *Recommendations for women at risk of recurrence of an NTD-affected pregnancy.* In August 1991, the Centers for Disease Control (CDC) published guidelines for use of folic acid at high intake levels (i.e., at 4 mg (4,000 μ g or 10 times the RDI)) by those women who are planning a pregnancy and who are at high risk of a recurrence of an NTD-complicated pregnancy (Ref. 10). CDC recommended that women who had

previously had a pregnancy resulting in a fetus or an infant with a NTD should be counseled about the increased risk of such a complication in subsequent pregnancies and should be advised that folic acid supplementation may reduce the risk of a recurrence. The guidelines stated that such women should consult their physician when planning a pregnancy and, unless contraindicated, should be advised to take 4 mg (4,000 μ g) of folic acid daily beginning at least 4 weeks before conception and continuing through the first 3 months of pregnancy (Ref. 10). The guidelines did not specifically address the issue of folate consumption among these women during the times when they were not planning to become pregnant or among women who did not have a history of an NTD-affected pregnancy.

FDA, in its proposed rule published in the *Federal Register* of November 27, 1991 (56 FR 60610), restated significant portions of the August 1991 CDC recommendation and noted the significance of this guideline for women at high risk of a recurrence of an NTD-affected pregnancy. The agency tentatively decided, however, not to authorize a health claim on the relationship between folic acid and NTD's. The agency noted that the amount of folic acid needed for reduction in risk of recurrence of NTD's in women at high risk of this complication is significantly in excess of usual dietary intakes and exceeds amounts permitted under current food additive regulations. In addition, the agency tentatively concluded that there was not significant agreement among qualified experts that intakes of folic acid lower than the level of 4 mg (4,000 μ g) per (l) day used in the MRC trial would have the same protective effect as intake of the study dose of 4 mg/day. Additionally, at that time, there was not significant agreement among qualified experts that intakes of folic acid lower than those studied in this recurrence intervention trial, and consistent with current food additive regulations, would have the same effect in women in the general U.S. population, who are at much lower risk of an occurrence of an NTD-affected pregnancy than were the women at high recurrent risk who participated in the MRC study (56 FR 60610).

2. Reopening of the Comment Period

Subsequent to publication of the proposed regulation (56 FR 60610, November 27, 1991) and after the period for submitting comments in response to the proposal closed on February 25, 1992, FDA became aware of the possibility of significant new data on

folate and NTD's. Therefore, in the *Federal Register* of July 23, 1992 (57 FR 32751), the agency reopened the comment period to permit the inclusion of any new scientific data and information, particularly information that might become available as a result of a meeting on folic acid and NTD's that was to be held at CDC on July 27, 1992. The reopening of the comment period also provided an opportunity for the public to comment on that scientific data and information.

a. *New data.* As a result of the reopening of the comment period, preliminary data from a randomized, controlled trial that was conducted in Hungary (hereafter referred to as "the Hungarian study") of the effectiveness of multivitamin and multimineral supplements providing daily intakes of 0.8 mg (800 µg) of folic acid (i.e., twice the RDI) in reducing the risk of occurrence of NTD's became publicly available (58 FR 2606, Ref. 30). The agency also received information on the results of a case-control study of periconceptional use of multivitamins containing folic acid at daily doses of 0.4 mg (400 µg) and higher and the risk of occurrence of NTD's in women in Boston, Philadelphia, and Toronto (58 FR 2606, Ref. 31).

b. *PHS recommendation.* In September 1992, while FDA's rulemaking was in progress, the PHS (Ref. 11) issued a recommendation that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 mg (400 µg) of folic acid/day for the purpose of reducing their risk of having a pregnancy affected with spina bifida or other NTD's. The recommendation was based on data suggesting that folic acid, when given at a high dose (4 mg or 4,000 µg), can reduce the risk of recurrence of NTD's (Ref. 4) and on a synthesis of information from studies that used multivitamins containing folic acid at dose levels from 0 to 1,000 µg/day can. Based on information provided in these studies, PHS inferred that folate alone at levels of 0.4 mg (400 µg)/day can reduce the risk of NTD's in some women. The PHS recommendation identified three approaches to delivering folate to women of childbearing age in the general population, including improvements in dietary habits, daily use of folic acid supplements throughout the childbearing years, and fortification of the U.S. food supply.

The PHS recommendation also identified several issues that remained outstanding. Among these issues were: (1) The appropriate intake of folate for reduction in risk of NTD's; (2) the

potential role of other nutrients in reduction in risk of NTD's; (3) the "folate-preventable" fraction of NTD-affected pregnancies in women in the U.S. population; and (4) safety concerns, including effects of increased folate intakes in complicating the diagnosis of vitamin B₁₂ deficiency if the food supply were to become highly fortified with folic acid. The PHS statement also noted that because the effects of high intakes of folate are not well known, but include complicating the diagnosis of vitamin B₁₂ deficiency, care should be taken to keep total folate consumption at less than 1 mg (1,000 µg)/day except under the supervision of a physician (Ref. 11).

The target population for this recommendation includes about 70 million women of childbearing age in the United States throughout the approximately 30 years in which they are capable of becoming pregnant. The Department of Health and Human Services (DHHS)/PHS report estimated that about a 50-percent reduction in NTD births could occur if all women of childbearing age consumed 0.4 mg (400 µg) folic acid daily throughout their childbearing years (Ref. 11).

3. The Folic Acid Subcommittee

Given the seriousness of NTD's and the safety and other concerns stated in the PHS recommendation, the agency decided that it needed expert advice in deciding whether to authorize a health claim on folate and NTD's and in resolving certain separate but related issues involving the safety of folic acid. The agency convened the Folic Acid Subcommittee to consider the outstanding issues on folic acid (57 FR 52781, November 5, 1992). The Folic Acid Subcommittee had its first meeting on November 23 and 24, 1992 (Ref. 12). The agency asked the Folic Acid Subcommittee to provide recommendations on several issues, including identification of the appropriate target population for a folate-NTD's health claim, the appropriate daily intake of folate to reduce the risk of NTD's, safety concerns for the target population and the general population, and appropriate methods for presenting a health claim, if one is to be authorized, to the target population. The Folic Acid Subcommittee evaluated these issues in the broadest public health context and provided the agency with recommendations on educational activities for health professionals as well as for the target population, the need for surveillance both for changes in incidence of NTD's and for adverse effects of increased folate intake,

labeling of foods (including health claims), and fortification of the food supply with folic acid. The Folic Acid Subcommittee, however, was unable to resolve all of the issues at its November 1992 meeting, particularly those involving food fortification.

4. The Final Rule

The 1990 amendments required that, within 2 years of their passage, FDA publish final regulations on the 10 nutrient-disease relationships. Therefore, in the *Federal Register* of January 6, 1993 (58 FR 2606), the agency published a final rule on a health claim for folic acid and NTD's. The agency did not authorize a health claim for folic acid and NTD's at that time. The agency reaffirmed its support of the PHS recommendation that all women of childbearing age in the United States who are capable of becoming pregnant consume 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other NTD's. The agency noted, however, that while the PHS recommendation evidenced that significant scientific agreement exists regarding the relationship between folate and NTD's, unresolved questions about the safe use of folic acid in food remained. The agency concluded that it could not authorize a health claim for folate until the questions regarding the safe use of this nutrient, as well as other concerns raised by PHS, were satisfactorily resolved. The agency stated its intention to work expeditiously to try to resolve these issues, including a review of the recommendations of the Folic Acid Subcommittee.

On April 15, 1993, FDA reconvened the Folic Acid Subcommittee (Ref. 13). FDA updated the Folic Acid Subcommittee on work done by FDA staff on fortification models. FDA asked for clarification on what appeared to be an inconsistency in positions taken by the Folic Acid Subcommittee relative to health claims. (At the November 23 and 24, 1992, meeting, the Folic Acid Subcommittee supported the PHS recommendation but recommended against use of health claims). Following expressions of diverse opinions of the potential effectiveness of health claims as an educational tool and by close votes by subcommittee members, the Folic Acid Subcommittee supported FDA actions to propose to authorize a health claim and to propose to fortify cereal-grain products.

D. The Purpose and Scope of This Document

The sections above describe the significant, and in some cases,

conflicting factors that the agency must consider in addressing the topic of folate and NTD's. In trying to resolve these conflicts, the agency has posed a series of questions for itself. These questions, and the agency's proposed answers, provide the basic outline for the remainder of this document.

The questions addressed by FDA include the following:

(1) Is a health claim on food labels appropriate for the relationship between folate and NTD's?

(2) Should the food supply be fortified with folic acid to ensure that women have adequate folate intakes? If so, is it necessary to limit the foods to which folic acid can be added and the levels at which it can be added to specific foods?

(3) If there are to be limitations on the foods that can be fortified with folic acid, which foods are most appropriate for fortification and at what levels should they be fortified?

(4) If the agency concludes that a health claim can be safely implemented, what should such a claim say about folate and NTD's?

In this document, the agency is proposing to authorize a health claim relating diets adequate in folate to reductions in the risk of NTD-affected pregnancies. FDA has tentatively concluded, based on the totality of the scientific evidence, that there is significant scientific agreement among qualified experts supporting a relationship between folate and NTD's. The agency has also tentatively concluded that, based on its discussions with the Folic Acid Subcommittee and its analyses of food intake data, daily folate intakes can be maintained within safe ranges by allocating fortification with folic acid to specific foods in the food supply through an amendment to the food additive regulation for folic acid.

In companion documents published elsewhere in this issue of the *Federal Register*, the agency is proposing to amend the food additive regulation for folic acid and to amend the standards of identity for specific cereal-grain products. The agency will seek specific comment on the companion proposals and on this proposal from the Folic Acid Subcommittee, the experts who participated in the November 23 and 24, 1992, meeting, and the agency's Food Advisory Committee. After the advisory committee meets, the agency will make these comments available for public review and comment, as part of this rulemaking, as soon as possible. FDA encourages public comment on the views that it receives from these experts.

II. Regulatory History of Folic Acid

FDA regulates folic acid as a drug or as a food additive, depending upon its intended use.

A. The Drug Regulation

The agency evaluated the use of folic acid as a drug in the *Federal Register* of April 9, 1971 (36 FR 6843), in response to reports received from the National Academy of Sciences (NAS) on the therapeutic uses of folic acid. The agency concluded that folic acid administered orally or parenterally is effective in the treatment of megaloblastic anemias of tropical and nontropical sprue, those of nutritional origin, and those that may occur during pregnancy, infancy, and childhood. The agency found that administration of folic acid alone is improper therapy in the treatment of pernicious anemia and other megaloblastic anemias where vitamin B₁₂ is deficient, because such treatment may delay the appearance of (i.e., mask) the anemia of vitamin B₁₂ deficiency.

The agency found that in the presence of excess folic acid and inadequate vitamin B₁₂, the anemia of vitamin B₁₂ deficiency, which is generally the earliest indicator of the deficiency, may not develop (i.e., may be masked), thus delaying the diagnosis of the deficiency. Other serious consequences of the deficiency (e.g., severe and often irreversible neurologic damage), however, may progress and worsen because of the failure to detect the anemia at an early stage of the deficiency and initiate appropriate therapy with vitamin B₁₂. This interaction between the functions of folic acid and vitamin B₁₂ (i.e., the ability of folic acid to mask the anemia of vitamin B₁₂ deficiency) has been recognized for many years and is the basis for the precautionary statement on oral and parenteral preparations of folic acid for therapeutic use. In the final rule, the agency stated the conditions under which it would approve new drug applications for folic acid preparations (36 FR 6843). The labeling conditions included the following precaution: "Folic acid especially in doses above 1.0 mg daily may obscure pernicious anemia, in that hematologic remission may occur while neurological manifestations remain progressive."

In the *Federal Register* of October 17, 1980 (45 FR 69043 at 69044), the agency amended the "Precautions" statement to be included in the labeling of oral and parenteral preparations of folic acid for therapeutic use in treating patients with megaloblastic anemia of folate deficiency, because the agency found

that the revision more accurately stated the level at which folic acid may obscure pernicious anemia. The agency stated: "While obscuration of pernicious anemia does not occur at levels of 0.1 mg of folate/day, hematologic remissions in pernicious anemia have been reported at levels as low as 0.25 mg of folate per day." The precautions section of the labeling conditions for folic acid was amended to read as follows: "Folic acid in doses above 0.1 mg daily may obscure pernicious anemia in that hematologic remission can occur while neurological manifestations remain progressive."

B. The Food Additive Regulation

In the *Federal Register* of August 2, 1973 (38 FR 20725), FDA published a final rule establishing safe conditions of use for folic acid (folacin) in food (§ 121.1134 (21 CFR 121.1134)). In determining the safe conditions of use for folic acid, the agency considered the Recommended Dietary Allowance (RDA) established by NAS and other relevant information. In 1977, § 121.1134 was recodified as § 172.345 (21 CFR 172.345).

The food additive regulation provides that folic acid can be added to foods if the maximum daily intake does not exceed 0.4 mg (i.e., 400 µg)/day for food labeled without reference to age or physiologic state. The regulation also includes limitations based on age and the conditions of pregnancy or lactation. Daily intake is not to exceed 0.1 mg for infants, 0.3 mg for children under 4 years of age, 0.4 mg for adults and children 4 or more years of age, and 0.8 mg for pregnant or lactating women (§ 172.345). As currently written, however, this regulation provides no guidance to manufacturers as to how to reach the stated limit, and, as such, is inadequate to allocate folic acid safely in the food supply.

III. The Nature of the Relationship Between Folate and NTD's—Review of the Scientific Evidence

A. Background

1. Folates

The term "folates" is a generic descriptor for a group of compounds that have nutritional properties and chemical structures similar to those of pteroylglutamic acid (PGA, the parent form of the vitamins) (Ref. 14). Naturally-occurring folates in foods are in the reduced form (i.e., the dihydro or tetrahydro form) and are often conjugated to a number of glutamic acid residues (i.e., folylpolyglutamates). Synthetic folic acid added as a fortificant to foods, including dietary

supplements, is the oxidized, monoglutamate form of the vitamin.

During passage through the intestinal mucosa and liver, the reduced folylpolyglutamates found in foods are deconjugated (i.e., excess glutamic acid residues are removed) and converted to N^5 -methyltetrahydrofolate, a reduced form with one methyl group that is the predominant circulating form of the vitamin in the serum and red blood cells. Folic acid (the oxidized, monoglutamate form of the vitamin), at low levels of intake, is also transported and reduced to the biologically active forms of the vitamin. Reduction of the oxidized folic acid is essential for its ability to function as a vitamin (i.e., to be involved in metabolic reactions involving one-carbon units) in human tissues (Ref. 14).

At median dietary intakes of above 200 $\mu\text{g}/\text{day}$, dietary folates are converted to the circulatory N^5 -methyltetrahydrofolate form. The processes required to reduce and metabolize the vitamin can be saturated. At increasing levels of intake of synthetic folic acid, progressively more of the free vitamin circulates through the body in its oxidized form, and increasing amounts are excreted unmetabolized in the urine (Ref. 16).

As a vitamin, folate functions metabolically in the synthesis of amino acids and nucleic acids. Insufficient quantities of folate in the diet lead to impaired cell multiplication and alterations in protein synthesis (Ref. 15). These effects are most noticeable in rapidly growing or dividing cell populations (Ref. 15). Pregnancy increases the need for folate and many other nutrients because of the need of the mother to maintain adequate nutrition and to meet the nutritional requirements of the developing fetus (Ref. 15).

2. NTD's

NTD's are serious birth defects of the brain (e.g., anencephaly or absence of the forebrain and skull) or spinal cord (e.g., spina bifida or defective closure of the vertebrae around the spinal cord) that can result in infant mortality or serious disability. The neural tube forms between the 18th and 20th days of pregnancy and closes between the 24th and 27th days. The neural tube, therefore, forms and closes before most women are aware of their pregnancy.

Each year, NTD's occur in approximately 2,500 cases in the United States (i.e., in about 0.6/1,000 live births). During recent decades, the NTD rate in the United States has declined from 1.3/1,000 live births in 1970 to 0.6/1,000 live births in 1989 (Ref. 17).

Factors that have contributed to this decline are not completely understood. Increased use of prenatal diagnosis and termination of pregnancy have been proposed as contributing factors; however, the declining trend in NTD's predates the widespread use of prenatal diagnosis (Ref. 18). The current U.S. rate of about 0.6/1,000 live births compares to rates of 2.8/1,000 in Hungary, 6.4/1,000 in Northern Ireland, and 6 to 13/1,000 in northern China. In 1989, spina bifida and anencephaly accounted for 533 infant deaths, or about 1.3 percent of all infant mortality in the United States. Although NTD's are not a major cause of infant mortality, they contribute significantly to life-long and often severe disabilities (Ref. 17).

The majority of NTD's are believed to have a multifactorial basis including both genetic and environmental factors. Environmental factors associated with NTD's include maternal health (e.g., febrile illness) (Ref. 19; and see 56 FR 60610), maternal use of certain antiseizure drugs (e.g., valproic acid, carbamazepine) (Ref. 20; and see 56 FR 60610), and environmental contaminants (Refs. 21 and 22). Another risk factor is a personal history of a pregnancy affected with an NTD (Ref. 23). Recurrence rates of 2 to 3 percent have been observed among U.S. women who have had a previous child with an NTD versus occurrence rates of about 0.06 percent in women in the general population. However, 90 to 95 percent of infants with an NTD are born to women who do not have a family history of these defects.

3. Relationship of Folates and NTD's

Several lines of evidence led to the hypothesis that nutritional factors might be involved in causing some cases of human NTD's (see 56 FR 60610, November 27, 1991, and 58 FR 2606, January 6, 1993 for references). Among the nutrients that were thought to play a role in the development of NTD's, folate, a B vitamin, received the greatest attention because of early observational studies in humans and because of the well-recognized role of folate in cell division and growth. Because the neural tube (the precursor of the brain and spinal cord) forms early in embryonic development (before the end of the 4th week of gestation), interventions aimed at reducing the risk of these defects must occur periconceptionally (i.e., during the interval extending from at least 1 month before conception and continuing through the first 6 weeks of pregnancy), often before a woman realizes that she is pregnant.

B. Review of the Scientific Evidence

Both in the November 27, 1991, proposed rule and in the January 6, 1993, final rule, the agency reviewed the totality of the publicly available scientific evidence on whether there is a relationship between folic acid and NTD's (see 56 FR 60610). Because of the agency's previous extensive reviews, only a brief overview of these studies will be provided here. Studies that became publicly available subsequent to publication of the final rule will also be reviewed.

Several different types of human studies have examined the relationship between folate and risk of NTD-affected pregnancies. The available human studies consist of several intervention trials and observational studies. In intervention trials (or clinical trials), the effects of periconceptional treatment with defined intakes of folic acid-containing supplements or placebos are compared in groups of subjects under controlled conditions. Observational studies, unlike intervention or clinical trials, do not compare the effects of defined treatments with the effects of a placebo. Rather, observational studies provide information on associations between an outcome or lack of an outcome (i.e., NTD's) and other factors (such as dietary intakes or supplement use) that differ between two outcome groups.

The populations in which studies of folate and NTD's have been performed have also varied. A number of intervention trials have examined the effects of periconceptional use of folic acid-containing supplements in women with a personal history of an NTD pregnancy because such women are at high risk of having another such pregnancy. Such trials are called *recurrence* trials. Studies with women in the general population without a personal history of an NTD pregnancy are called *occurrence* studies.

1. Intervention Trials in Women at Risk of Recurrence of NTD-Affected Pregnancies

Before 1991, three studies, two carried out in the British Isles and one carried out in Cuba, had suggested that supplementation with folic acid-containing multivitamins or with high levels of folic acid may reduce the risk of recurrence of NTD's in women at high risk of this complication. Two of these trials used high doses of folic acid (4 or 5 mg; 4,000 or 5,000 μg) daily and observed statistically nonsignificant trends in reduction in risk of NTD's (Refs. 1 and 3). The third trial showed a statistically significant beneficial

effect of a multivitamin supplement containing 0.36 mg (360 µg) of folic acid and vitamins A and D, thiamin, riboflavin, vitamin B₆, niacin, and vitamin C (see Table 1; Ref. 2).

In July 1991, the MRC published the results of a well-conducted randomized clinical trial in which women at high risk of a recurrence of an NTD-affected pregnancy, because of a personal history of such a pregnancy, were given supplements containing a high dose (i.e., 4 mg; 4,000 µg; 10 times the RDI) of folic acid with or without other vitamins daily (see 56 FR 60610 for review). The outcomes of their pregnancies were compared with those of women who had received identical supplements except for folic acid (Ref. 4). One thousand eight hundred seventeen women were recruited for this trial, of whom 1,195 subsequently had informative pregnancies (i.e., the outcome of the pregnancy with respect to the recurrence of an NTD in the fetus or infant was known). The great majority of patients in this study were from the United Kingdom or Hungary, areas with high occurrence rates of NTD's (e.g., 6.4/1,000 live births in Northern Ireland and 2.8/1,000 live births in Hungary). The data from this trial demonstrated that daily doses of 4 mg (4,000 µg) of folic acid before and during early pregnancy resulted in a 70 percent reduction in recurrence of NTD's in this group of high-risk women.

As stated above, this study clearly demonstrated, for the first time, a significant reduction in recurrence of NTD's with high levels of folic acid but not with other vitamins. This study established a specific role for folic acid in reducing the risk of recurrence of NTD pregnancies in women with a previous history of this defect, but extrapolation of these results to women in the general population at much lower risk and to lower levels of folate intake (i.e., 400 µg folate daily, or 100 percent of the RDI) was problematic. The level of folic acid used in the MRC trial, 4 mg (4,000 µg/day), is within the dose level regulated as a drug by FDA. The results of the MRC trial also showed that approximately 25 percent of NTD recurrences were resistant to folic acid supplementation, an observation that likely reflects the heterogeneous or multifactorial etiology of NTD's.

2. Intervention Trial in Women at Risk of Occurrence of NTD-Affected Pregnancies

In August of 1992, preliminary data from a randomized, controlled trial that was conducted in Hungary of the effectiveness of multivitamin and multimineral supplements providing

daily intakes of 0.8 mg (800 µg) of folic acid (two times the RDI) in reducing the risk of occurrence of NTD's became publicly available (see 58 FR 2606) (Refs. 24 and 25). The rate of NTD's is 2.8/1,000 live births in Hungary.

In the Hungarian study (Ref. 24), women took multivitamin and multimineral preparations containing 0.8 mg (800 µg) of folic acid, 11 other vitamins, and 7 minerals (see Table 1). A control group of women took a placebo containing three trace minerals, calcium ascorbate (a source of vitamin C), and lactose (a sugar). Results of 4,156 pregnancies were reported. There were no occurrences of NTD's in the folic acid-containing multivitamin and multimineral group compared to 6 occurrences in the placebo group. At the time of closure of the trial, outcomes of several hundred pregnancies in both groups were unknown.

3. Observational Studies of Occurrence of NTD's

In developing its proposed rule, FDA reviewed the four available observational studies of associations between supplement use and risk for occurrence of NTD's (three case-control studies and one prospective cohort study) (56 FR 60610). The studies of Bower and Stanley (Ref. 8) and Milunsky et al. (Ref. 6) found statistically significant associations between reduced rates of NTD's and use of folic acid-containing multivitamin supplements during the periconceptional interval. The composition of the multivitamin supplements used in these studies was either undefined or, in one study (Ref. 6), the majority of preparations also contained vitamins A, C, D, or E in addition to folic acid (Table 2). These studies were unable to determine whether folic acid per se, other nutrients, or combinations of nutrients were specifically related to reduction in risk of NTD's. One study showed that timing of supplement use was important in that use of folic acid-containing supplements during the first 6 weeks of pregnancy was associated with a decreased incidence of NTD's, but no relationship was observed if use of the supplement was begun after 6 weeks of pregnancy (Ref. 6). This study also found from calculations of dietary folate intakes in nonsupplement users that dietary intakes of folate greater than 100 µg/day (0.1 mg) were associated with reduced risk of occurrence of NTD pregnancies. Conversely, one case-control study of more than 1,600 women carried out in areas of low prevalence of NTD's in the United States failed to support the findings of a positive effect

against occurrence of these defects in women who consumed folic acid-containing multivitamin supplements or fortified breakfast cereals (Ref. 7).

In August 1992, the agency received information on the results of a case-control study of periconceptional use of multivitamins containing folic acid at daily doses of 0.4 mg (400 µg) and higher and the risk of occurrence of NTD's in women in Boston, Philadelphia, and Toronto (see 58 FR 2606). The results of this study in U.S. and Canadian populations were published in March 1993. The study (Ref. 26) covered 436 recurrent NTD cases and 2,615 control cases with other major malformations occurring between 1988 and 1991 in Boston, Philadelphia, and Toronto. Eight percent of cases (i.e., 35 cases) and 13 percent of controls (i.e., 340 controls) used multivitamin supplements periconceptionally. The multivitamin supplements used were defined as preparations containing "at least two vitamins, one of which was water-soluble" (see Table 2 for definition of supplements). The authors reported an approximate 40 percent reduction in prevalence of NTD's associated with use of supplements. The most common dose of folic acid in the supplements was 0.4 mg (400 µg). For nonusers of supplements, there was a statistically significant trend of decreasing risk of occurrence of NTD's associated with dietary folate intakes of 0.25 mg (250 µg, or 62 percent of the RDI)/day and higher (Table 3). Reductions in risk associated with dietary folate intakes alone were 30 to 40 percent.

PHS, in issuing its September 1992 recommendation (Ref. 11), examined the available human studies discussed above (except the Werler et al. (Ref. 26) study which was not yet publicly available) and concluded:

In summary, the data available indicate that folic acid can help avert NTDs (neural tube defects) when given at high-dose levels (i.e., 4.0 mg per day). The results of the British MRC study showed that the addition of other vitamins to 4.0 mg of folic acid confers no extra benefit in averting NTDs. Based on a synthesis of information from several studies, including those which used multivitamins containing folic acid at a daily dose level of ≥ 0.4 mg, it was inferred that folic acid alone at levels of 0.4 mg per day will reduce the risk of NTDs. The protective effect found in the studies of lower-dose folic acid, measured by the reduction in NTD incidence, ranged from none to substantial.

4. Studies in Animal Model Systems

Studies with animal model systems are one of several lines of investigation that are used to establish causal relationships and to elucidate

mechanisms of actions between deficiencies or excesses of various nutrients and adverse outcomes such as birth defects. The agency reviewed relevant animal studies in its proposed rule (56 FR 60610) and noted that such studies have provided some support for the hypothesis that nutrient deficiencies may be one factor in the complex etiology of NTD's. For example, deficiencies of nutrients such as vitamin B₁₂, vitamin B₆, pantothenic acid, and vitamin E have been reported to cause NTD's in some species (Ref. 19). In its proposed rule and final rule, the agency reviewed studies that demonstrated that:

(1) In rats and mice, folate deficiency alone does not produce NTD-affected embryos in a reproducible manner (Refs. 27 and 28), but that rats fed folate-deficient diets in conjunction with antifolate drugs during pregnancy produce embryos with multiple congenital abnormalities (Ref. 29);

(2) Excess vitamin A administered in early pregnancy increases the incidence of NTD's in a mouse model system, and that compounds such as folic acid, folic acid, vitamin B₁₂, and vitamin E do not significantly affect the incidence of this defect (Ref. 30);

(3) NTD's in the golden hamster model system can be induced by maternal hyperthermia or ethanol following exposures in early gestation, and that folate supplementation begun before such treatments does not prevent the alcohol- or heat-induced defects (Ref. 31); and

(4) There are conflicting reports regarding whether the anticonvulsant drug valproic acid, suspected of causing NTD's in humans, does so through effects on folate metabolism (see 56 FR 60610 and 58 FR 2606 for review).

Overall, these animal studies do not provide evidence for a consistent association between folate nutrition and NTD's, although they do show that disturbed folate metabolism may be one factor in the complex etiology of these defects.

5. Related Data

a. *Maternal vitamin status.* Women with a personal history of an NTD pregnancy have generally been the subject of studies to try to relate maternal nutritional status to pregnancies affected by NTD's. Measurement of maternal or fetal blood levels of specific vitamins is one method used to test the hypothesis that folate status is directly related to risk of an NTD pregnancy. In its proposal (56 FR 60610) and final rule (58 FR 2606), FDA reviewed studies in which levels of various vitamins were measured in the

blood of women during or following the periconceptional interval to determine whether maternal vitamin status is related to risk of an NTD-affected pregnancy (Refs. 32, 33, 34, and 35). These studies and studies that became available after publication of the final rule are summarized below.

Yates et al. (Ref. 34), in a study on Scottish women, reported that red blood cell folate levels were significantly lower in women who had two or more NTD pregnancies than in control women. No differences were found in serum folate, vitamin B₁₂, or other serum vitamin measurements (plasma or white blood cell vitamin C, vitamin A, thiamin, riboflavin, vitamin B₆, vitamin E) between cases and controls. The authors reported that dietary intakes of folate among the groups of mothers who had NTD-affected pregnancies and those who did not were not significantly different, and dietary folate intakes did not correlate with pregnancy outcome (Ref. 34).

In another study, Mills et al. (Ref. 35) measured levels of folate, vitamin B₁₂, and vitamin A in maternal serum samples drawn early in pregnancies resulting in offspring with NTD's and in control pregnancies. The results of this population-based study in Finland, a low prevalence area for NTD's, showed no relationship between maternal serum folate, vitamin B₁₂, and vitamin A during pregnancy and risk of NTD's.

In a study published after publication of FDA's final rule, Mooij et al. (Ref. 36) investigated whether periconceptional clinical profiles of vitamin status in women in the Netherlands could provide a means of identifying women at risk of recurrence of an NTD pregnancy. Mooij et al. (Ref. 36) evaluated vitamin status in women who had a history of an NTD pregnancy and who planned a further pregnancy. Participants in the nonrandomized study were volunteers.

Vitamin supplements (one multivitamin plus 5 mg (5,000 µg) of folic acid daily) were offered to 50 women. Eighteen (18) other women were willing to participate in the study but did not want to use supplements. Supplementation began at least 28 days before conception and continued until week 12 of gestation. Vitamin levels were measured in serum or red blood cells preconceptionally and at weeks 6 and 9 of gestation. Six of the 50 vitamin-supplemented women were subsequently excluded because of inadequate data collection. A total of 62 pregnancies were evaluated.

A comparison of preconceptional mean serum or red blood cell vitamin concentrations between the two groups

revealed no significant differences for any of the vitamins measured (Ref. 36). During early pregnancy, serum levels of vitamin C and vitamin B₁₂ decreased significantly in unsupplemented women but not in the vitamin-supplemented women. Serum and red blood cell folates did not decrease significantly during early pregnancy in unsupplemented women, while significant increases in serum and red blood cell folate occurred in early pregnancy in vitamin-supplemented women. The authors concluded that evaluation of vitamin profiles is not a suitable means of identifying women at risk for NTD's before pregnancy (Ref. 36).

Thus, clinical studies that measured maternal folate status provide no consistent evidence for an association between folate nutritional status and NTD's.

b. *Potential role of nutrients other than folate in etiology of NTD's.* It is well recognized that NTD's may be caused by a number of environmental agents and genetic factors. Nutritional factors other than folate are hypothesized to be involved in causing some human NTD's (see 56 FR 60610 for references). For example, animal studies have shown that deficiencies of some vitamins during pregnancy (such as vitamin B₁₂, vitamin B₆, and pantothenic acid) produce a variety of fetal abnormalities, including NTD's. Several studies showed that decreases in maternal serum levels of vitamin C and vitamin B₁₂ were associated with pregnancies complicated by NTD's (Refs. 32, 36, 37, and 38). Epidemiologic studies of NTD's in humans suggest a link with nutrition because of variations in prevalence of such defects with social class, dietary habits, and season (see 56 FR 60610 for references).

Several biological mechanisms have been suggested to explain the causes of NTD's or to explain the roles of putative protective agents. In addition to studies and possible causes already discussed, several other studies have attempted to elucidate additional mechanisms for these defects.

i. *Genetic defects.* It has been postulated that a genetic defect may contribute to some NTD's both in animal model systems and in humans. For example, the disorder homocystinuria (excessively high urinary levels of homocystine, a metabolic product of the essential amino acid, methionine, and an intermediate in the synthesis of the amino acid cystine) is an inherited disorder of the metabolism of methionine. The disorder is caused by a deficiency of an enzyme known as

cystathionine B-synthetase that requires vitamin B₆ for its activity. Folate as well as vitamins C, B₆, and B₁₂ are believed to influence the complex metabolism of the amino acid methionine. All of these vitamins must be present in adequate amounts for normal functioning of these complex metabolic pathways.

Stegers-Theunissen et al., (Ref. 39) have performed studies that looked at whether a genetic error in the metabolism of homocysteine and the several vitamins required for homocysteine metabolism may be a risk factor for having a child with an NTD. These authors measured the levels of relevant vitamins and homocysteine during oral methionine loading tests given to 16 women who had given birth to an infant with an NTD and to 15 control women. These authors reported that 5 of 16 women who had an infant with an NTD had clinically demonstrable methionine intolerance in the absence of liver and kidney dysfunction and postulated that an inborn error of homocysteine metabolism may be a risk factor for an NTD-complicated pregnancy (Ref. 39). These authors suggested that an accumulation of plasma homocysteine which arises as a result of the genetic defect may be toxic for the developing embryo. Supplementation with high doses of vitamin B₆ and folate may lower the high blood levels of homocysteine. Steegers-Theunissen et al. (Ref. 39) noted that there was a high incidence of heterozygosity (a heterozygote is a person who carries one gene for a metabolic disorder but who lacks the second gene necessary for the metabolic disorder to be fully expressed) for homocystinuria among the women whose infants had NTD's (31 percent) as compared with the incidence of about 1 percent in the normal population.

ii. *Vitamin B₁₂ deficiency.* A possible role for vitamin B₁₂ has also been suggested. Recently, Adams et al. (Ref. 41) reported the results of a case-control study of midtrimester sera from 33 NTD cases and 132 control cases from two maternal serum alpha-fetoprotein prenatal screening programs in the United States. Adams et al. (Ref. 41) measured serum levels of methylmalonic acid (elevated levels are an indicator of vitamin B₁₂ deficiency (Ref. 40)). Adams et al. (Ref. 41) found a highly significant difference in serum methylmalonic acid between cases and controls. Mothers with serum methylmalonic acid concentrations greater than the 75th percentile were at significantly increased risk of carrying an NTD-affected pregnancy. These

findings may suggest a role for vitamin B₁₂ in NTD's.

iii. *Pantothenic acid deficiency.* A possible role for pantothenic acid has also been suggested. In a recent letter to the editor of the *New England Journal of Medicine*, Thurston and Hauhart (Ref. 42) noted that the multivitamin and multinutrient preparation used in the recently completed Hungarian trial (Ref. 24) contained pantothenic acid. These authors discussed mechanistic considerations regarding metabolic functions of pantothenic acid and possible interactions between pantothenic acid and valproic acid, an antiepileptic drug whose use in the first trimester of pregnancy increases the risk of NTD's to about 30 times over that in the general population. They also noted that the birth defect exencephaly (exencephaly is considered a defect in rodents that is analogous to NTD's in humans) is characteristic of fetuses of rats that are pantothenic acid-deficient (Ref. 19). They proposed that provision of pantothenic acid might have additional protective effects against NTD's (Ref. 42).

In responding to Thurston's and Hauhart's comments, the authors of the Hungarian trial (Ref. 43) noted:

We cannot be sure that the preventive effect [of the multivitamin and multinutrient supplement] was due to folic acid alone or in association with the other components of the multivitamin. Folic acid, vitamin B₆, vitamin B₁₂, vitamin C, and zinc interact with one another in many metabolic pathways; thus, folic acid may have a synergistic effect with other vitamins. It is also possible that pantothenic acid (vitamin B₅) has some protective effect against neural tube defects.

c. *Role of other factors (maternal health, environmental factors).* A wide variety of factors have been postulated as contributing to the etiology of NTD's (see 56 FR 60610 and 58 FR 2606 for references). Several areas of increased prevalence of NTD's have been described recently, one along the U.S.-Mexico border in Texas (Ref. 44) and another in northern New Jersey (Refs. 21 and 22). A high prevalence of NTD's has also been reported in South Carolina (Ref. 13). Several studies have been conducted to identify factors that may contribute to elevated risk of NTD's in these areas. Information related to such occurrences in two of these areas is summarized below.

i. *Maternal health.* In early 1991, an apparent cluster of NTD (primarily anencephaly) births occurred in Brownsville, Texas (Ref. 44). The Texas Department of Health began a comprehensive investigation and completed a case-control study of 28 cases with dates of conception from

January 1, 1989 through January 31, 1991, and 26 normal control births matched by estimated date of confinement. An extensive questionnaire focusing on nutritional, occupational, medical, and environmental factors was also administered to case and control mothers.

Various medical history characteristics were analyzed in this study. Ninety-seven percent of the women who had NTD births reported health problems prior to pregnancy. Twenty-five percent reported febrile illness, and 43 percent reported use of prescribed medications. Corresponding percentages for the control group were: Health problems prior to pregnancy, 0 percent; febrile illness, 12 percent; and use of prescribed medications, 26 percent. Mothers who reported taking any medication (except prenatal vitamins) during pregnancy had a significantly increased risk of pregnancies with NTD's than did mothers who did not use medications during pregnancy (Ref. 44).

The report noted that there were no statistically significant differences in distributions of red blood cell folates between cases and controls. However, six red cell folate values reported as low (less than 140 nanogram/milliliter red blood cells, considered indicative of folate deficiency) were all found in the control group (Ref. 44).

ii. *Environmental exposures.* Several studies have suggested associations between maternal exposure to organic compounds at the workplace or at the home in increased rates of birth defects of the central nervous system (Refs. 21 and 22).

In November 1992, the New Jersey Department of Health reported the results of studies that examined births in New Jersey between 1985 and 1988 (Refs. 21 and 22). The project focused on the development and application of methodology appropriate to assess the relationship between exposure to environmental pollutants and adverse reproductive outcomes. The New Jersey Department of Health utilized its population-based birth defects registry and its vital records, as well as data obtained from the New Jersey Department of Environmental Protection, to evaluate the relationship between residing in an area served by a water supply subsequently reported to be contaminated with organic compounds and adverse reproductive outcomes. Exposures to the contaminants were based on place of residence.

The study analyzed 82,825 total births in the study area between 1985 and

1988. Ninety-eight percent (i.e., 81,055) were singleton (single) births. Congenital anomalies were reported in approximately one (1) percent of all live births (i.e., 791 births). Among births with congenital anomalies, the most frequent adverse outcomes involved cardiac defects (0.46 percent of all live births (370 cases)). Central nervous system defects, including the subset NTD's, numbered 121 (0.15 percent) and 57 (0.07 percent), respectively, of all live births. The rate of NTD's tube defects reported (i.e., 0.07 percent) is about the current prevalence in the U.S. population (i.e., about 0.06 percent; about 6/10,000 live births).

Analyses conducted in the final phase of the project focused on four counties in northern New Jersey (Refs. 21 and 22). The study population included all singleton births and fetal deaths occurring during 1985 through 1988 to mothers residing in one of 75 study towns at the time of birth or fetal death. The contaminants in drinking water of primary interest included total trihalomethanes (TTHM) and the total concentrations of 14 volatile organics tested by New Jersey's Department of Environmental Protection and Energy's A-280 program. Other specific volatile organics were also analyzed in drinking water supplies. Analyses included data from an individual-based cross-sectional study utilizing vital records data for the entire study population without interviews. A second individual-based study utilized a case-control design to sample the study population and to collect more detailed information on each subject through interviews with mothers of the subjects.

Risk of NTD's was found to be increased more than 3-fold in women in residential areas with water supplies containing TTHM at levels greater than 80 parts per billion (ppb) compared with those served by water supplies containing TTHM at the lowest measured concentrations of less than 20 ppb.

C. Federal Government Statements and Other Authoritative Reviews

1. Background

Both in the proposal (56 FR 60610) and in the final rule (58 FR 2606), FDA reviewed Federal government documents including the Surgeon General's Report on Nutrition and Health (Ref. 45), the USDA/DHHS "Nutrition and Your Health: Dietary Guidelines for Americans" (Ref. 46), the NAS' "Diet and Health: Implications for Reducing Chronic Disease Risk" (Ref. 47), and other authoritative statements related to the topic of folic acid and

NTD's. In addition, the agency reviewed statements from professional organizations and recommendations from other countries. These reports and statements, which were published before the results of the MRC trial (Ref. 4), the Hungarian trial (Ref. 24), and the Boston case-control study (Ref. 26) became available, found that the available evidence did not provide a basis on which to conclude that the periconceptional use of vitamins and minerals will reduce the risk of NTD's among women in the general U.S. population.

Following the passage of the 1990 amendments, the agency contracted with the Life Sciences Research Office (LSRO) of the Federation of American Societies for Experimental Biology (LSRO/FASEB; Contract No. 233-88-2124, Task Order No. 9) to independently evaluate the scientific literature respecting folic acid and NTD's (Ref. 48). The LSRO report concluded that "there is evidence that women who take folic acid or folic-acid-containing vitamin supplements during the periconceptional period have a lower risk of bearing infants with neural tube defects." The agency noted in its final rule (58 FR 2606 at 2610 January 6, 1993) that, although the final LSRO report (Ref. 49) did not address several issues specifically relevant to health claims questions, there were significant areas in which the agency's proposed rule and the LSRO report were in agreement. These included:

- (1) Four mg of folic acid has been demonstrated to have a protective effect against recurrence of NTD's in women at high risk of this complication;
- (2) There is no evidence that the effect of folic acid is long-lasting as a protectant or potential protectant against NTD's;
- (3) In addition to maternal and fetal nutrition, other individual, dietary, nutrition, and health factors also contribute to risk of NTD's;
- (4) There are significant gaps in our knowledge of the etiology of NTD's and of how folic acid, either alone or in conjunction with other vitamins, may protect against NTD's; and
- (5) It is currently unknown whether NTD's are caused by a gene-induced or drug-induced dependency requiring a higher than physiologic intake of folate or other micronutrient (58 FR 2606).

In 1992, the Institute of Medicine (IOM) of NAS updated its report *Nutrition During Pregnancy* (Ref. 50) to reflect new data (primarily the results of the MRC trial; Ref. 4) that had become available since the first publication of the report. Data from the Hungarian randomized intervention trial (Ref. 24)

and the Boston case-control study (Ref. 26) were not publicly available at the time the report was updated. The IOM report noted that a previous history of an NTD should alert health care providers to the need for preventive measures before a subsequent pregnancy. The report recommended that women with a history of an NTD-complicated pregnancy follow the CDC recommendations (Refs. 51 and 52) for high-dose folic acid supplementation (preconceptionally and throughout the first trimester, under a physician's supervision) to reduce their risk of recurrent NTD's (Refs. 51 and 52). The report noted that questions remain concerning the etiology of NTD's, the most appropriate dosage of folic acid, and the appropriate role of nutrition in preventing first occurrences.

2. Recent Statements of Federal Agencies and Professional Organizations

a. *Health Resources and Services Administration*. In May, 1993, the Maternal and Child Health Bureau of the Health Resources and Services Administration, DHHS, (Ref. 17), as part of its responsibility to provide education to health professionals, prepared a fact sheet on folic acid and NTD's for physicians and other health care providers. This fact sheet provides specific nutrition education information to health care providers as a method of implementing the PHS recommendation and provides specific examples of dietary plans that provide over 0.4 mg of folate/day for women with energy needs and caloric intake lower than 2,200 calories. The report notes that women who cannot be assured of adequate dietary folate intake should be informed of the option of using a folate supplement. The report notes that even if the PHS recommendation is followed, about 50 percent of NTD cases will continue to occur in spite of increased folate intake, and that periconceptional folate intake does not negate the need to offer prenatal screening for maternal alpha-fetoprotein and other markers. Noting that the safe range of folate intake is unclear, the report stated that high doses of folate present certain potential problems including masking of pernicious anemia and risks to persons undergoing therapy with medications that interfere with folate metabolism (Ref. 17).

b. *The Committee on Obstetrics (Maternal and Fetal Medicine) of the American College of Obstetricians and Gynecologists (ACOG)*. The ACOG recently published its opinion regarding the use of folic acid to reduce the risk of recurrent NTD's and possible

reduction in risk of first occurrences of NTD's (Ref. 20). The ACOG report identified women at increased risk for a first occurrence as those with a close relative (e.g., sibling, niece, nephew) with an NTD; with insulin-dependent diabetes mellitus; or with seizure disorders who are being treated with valproic acid or carbamazepine. The ACOG report (Ref. 20) noted that the efficacy of folic acid supplementation has not been evaluated in these patients, whose risk for an occurrence of an NTD is 0.3 to 1.0 percent, compared to a risk of about 0.06 percent in women without these characteristics.

The ACOG report noted that because of difficulties associated with taking daily supplements throughout the childbearing years and because of variations in the amount and availability of folate in foods, it is not clear how the PHS recommendation that all women of childbearing age who are capable of becoming pregnant should consume 0.4 mg folic acid/day throughout their childbearing years can be accomplished. With respect to fortification of food with folic acid, the report noted that this strategy will require careful consideration of the risk-benefit ratio for the entire population, including those with vitamin B₁₂ deficiency.

The ACOG report noted that to date no prospective randomized controlled trials on the use of folic acid supplementation to prevent NTD's in the United States have been reported, and that without such trials, the potential benefit in the U.S. population can be estimated only indirectly. The ACOG report stated that because the benefit of folic acid in reducing the risk of first occurrences of NTD's defects has not been established by prospective randomized trials, obstetricians should continue to offer screening for elevated serum alpha-fetoprotein to pregnant women, including those who consume 0.4 mg of folic acid daily.

c. *The American College of Rheumatology.* The American College of Rheumatology, in a statement regarding use of folic acid in conjunction with the antifolate medication Methotrexate in patients with arthritis, stated that consumption of folic acid at a dose of 1 mg/day does not appear to inhibit the efficacy of low-dose weekly Methotrexate therapy in rheumatoid arthritis, and that the PHS recommendation for women of childbearing age to consume 0.4 mg of folic acid/day should have no impact on the efficacy of low dose weekly Methotrexate regimens (Ref. 53).

3. Recommendations in Other Countries

a. *The Netherlands.* The Netherlands Food and Nutrition Council (the council), in its "Report on the Relationship Between Folic Acid Intake and Neural Tube Defects" (Ref. 54), concluded that research results do not justify recommendations to stimulate the use of folic acid supplements or multivitamin supplements as a method of primary prevention of NTD's. The report noted that no studies have been carried out on the link between folic acid intake, the folic acid status of the mother, and the occurrence of NTD's, and that it is vital to know whether maternal folic acid status or folic acid intake in the periconceptional period constitutes a risk indicator for the occurrence of NTD's. The Council's report recommends that women of childbearing age eat diets that provide 200 to 300 µg (0.2 to 0.3 mg) of folic acid/day.

b. *The United Kingdom.* The United Kingdom Guidelines to physicians, nursing officers, and directors of public health (Ref. 55) recommend that women likely to become pregnant increase their intakes of folate/folic acid by eating more folate-rich foods, not over-cooked, and by eating foods fortified with folic acid. It also recommends that women planning a pregnancy should consume a 0.4 mg folic acid supplement daily from the start of trying to conceive until the twelfth week of pregnancy.

The guidelines further recommend that an increased range of folic acid-fortified breads and cereals should be made available and recommended fortification levels for specified foods as follows: Soft grain bread, 105 µg folic acid/serving (typical serving size=2 slices); cornflakes or branflakes, 100 µg folic acid/serving.

c. *Canada.* The Health Protection Branch, Health and Welfare Canada (Ref. 56) has recommended that:

(1) As early as possible when planning a pregnancy, women should consult their physicians about folic acid supplements;

(2) Women who have had a previous pregnancy with an NTD are at a high risk of recurrence and should consult their physician about folic acid supplements; and

(3) All women of childbearing potential should follow Canada's *Food Guide to Healthy Eating* and take care to choose more foods that are high in folate.

With respect to supplement use, Health and Welfare Canada recommends that women consult their physicians before deciding on taking a folic acid supplement. They note that a

high intake of folic acid (greater than 1 mg/day) may complicate the diagnosis of vitamin B₁₂ deficiency, and that although vitamin B₁₂ deficiency is rare in reproductive-age women, irreversible neurologic damage may occur if vitamin B₁₂ deficiency is not diagnosed and properly treated. The report also notes that folic acid may have an adverse effect on the drug control of epilepsy. Women taking anticonvulsants and those taking folic acid antagonists such as Methotrexate should be individually counselled by their physician regarding folic acid supplementation.

In addition, Health and Welfare Canada was concerned about increased use of multivitamins to obtain folic acid. The report noted that multivitamins usually contain vitamin A, and that too much vitamin A can harm a developing fetus or have toxic effects on an individual. For these reasons, the recommendation stated that the daily dosage recommended on the multivitamin label should be followed.

D. Summary of FDA's Discussions With the Folic Acid Subcommittee

1. Background

As explained above, in October 1992, FDA empaneled the Folic Acid Subcommittee to help resolve the outstanding issues identified in the PHS recommendation. The Folic Acid Subcommittee members were drawn primarily from existing FDA advisory committees, including the Food Advisory Committee, and included individuals with expertise in the fields of food composition, epidemiology, human nutrition, folate metabolism, geriatrics, food fortification, rheumatology, women's health, consumer interests, oncologic drugs, pediatrics, and hematology.

2. Folic Acid Subcommittee Meeting, November 23 and 24, 1992

The first meeting of the Folic Acid Subcommittee was held on November 23 and 24, 1992 (57 FR 52781; Refs. 12 and 57). Areas of expertise represented by consultants invited to speak to the Folic Acid Subcommittee at its first meeting on November 23 and 24, 1992 included NTD's, epidemiology, folate metabolism, special populations, bioavailability of folates, pernicious anemia and vitamin B₁₂-related problems, convulsive disorders, food fortification, folate as a drug, and Federal food programs such as school lunch programs and the Women, Infants, and Children (WIC) program.

At the open meeting held November 23 and 24, 1992, the Folic Acid Subcommittee heard testimony from

expert speakers and others on the daily intake of folate adequate for reduction in risk of NTD's, safety concerns for persons in the target population and in the general population, and the appropriateness of a health claim on the labels or labeling of foods (Ref. 12).

a. Issues. The Folic Acid

Subcommittee's discussion of the target population and of the appropriate daily folate intake focused on questions of the appropriate level of folate in food to attain the claimed effect and yet to ensure safety; the importance of timing of intervention because the neural tube closes early in pregnancy, often before a woman realizes that she is pregnant; the adequacy of the evidence relating folate nutritional status itself to risk of NTD's; and safety concerns relative to the potential for increased folate intake to mask the hematologic manifestations of vitamin B₁₂ deficiency and thus to delay diagnosis and treatment of this deficiency while irreversible neurologic damage progresses.

With respect to identifying women in the target population who may be at particular risk of occurrence of an NTD-affected pregnancy, the Folic Acid Subcommittee acknowledged that it was not possible to identify such women. There was agreement that because many pregnancies are unplanned, and because the neural tube forms and closes very early in gestation, the recommendation for adequate intake of folate should be directed at all women throughout their childbearing years. Expert speakers noted the inherent difficulties in reaching the entire target population of women of childbearing age with educational programs alone and in motivating them to change eating practices. The speakers discussed the advantages of food fortification in reaching the greatest number of the target population without requiring conscious changes in food selection practices. The expert speakers and the members of the Folic Acid Subcommittee also considered issues of effectiveness of dietary intake and of doses of folate lower than the recommended 0.4 mg (400 µg) in reducing risk of NTD's. They discussed results of several studies suggesting protective effects against NTD's of dietary folate intakes lower than 0.4 mg (400 µg)/day (i.e. at levels of 0.25 mg or more daily).

In considering the available data regarding folic acid and NTD's, some members of the Folic Acid Subcommittee raised questions as to whether the available data were sufficiently sound or generalizable to the U.S. population to warrant a conclusion that fortification of the entire

food supply or universal supplement use would reduce the risk of occurrence of NTD's in women in the U.S. population. They noted that since a fortification strategy would affect 250 to 260 million people, the data on which the need for such a proposed intervention is based should be examined critically. Other members, although noting uncertainties in the data, found the data sufficiently convincing to recommend some types of public health action to implement these findings for U.S. women.

With respect to safety considerations raised by the possible fortification of the food supply, the greatest concern was for persons at risk of vitamin B₁₂ deficiency. The population groups for which there was most safety concern because of relatively high prevalences of low serum vitamin B₁₂ levels, were the elderly, young African-American women, and acquired immunodeficiency syndrome (AIDS) patients. Additional safety questions included consideration of persons taking antiepileptic medications and those prescribed antifolate medications for a wide range of disorders.

In considering how to ensure that women have an adequate folate intake, the Folic Acid Subcommittee discussed the possibility of educating women of childbearing age on improving their dietary habits, use of supplements throughout a woman's childbearing years, and fortification of the food supply with folic acid to achieve the recommended intake. The majority of the members of the Folic Acid Subcommittee and many of the invited expert consultants expressed concern about the current lack of monitoring and surveillance for potential adverse effects of increased folate intake.

b. Recommendations. At the close of its November 23 and 24, 1992, meeting, the Folic Acid Subcommittee provided several recommendations. Those relevant to the health claim issue were:

i. Health claims. The Folic Acid Subcommittee members supported the PHS policy regarding folic acid and NTD's. The Subcommittee, however, recommended against a health claim on food labels or labeling because the majority of the Subcommittee members expressed concern that the data on the specific relationship between folate, at levels attainable from usual diets, and NTD's were not strong enough to support a food label health claim on this relationship.

ii. Educational activities. The Folic Acid Subcommittee recommended that PHS and FDA develop and implement an educational program, directed at women of childbearing age,

emphasizing the importance of sound dietary choices to achieve nutrient intakes provided in dietary guidelines. The Folic Acid Subcommittee also stated that the PHS should work with health professionals and others to develop and implement educational efforts that emphasize the importance of diets that meet established dietary guidelines, the importance of maintaining intake of folate sufficient to reduce the risk of NTD's, and the importance of detection, diagnosis, and treatment for persons with low vitamin B₁₂ status.

c. Comments. Following the November 23 and 24, 1992, meeting of the Folic Acid Subcommittee, the agency received letters from several experts who were invited to speak at the subcommittee meeting. One expert noted that the National Research Council (NRC) in 1989 identified 0.4 mg (400 µg) folic acid as RDA for pregnant women and urged the agency to adopt 0.4 mg (400 µg) folic acid as the RDA for all women capable of becoming pregnant. The agency notes that it is currently using the value of 800 µg (0.8 mg)/day as the RDI for pregnant women and 400 µg (0.4 mg)/day as the RDI for the general population, including women of childbearing age, in accord with the requirements of § 101.9 (21 CFR 101.9) as amended in the Federal Register of January 6, 1993, and the requirements of the DS Act of 1992 that FDA not change the U.S. Recommended Daily Allowance levels for nutrients until at least November 8, 1993.

One expert stated that health claims should not be allowed for folic acid-fortified foods or folic acid-containing supplements unless such claims were balanced by a statement that use of such products may increase the frequency of irreversible neurologic damage from vitamin B₁₂ deficiency, and that among Black and Hispanic females, folic acid fortification or supplementation is likely to do more harm than good. The agency notes that its proposed requirements for a health claim for folate and NTD's include a requirement that fortified products containing more than 100 µg folic acid per serving carry a statement warning against intake above 1 mg/day (proposed § 101.79(c)(2)(i)(G)).

Several experts expressed concerns about the potential risks of excess folate intakes, particularly in persons over 50 years of age, or of prolonged exposure. These comments also expressed concern that adequate surveillance systems to detect adverse effects of whatever policy is implemented with respect to folic acid were needed. They also noted that no adequate surveillance system for potential masking of vitamin B₁₂

deficiency exists at this time, and that a real commitment should be made to this task.

The agency notes that issues related to establishing surveillance systems for adverse effects of increased folate intakes, particularly with respect to vitamin B₁₂-related problems, were discussed at a public meeting held at the Centers for Disease Control on August 12, 1993 (58 FR 40149 and Ref. 58). The experts agreed that establishment of surveillance systems for masking the anemia of vitamin B₁₂ deficiency would be extremely difficult, but CDC indicated a commitment to this task. FDA also notes that it has a long-standing history of collaborating with the National Center for Health Statistics (NCHS) of CDC to use nutritional assessment data from their National Health and Nutrition Examination Surveys (NHANES) to monitor the nutritional status of the U.S. population. FDA intends to continue this collaboration, particularly as it relates to folate and vitamin B₁₂.

Several experts stated that, with respect to reduction in risk of NTD's, the 400 µg (0.4 mg) dose of folic acid is an artificial goal and cited studies (Refs. 6, 8, 9, and 26) that show strong protective effects of dietary folate intakes at levels greater than 100 µg/day.

The agency recognizes the importance of the dietary studies that have shown protective effects against occurrence or recurrence of NTD's at intakes of folate lower than 0.4 mg (400 µg) and has summarized the findings of these studies in Table 3. The agency agrees that consumption of diets providing adequate amounts of folate is important and notes that it used the findings of studies that showed a benefit from diet in its development of the model health claims included in this proposal.

Another comment included a recommendation for a modification of the method used by the agency in estimating daily folate intakes by individuals. Specifically, the comment suggested that the within-individual component of variance resulting from use of the mean of 3 days of daily intake be removed, and that the intake distributions be recalculated using only the between-individual component of variance.

The agency did not use this suggested modification in its analyses because FDA believes that systematic bias is a more serious problem than random error, and that use of sophisticated mathematical corrections would attribute a degree of precision to the food intakes values that is not justified.

3. Folic Acid Subcommittee Meeting, April 15, 1993

a. *General description.* FDA reconvened the Folic Acid Subcommittee on April 15, 1993 (58 FR 15149, March 19, 1993; Refs. 13 and 58). The purpose of this meeting was to obtain comments on the options that FDA had developed on possible ways to increase the folate intake of women of childbearing age. These options included fortification of specific products, such as cereal-grains, at levels of 70, 140, or 350 µg folic acid/100 g and use of food labeling to provide information to consumers (e.g., health claims and content and descriptive labeling that would serve to identify "good sources" and "excellent sources" of dietary folate). The agency noted that, with respect to health claims, at the November 23 and 24, 1992, meeting, the majority of Folic Acid Subcommittee members did not believe that the data on a specific relationship between folic acid, at levels attainable from usual diets, and NTD's was strong enough to support a claim. The agency, among other things, asked for clarification of the opinions of the Folic Acid Subcommittee members on this issue.

b. *Health claims.* As stated above, FDA pointed out that there was an apparent inconsistency in the Folic Acid Subcommittee's recommendations regarding health claims in that the majority of Folic Acid Subcommittee members did not believe that the scientific data on a specific relationship between folate, at levels attainable from usual diets, and NTD's were strong enough to support a food label health claim for this relationship. On the other hand, the Subcommittee supported the PHS recommendation that women of childbearing age should consume 0.4 mg of folate/day to reduce the risk of an NTD pregnancy, which, if it were to appear on a food label, would constitute a health claim as defined by the 1990 amendments.

The agency asked the Folic Acid Subcommittee whether it would still recommend against authorizing a health claim, and whether such a claim, if authorized, could provide useful information at point of purchase in helping consumers understand the relationship between folate and risk of NTD's within a total diet without being misleading or raising undue safety concerns. The agency also asked the Folic Acid Subcommittee for its views on specific elements that might be included in a health claim.

Extensive discussion by the Folic Acid Subcommittee of this matter revealed a shift in views, with five of

the nine Folic Acid Subcommittee members favoring, and four of nine opposing, a food label health claim on the relationship between folate and NTD's. Those favoring a health claim cited its potential educational value. One member favored a health claim only as part of a general educational effort directed both at women of childbearing age and at members of the general population who may be at risk of adverse effects from increased intakes of folate. Another member favoring a carefully worded health claim cited its potential to encourage increased consumption of folate while simultaneously providing a label warning regarding excess intakes.

Those opposing a health claim cited the weakness of the data supporting the nutrient-disease relationship, including the very small number and the observational nature of studies relating intake of folate at levels attainable from usual diets to reduced risk of NTD's. Other members opposing a health claim expressed concern that strong marketing efforts for health claim-labeled foods could cloak the weakness of the science base for the claim, and that such efforts could be potentially misleading to many women who might be led to believe that they could avoid all birth defects through use of folate.

4. Summary Presented to the Food Advisory Committee

The results of the Folic Acid Subcommittee's meeting were summarized for FDA's Food Advisory Committee on April 16, 1993 by the Chairman of the Folic Acid Subcommittee. Additional views were presented to the Committee by several Folic Acid Subcommittee members. The Food Advisory Committee Chairman noted that although the **Federal Register** notice announcing the Folic Acid Subcommittee meeting on April 15, 1993 (58 FR 15149) had stated that the parent Food Advisory Committee would take action on the Folic Acid Subcommittee's recommendations on April 16, 1993, no action would be taken because the Subcommittee's activities were still in progress. The Chairman noted the division among the members of the Folic Acid Subcommittee on the issue of whether a health claim should be authorized by FDA.

E. Tentative Decision To Authorize a Health Claim on Labels and in Labeling of Foods in Conventional Form and Dietary Supplements

In its final rule published January 6, 1993 (58 FR 2606), FDA announced its decision not to authorize a health claim

on the relationship between folic acid and NTD's. The agency noted that section 403(r)(3)(B)(i) of the act authorizes the agency to grant a health claim on food other than dietary supplements when there is significant scientific agreement that the scientific data relating a nutrient to a disease or health-related condition support such a claim. The agency noted in its final rule that the PHS recommendation evidenced that such agreement exists.

The agency also noted, however, that sections 402(a), 403(r)(3)(A)(ii), and 409 of the act (21 U.S.C. 348), require that the use of a substance in food that is the subject of a health claim be safe. The PHS recommendation itself (Ref. 11) stated that questions remained about the safety of high intakes of folate by both the target population and other segments of the population who might be unintentionally exposed to high intakes of folic acid if overfortification of the food supply were to occur as a result of the PHS recommendation or efforts to qualify to bear a health claim. The agency also noted that there were several other unresolved scientific questions that required discussion before a health claim could be authorized. Based on the concerns expressed in its final rule, FDA concluded that it could not authorize a health claim on folic acid and NTD's at that time.

In developing this proposal, the agency reviewed all of the publicly available studies on the relationship between folate and NTD's. Based on its own review of the totality of the scientific evidence, FDA has tentatively concluded that the available data show that diets adequate in folate can reduce the risk of NTD's.

The strongest evidence for this relationship comes from the MRC intervention study that showed that women at risk of recurrence of an NTD-affected pregnancy who consumed a supplement containing 4 mg (4,000 µg) folic acid daily had a reduced risk of having a child with NTD's. This study clearly demonstrated, for the first time, a significant reduction in recurrence of NTD's with high levels of folic acid but not with other vitamins or minerals. This study established a specific role for folic acid in reducing the risk of recurrence of neural tube pregnancies in women with a previous history of this defect.

In addition, based on its review of the Hungarian intervention trial that used a multivitamin and multimineral preparation containing 0.8 mg (800 µg) of folic acid, and its review of the five published observational studies that reported use of multivitamins

containing 0 to 1,000 µg of folic acid, the agency has tentatively concluded that most of these studies had results consistent with the conclusion that folate, at levels attainable in usual diets, may reduce the risk of occurrence of NTD's.

Although most of the available studies used dietary supplements containing approximately 400 µg or more of folic acid daily, several studies also showed a beneficial effect of dietary intakes of 250 µg or more daily, a level consistent with the estimated folate intake necessary to saturate body stores of folate (Ref. 12).

In reaching this tentative conclusion, FDA acknowledges that there are significant gaps in existing knowledge about the etiology of NTD's; about how folate, either alone or in combination with other nutrients, reduces the risk of NTD's; and of the dose-response relationship of folate intake to reduction in risk of NTD-affected pregnancies. However, even with these uncertainties, PHS, in examining the data from the available human studies, found the evidence sufficiently consistent to develop its recommendation that all women capable of becoming pregnant should consume 400 µg folic acid daily. FDA supported this decision at the time it was made (Ref. 11) and in its final rule (58 FR 2606). Additional support was expressed by FDA's Folic Acid Subcommittee. Thus, the agency has tentatively concluded that, as evidenced by the PHS recommendation and the agency's discussions with the Folic Acid Subcommittee (Ref. 12), there is significant scientific agreement on the relationship between folate and a reduction in the risk of NTD's.

The agency has also extensively reviewed safety issues identified in its proposed and final rules and discussed these issues with the Folic Acid Subcommittee (Ref. 12). Based on its review of the scientific evidence, its discussions with the Folic Acid Subcommittee, and the comments it has received, the agency has tentatively concluded that safety problems can be resolved by setting a safe upper limit of intake of 1 mg of folate/day for all population groups. Thus, the agency has tentatively concluded that a health claim on the topic of folate and NTD's will not increase risk to persons in the general population or in the target population of a disease or health-related condition when daily intakes of folate are limited to 1 mg. FDA tentatively concludes that daily folate intakes can be maintained within safe limits by allocation of folic acid to specific foods in the food supply through an

amendment to the food additive regulation for folic acid.

Therefore, in this document, the agency is proposing to authorize a health claim for folate and NTD's on the labels and labeling of foods and on dietary supplements. In companion documents published elsewhere in this *Federal Register*, the agency is proposing to amend the food additive regulation for folic acid and to amend the standards of identity for specific cereal-grain products.

IV. Summary of Proposed Resolution of Safety Concerns

The agency has tentatively concluded, based on its review of the scientific evidence, its discussions with the Folic Acid Subcommittee, and its review of comments that it has received, that there are risks attendant on excessive intakes of folate. The primary concern is for persons with vitamin B₁₂-related conditions, although risks may also be created for pregnant women, persons on antiepileptic (i.e., antiepileptic) medications, and those on antifolate medications.

The agency's review of the scientific literature, its discussions with the Folic Acid Subcommittee, and its review of the comments that it received, also show that these safety concerns can be largely resolved by limiting addition of folic acid to food through the agency's authority to regulate the use of food additives. The agency has tentatively concluded that its overriding responsibility in seeking to ensure that there is adequate folate in the food supply is to ensure that even with the fortification of foods that it is proposing to provide for, the amount of folate that people are reasonably expected to consume is within the safe upper limit of consumption. The agency has tentatively concluded that the safe upper limit of daily intake of folate for the general population is 1 mg.

The agency is providing a summary of specific safety issues in this document. Additional references can be found in the agency's proposed rule (56 FR 60610, November 27, 1991), its final rule (58 FR 2606; January 6, 1993), and in the extensive briefing materials provided to participants at the Folic Acid Subcommittee meetings (Refs. 57 and 58).

A. Vitamin B₁₂-Related Issues

1. Review of Available Data

As noted above, in the presence of excess folate and inadequate vitamin B₁₂, the megaloblastic anemia of vitamin B₁₂ deficiency may not develop, but severe and irreversible nerve damage

may continue (Ref. 14). This interaction between the functions of folate and vitamin B₁₂ has been recognized for many years (Ref. 14). Because the anemia of vitamin B₁₂ deficiency is often the first clinical symptom to appear, and one that requires further tests to accurately identify its cause, the activity of folate to "mask" the development of the anemia of vitamin B₁₂ deficiency is the basis for the requirement for the precautionary statement on oral and parenteral preparations of folic acid used for treating folate-deficiency anemias.

Following the identification and chemical synthesis of folic acid in 1946, but before the isolation of vitamin B₁₂, folic acid, usually in doses of 5 mg or higher, was used to treat pernicious anemia. A number of studies reported that the anemia in many pernicious anemia patients is correctable, at least temporarily, by administration of folic acid (Refs. 60, 61, 62, 63, 64, and 65). However, a number of other studies showed that, while doses of 5 mg of folic acid daily can reverse the hematologic abnormalities of vitamin B₁₂ deficiency (Refs. 66, 67, 68, 69, and 70), neurologic damage progresses. Hall and Watkins (Ref. 66) reported neurological degeneration within 2 to 5 months in 14 patients with vitamin B₁₂ deficiency who were treated with oral doses of 5 to 20 mg folic acid. In another study, 55 of 98 patients (56 percent) in a clinical study in which patients with pernicious anemia were treated with 5 mg folic acid orally for up to 3.5 years suffered hematologic relapses, neurologic relapses, or combined system relapses (Ref. 68). Although the neurologic degeneration was not caused by the folic acid treatment, their data clearly demonstrate the potential of folic acid to mask the anemia of vitamin B₁₂ deficiency without stopping degenerative results of this deficiency.

The first demonstration of dramatic beneficial effects of vitamin B₁₂ in treating pernicious anemia occurred in 1948. The advent of the specific therapy for the pernicious anemia of vitamin B₁₂ deficiency during the late 1940's and early 1950's diminished the use of high levels (5 mg or 5,000 µg) of folic acid in patients with this condition. Because 1 mg of folic acid became the more common therapeutic dose for folate deficiency, there are limited data available on the effects of doses of folic acid lower than 5 mg in persons with pernicious anemia.

Despite the lack of systematic evaluation of the effect of folic acid on the anemia of vitamin B₁₂ deficiency at intakes less than 5 mg/day, several case reports have described hematologic

improvement in pernicious anemia with doses of folic acid lower than 1 mg (e.g., 200 to 500 µg) (Refs. 64, 65, 72, 73, and 74). Chosy et al. (Ref. 73) reported that daily injections of 400 µg (0.4 mg) of folic acid caused hematologic responses in three of five patients with pernicious anemia. Other investigators have reported suboptimal responses to 0.5 mg of folic acid administered intramuscularly or orally to patients with pernicious anemia (Refs. 64 and 65). On the basis of the reticulocyte response, 0.2 mg (200 µg) of folic acid has been used to differentiate between the megaloblastic anemias caused by folate deficiency and vitamin B₁₂ deficiency (Ref. 14). Some investigators, however, have not been convinced that amounts of folic acid within the range of 200 to 500 µg/day (0.2–0.5 mg) would mask pernicious anemia (Refs. 72 and 75). Marshall and Jandl (Ref. 72) concluded that from 200 to 500 µg of folic acid daily should suffice for the prevention of folic acid deficiency without endangering patients with undiagnosed pernicious anemia, while larger doses should be reserved for prescription use in patients with abnormal absorption or utilization of folic acid. The results of these studies show, in general, that responses of doses of folic acid below 1 mg have been less predictable than those to doses of 5 mg and higher.

In summary, the available evidence shows that as many as 50 percent or more of patients with pernicious anemia will show a normalization of their anemias with doses of 5 mg of folic acid and higher. Although there are no systematic studies to evaluate the effect of folate on masking the pernicious anemia of vitamin B₁₂ deficiency between intakes of 1 and 5 mg daily, several case reports suggest that some patients with pernicious anemia will respond to folate in doses of less than 1 mg/day. Results at these low levels are often suboptimal and less predictable than those occurring at higher intakes.

2. Current Information Regarding Vitamin B₁₂ Deficiency in the United States

There is currently no way to determine how many persons in the general U.S. population have undiagnosed vitamin B₁₂ deficiency, and thus, how many are potentially at risk of developing pernicious anemia. However, vitamin B₁₂ deficiency anemias are not uncommon in the U.S. population. Although not appropriate for determining prevalence, information from NCHS provides some evidence of the potential magnitude of this condition. There were 740,000 patient

visits to physicians' offices with a diagnosis of pernicious anemia during the 2-year interval 1989–1990 (Ref. 76). Approximately 524,000 of these visits were by women (Ref. 76). (The number of "visits" recorded in the ambulatory care surveys mentioned above may include multiple visits by some patients and therefore, these data do not represent numbers of patients.) An additional 16,000 patient visits during this interval involved a diagnosis of other vitamin B₁₂ deficiencies (for example, those associated with consumption of vegetarian diets). NCHS records from the National Hospital Discharge survey for 1990 identified 31,000 discharges that included a diagnosis of pernicious anemia and an additional 7,000 discharges that included a diagnosis of other vitamin B₁₂ deficiency anemias (Ref. 77).

3. Evaluation of Vitamin B₁₂ Status

Experts at the November 23 and 24, 1992, Folic Acid Subcommittee meeting noted that there are an unknown but likely significant number of cases of undiagnosed, untreated, and stopped-treatment cases of vitamin B₁₂ deficiency in the U.S. population. Evaluation of vitamin B₁₂ status is usually not performed during routine clinical examinations. In addition, physicians may not further evaluate low serum vitamin B₁₂ levels when such are reported, particularly when anemia and macrocytosis are absent and the serum vitamin B₁₂ level is only slightly low (Ref. 81). The diagnosis of vitamin B₁₂ deficiency is not always straightforward. For example, Lindenbaum et al. (Ref. 40) reported that while serum vitamin B₁₂ levels have been generally considered to be essentially 100 percent sensitive in the detection of clinical disorders caused by vitamin B₁₂ deficiency, there are a significant minority of patients with vitamin B₁₂ deficiency whose serum vitamin B₁₂ levels are normal. In such individuals, measurements of serum metabolite concentrations of methylmalonic acid and total homocysteine may be necessary to facilitate the diagnosis of vitamin B₁₂ deficiency (Ref. 40).

In addition to the difficulties with determining vitamin B₁₂ status mentioned above, participants in the Folic Acid Subcommittee meetings noted that, despite modern analytical tools available, diagnoses of vitamin B₁₂ deficiency can be missed because automated systems are used for routine blood analysis, and direct examination of peripheral blood smears (a laboratory measure that detects red blood cell abnormalities characteristic of various vitamin deficiencies) is not as routine as

was once the case. Often, a number of visits to a physician may be needed, or visits to more than one physician, before an accurate diagnosis of vitamin B₁₂ deficiency is made. Additionally, physicians may not recognize that some patients with neuropsychiatric symptoms may have vitamin B₁₂ insufficiency.

4. Uncertainties Regarding the Number of Persons Potentially at Risk From High Intakes of Folate

Pernicious anemia is responsible for about 70 percent of vitamin B₁₂ deficiency states (Ref. 12). It is recognized that among African-Americans, particularly African-American women, pernicious anemia is not confined to the elderly, as it generally is among Caucasians (Refs. 78, 79, and 80) but occurs at younger ages (e.g., in young African-American women less than 40 years of age). A large number of people have subnormal levels of serum vitamin B₁₂ without having any classical manifestations of vitamin B₁₂ deficiency (Refs. 82 and 83). Ten to 20 percent of elderly persons, more than 25 percent of demented patients, 15 to 20 percent of AIDS patients, and 15 to 20 percent of patients with malignant diseases have low serum vitamin B₁₂ levels. In addition, 5 to 10 percent of all patients, regardless of age or clinical status, are found to have low serum vitamin B₁₂ levels. Metabolic and subtle neurologic dysfunction are demonstrable in a significant fraction of such cases (Ref. 82). Very little is known about whether folate supplementation has any effect on such persons with low serum vitamin B₁₂ levels (Ref. 82). Participants in both FDA's Folic Acid Subcommittee meetings and the recently convened CDC meeting expressed similar uncertainties regarding potential effects of increased folate intake in the large number of persons with low vitamin B₁₂ status (Refs. 12 and 59).

The potential effect of increased folate intakes on nontarget populations with poor or marginal vitamin B₁₂ status (including but not limited to pernicious anemia) was the major safety issue discussed by the Folic Acid Subcommittee during the November 23 and 24, 1992 meeting (Ref. 12). Some expert speakers, citing data on the prevalence in the United States of undiagnosed pernicious anemia, expressed concern about masking this condition when high folic acid intakes correct the hematologic effects of a vitamin B₁₂ insufficiency, thus delaying diagnosis and treatment while irreversible neurologic damage progresses. Other speakers felt that the

safety concerns were overplayed. They noted that diagnoses can be made from the neurologic symptoms and by use of other tools available to physicians. Most expert speakers agreed that physicians and health care professionals need to be trained to be more sensitive to the diagnosis of vitamin B₁₂ deficiency.

Some expert speakers and Folic Acid Subcommittee members also noted that there is a lack of recent experience in the United States with individuals taking high doses of folic acid (Ref. 12). Expert consultants to FDA's Folic Acid Subcommittee also pointed out that there is a lack of data from which to estimate the potential risk if folic acid intake is increased in persons with vitamin B₁₂-related problems. Estimates of the size of the population potentially at risk (roughly 13,000 individuals by one estimate and higher by other estimates) were presented by the expert consultants and were discussed by the expert consultants in relation to the potential reduction in the number of NTD-affected pregnancies that might be realized per year by increased folate intakes (estimated at about 1,250 to 2,000). The expert consultants cautioned that the data were inadequate to accurately assess the size of the population potentially at risk.

5. Tentative Conclusion Regarding Safe Upper Limit of Intake for Persons With Vitamin B₁₂ Deficiency

Based upon its review of the scientific literature and its discussions with the Folic Acid Subcommittee, FDA has tentatively concluded that safety issues with respect to persons in the population with vitamin B₁₂-related problems can be resolved by setting a safe upper limit of intake of 1 mg of folate/day from all sources for all population groups when considering options for food fortification. This tentative conclusion is based on data that show that, in persons with pernicious anemia, adverse effects have been reported consistently and with high frequencies with daily intakes of 5 mg folic acid and above. Hematologic responses in persons with pernicious anemia have also been reported, although infrequently, at oral or intramuscular exposures below 1.0 mg (see references above). The agency recognizes that once vitamin B₁₂ became available in the late 1940's and was used successfully in the treatment of pernicious anemia, treatment of this disease with high doses (5 mg or more) of folic acid diminished, and thus, data on effects of intakes between 1 and 5 mg daily were not generated. Thus, the shape of the intake-response curve for adverse effects of folic acid intakes

between 1 and 5 mg is not known. Experts at the recent CDC meeting were asked specifically about this issue, and they stated that, because of the lack of data, it was not possible to state that continuous intakes of 1 mg or more daily by persons with vitamin B₁₂ deficiency were safe (Ref. 59).

They noted, additionally, several concerns at intakes above 1 mg daily. One such concern was based on knowledge of the metabolism of folic acid. For example, after an oral dose of 0.5 mg (500 µg) of synthetic folic acid, a small but measurable amount of unmetabolized folic acid appears in the urine (Ref. 16). As intakes increase, substantially larger amounts of the oxidized form of the monoglutamate folate circulate in the blood and are excreted in the urine. The oxidized form of folic acid, normally not found in body tissues to an appreciable degree, passes through the systemic circulation before being excreted, thus exposing body tissues to a form of the vitamin not normally encountered. The effect of long-term continuous exposure to this form of folate has not been evaluated.

In reaching its tentative decision regarding use of a safe upper limit of intake of 1 mg folate/day, FDA recognizes that there are considerable uncertainties in determining the number of persons in the general population who have low vitamin B₁₂ status and who may be at particular risk from increased intakes of folate. The agency is also aware of the lack of safety data for long-term intakes of folate between 1 and 5 mg/day, the existence of limited data regarding adverse effects of intakes below 1 mg, and the arguments regarding the lack of safety data on continuous exposure of body tissues to free circulating folic acid in oxidized form when intakes exceed 1 mg daily. The agency knows of no data that would support the long-term safety of continuous daily folate intakes of more than 1 mg and knows of no data to support a level of intake somewhat above or below 1 mg. FDA, however, notes that the value of 1 mg for a safe upper limit of daily folate intake could be modified if data were available to support such a decision. FDA solicits comments, particularly data, on this point.

The Folic Acid Subcommittee at its April 15, 1993 meeting supported the agency's use of 1 mg of folate daily as an upper intake limit for fortification, and the PHS recommendation states that women of childbearing age should not exceed intakes of 1 mg/day. A safe upper limit of daily folate intake of 1 mg was also discussed by experts who attended a recent CDC workshop on

surveillance for adverse effects of increased folic acid intakes. Those experts stated that there was little likelihood of problems at daily intakes lower than 1 mg, that the risk associated with continuous intakes of 5 mg and higher is well documented, and that the limited case reports and concerns regarding high circulating levels of free folic acid raised questions about safety of intakes between 1 and 5 mg daily (Ref. 59).

B. Risks to Pregnant Women

About 4 million pregnancies occur in the United States each year. In *Nutrition During Pregnancy* (Ref. 50), IOM stated that the safety of large doses of folic acid during pregnancy has not been systematically determined (Ref. 50). IOM noted that large doses of folic acid may inhibit the absorption of other nutrients by competitive interaction and can also obscure the diagnosis of onset or relapse of pernicious anemia, which IOM stated is extremely rare in women of childbearing age. IOM recommended modest supplementation for some segments of the U.S. population at risk of folate inadequacy. Such subpopulations include some pregnant women who lack the knowledge or financial resources to purchase adequate food; abusers of alcohol, cigarettes, or drugs; those with malabsorption syndromes; adolescents; and women bearing more than one fetus.

A potential risk of high folate intakes involves effects of high blood levels of free folic acid on the embryo during early gestation. The concern regarding the lack of safety data for increased doses of folic acid in pregnant women has been discussed in the scientific literature since the report of the successful MRC trial (Ref. 4). The principal investigator of that study (Ref. 4), in which women at high risk of a recurrence of an NTD pregnancy were treated with 4 mg folic acid daily, noted that the study did not have the power to ascertain the safety of such high level supplementation in the population studied.

Following publication of the results of the MRC trial (Ref. 4), Leeming et al. (Ref. 84) stated that while 4 mg of folic acid until 12 weeks of pregnancy may reduce the incidence of NTD's in women at high risk of recurrence, there may also be damaging effects. These authors suggested that substantial amounts of unmetabolized folic acid appear in the plasma after a single high dose, and that continuous high circulating levels of free folic acid may damage developing neural tissue during early embryonic development. They further noted that high levels of folic

acid are not normally found in the circulation (Ref. 16). Scott et al. (Ref. 85) also suggested the seriousness of risk during early embryonic development, since folic acid is concentrated in crossing the placenta and accumulates in fetal tissue. Leeming et al. (Ref. 84) stated that while the fully developed brain may be protected from neurotoxic effects of high circulating levels of folic acid, no information is available as to whether developing neural tissue is similarly protected (Ref. 85).

The agency discussed uncertainties and lack of data regarding potential effects of high folic acid levels on the fetus and its tentative decision to propose a safe upper limit of folate intake of 1 mg/day with respect to safety for persons with vitamin B₁₂-related problems with the Folic Acid Subcommittee at its November 23 and 24, 1993 meeting. The Folic Acid Subcommittee did not believe that folate intakes less than 1 mg/day posed a risk to pregnant women. Support for this view is also provided by the fact that the NRC RDA for pregnant women has been set at 800 µg folate daily for many years. The agency is not aware of data showing that such intakes have posed risks to pregnant women. The agency, however, is not aware of any data showing safe use above this level. The agency has tentatively concluded that an upper limit of intake of 1 mg of folate/day is safe for pregnant women.

C. Persons With Epilepsy

There are approximately 2.5 million persons in the United States with epilepsy and an estimated 200,000 persons whose epilepsy is not controlled (Ref. 12). The possibility has been raised that high intakes of folic acid may reverse the effectiveness of anticonvulsant medications (Ref. 86) because folic acid and certain anticonvulsants compete with each other for receptors on brain cells. A potential concern is whether high intakes of folic acid exacerbate seizures in persons with uncontrolled- or drug-controlled epilepsy.

Most studies of the effects of folic acid in persons with drug-controlled epilepsy have involved institutionalized individuals. Their responses to very high doses of folate (e.g., generally 5 to 15 mg orally; 30 mg, orally, or 75 mg intravenously) have been variable. For example, while increases in fit frequency in response to oral folic acid in the range of 5 to 30 mg daily have been noted in several isolated cases (Refs. 87, 88, and 89), no such effects were found in several controlled studies including double-blind, crossover studies utilizing 15 to 20 mg folic acid/

day in patients with drug-treated epilepsy (Ref. 90, 91, 92, 93, and 94). More recently, several studies of epileptic patients treated with Dilantin and given 3 to 5 mg folic acid daily for gingival hyperplasia for periods of 4 months to 1 year reported no change in seizure frequency (Bachman, 1989; Brown, 1991, cited on pages 216 and 217 of Ref. 12).

Based on its review of the available data, the agency has tentatively concluded that daily intakes of 1 mg of folate are not likely to interfere with the effectiveness of anticonvulsant medications used in the treatment of epilepsy. The available data were reviewed at the November 23 and 24, 1992 meeting of the Folic Acid Subcommittee (Ref. 12). The Folic Acid Subcommittee agreed that, based on the scientific data currently available, there is no indication that there is increased risk for patients with epilepsy with daily intakes of folic acid of up to 1 mg of folic acid (Ref. 12). Based on these factors, the agency has tentatively concluded that its decision to set an upper limit of intake of 1 mg of folate/day is safe for persons with epilepsy.

D. Persons Taking Drugs That Interfere With Folate Metabolism

Folate antagonists such as Methotrexate are used in the treatment of various cancers, including leukemias (Ref. 95). In addition, low doses of Methotrexate are currently used in the treatment of psoriasis, rheumatoid arthritis, and bronchial asthma. Other drugs that interfere with folate metabolism include Pyrimethamine, Trimethoprim, Triamterene, sulfasalazine, colchicine, phenytoin, and Trimetrexate (Ref. 95). Recognition of the therapeutic usefulness of these antifolate drugs for the treatment of psoriasis, rheumatoid arthritis, bronchial asthma, malaria, hypertension, Crohn's disease, gout, epilepsy, and AIDS has developed during the last 30 years. Taken together, these conditions affect significant portions of the general U.S. population (Ref. 95). The safety of significantly increased folate intakes by persons with these disorders, whether or not they are receiving antifolate medications, remains an open question (Ref. 96). In addition, the question of whether significantly increased intakes of folate would reduce the efficacy of these antifolate medications must also be considered.

Morgan et al. (Ref. 97) studied the effects of administration of 1 mg folate daily in patients with rheumatoid arthritis during low-dose Methotrexate therapy for 6 months. Administration of

the folic acid supplement significantly lowered toxicity scores for the Methotrexate therapy, without affecting efficacy of the therapy, as measured by joint counts, joint indices, and physician and patient evaluation of the disease activity. There has not been a controlled trial of the effects on Methotrexate toxicity or therapeutic effectiveness with the use of folic acid supplementation at doses higher than 1 mg daily. Some investigations have prescribed folic acid at doses higher than 1 mg/day for Methotrexate-treated rheumatoid arthritis patients (Refs. 98 and 99), but this use has been controversial because of potential effects on disease responses (Refs. 100 and 101).

The agency discussed the issue of potential effects of increased folate intakes on persons taking antifolate drugs for a number of medical conditions with the Folic Acid Subcommittee at its November 23 and 24, 1992, meeting. The agency noted that there is relatively little data on effects of increased intakes of folate by persons taking antifolate medications for treatment of inflammatory and other diseases. This topic was the subject of several comments submitted to the agency following the November 23 and 24, 1993, Folic Acid Subcommittee meeting.

A physician wrote to express concern regarding increased intake of folate and the possible adverse effects of such intake on patients with myositis and other rheumatic diseases who are taking the antifolate Methotrexate (Ref. 102). The physician noted that studies suggesting beneficial effects of increased folate intake by such patients were small, and that the effects of prolonged intakes of folate are uncertain. The physician also noted that the possible adverse effects of folate supplementation may be more severe in children undergoing treatment for rheumatic disease given their smaller mass and narrower margin of safety with Methotrexate therapy.

Another comment noted the controversy about the use of folate supplements in patients with rheumatoid arthritis treated with Methotrexate (Ref. 103). The comment stated that the concern about potential toxicity in children taking Methotrexate for treatment of juvenile rheumatoid arthritis was not supported, to the commenter's knowledge, by any data, and that the knowledge of human folate homeostasis is limited. The comment stated that because low-dose Methotrexate is now used in the treatment of psoriasis, asthma, inflammatory bowel disease, and

juvenile rheumatoid arthritis, the issue of folate status takes on increased importance in several groups of patients. The comment stated that there was a need to develop sensitive, reliable, and inexpensive assessment tools for determining folate status. The comment urged FDA to carefully weigh any decision about food fortification with folic acid until there is more understanding about the consequences of folate repletion and depletion on human health.

As noted above, the American College of Rheumatology, in a statement regarding use of folic acid in conjunction with the antifolate, Methotrexate, in patients with arthritis, stated that consumption of folic acid at a dose of 1 mg/day does not appear to inhibit the efficacy of low-dose weekly Methotrexate therapy in rheumatoid arthritis (Ref. 53).

With respect to adverse effects of increased folate intakes to persons taking antifolate medications, the agency has tentatively concluded from its review of the limited data currently available (see above), its discussions with the Folic Acid Subcommittee, and the comments that it received, that its tentative decision to set a safe upper limit of 1 mg folate/day for all population groups will not increase risk of adverse effects to persons taking antifolate medications because doses of up to 1 mg folate/day have not been reported to reduce the effectiveness of medications that interfere with folate metabolism.

The agency is, however, requesting scientific data and information on this matter because there are large numbers of patients taking low levels of antifolate drugs on a chronic basis, and the current scientific literature on potential adverse effects of significant increases in folic acid intakes (e.g., intakes greater than 1 mg/day) is very limited.

E. Others

Competitive interactions between folic acid and other nutrients have also been reported (Refs. 104 and 105). There have been contradictory reports related to potential adverse effects of folic acid supplementation on zinc status. Simmer et al. (Ref. 105) measured zinc absorption during the second trimester in 10 healthy pregnant women with normal medical histories and in ten healthy volunteers and found that oral iron-folate supplements containing 100 mg ferrous iron and 350 µg folate reduced the intestinal absorption of an oral dose of 25 mg zinc (provided as 100 mg zinc sulfate). Simmer et al. (Ref. 105) also reported that folate alone decreased zinc absorption. The study of Simmer et

al. (Ref. 105) did not include a control group of pregnant women.

Some other studies have suggested that folic acid supplements interfere with intestinal zinc absorption in humans and animals (Refs. 106 and 107). Ghishan et al. (Ref. 104) described the formation of zinc-folate complexes in the intestine and suggested this as a possible mechanism for folate-zinc interactions. However, other studies have provided inconsistent findings relating to a zinc-folate interaction. For example, in a study of 450 pregnant women, Mukherje et al. (Ref. 108) found a high degree of correlation between elevated serum folate, low plasma zinc, and the occurrence of fetomaternal complications, while another study of 285 pregnant women did not provide evidence of deleterious effects of folic acid supplementation on maternal zinc nutrition (Ref. 109). Butterworth and Tamura (Ref. 96) and Zimmerman and Shane (Ref. 110) have reviewed the varying results of potential effects of folate on zinc status reported in the literature. Zimmerman and Shane (Ref. 110) concluded that there is no convincing evidence that folate supplementation compromises zinc status in pregnancy. They stated, however, that until the issue is clarified, it may be prudent to ensure adequate maternal dietary zinc intake during folic acid supplementation, particularly in women receiving 4 mg folic acid/day. In summary, there have been no long-term studies to quantitate the effects, if any, of increased folate intake on metabolism of other nutrients.

The limited scientific data available on the topics outlined above were presented to the Folic Acid Subcommittee at its November 23 and 24, 1992, meeting. Based on its review of the scientific data currently available on interactions between folate and other nutrients or drugs, and its discussions with the Folic Acid Subcommittee and expert consultants, the agency has tentatively concluded that its decision to set an upper limit of daily folate intake of 1 mg for all population groups will not cause adverse effects because the available scientific data does not provide evidence for the occurrence of such effects at intakes of folate at levels attainable from usual diets. The agency also recognizes that because of the uncertainties in the data on the safety of folic acid intakes, some deviation (either up or down) from the proposed 1 mg limit may be warranted. The agency specifically requests data on this issue.

V. Addition of Folic Acid to Foods

If FDA adopts this proposal and authorizes a health claim on folate and

NTD's, it creates the likelihood that vendors will fortify their products with folic acid to qualify to make a claim. One of the prime ways that FDA has of protecting the public against risks created by the possibility of greatly increased fortification of the food supply is its authority to regulate the use of food additives.

FDA's current food additive regulation for folic acid (§ 172.345 (21 CFR 172.345)) provides that:

Folic acid (folacin) may be safely added to a food for its vitamin property, provided the maximum intake of the food as may be consumed during a period of 1 day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive in excess of 0.4 milligram for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 0.1 milligram for infants, 0.3 milligram for children under 4 years of age, 0.4 milligram for adults and children 4 or more years of age, and 0.8 milligram for pregnant or lactating women.

However, the agency recognizes that, as currently written, the regulation lacks the necessary detailed guidance to enable vendors of foods to decide which foods are appropriate for fortification, and the levels at which folic acid can be added. Nothing in FDA's current food additive regulation would prevent the addition of folic acid to virtually any food. As currently written, the food additive regulation is not a practical way to regulate the folic acid content of the food supply or to assist consumers in achieving specified folate levels in their diets.

In addition to its authority to regulate the use of food additives, and specifically with respect to the safety of substances that are the subject of health claims, the agency cannot authorize a health claim if ingestion of the substance that is the subject of the claim will increase the risk of a disease or a health-related condition in persons in the general population (see section 403(r)(3)(A)(ii) of the act). From the discussion above, it is clear that if the intake of folate is not limited, it can have such an effect in persons in the general population.

FDA has tentatively concluded, however, that a health claim for folate can be safely implemented if folic acid addition to the food supply is controlled through an amendment to the food additive regulation for folic acid. The agency is proposing to amend § 172.345 to set limitations for use of folic acid on a per serving basis; to allow for the addition of folic acid to foods for which there exists a standard of identity as authorized in the standard; and to make

breakfast cereals and dietary supplements the only nonstandardized foods to which folic acid may be added. The description and documentation for these proposed actions are described below, and the specific actions are proposed in companion documents published elsewhere in this *Federal Register*.

The agency's objectives in considering safety issues are not limited only to consideration of how to safely authorize a health claim. Given the potential of folate to reduce the risk of NTD's, FDA has tentatively decided that, as a public health matter, it would also be prudent to provide for fortification of the food supply to increase the likelihood that all women of childbearing age will have adequate folate intakes. Because neural tube birth defects arise very early in pregnancy, and because many pregnancies are unplanned, women must have adequate folate intakes throughout their childbearing years to reduce the risk of this complication. Thus, fortification of staple foods is one means of increasing the likelihood that women will have adequate intakes of folate.

The agency's goal of developing a fortification program that will increase folate intakes by women in their childbearing years while preventing excessive intakes by other segments of the population creates significant issues that FDA must consider in addressing how best to develop a folate fortification plan. For example, in trying to meet the goal of increasing the folate intake of the target population, the agency must also consider the effects of fortification on the folate intakes of others outside the target population and on heavy consumers within the target population and take steps to ensure that safety concerns are not created. Conversely, limiting intakes of folate to levels that are clearly safe for the general population may make it difficult for many target women to reach their intake goals without significant changes in their dietary patterns. To work within these competing considerations, FDA has tentatively concluded that its overriding responsibility in developing a folic acid fortification policy is to establish a safe range of intake for all population groups and then to maximize folate intakes of the target population within this safe range.

A. Background: Fortification Policy

The addition of nutrients to specific foods has been an effective way of maintaining and improving the overall nutritional quality of the food supply. When fortification programs were first initiated, deficiency diseases were

widespread in the U.S. population. Today, in part because of food fortification programs, deficiency diseases rarely occur in the general U.S. population.

To help implement these fortification programs, FDA established standards of identity for several enriched cereal-grain products that require fortification at specified levels with four nutrients, thiamin, riboflavin, niacin, and iron (6 FR 2574), (8 FR 9170), (15 FR 5102), and (17 FR 4453). The addition of these nutrients serves to replace milling losses and to supplement inadequate dietary intakes.

In 1974, the Food and Nutrition Board of the NRC (the Board) published its "Proposed Fortification Policy for Cereal-Grain Products" (Ref. 111). Using available food consumption data, the Board recommended expansion of the then-current enrichment program for cereal-grain products. The Board stated that nutrients should be added to all cereal-grain products wherever technically feasible, because cereal-grain products meet the criteria for carriers of nutritional fortification for most nutrients (Ref. 111). The Board identified fortification levels in cereal-grain products for a number of nutrients, including a recommendation that cereal-grain products be fortified with folic acid at a level of 0.3 mg/pound (70 µg/100 g). Fortification at this level would approximately restore the folate lost during milling.

Technical feasibility studies of aspects of the recommended fortifications were carried out following the 1974 NRC recommendation, with results presented at a workshop in 1977 (Ref. 112). Levels of folate in milled wheat flours, determined during baseline studies, were found to be 0.076 ± 0.018 mg/pound (mean \pm SD; 76 ± 18 µg/pound; mean = 18 µg/100 g) (Ref. 112). Thus, a level of fortification of 0.3 mg/pound (70 µg/100 g) represents an approximate fourfold increase above levels of folate found in milled wheat flours. The agency has used the NRC report (Ref. 111) and the data provided at the 1977 workshop (Ref. 112) as a general guide in developing its options for fortification. The agency recognizes that this report and data are about 20 years old. However, to the agency's knowledge, no more recent report or data directly applicable to fortification issues are available.

In 1980, FDA codified in § 104.20 (21 CFR 104.20) a uniform set of principles to serve as a model for the rational fortification of foods. This set of principles is generally followed by the agency in promulgating regulations for

enriched foods. The agency defined "fortification" as the addition of discrete nutrients, such as vitamins, minerals, or proteins, to foods (45 FR 6323, January 25, 1980). The agency stated that fortification should serve as a means of maintaining and improving the overall nutritional quality of the food supply.

The agency stated that fortification is appropriate to correct a dietary insufficiency recognized by the scientific community (that is, available scientific data must demonstrate that the nutrient deficiency clearly exists within a defined population); to restore nutrients lost in processing; to balance the vitamin, mineral, and protein content of a food based on caloric density; to avoid nutritional inferiority; and to comply with an existing regulation (§ 104.20). In addition, the agency stated that foods that are appropriate vehicles for fortification are those that are consumed by a significant portion of the population in an amount adequate to meaningfully increase intakes of a nutrient, and those in which the nutrients will be provided in a bioavailable form and in which nutrients will be stable under normal conditions of storage and use. The agency also stated that the level of nutrients added in fortifying a food must preclude toxic effects (§ 104.20).

As noted above, the PHS recommendation identified fortification of the general food supply as one approach for delivering folate to women of childbearing age. At its November 23 and 24, 1992, meeting, the Folic Acid Subcommittee extensively discussed the advantages and disadvantages of folic acid fortification. Several members expressed concern regarding potential adverse effects of increased folate intakes if fortification of the food supply were not adequately controlled. They noted that everyone, both target and nontarget populations would unavoidably be exposed to higher folate intakes.

The Folic Acid Subcommittee recognized the need for adequate folate nutrition throughout the childbearing years, and the fact that, to be effective, folate must be provided in the periconceptional interval. In this context, the members of the Folic Acid Subcommittee discussed the advantages of fortification: (1) The availability of increased folate to all women in the target population, regardless of economic or educational status, and (2) the passive nature of fortification in increasing folate intakes (i.e., exposure occurs without the need to change food selection practices or to remember to take a supplement). The Folic Acid

Subcommittee recommended that FDA develop a fortification strategy such that 90 percent of women of childbearing age (10th percentile of intake) could receive at least 400 µg of folate (0.4 mg)/day from all sources, while preventing excessively high folate intakes by nontarget groups.

At its April 15, 1993, meeting, the Folic Acid Subcommittee reviewed FDA's analyses of possible fortification scenarios. Following further discussion, six of nine Folic Acid Subcommittee members supported some fortification of the food supply, although they differed as to whether a level of 70 or 140 µg/100 g of flour was an appropriate base level. Three members were opposed to any fortification. Those in favor of fortification generally stated that this method had the capability of providing increased folate to the greatest number of women in the target population. Those opposing fortification expressed concern about the amount of uncertainty regarding the potential adverse effects and intake estimates.

FDA has tentatively concluded that implementation of a fortification plan for addition of folic acid to the food supply can effectively increase the folate intakes of women of childbearing age to assist them in reducing their risk of having an NTD-affected pregnancy. The agency's tentative conclusion is based on the following:

(1) Because the neural tube forms and closes within the first 4 weeks of pregnancy, folate is needed before conception and during early pregnancy, often before a woman knows that she is pregnant, if it is to have a beneficial effect on risk of NTD's;

(2) About half of the pregnancies in the United States are unplanned (Ref. 113);

(3) Use of a supplement on a daily basis throughout their approximately 30 years of childbearing potential may be a problem for many women, either because of their inability to afford such supplements or their failure to take them on a daily basis; and

(4) Fortification has the advantage of providing folic acid in a continuous and passive manner. For example, a low level of fortification in foods consumed with great frequency would increase the likelihood of obtaining adequate folate on a daily basis.

Thus, the agency is proposing to fortify the U.S. food supply with folic acid as an apparently effective means for improving the folate nutrition of women in their childbearing years. This proposal is consistent with the PHS recommendation and with the views of a majority of the members of FDA's Folic Acid Subcommittee. In

implementing this program, however, the agency is mindful that development of strategies involving fortification of the general food supply requires careful consideration of potential adverse effects of such proposed fortification on the entire population. Authorization of a health claim for fortified or other folate-rich food also requires resolution of concerns about potential adverse effects of increased folate intakes.

B. Safe Fortification: Upper Limit of Folate Intake

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause," a food additive cannot be approved for a particular use unless a fair evaluation of the data available to FDA establishes that the additive is safe. Sections 409(c)(5)(A) and 409(c)(5)(B) of the act state that the probable consumption of a food additive, and the cumulative effect of the additive in the diet of humans, may be considered in determining whether a proposed use of a food additive is safe.

The agency has tentatively decided to use 1 mg (1,000 µg)/day of total folate intake as the safe upper limit for such intake. Total folate includes both the naturally occurring pteroylpolyglutamates found in foods and the folic acid (pteroylglutamic acid) used as a fortificant in conventional foods and as a source of folate in dietary supplements and breakfast cereals. The agency's tentative conclusion to use 1 mg/day as the safe upper limit is based on: (1) The scientific evidence and discussion of experts that there are no data to ensure that adverse effects are not likely to occur at daily intakes of 1 mg and above, (2) the PHS recommendation that women of childbearing age should not exceed intakes of 1 mg (1,000 µg) of folate/day (Ref. 11), (3) the support by the Folic Acid Subcommittee of FDA's use of 1 mg of total folate/day as a safe upper limit guide for fortification (Ref. 58), (4) the uncertainties in food intake estimates and the difficulty in correcting for bioavailability, and (5) the need for some margin of safety between estimates of intakes and the safe upper limit of daily intake. A further discussion of how the agency arrived at this proposed level follows.

1. General

The agency considered the following factors in determining how to identify a safe upper limit of daily intake of folate:

a. Current range of daily intakes.
FDA's estimates of current intakes from foods alone (Table 4) show that, across all population groups, the range of daily folate intakes is 110 to 200 µg/day for

low consumers and 350 to 560 µg/day for high consumers. Corresponding folate intakes from foods and dietary supplements are 150 to 220 µg/day for low consumers and 470 to 810 µg for high consumers.

b. *Recommended Dietary Allowances.* The NRC RDA's are defined as the levels of intake of essential nutrients that, on the basis of scientific knowledge, are judged by the Board to be adequate to meet the known nutrient needs of practically all healthy persons. The RDA's are neither minimal requirements nor necessarily optimal level of intake. Rather, the RDA's are safe and adequate levels (incorporating margins of safety intended to be sufficiently generous to encompass the presumed variability in requirement among people) reflecting the state of knowledge concerning a nutrient, its bioavailability, and variations among the U.S. population. RDA's for folate ("folacin") for various age groups have been between 100 and 400 µg, except for pregnant or lactating women, since 1968 (Refs. 46, 47, and 48 in 58 FR 2606).

c. *Current fortification practices.* Because standards of identity for cereal-grain products, fruit juices, and dairy products have not permitted or required the inclusion of folic acid, and because the current food additive regulation for folic acid imposes a limit of 400 µg (0.4 mg)/day on folic acid added to dietary supplements labeled for use by persons 4 years and older and a limit of 400 µg (0.4 mg)/day on folic acid added to breakfast cereals, there has not been widespread fortification of foods in the United States with folic acid. Thus, daily folate intakes by persons in the general population have apparently been below 1 mg.

2. Differences in Bioavailability Between Free Folic Acid and Food Folates

It is well recognized that the bioavailability of free folic acid, the form included in fortified foods and in dietary supplements, is severalfold higher than that of naturally occurring food folates. Estimates of the increased bioavailability ("potency") of free folic acid relative to food folates range from at least twofold to fourfold or greater (Ref. 45 in 58 FR 2606). The bioavailability of folates in foods ranges from approximately 25 to 75 percent depending upon a variety of factors that are incompletely understood. The majority of food folates occur as reduced folylpolyglutamates (i.e., forms that contain a number of glutamate residues), and the glutamates must be cleaved by intestinal conjugase before absorption.

Folate utilization may be reduced under conditions that inhibit conjugase activity and by natural conjugase inhibitors found in certain foods (Ref. 114). Crystalline folic acid, the oxidized monoglutamate form of the vitamin and the form used in food fortification and in dietary supplements, is generally assumed to have a bioavailability of approximately 100 percent. However, folic acid is likely to take on the bioavailability of folate in its food vehicle and that of the overall meal in which it is consumed because it binds to food constituents such as proteins and carbohydrates (Ref. 115). Additionally, consumers vary in whether they take folic acid supplements with or without food and in the type of beverage that they consume with supplements taken between meals. Thus, the bioavailability of folic acid added to foods in conventional food form or consumed from supplements could range from close to 100 percent if taken between meals to 25 percent or less if consumed as part of a meal containing folates of low bioavailability.

At its November 23 and 24, 1992, meeting, the Folic Acid Subcommittee discussed whether some adjustment should be made for variations in bioavailability of different sources of folate (Ref. 12). There was some discussion as to whether different forms of folate should be weighted differently in estimating a safe daily intake and in determining their effectiveness in reducing the risk of NTD's in women in the target population. This issue was largely unresolved at that time.

3. Safe Upper Limit of Intake

Based on the considerations above, the agency has tentatively decided to use 1 mg (1,000 µg)/day of total folate intake as the safe upper limit for achieving folate intakes.

The agency recognizes that the use of 1 mg as the upper intake limit is not without controversy. This subject engendered considerable discussion at FDA's November 23 and 24, 1992, Folic Acid Subcommittee meeting and, as noted above, was largely unresolved at that time. It also has been the subject of several comments received subsequent to the November 1992 meeting.

One question is whether the 1 mg daily limit should be based on total folate (i.e., food folates plus folic acid from fortified foods and supplements), or whether the 1 mg daily limit should be based only on folic acid from fortified foods and supplements (i.e., intake of folic acid above the background of intake of food folates). Proponents of the latter position

contend that the data showing potential safety concerns above 1 mg daily are based only on administration of free folic acid and do not take into account background food folate intakes (Ref. 13). They suggested that safety concerns are not well documented (Ref. 13), and that daily limits of folic acid intake higher than 1 mg/day are needed because folate intakes from fortification options limited by a 1 mg/day ceiling would be too low to be effective in providing sufficient folate to reduce the risk of NTD's for any but a small fraction of the target population of women of childbearing age (Ref. 13).

Conversely, an expert speaker at the November 1992 meeting expressed concerns about intakes in excess of 1 mg folate/day by individuals, particularly those individuals over 50 years, who may be at risk of vitamin B₁₂ deficiency (Ref. 116). This speaker noted that there is no evidence to support the position that risk to the general population is negligible as long as food fortification provides less than 1 mg (1,000 µg) of dietary folate daily. The expert speaker urged the agency, if it proceeded with fortification plans, to develop a surveillance mechanism that could provide early identification of any adverse effect of fortifying the diets of most Americans with folate. FDA notes that it is working with other agencies within PHS to improve surveillance mechanisms for monitoring possible adverse reactions to increased folate intakes.

FDA has carefully considered the conflicting views on the safe upper limit of intake for folate. Based on the current state of the scientific evidence and the factors listed above, FDA tentatively concludes that an upper safe limit of intake of 1 mg folate is necessary to ensure the safety of the food supply. FDA has also tentatively concluded that the safe upper limit of 1 mg daily should be based on folate, rather than on added folic acid, and that it should not be adjusted for bioavailability factors. FDA's use of this value is based on its review of the scientific record, on its discussions with the Folic Acid Subcommittee and the fact that much of the concern that has been expressed about intakes above 1 mg folate/day has not been qualified based on the source of the folate. The upper limit of safe intake that FDA is proposing represents the agency's best scientific judgment at this time. FDA solicits comments and data on this tentative judgment. The agency recognizes the significance of this proposed upper limit to its analysis of options for fortification. The agency also recognizes that this value may need to be adjusted based on comments that

it receives. FDA will carefully consider any data that it receives on the issue of the safe upper limit of daily folate intake and will make necessary adjustments in this level based on its review of the data that are submitted.

C. Models Used and Fortification Options Evaluated

In developing its options for fortification and in reaching its tentative conclusions, the agency considered both effectiveness in reaching most women in the target population and maintenance of a safe level of daily intake (that is, an intake of 1 mg or less) for "high consumers" of folate both within the target population and in the general population. The agency considered the following in reaching its tentative conclusions:

(1) The expected daily intakes of "high consumers" of all age and gender groups and special risk groups must be evaluated for safety because the entire population will be passively and continuously exposed to folic acid in a fortified food supply;

(2) The effectiveness of a fortification option in reaching the target population can be evaluated by examining intakes at the lower end of the estimated intake distribution curve;

(3) Because estimates of folate intake from survey data are underestimates of true intakes because of the very low calorie intakes associated with some reported intakes, appropriate adjustments in intake distributions may be necessary; and

(4) Bioavailability cannot be meaningfully factored into fortification scenarios because issues of bioavailability are very complex, and no systematic data are available on many of the factors that affect bioavailability.

FDA presented estimates of the potential effects of food fortification on folate intakes to the Folic Acid Subcommittee at its November 23 and 24, 1992, meeting and in its final rule denying a health claim on folic acid and NTD's (58 FR 2606 at 2621). The estimates were based on intakes resulting from fortification of foods at specified levels of folic acid on a "per serving" basis. The "folic acid per serving" approach had the advantage of being rapidly performed, while reflecting changes in intakes that could occur with various fortification scenarios. This initial approach, however, needed refinement. FDA provided refined estimates, which were based on fortification of foods (e.g., fruit juices, dairy products) and food ingredients (e.g., cereal-grain products), to the Folic Acid Subcommittee at its April 15, 1993, meeting. In general, both

types of estimates provided similar results regarding the effects of fortification on estimated folate intakes.

1. Data Base Chosen

The agency used USDA's 1987 to 1988 NFCS data base (Ref. 117) to estimate the potential effects of fortification of specific components of the food supply on folate intake by women in their childbearing years and by persons in the general population. The NFCS was designed to produce nationally representative estimates of food and nutrient intakes. Each respondent provided 3 days of dietary data. Such data provide better estimates of individual food intake than do, for example, 24-hour recall data, or food frequency data. In addition, for each respondent, the survey provided general information about supplement intake and brand-specific information about consumption of breakfast cereals.

FDA used the 1987 to 1988 NFCS because it provides the most recent nationally representative food consumption data available for all age/sex groups. Other recent food consumption surveys that FDA considered using lacked data on older children, adolescents, and older adults (for example, 1985 and 1986 USDA CSFII). Unlike other surveys, the 1987 to 1988 NFCS also includes brand name information on commonly fortified foods such as breakfast cereals, thereby allowing an estimate of folate intake from this category of foods based on manufacturers' current fortification practices. Thus, the 1987 to 1988 NFCS provided data that were particularly pertinent to the agency's needs and that were not available in other more recent surveys.

A disadvantage of using the 1987 to 1988 NFCS is the caution needed in interpreting the results because of the low response rate (Ref. 118). FDA considered using other national surveys with higher response rates (i.e., the 1977 to 1978 NFCS or 1976 to 1980 NHANES were considered), but they were judged by the agency to be too outdated to be useful or to lack the information necessary to reflect current folate fortification of breakfast cereals.

The low response rate of the NFCS may suggest a possible source of bias in the agency's estimates. However, an expert panel convened to assess the impact of the low response rate in this survey concluded that the presence or absence of a nonresponse bias could not be demonstrated with certainty (Ref. 118), and distribution data of the type used in the NFCS analysis have generally been consistent with results

from other nationally representative surveys with higher response rates.

2. General Approach

The approach that FDA used to estimate folate intakes is based on the most relevant regulatory and food manufacturing units, e.g., servings of breakfast cereals, grams of cereal-grain products used as food ingredients, or measured portions of fruit juices or dairy products. Using information from NFCS respondents on the types and amounts of foods that they consumed over a 3-day period, general information on their use of dietary supplements and breakfast cereals, and a folate composition data base that provided specific information on folate content of foods and food ingredients (Ref. 119), FDA summed the total folate intake from all sources for each individual and obtained a value for mean folate intake per day. The agency used this average value from 3 days of data as the "usual" intake for an individual. FDA calculated distributions of folate intakes by age/sex groups from these values. The agency used the data to estimate the potential impact of various fortification options by altering the folate composition of selected foods and ingredients in the data base. For example, the agency recalculated intake estimates to determine the intake levels if all cereal-grain products contained 70 µg folic acid/100 g, or if selected juices or dairy products contained 140 µg folic acid/100 g.

The results of such estimations reflect likely changes in total folate intake if selected foods are fortified at one of several levels. These estimations were all based on current dietary patterns. The agency is aware, however, that individuals may change their dietary patterns by selecting folate-rich foods in response to a health claim. However, the agency knows of no way to estimate the magnitude of such changes in dietary patterns or to estimate their net effects in increasing folate intakes.

The NFCS provided qualitative information on dietary supplement use. In deciding whether to assign a folate contribution (i.e., value) to a reported supplement used, FDA considered whether the supplement was likely to contain folic acid. The response categories that FDA treated as being likely to contain folic acid included: "multivitamin," "multivitamin with iron or other minerals," "other combination of vitamins and minerals," or "other single vitamins/minerals." FDA considered the following response categories as representing supplements that were not likely to contain folic acid:

"combination of vitamin C and iron," "vitamin C," "iron," or "calcium."

In NFCS, consumers reported the frequency with which they consumed supplements described in the general terms above as "every day" or "almost every day," "every so often," or "not at all." Current marketing practice is to include folic acid in supplements labeled for use without reference to age or physiologic state at 400 µg. Thus, FDA included in daily folate intakes a value of 400 µg for those respondents 4 or more years of age who reported that they took supplements "every day" or "almost every day" and a value of 200 µg/day for those who said they took supplements "every so often." For persons 1 to 3 years of age who reported that they took supplements "every day" or "almost every day," FDA assigned an intake value of 200 µg/day. FDA assigned an intake value of 100 µg/day for persons 1 to 3 years of age who responded that they consumed supplements that might contain folic acid "every so often."

a. *Foods chosen for consideration as vehicles for fortification.* FDA expects that there will likely be a significant increase in consumption of folate by women in their childbearing years, and by the general population, if a health claim were to be authorized because manufacturers will add folic acid to their products in order to claim that these products are useful in reducing the risk of birth defects, and consumers will have point-of-purchase information available to them in making decisions regarding food selections. In its January 1993 final rule (58 FR 2606), the agency presented estimates of intakes of total folate and free folic acid that might result from uncontrolled fortification of foods with folic acid (i.e., FDA considered for these estimates that foods were fortified to the current unit limit of 400 µg) (58 FR 2606 at 2621; Table, Estimates A and B). The estimates showed that daily intakes of total folate of low consumers and high consumers could reach 4,700 µg (4.7 mg) and 9,100 µg (9.1 mg), respectively, if such fortification were to occur. Intakes of multiple doses of free folic acid in the form of dietary supplements and from its increased presence in the food supply could result in daily intakes of more than 3 mg (3,000 µg) by low consumers and approximately 7 mg (7,000 µg) by high consumers (58 FR 2606 at 2621; Table, Estimates A and B). These estimated intakes significantly exceed the agency's safe upper limit of intake of 1 mg of folate/day.

After reviewing these results, the agency tentatively concluded that limitations on the types of foods that

might be fortified, and on the amounts of folic acid that might be added to such foods, were necessary to prevent unsafe levels of folic acid fortification of the food supply.

In examining options for providing folate to women of childbearing age through food fortification, the agency considered various options including allocation of folate to products such as cereal-grain products, fruit juices, and dairy products. It also considered current practices with respect to inclusion of folic acid in breakfast cereals and in dietary supplements.

In selecting foods to consider as vehicles for fortification, the agency started with the basic principle that fortification of staple products that are commonly consumed in significant amounts by virtually all members of the target population is most likely to effectively result in increased intakes of a specific nutrient by the target population. The agency notes that cereal-grain products were the fortification vehicle recommended by the Board (Ref. 111). These foods are consumed on a daily basis by more than 90 percent of women of childbearing age (Ref. 120).

In identifying specific cereal-grain products for fortification, the agency considered those products with established standards of identity: Enriched bread, rolls, and buns; enriched wheat, corn, and rice flours; enriched corn grits and enriched corn meals; enriched farinas; enriched rice; enriched macaroni products; and enriched noodle products (21 CFR parts 136, 137, 139). The dry (i.e., uncooked) cereal-grain products that were part of the fortification scenarios included wheat flours, rice, farinas, corn meals, corn grits, and macaroni, spaghetti, and noodles. Under standards of identity, the addition of specified amounts of certain nutrients to such products allows them to be labeled as "enriched." Folic acid is not currently among the nutrients permitted or required to be included in "enriched" products. To permit or require addition of folic acid to such products, the standards of identity for specific cereal-grain products must be amended (see companion document published elsewhere in this Federal Register).

Because of data showing that 90 percent of women of childbearing age report consumption of cereal-grain products on a daily basis (Ref. 120), all fortification options the agency considered included fortification of cereal-grain products.

FDA also considered including breakfast cereals in its fortification strategy because they represent a

traditional source of many nutrients, including folic acid, for those who consume them. Breakfast cereals are also consumed by many women of childbearing age. Folic acid can be readily added to breakfast cereals. Its level in these foods is limited only by the limits established in the food additive regulation (21 CFR 172.345). Similarly, because approximately 30 to 40 percent of women of childbearing age use dietary supplements (Ref. 121), the agency also included the availability and continued use of dietary supplements in fortification options.

The agency was concerned that some women of childbearing age may not eat sufficient amounts of cereal-grain products, or breakfast cereals, or use dietary supplements, and consequently, fortification options limited to these folate sources might not be able to significantly increase the folate intakes of such women. Other foods with standards of identity that are frequently fortified include dairy products and juices (including milk, yogurt, fruit juices, and canned fruit nectars). Folic acid is currently not among the nutrients that are permitted or required in these foods under applicable standards of identity. Thus, in some of the fortification options, the agency evaluated the additional impact on folate intakes of fortification of both fruit juices and dairy products.

b. *Folate composition data.* FDA used an ingredient file prepared by the USDA's Human Nutrition Information Service (HNIS) to estimate total folate intakes (Ref. 119). Data in the ingredient file was based either on the levels of folate in foods and their ingredients in the U.S. food supply or on various changes that reflected the effects of several fortification options. Since the USDA ingredient file identified the grain ingredients of interest for all food categories in the survey, FDA was able to use the data in the file to estimate the total dietary effects of fortifying these grain ingredients. For example, the file allowed the agency to determine the effect on folate intakes that could result from fortifying the flour consumed in breads, rolls, buns, or cake as well as the flour consumed as a component of a frozen dinner (e.g., pizza crust, noodles, rolls, or breadings).

In one set of analyses, FDA estimated the effects of fortification on intakes by assuming fortification of cereal-grain products with 0.070, 0.140, and 0.350 mg folic acid/100 g. The value of 0.070 mg/100 g (0.30 mg/pound) is the amount recommended by the Board in 1974 (see above). Values of 0.140 and 0.350 mg/100 g represent twofold and

fivefold increases, respectively, above the Board's recommended level.

In a second set of analyses of potential intakes from fortified foods, the agency applied the levels of fortification used above to a broader range of food products including certain dairy products and fruit juices. Examples of dairy products and fruit juices to which fortification levels were applied included fluid cows' milk, reconstituted dry milk, condensed and evaporated milks, yogurts, and fruit juices such as orange, grapefruit, lemon, pineapple, apple, and grape.

Many breakfast cereals (dry ready-to-eat and cooked), as defined in 21 CFR 170.3(n)(4), are currently fortified with 100 µg of folic acid/labeled serving (25 percent of the RDI). Other breakfast cereals contain 35 to 45 percent of the RDI for folate (140 to 180 µg/labeled serving), while a limited number contain 100 percent of the RDI for as many as 17 minerals and vitamins, including folic acid (RDI for folate, 400 µg). The NFCS provided brand-specific information about breakfast cereal consumption. Values for folate content of these breakfast cereals were obtained from brand-specific data provided in the USDA data base. For about the 50 top-selling ready-to-eat dry cereals, in instances in which the current folic acid content of the breakfast cereal (identified from a review of food labels in a local supermarket) differed from the value used in the USDA data base, FDA updated the USDA data base values with the more recent values. Thus, values assigned to these breakfast cereals were generally reflective of what is currently in the marketplace. (Note: This correction was not applied to cooked breakfast cereals because of lack of brand-specific information.)

For dietary supplements, FDA assumed current marketing practices of including 400 µg (0.4 mg) folic acid/daily dose for supplements labeled without reference to age or physiologic state. The agency added a value of 400 µg/day to folate intakes for regular use of folic acid-containing supplements and added a value of 200 µg/day to folate intakes for irregular use of folic acid-containing supplements.

With the availability of health claims for folic acid and NTD's, the breakfast cereal market is likely to increase folic acid fortification to higher levels than are currently used. For purposes of considering possible effects of changes in levels of fortification of breakfast cereals on estimates of total daily folate intake, FDA considered two possibilities: (1) All breakfast cereals would be fortified to a level of 100 µg folic acid/serving (i.e., 25 percent of the

RDI/serving); and (2) all breakfast cereals would be fortified to a level of 400 µg folic acid/serving (i.e., 100 percent of the RDI/serving). The agency estimated folate intakes that might result from these two possibilities in a food supply in which cereal-grain products were also fortified (i.e., the agency used levels of cereal-grain fortification of 0.07, 0.140, and 0.35 µg folic acid/100 g for these estimations).

c. *Analysis.* FDA conducted all data analyses using the procedures of Statistical Analysis System (SAS). In addition, the agency weighted all of the results using factors provided with the data tapes that were designed to provide results representative of the U.S. population. Results were presented as distributions of average daily intakes of folate by age/sex groups.

FDA evaluated each fortification option by examining folate intakes at the low end of the distribution curve for the target population (hereafter referred to as "low consumers"). Thus, the higher the folate intake of low consumers in the target population, the more effective the fortification option would be in meeting the folate intake goals for the target population. The values for "low consumers" represent the minimum intakes for target women.

FDA evaluated the safety of intakes that would result from a particular fortification scheme by examining estimated folate intakes at the high end of the intake distribution curves (hereafter referred to as "high consumers"). Obviously, the highest intakes represent the greatest potential risks.

3. Reasonableness of Results: Possible Sources of Error in Intake Estimates

a. *Underestimation of food intake.*

Food intake data frequently underestimate the actual food intake of respondents (Ref. 122). Clinical studies have shown substantial discrepancies between food intake reported by volunteers and intake subsequently determined to be required for weight maintenance. An average underreporting of 18 percent below maintenance food intake for men and women was found in one study of 266 volunteers (Ref. 122).

To assess the reasonableness of the estimated folate intakes from the 1987 to 1988 NFCS, the agency compared mean energy (calorie) intakes of survey respondents as calculated from reported food intakes to energy requirements estimated by the Food and Nutrition Board of NAS (Ref. 123) for various sex/age groups. In the 1987 to 1988 NFCS, calculated mean energy intakes of women 19 to 50 years, based on 3-day

dietary data, were about 1,500 calories, whereas the most recent estimated average energy requirement for this gender/age group is 2,200 calories. The reported intakes represent about 70 percent of the average required intake, or an average reported energy intake about 30 percent below the most recent average energy allowance. Although FDA frequently uses 90th percentile intakes to evaluate intakes of high consumers (Ref. 124), in the present analysis, the 95th percentile for energy more closely corresponds to the upper range of energy requirements. Conversely, at the low end of the distribution curve, energy intakes based on reported food patterns are so low (approximately 1,200 calories for women of childbearing age) that normal weight maintenance would not be possible. Such diets could not be maintained, therefore, for more than short periods of time and are unlikely to represent "usual" intakes. FDA therefore used the 25th percentile intakes to estimate the level of folate intake that would be achieved by "low consumers," and the 95th percentile intakes to estimate the level of intake that would be achieved by "high consumers." The agency considers the adjusted intakes that it used to represent a reasonable intake range over time by most persons in an age/sex group. The agency also notes that in adjusting folate intake estimates to correct for underreporting of food intake, it assumed underreporting both for conventional foods and dietary supplements.

To evaluate possible bias because of the high nonresponse rate of the 1987 to 1988 NFCS, FDA compared the estimated mean daily intake of folate without fortification options or supplement use for women 19 to 50 years in the 1987 to 1988 NFCS (i.e., 189 µg folate/day) to mean daily folate intakes reported for this gender/age group in two other recent USDA surveys that had better response rates. The 1986 Continuing Survey of Food Intake by Individuals (CSFII) (Ref. 125) reported a mean daily intake of folate of 193 µg and the 1985 CSFII reported a mean daily folate intake of 189 µg (Ref. 126). Thus, results from these three surveys are comparable.

b. *Underestimation of folate content of foods.* There is general agreement that the methods currently used for folate analysis in foods are unsatisfactory (Ref. 115). Methods for liberation of naturally occurring folylpolyglutamates from complex food matrices and their hydrolysis to forms that can be accurately quantified by microbiological assay are difficult and are frequently

incomplete. Comparison of newer methods of sample preparation with older methods has revealed underestimates in the range of 20 percent for vegetables such as spinach and cauliflower and 50 percent for canned tuna (Ref. 115). Thus, commonly used methods of folate analysis may significantly underestimate the folate content of foods.

Additionally, to ensure that fortified foods (including breakfast cereals and dietary supplements) contain at least the amounts of nutrients, such as folic acid, that are declared in the label, manufacturers add excess amounts of the nutrients in preparing the foods. Since label values were used to define the folate composition of fortified breakfast cereals and dietary supplements, however, the values that are used are likely to understate the actual folate content of these foods.

c. Overall reasonableness of intake estimates. Taken together, the two factors of underreporting of food intake and underestimation of folate content of foods will likely result in significant underestimates in folate intakes. For example, if the magnitude of the combined underestimate was 30 percent, an estimated intake value of 750 μg of folic acid/day might actually be 940 μg /day, and an estimated intake of 200 μg /day might actually be 260 μg /day.

FDA has tentatively concluded that except for the crude adjustment to bring folate intake estimates in line with estimated energy needs, more sophisticated mathematical adjustments are not appropriate because they would attribute the estimates with more precision (or certainty) than is justified by the nature of the data upon which the estimates are based. In addition, because of the questions about bioavailability that are described above, the agency tentatively considers bioavailability to be too unpredictable to be factored into the analyses. Because of the multiple and variable sources of systematic error, the lack of information on the nature of interactions among these various sources of error, questions of variations in bioavailability of folate from various food and supplement sources under different meal/eating conditions, and the lack of systematic data addressing these questions, FDA was not able to identify a mathematical "adjustment" factor that it considered to be reasonably accurate or universally applicable. Therefore, the agency has not included any such factors when calculating estimates of folate intakes or in identifying appropriate levels of food fortification.

4. Results

a. Estimates. Estimates of current intakes of folate by low and high consumers with and without supplement use and the results of estimations for 12 options for fortifying cereal-grain products, fruit juices, and dairy products are shown in Table 4.

As shown in the results of intake estimations in Table 4, at all three fortification levels examined, when fortification included fruit juices and dairy products in addition to cereal-grain products (Estimate Nos. 9 to 11), intakes of high consumers exceeded 1,000 μg /day for most age groups even without supplement use. For example, if cereal-grain products, fruit juices, and dairy products were fortified with 350 μg folic acid/100 g (Table 4, Estimate Nos. 11 and 14), women of childbearing age who were "high consumers" could consume 480 to 830 μg or more of folate/day without supplement use and 630 to 870 μg or more of folate/day with supplement use, intakes consistent with the PHS recommendation. With this fortification level, estimated daily intakes of folate by children 1 to 10 years of age who were "high consumers" could reach 4,020 to 4,550 μg without supplement use and 4,260 to 4,620 μg /day with supplement use, values that are several multiples of their current RDA's and in excess of the upper safe limit of intake of 1,000 μg (1 mg). In addition, with this level of fortification, estimated daily intakes of folate by adults 51+ years who were "high consumers" could fall in the range of 2,670 to 3,240/day without supplement use and 2,900 to 3,750 μg /day with supplement use. These intakes exceed the upper limit of safe intake of 1 mg/day.

Fortification of cereal-grain products, juices, and dairy products with lower levels of folate (for example, at 70 μg /100 g) also results in daily folate intakes of high consumers in many groups in excess of 1 mg. FDA has tentatively concluded, therefore, not to allow fortification of dairy and juice products because such fortifications could result in potentially unsafe intakes by large segments of the population.

FDA then examined the effects of limiting fortification to cereal-grain products. The agency examined the same fortification levels: 70, 140, or 350 μg folic acid/100 g (Table 4). Pros and cons of these options are listed in Table 5. For reference purposes, examples of levels of folic acid that could be present in typical products (i.e., breakfast cereals and noodles manufactured from enriched flours, enriched breads) are also included in Table 5.

If cereal-grain products were fortified with 70 μg folic acid/100 g (Table 4, Estimate Nos. 3 and 6), folate intakes by adult population groups of "high consumers" would remain below 1 mg/day. If fortification of cereal-grain products was increased to 140 μg /100 g, intakes by adults 51+ years who were "high consumers" and who used supplements would approach 1 mg/day (Table 4, Estimate Nos. 4 and 7). Fortification of cereal-grain products at 350 μg /100 g (Table 4, Estimate Nos. 8) could result in estimated daily intakes by "high consumer" adults 51+ years of 980 to 1,100 μg when supplement use is included. When cereal-grain products are fortified at levels of 350 μg folic acid/100 g, daily intakes of folate by high consumers among children 1 to 3 years and 4 to 10 years are 670 and 1,030 μg with supplement use (Table 4, Estimate No. 8), values 2 to 3 times the RDA's for these age groups.

b. Potential effects of fortification options for consumers who follow Federal government dietary guidelines. As a further check on the reasonableness of the fortification options, FDA considered it prudent to evaluate the likely effects of fortification on folate intakes of consumers who follow government dietary guidance such as the U.S. Dietary Guidelines for Americans and the DHHS/USDA Food Guide Pyramid (Ref. 127). Fortification should not make compliance with the U.S. Dietary Guidelines unsafe.

The USDA Food Guide Pyramid recommends consumption of 6 to 11 servings of cereal-grain products/day, 2 to 3 servings of dairy products, 3 to 5 servings of vegetables, 2 to 3 servings from the meat group, and 2 to 4 servings of fruit. Estimates of folate intakes that could result from food consumption patterns consistent with Food Pyramid Guidelines with fortification of cereal-grain products at 70, 140, and 350 μg /100 g and breakfast cereals at 100 μg /serving (25 percent of the RDI) and 400 μg /serving are shown in Tables 6A and 6B. The estimates are based on consumption patterns at both the low (Table 6A) and high (Table 6B) ends of the USDA Food Pyramid Ranges.

FDA estimates that women who consumed 6 servings/day of cereal-grain products fortified with 70 μg folic acid/100 g and consumed a breakfast cereal fortified with 100 μg folic acid/serving would obtain 53 percent of the RDI (i.e., 210 μg /day) from these sources alone (Table 6A). Intake from these sources alone could be 510 μg folate/day if a breakfast cereal fortified with 400 μg folic acid were chosen instead of a breakfast cereal fortified with 100 μg folate. Consumption of 6 servings of

cereal-grain products fortified with 140 or 350 µg folic acid/100 µg and use of a breakfast cereal fortified with 100 µg folic acid/serving could provide 80 percent and 153 percent, respectively, of the RDI from these fortified food sources alone. Intakes from these sources alone could be 620 µg folate/day or 910 µg folate/day if a breakfast cereal fortified with 400 µg folic acid were consumed as part of a food supply in which cereal-grain products were fortified with 140 or 350 µg folic acid/100 µg, respectively.

FDA also estimates that women who followed a dietary pattern consistent with the upper end of the USDA Food Pyramid Range for cereal-grain products (i.e., 11 servings/day) and chose a breakfast cereal fortified with 400 µg of folate/serving (i.e., 100 percent of the RDI) could consume 620, 840, or 1,420 µg folate/day from these sources alone, depending upon whether cereal-grain products were fortified with 70, 140, or 350 µg folic acid/100 µg (Table 7B). Consumption of diets high in rich natural sources of folate such as specific vegetables and use of a dietary supplement of 400 µg folic acid could lead to daily intakes of folate of 1,670 µg, 1,890 µg, and 2,470 µg, with cereal-grain products fortified at 70, 140, or 350 µg/100 µg.

The estimates shown in Table 6A suggest that, without supplement use, consumers who followed even the low end of recommendations from the USDA Food Pyramid Food Guide could readily consume 420 or more µg of folate/day from all sources if cereal-grain products were fortified at 70 µg/100 g. For such "low" consumers who did not use supplements, daily intakes of folate from all sources could reach 530 or 820 µg/day with a food supply in which cereal-grains products were fortified with 140 µg or 350 µg folic acid/100 g, respectively.

c. *Potential effects of changes in fortification of breakfast cereals.* The agency also compared the effects on estimated intakes if there were a change in the current marketing practices for breakfast cereals. The agency considered effects on intakes if all cereals were fortified at levels of 100 µg/serving or 400 µg/serving, with results shown in Table 7. Since the great majority of breakfast cereals are currently fortified with 100 µg of folic acid/serving, comparisons of current intakes with those that might result from fortification of all breakfast cereals at 100 µg/serving show that they are essentially the same. However, the agency's estimates show that if all breakfast cereals were to be fortified at a level of 400 µg of folate/serving as part of a food supply in which a wide range of cereal-grain

products were also fortified, intakes by high consumers in many population groups could approach or exceed the safe upper limit of intake of 1 mg. This result is true for some high consumers even without fortification of cereal-grain products and becomes more apparent as the level of fortification in cereal-grain products increases from 70 to 350 µg/100 g.

D. Tentative Conclusions—Options for Fortification

The estimates above suggest that fortification of standardized cereal-grain products at 70 µg/100 g or 140 µg/100 g, the availability of dietary supplements at 400 µg folic acid/unit, and the availability of breakfast cereals fortified at 100 µg folic acid/serving could provide folate intakes below 1 mg folate daily for most persons.

The agency notes that several presenters at the April 15, 1993 Folic Acid Subcommittee meeting recommended fortification of cereal-grain products at 350 µg/100 g because they felt that safety issues were exaggerated, and that intakes somewhat above 1 mg/day posed little or no hazard. Conversely, members of the Folic Acid Subcommittee who favored fortification were about evenly divided between fortification at 70 or 140 µg/100 g (Ref. 13). Those favoring fortification at levels of 70 or 140 µg folic acid/100 g stated that such levels could provide increased intakes of folate for women in their childbearing years while ensuring that intakes for nontarget groups in the population below 1 mg/day.

The level of fortification of cereal-grain products of 140 µg/100 g represents approximately twice the level recommended by the NRC in 1974 and is the higher of two levels proposed by the Folic Acid Subcommittee. The estimates for intake of folate from food by high consumers among adults 51+ years (those who are potentially at greatest risk of vitamin B₁₂ deficiency) are 800 to 840 µg/day (Table 4, Estimate No. 7). However, if standardized cereal-grain products were fortified at 350 µg/100 µg, the estimated maximum intake from foods could be 980 to 1,050 µg/day (Table 4, Estimate No. 8). The agency has tentatively concluded that this level of cereal-grain fortification could provide intakes that exceed the safe upper folate intake limit and thus, because proposed fortification of cereal-grain products will provide continuous and unavoidable exposures, does not meet the requirement that a food fortification scheme be safe.

FDA tentatively finds, based on available data, that fortifying cereal-grain products with 140 µg of folic acid

and allowing breakfast cereals to contain up to 400 µg of folic acid/serving will also result in daily folate intakes by significant portions of the population in excess of the safe upper limit of 1 mg/day. For example, intakes by high consumers in all adult population groups could reach (e.g., 950 to 980 µg/day for women 19 to 51+ years) or exceed (e.g., 1,440 for males 11 to 18 years) 1 mg/day. Daily intakes of high consumer males 19 to 50 years and 51+ years could be 1,090 and 1,060 µg folate, respectively. These values are not consistent with the maximum intake limit of 1 mg folate/day. Therefore, the agency cannot authorize a fortification scheme that would produce them.

The agency recognizes that breakfast cereals, unlike breads and other cereal-grain products, are generally consumed only once/day by most adults. Thus, consuming a single daily serving of a highly fortified breakfast cereal is different than consuming multiple daily servings of highly fortified cereal-grain products. However, some consumers such as teenagers may consume multiple servings/day of breakfast cereals, and children may consume breakfast cereals as snacks. Because of increased intakes that might be achieved through such eating patterns, the agency considered the option of proposing that fortification of all breakfast cereals be limited to 100 µg/serving (Table 7). With this option, estimated intakes would remain below 1 mg by all population groups, even if cereal-grain products are fortified with 140 µg folic acid/100 g, and supplements of 400 µg folic acid/unit are available.

FDA recognizes that this proposed action will have the effect of requiring the reformulation of a small number of breakfast cereals. It is not the agency's desire to have such an effect, but it appears to be unavoidable given the current state of the record. The agency is prepared to reconsider this approach if interested persons submit comments that provide data or other information that show that folate consumption can be kept within safe limits with breakfast cereals fortified to 400 µg/serving.

The agency also recognizes that some may find an inequity in the agency's treatment of dietary supplements, with respect to which the agency is proposing to allow continued marketing of a 400 µg folic acid supplement, as compared to its treatment of breakfast cereals, with respect to which it is proposing to establish a 100 µg/serving limit for folic acid. FDA tentatively finds that this approach is appropriate because supplements tend to be used to supplement the diet for specific purposes, while breakfast cereals are

eaten more generally as part of the usual diet. However, the agency requests comment on this matter. While commenters should feel free to suggest alternate approaches, including other combinations of options, such comments will be most useful if they explain how the suggested approach will ensure that total dietary intake of folate will remain within safe limits.

The agency recognizes that its proposal to fortify cereal-grains products at 140 µg/100 g, to allow for fortification of breakfast cereals at 100 µg/serving, and to retain the current limitations for use of folic acid in supplements (i.e., 400 µg folic acid/unit), present a dilemma in that by limiting fortification to levels that provide safe intakes for the general population, the estimated daily folate intake by "low consumers" among women of childbearing age may not reach the PHS recommended levels of 400 µg/day without changes in their food selection practices. However, the proposed fortification levels will mean that, under FDA's estimate, "low consumers" among women of childbearing age will consume 230 to 250 µg/day (Table 4, Option 7). These values represent an increase of 80 to 100 µg over current daily intakes. Significantly, several studies have found that dietary intakes of 250 µg or more daily are associated with a reduced risk of NTD's. Moreover, these levels are also close to intake levels estimated to be sufficient to saturate body tissue stores of folate (Ref. 14). The increased intake of 80 to 100 µg/day is also consistent with the opinion of one Folic Acid Subcommittee member that increases of about 100 µg/day above current intakes could provide protective effects. The agency also notes that intakes of 230 to 250 µg/day are minimum intakes for women of childbearing age, and that most women will have intakes above this level, with some estimated to be close to 800 µg/day. Thus, the agency tentatively finds that even though "low consumers" may not achieve the 400 µg/day recommended by PHS, on balance, particularly in light of the potential effects of higher levels of fortification on the nontarget population, the proposed fortification scheme will produce acceptable results.

Moreover, the agency explained above why it believes that its estimates may underrepresent folate intakes. The agency also noted that its estimates did not factor in any effect that the presence of health claims on food labels will have on food selection choices of women of childbearing age. The agency expects that the availability of health claims on cereal-grain products fortified at the

level proposed will result in increased consumption of such products and hence increased folate intake, beyond that that would occur without a health claim. Thus, the availability of a health claim on cereal-grain products fortified at the level proposed and on other sources of dietary folate could lead to food choices that could result in adequate folate intakes even by "low consumer" women of childbearing age.

The agency has tentatively concluded that by providing for moderate increases in folate intakes through fortification and by then providing point-of-purchase information of foods that are good sources of folate on the relationship of adequate folate intake and reduction in risk of NTD's, women of childbearing age will have considerable flexibility in making their dietary choices (including use of supplements) to achieve the PHS recommended intake. This flexibility will also be available to persons who need to or who may wish to limit their folate intakes, and who would find it much more difficult to do so if higher folate levels were used in cereal-grain products, whose use in the diet is difficult to avoid or to significantly reduce.

FDA also calculated examples of likely individual intakes from fortified foods using various levels of fortification (Tables 6A and 6B). For example, a woman who made food choices from the "low" range of the USDA Food Guide Pyramid and who consumed 5 servings/day of cereal-grain products fortified at 140 µg/100 g and ate 1 bowl of cereal containing 100 µg of folic acid would consume about 320 µg of folic acid (i.e., 80 percent of the RDI) from these sources alone (Table 6A). Addition of a serving or two of vegetables, or of a serving of fruit, could lead to a folate intake above 500 µg/day, well in excess of the PHS recommended level of 400 µg of folate/day.

However, if cereal-grain products were fortified at 350 µg/100 g, and the dietary choices indicated above were made, a "low consumer" would obtain 610 µg folic acid daily (153 percent of the RDI) from these sources alone (Table 6A). The agency notes, however, that if cereal-grain products are fortified at the level of 350 µg folic acid/100 g, "high" consumers could reach intakes of folic acid of more than 1,000 µg/day from bread, noodle, rice, and pasta products alone (Table 6B). Additional consumption of breakfast cereals, fruits, vegetables, and a dietary supplement by "high consumers" could result in daily intakes of about 2.5 mg, significantly above the agency's proposed safe upper limit of daily intake of 1 mg.

In summary, FDA has tentatively concluded that its overriding responsibility is to establish a safe range of intakes for all population groups, to maximize folate intakes of the target population within this safe range, and to ensure the safe use of health claims. However, given the dilemma of trying to increase intakes of women of childbearing age while ensuring that intakes by "high consumers" across all segments of the U.S. population are safe, and given the uncertainties in the available data, FDA asks for comment on the appropriateness of its approach and of other options, including higher and lower levels of fortification. In this regard, FDA will carefully consider any data that it receives on the issue of fortification level and target foods and will make any appropriate adjustments based on the review of the data it receives.

The agency also requests comments on several other possibilities for fortification. Specifically, the agency is requesting comments on:

(1) Whether cereal-grain products might be fortified at a lower level (e.g., 70 µg/100 g), thus leaving a greater margin of safety for consumers of supplements and highly fortified cereals and greater flexibility in amounts of folic acid that might be permitted in other foods;

(2) Whether both dietary supplements and breakfast cereals should be limited to the same but lower level (e.g., 100 or 200 µg folic acid/unit or/serving);

(3) Whether, in a food supply that includes a wide range of fortified cereal-grain products, an additional caution statement should be required for all products fortified at 100 percent of the RDI (i.e., 400 µg folic acid/unit or/serving), given that consumption of multiple servings/day of such products (e.g., more than two) will result in daily folate intakes well above 1 mg; and whether a higher level of fortification (e.g., 350 µg/100 g) is more appropriate than the level that FDA is proposing (140 µg/100g).

The agency also requests data on the safety of fortification options for children. In examining the intakes of children, who are among the high consumers of breakfast cereals and dietary supplements, the agency is specifically requesting comments on whether long term, continuous intakes of free folic acid by children at levels of three to four times their RDI's present safety concerns, and if so, what those concerns are. The agency notes that when intake of folate by children increases markedly (e.g., by several multiples of their RDI's), the majority of the increased intake will likely appear

in the blood stream as unmetabolized folic acid. In this regard, the agency calls attention to its estimates that among children 1 to 3 and 4 to 10 years, high consumers could ingest 810 to 1,220 µg folate/day if cereal-grain products were fortified at 140 µg/100 g and if all breakfast cereals were fortified at 400 µg/serving.

Several comments (Ref. 59) suggested that higher folate fortification could be safely implemented if simultaneous fortification with vitamin B₁₂ (cobalamin) at a level of 1 mg is also required. These comments are based on assumptions that the greatest potential for adverse effects with high folate intake is its masking of the anemia of vitamin B₁₂ deficiency, with continued progression of neurologic damage, and that provision of oral vitamin B₁₂ in sufficiently high levels will negate this concern. FDA is aware that doses of about 1 mg/day of vitamin B₁₂ (500 times the RDI for this vitamin) without intrinsic factor (i.e., without the protein factor necessary for the absorption of vitamin B₁₂, and the factor whose lack causes pernicious anemia) have provided adequate treatment for some persons with pernicious anemia (Ref. 129). However, Hathcock and Troendle (Ref. 129), in a recent editorial, note that regardless of the widespread availability of oral vitamin B₁₂ preparations, patients with pernicious anemia or others at risk of vitamin B₁₂ deficiency should be diagnosed, treated, and monitored by a physician.

Several experts at the CDC's recent meeting on surveillance for adverse effects of increased intakes of folate (Ref. 59) commented on the suggestion that high doses of vitamin B₁₂ be added to foods and supplements fortified with folic acid to reduce the potential for adverse effects in persons with vitamin B₁₂ deficiency. One expert noted that vitamin B₁₂ may be converted into analogs, some of which may have antivitamin B₁₂ activity, in the presence of certain other nutrients (e.g., vitamin C, thiamin, iron), and that attempts to fortify with vitamin B₁₂ would require a demonstration that the vitamin B₁₂ added with folic acid remained biologically active and safe.

At this time, FDA is not proposing to include the addition of vitamin B₁₂ to foods fortified with folic acid. FDA requests comments, specifically data, on the appropriateness, potential effectiveness, and safety of use of simultaneous fortification with high levels of vitamin B₁₂ for the purpose of possibly minimizing the adverse effects of increased folic acid intakes. FDA will consider such comments in arriving at a final rule in this matter. FDA is

proposing in separate documents published elsewhere in this issue of the **Federal Register** that standardized enriched cereal-grain products be fortified with folic acid at the level of 140 µg folic acid/100 g, that breakfast cereals be allowed to include up to 100 µg/serving, and that dietary supplements be allowed to contain up to 400 µg folic acid/daily dose when labeled without reference to age or physiologic state. While the agency believes that fortification at either 70 µg or 140 µg folic acid/100 g is safe, it is proposing to require 140 µg/100 g as the folic acid fortification level because this level will provide a better opportunity for a larger portion of the target population to achieve significantly increased folate intakes.

The results of FDA's analysis of food fortification options show that fortification of the U.S. food supply alone cannot increase daily intakes of folate for all women of childbearing age to 400 µg/day if current dietary patterns are continued without increasing the potential for adverse effects in nontarget segments of the population. Apparently some women (i.e., "low consumers") in the target population eat such small amounts of the staple foods that are candidates for fortification that no matter how high the fortification levels are set, the added folic acid would not reach them. The inability of fortification alone to increase the intakes of all target women to 400 µg/day was recognized by a number of experts who consulted with the Folic Acid Subcommittee at its November 23 and 24, 1992 meeting.

VI. Proposed Requirements for Health Claims

A. Relationship Between Folate and NTD's

The 1990 amendments required FDA to evaluate the topic of folic acid and NTD's with respect to its appropriateness for a health claim. The term "folic acid" is the name given to the parent compound of the folate vitamin forms, whereas the term "folates" is used as a descriptor for the entire group of folate vitamin forms and includes both folic acid and the folylpolyglutamates found in foods. In reviewing the scientific evidence on the relationship between folate and NTD's, the agency noted that some studies reported effects of use of supplements of folic acid in combination with intakes of food folates, while other studies reported effects of dietary intakes of food folates alone. Based on its review of these studies, the agency has tentatively concluded that the diet/disease relationship is more correctly

expressed as "folate and neural tube defects" rather than as "folic acid and neural tube defects".

Therefore, FDA is proposing in § 101.79 to authorize health claims on labels or in labeling of foods in conventional form or dietary supplements on the relationship between folate and NTD's. Proposed paragraph § 101.79(a)(1) defines the disease or health-related condition that is the subject of the claim. NTD's are rare but serious birth defects that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of NTD's and account for about 90 percent of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

Proposed § 101.79(a)(2) describes the effect of folate intake on the risk of NTD's. FDA's tentative conclusion based on its review of the totality of the scientific evidence and its resolution of safety issues, as reflected in this section of the regulation, is that the available data show that folic acid alone may reduce the risk of recurrence of NTD's when given at high levels (i.e., 4 mg (4000 µg)/day or 10 times the RDI) to women at high risk of such a recurrence. Additionally, based on a synthesis of information from several observational studies that reported use of multivitamins containing 0 to 1,000 µg of folic acid, the PHS, including FDA, concluded that folic acid intake at levels of 0.4 mg (400 µg or 100 percent of the RDI)/day may reduce the risk of occurrence of NTD's (Ref. 11). PHS also stated that a reasonable estimate of the expected reduction in the United States is 50 percent.

B. Significance of the Relationship

Proposed § 101.79(b)(1) summarizes the significance of appropriate folate intake relative to reduction in risk of NTD's in the general U.S. population and within the total dietary context. This paragraph recognizes that reduction in adverse pregnancy outcomes, such as birth defects, is an important public health goal. Because most NTD's occur in women without a history of such outcomes, interest in reducing the risk of first occurrences has been very high.

In the United States, about 2,500 cases of NTD's occur among about 4 million annual births (i.e., in approximately 6 of 10,000 live births). The majority of NTD's are isolated defects and

apparently are produced by a number of factors (Ref. 12). The single greatest risk factor is a personal history of a pregnancy affected with an NTD (Ref. 12). However, about 90 percent of infants with an NTD are born to women who do not have a family history of these defects (Ref. 12).

Proposed § 101.79(b)(2) identifies populations at risk for NTD's. NTD's have been reported to vary with a wide range of factors including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health including maternal age and reproductive history (56 FR 60610). Women with a close relative (i.e., sibling, niece, nephew) with an NTD, with insulin-dependent diabetes mellitus, and with seizure disorders who are being treated with valproic acid or carbamazepine are at significantly increased risk compared with women without these characteristics (Ref. 20). Rates for NTD's also vary within the United States, with lower rates observed on the west coast than on the east coast (56 FR 60610). Recent data from State-based birth defects surveillance systems show declining trends for NTD's in the United States for about the last 30 years (Ref. 18).

In proposed § 101.79(b)(3), FDA notes that PHS (Ref. 11) estimated that if all women of childbearing age in the United States who are capable of becoming pregnant consumed 0.4 mg of folic acid daily throughout their childbearing years, there would be about a 50 percent reduction in the number of infants born with NTD's (i.e., a reduction from about 2,500 annually to about 1,250 annually). The protective effect of about 0.4 to 1 mg of folic acid daily, measured by the reduction in incidence of occurrence of NTD's, has ranged from none to substantial (Refs. 5, 6, 9, and 26). Thus, PHS stated that a reasonable estimate of the expected reduction in the United States is 50 percent (Ref. 11).

C. General Requirements

The agency is proposing in § 101.79(c)(1) to require that to bear a health claim on the relationship between folate and NTD's, foods must meet the general requirements for health claims in § 101.14 (published in the *Federal Register* of January 6, 1993 (58 FR 2478), except for the requirement in § 101.14(d)(2)(vii) that the food be "high" in the subject nutrient.

Folate is ubiquitously distributed among many foods in the U.S. food supply. While a number of foods (e.g., some legumes, okra, broccoli, spinach, turnip greens, asparagus, Brussels

sprouts, endive, lentils) contain more than 80 µg of folate/serving, the great majority of foods contain folate at lower levels. For example, oranges, grapefruit, many berries, cabbage, lettuce, corn, cauliflower, peas, many vegetable juices, beets, and parsnips contain folate at levels of 40 to 80 µg/serving (Ref. 129).

The agency is concerned that if it required (in accord with § 101.14(d)(2)(vii)) that the food contain 20 percent of the RDI for folate (i.e., 80 µg) or more/reference amount customarily consumed, many good food sources of folate would not be able to qualify to bear a health claim without fortification. The current dietary guidance recommendations of five or more servings of fruits and vegetables/day, and six or more servings of grain products/day, if followed, would likely result in daily intakes of folates of 0.4 mg or more. Thus, use of a qualifying criterion consistent with that used to define a "good" source of folate provides for an amount that allows a wide variety of fruits, vegetables, and grain products to qualify and is consistent with current dietary guidelines for general dietary patterns. Because health claims on foods in conventional food form are required to be made within the context of a daily diet, and because FDA has proposed a similar requirement for health claims for dietary supplements, it seems contrary to the intent of the 1990 amendments to set requirements that would essentially limit a health claim to fortified foods or dietary supplements and to a relatively few fruits and vegetables. Accordingly, FDA is proposing in § 101.79(c)(1) and (c)(2)(ii) that foods may bear a folic acid health claim if they contain 10 percent or more of the RDI for folic acid/reference amount customarily consumed (i.e., must meet the definition for a "good source" claim in § 101.54). (Ref. 129).

The general requirements for health claims in § 101.14, among other things, prohibit a health claim if any of the specified disqualifying nutrient levels are exceeded. This requirement ensures that folic acid/NTD health claims will not appear on foods that contain amounts of fat, saturated fat, cholesterol, or sodium that may increase the risk from the total diet of a disease or health-related condition. A thorough discussion of the criteria for identifying risk nutrients and the levels of these nutrients allowed in foods that bear health claims is found in the preamble to the final rule on general principles for health claims (58 FR 2478).

D. Specific Requirements

1. Relationship Statement

In § 101.79(c)(2), the agency is proposing to require that the claim on the relationship of folate and NTD's state that women who are capable of becoming pregnant and who consume adequate folate daily may reduce their risk of having a pregnancy affected by spina bifida or other NTD's.

The agency is proposing to require that the claim specifically relate adequate intake of folate during the childbearing years to reduced risk of NTD's (proposed § 101.79(c)(2)(i)(A)). This proposed action is consistent with observational data (Refs. 6, 8, and 26) showing that adequate intake of folate during the childbearing years may reduce the risk of occurrence of such birth defects.

The agency considered the use of synonyms for "folate" and the need to aid consumers in understanding this nutrient. The agency, therefore, has provided, in proposed § 101.79(2)(i)(B), for the use of synonyms and for additional description of this term through use of phrases such as "folate," "folic acid," "folacin," "folate, a B vitamin," "folic acid, a B vitamin," or "folacin, a B vitamin." The terms "folate" and "folacin" are generic descriptors for compounds that have nutritional properties and chemical structures similar to those of folic acid (Ref. NAS). The terms "folate" and "folacin" are allowable synonyms under § 101.9 and proposed § 101.36. The term "folic acid" is specifically used in the PHS recommendation (Ref. 11), and by allowing use of this term, the PHS recommendation can be quoted directly on the label, if all other requirements for the health claim are met. The use of the descriptive term, "a B vitamin," in conjunction with "folate," "folacin," or "folic acid," is commonly used in lay information for consumers and may be useful for consumers in indicating the nutritive role of folate.

The agency considered whether women might be confused or not understand the term "neural tube defect" and has provided in proposed § 101.79(c)(2)(i)(C) for some qualification of this term through use of phrases such as "the birth defect spina bifida," "the birth defects spina bifida and anencephaly," "spina bifida and anencephaly, birth defects of the brain or spinal cord." Although a phrase like "reduce the risk of serious birth defects" might be simpler, the agency is concerned that if a claim were to state in general terms that "folic acid may reduce the risk of serious birth defects," women would be misled into believing

that folic acid would reduce their risk of other serious birth defects, and that they might consequently fail to consider other risk factors for birth defects (e.g., use of alcohol, drugs).

The agency is proposing to allow, as one option, reference to simply "the birth defect spina bifida" because that is the most common NTD in the United States for which some protective effect of folate has been demonstrated (Refs. 5, 6, 7, and 26). However, because the protective effect of folate has been shown for both spina bifida and anencephaly, both terms may be used. The agency considers that the optional use of the descriptive phrase, "birth defects of the brain or spinal cord" could be useful to consumers in better understanding the nature of the NTD and in differentiating this birth defect from others such as heart defects.

2. Multifactorial Nature

In § 101.79(c)(2)(i)(D), FDA is proposing to require that the claim contain a statement that NTD's are multifactorial in origin. The general requirements for health claims for foods in conventional food form (§ 101.14), which FDA has proposed to apply to health claims for substances in dietary supplements, provide that where factors other than dietary intake of the substance affect the relationship between the substance and disease or health-related condition, FDA may require that such factors be addressed in the health claim.

NTD's have many causes, some of which are not related to folate status. The single greatest risk factor currently recognized, as stated above, is a personal history of an NTD defect-affected pregnancy.

3. Prevalence

In § 101.79(c)(2)(i)(E), the agency is proposing to require that the health claim provide information that NTD's, while not of high prevalence in the United States are very serious birth defects. Because the affected population is few in number and not readily identifiable, FDA is proposing to require such information to prevent women from being misled into believing that NTD's are very common birth defects, or that, lacking a personal or family history of such defects, their risk of having a pregnancy affected with such a birth defect is very high. The prevalence of NTD's in the United States is currently about 6/10,000 live births, or about 2,500 cases/year. In addition, there may be no effect of periconceptional use of folic acid in areas of low prevalence or in areas where other factors are contributing to an increased prevalence.

Such a statement is consistent with scientific evidence that shows that in an area of low prevalence of NTD's in the United States, women who consumed folate from multivitamins or fortified cereals did not have a lower risk of having an NTD-affected pregnancy than did women who did not (Ref. 7).

Examples of the statements that the agency is proposing to require are "Such birth defects, while not widespread, are very serious." or " * * * birth defects * * * that, while not widespread, are very serious."

4. Reduction in Risk

In § 101.79(c)(2)(i)(F), the agency is proposing to require that the claim contain a statement that some but not all women may benefit from adequate intakes of folic acid. Such a statement is consistent with estimates provided with the findings in the PHS recommendation that about half of NTD's (about 1,250 annually) could be prevented if all women of childbearing age in the United States who are capable of becoming pregnant consumed 0.4 mg of folic acid daily throughout their childbearing years. Such a statement is necessary to prevent the claim from misleading women to believe that use of folic acid will prevent all occurrences of NTD's.

The agency is also proposing in this section that the claim not attribute any specific degree of reduction in risk of NTD's to maintaining an adequate folate intake throughout the childbearing years.

5. Safe Upper Limit of Intake

As discussed above, a comment received following the November 23 and 24, 1993 Folic Acid Subcommittee meeting suggested that any health claims related to folic acid and NTD's should be balanced by a warning statement that increased intakes of folate may increase the frequency of irreversible neurologic damage from vitamin B₁₂ deficiency, and that among African-American and Hispanic females, folic acid fortification or supplementation is likely to do more harm than good. The agency recognizes that for some groups in the population (see safety discussion above), there may be certain risks attendant upon increased consumption of folic acid. At the present time, the potential adverse effect that has been most extensively documented is that of the activity of increased intakes of folate in masking the anemia of vitamin B₁₂ deficiency while irreversible neurologic damage progresses.

In recognition of comments and safety concerns discussed above, FDA, in

§ 101.79(c)(2)(F), is proposing to require a statement on both fortified foods in conventional food form and on dietary supplements that contain more than 25 percent of the RDI (i.e., more than 100 µg/reference amount customarily consumed or, for supplements, per unit) about the maximum safe daily limit for folate consumption. Such a statement is necessary to prevent the claim from being misleading regarding potential risks from excessive intakes. As stated above, the safe intake limit is 1 mg/day. A fortified food that contains more than 100 µg/serving contributes more than 25 percent of the RDI and more than 10 percent of the daily limit. Consumption of such foods should be monitored by the consumer, so that they will not be consistently or significantly exceeding the daily limit. An example of the statement FDA is proposing to require is: "Folate consumption should be limited to 250 percent of the DV (i.e., to 1,000 µg per day)."

The agency is not proposing to require that this statement be included in claims on the relatively small number of conventional foods that contain more than 100 µg of folic acid without fortification (e.g., dark green leafy vegetables, certain legumes). The agency believes that there is no need for the consumer to monitor intakes of these foods because their folate content consists of reduced pteroylpolyglutamates whose bioavailability is generally considered lower than that of the folic acid (i.e., pteroylmonoglutamate) added as a fortificant to foods.

6. Limitation on the Claim

In § 101.79(c)(2)(i)(H), the agency is proposing that a health claim not state that a specified amount of folate is more effective in reducing the risk of NTD's than a lower amount (e.g., 100 µg). This proposed requirement is consistent with data showing that reduction in risk of NTD's has been associated with general dietary improvement (which is assumed to increase folate intake by unspecified amounts).

7. Identifying Sources of Folate

In § 101.79(c)(2)(ii)(B), the agency is proposing to require that health claims relating folate and NTD's identify sources of folate by stating that adequate amounts of folate may be obtained by making specific dietary choices of folate-rich foods, as well as through use of dietary supplements or fortified breakfast cereals. Several studies have shown that among women with a prior NTD-affected pregnancy who improved their poor diets to diets with adequate intakes of all nutrients in a subsequent

pregnancy, there was a 50 percent reduction in recurrence of NTD's (Ref. 9). In addition, several studies have shown that among nonusers of supplements, significant gradients (i.e., trends) in reduction in risk of NTD's are associated with increased intakes of folate and other nutrients (Refs. 8 and 26). One study has shown that among nonsupplement users, diets providing more than 100 µg/day of folate are associated with reduced risk of NTD's (Ref. 6). Thus, the agency has tentatively concluded that claims that fail to reveal that adequate amounts of folate can be obtained through attention to dietary choices would be misleading.

Examples of the statements that the agency is proposing to require to assist women in making dietary choices are: "Women * * * should choose well-balanced diets that include 2 to 4 servings per day of fruits (including citrus fruits and juices), 3 to 5 servings of vegetables (including dark green leafy vegetables and legumes), 6 to 11 servings of enriched grain products (such as breads, rice, and pasta) and fortified cereals throughout their childbearing years. Such diets provide many essential minerals and vitamins, including folate. Women who do not eat well-balanced diets or who may be concerned about their diets may choose to obtain folate from dietary supplements;" or "Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables and legumes, enriched grain products, including breads, rice, and pasta, fortified cereals, or from a dietary supplement;" or "Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or from a dietary supplement."

8. Nutrient Availability

Benefits of folate intake from food in conventional food form and from dietary supplements can only be obtained if the folate is available for metabolism by the body. As discussed above, the bioavailability of folates in foods ranges from approximately 25 to 75 percent, depending upon a variety of factors that are incompletely understood (Ref. 114). The majority of food folates occur as reduced folylpolyglutamates and must be cleaved by intestinal conjugase before absorption. Folate utilization may be reduced under conditions that inhibit conjugase activity and by natural conjugase inhibitors found in certain foods (Ref. 114). However, there are not enough

data on factors in specific foods or components of foods that affect folate bioavailability for FDA to determine conditions under which a health claim for folate in foods would be misleading because the folate was not assimilable. On the other hand, crystalline folic acid is generally considered to have a bioavailability greater than that of food folates because it is in the monoglutamate form and does not have to be cleaved by intestinal conjugases (Ref. 114).

A dietary supplement that contains folate that does not disintegrate and dissolve clearly does not provide the nutrient in an assimilable form. Thus, a claim for such a dietary supplement would be misleading because the supplement would not provide the nutrient that is the subject of the health claim.

Dietary supplements can be formulated in a manner that prevents rapid dissolution and disintegration, thereby preventing subsequent absorption of the nutrients they contain. Accordingly, FDA is proposing in § 101.79(c)(2)(ii)(C) to require that dietary supplements that contain folate and that bear a health claim meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution.

However, when U.S.P. standards do not exist, the agency recognizes the need for an alternative method of establishing the bioavailability of the nutrients in dietary supplements under the conditions of use stated on the product label. FDA is proposing that demonstrations of bioavailability in human or animal studies when conducted under the conditions of use stated on the product label (i.e., fed as an intact tablet, not crushed) will fulfill this requirement. Thus, proposed § 101.79(c)(2)(ii)(C) provides that if there are no applicable U.S.P. standards, the folate in the dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.

9. Prohibition of Claims on Fortified Products That Contain More than 100 Percent of the RDI for Vitamins A and D

The agency is aware that folate is often combined with other nutrients, particularly vitamins and minerals, in dietary supplement formulations. In light of the expectation that the presence of a health claim on the label of such products is likely to encourage the intake of these products, FDA is concerned that some consumers may try to increase their folate intake through the use of multiple doses of fortified

products or vitamin supplements. The agency is concerned that for some fortified products that contain both folate and vitamin A or vitamin D, consumers could be exposed to excessive vitamin A or vitamin D intakes in their attempts to obtain increased amounts of folate.

It is widely recognized that vitamin A in excessive amounts is teratogenic (Ref. 15). A high incidence (greater than 20 percent) of spontaneous abortions and of birth defects, including malformations of the cranium, face, heart, thymus, and central nervous system, have been observed in the fetuses of women ingesting therapeutic doses (0.5 to 1.5 mg/kilogram) of 13-*cis*-retinoic acid (isotretinoin) during the first trimester of pregnancy, and large daily doses of retinyl esters or retinol (≥ 6,000 retinol equivalents or 20,000 International Units (IU)) may cause similar abnormalities (Ref. 15).

Vitamin D is potentially toxic, with effects of excessive intakes including hypercalcemia and hypercalciuria (Ref. 15). Although the toxic level of vitamin D has not been established for all ages, consumption of as little as 1,800 IU of cholecalciferol/day has been associated with signs of hypervitaminosis in young children (Ref. 15). The toxic level of vitamin D may in some cases be only 5 times the RDA (Ref. 15).

The 1991 CDC recommendation for increased intake of folate by women with a history of an NTD-affected pregnancy warned against overconsumption of multivitamins because of the potential for excessive intakes of vitamins A and D from such preparations (Ref. 11). In addition, recent recommendations in Canada for women of childbearing age regarding folic acid and NTD's included consideration of the teratogenicity of high levels of vitamin A (Ref. 56).

Based on this information, FDA tentatively concludes that to prevent folate health claims from inadvertently encouraging excessive intakes of vitamins A and D, it is necessary to prohibit the health claim for folate on supplement formulations that contain more than 100 percent of the RDI of vitamin A and vitamin D. Therefore, FDA is proposing in § 101.79(c)(2)(iii) that the health claim be prohibited on foods in conventional food form and on dietary supplements that contain more than 100 percent of the RDI for vitamin A or vitamin D. Educational materials regarding increasing intake of folate to reduce the risk of NTD's should include precautionary information about excessive intakes of vitamins A and D.

10. Nutrition Labeling—Requirement that Nutrition Labeling Be Provided for Foods and Supplements Bearing Health Claims

FDA is proposing to require in § 101.79(c)(2)(iv) that the nutrition label of any food that bears a health claim on folate and neural tube defects include information about the folate content of the food. This proposed requirement is consistent with § 101.9(c)(8)(ii), which states that the declaration of vitamins and minerals on the nutrition label shall include any of the vitamins and minerals listed in § 101.9(c)(8)(iv) when a claim is made about them, and with proposed § 101.36(b)(3), which requires a listing of any vitamin or mineral listed in § 101.9(c)(8)(iv) that is present in the product. FDA also sets forth in proposed § 101.79(c)(2)(iv) how the information on folate content is to be presented. The agency is doing so in the interest of clarity.

E. Optional Health Claim Information

Consistent with general requirements for health claims (21 CFR 101.14), FDA is proposing optional information that may be included in the health claim. The agency is proposing to permit manufacturers, in addition to including the fact that risk of NTD's is multifactorial, to specifically identify other risk factors for NTD's (§ 101.79(c)(3)(i)). Although not identified in the regulation, specific examples of other risk factors might include a personal history of such a defect, maternal diabetes mellitus, use of the antiepileptic drug valproic acid, maternal febrile illness, or a close relative (sibling, niece, nephew) with an NTD.

The agency is also proposing to permit the claim to include statements from paragraphs (a) and (b) of § 101.79 that summarize the relationship between folic acid and NTD's and the significance of the relationship (proposed § 101.79(c)(3)(ii)). The proposed provision excludes from these permitted statements information specifically prohibited from the claim. This exception is consistent with the proposed prohibition in § 101.79(c)(i)(F) against statements that give specific degrees of reduction in risk of NTD's.

Proposed paragraph (a)(2) on the relationship between folic acid and NTD's includes a statement that a reasonable estimate of the expected reduction in NTD's incidence in the United States is 50 percent. This 50 percent estimate is based on observational studies that showed reductions in risk from none to substantial (Ref. 11), is population-

based, and does not apply to the reduction in risk for an individual. FDA believes that while the statement is appropriate in the context in which it is presented in paragraph (a)(2), it could be misleading to consumers in food label as part of a health claim. It is unlikely that a label statement about a 50 percent reduction in incidence could be properly qualified on a food label so that it would not incorrectly imply a 50 percent reduction in risk to the individual.

Available data clearly show that the single greatest risk factor for an NTD-affected pregnancy is a personal history of the defect. The agency tentatively concludes that a statement that women with a history of an NTD pregnancy should consult their physicians or health care providers before becoming pregnant would encourage them to obtain medical guidance and thus decrease their possibility of a recurrence of another NTD-affected pregnancy. The agency is proposing to permit such a statement as a part of the health claim (proposed § 101.79(c)(3)(iii)).

The agency is also proposing to include as optional information in the health claim a statement that the target folate intake goal is the RDI level of 400 µg/day and not to require that this information be included as part of the claim (proposed § 101.79(i)(3)(iv)).

Following the April 1993 Folic Acid Subcommittee meeting, an expert speaker commented that the 400 µg/day dose of folic acid was an artificial goal. The expert noted that there are no data demonstrating that 400 µg/day is the required amount, and that there are data to suggest that this amount is more than is required to reduce the risk of NTD's. The expert noted further that if 400 µg/day were required, little or no impact (with respect to reduction in risk of NTD's) should have been seen in those studies that looked at diet because daily dietary intakes of folate are generally below 400 µg. Studies by Werler et al. (Ref. 26), Bower and Stanley (Ref. 8), Laurence (Ref. 9), and Milunsky et al. (Ref. 6), all have suggested, however, that there are pronounced effects from levels of dietary folate lower than 400 µg/day.

In its January 6, 1993 final rule, the agency noted that a number of studies have shown significant effects of diet in reducing risk of NTD's. The findings of these studies are listed in Table 3. These studies suggest the potential efficacy of lower doses of folate in reducing the risk of NTD's, and the benefits of overall dietary improvement for women during their childbearing years. Some studies (Refs. 6 and 26) have shown significant

risk reduction at folate intakes well below 400 µg/day.

However, because the PHS recommends a 400 µg/day intake, the RDI is 400 µg, and the Folic Acid Subcommittee supported the 400 µg/day intake goal, the agency believes that it may be helpful to some consumers if the health claim for folate were to include information that the RDI of 400 µg/day is the target intake goal.

F. Model Health Claims

FDA is providing examples of model claims that meet the proposed requirements in proposed § 101.79(d). The agency is including these model claims to assist manufacturers in formulating an appropriate claim.

G. Effective Date

FDA is proposing that for fortified foods, the regulation authorizing a health claim on folate and NTD's become effective on the effective date for the amendment to the folic acid food additive regulation. In the final rule on a health claim for folic acid and NTD's on January 6, 1993 (58 FR 2606), FDA noted that it could not allow a health claim on this topic area until issues of safe use could be resolved. FDA, at that time, was concerned that a health claim could motivate manufacturers to increase fortification of foods in order to qualify for health claims, and consumers could also increase use of foods bearing a health claim. Taken together, these two events could result in potentially high intakes of folic acid for which safety was an issue.

In this document, FDA has tentatively concluded that by amending its food additive regulation for folic acid, it can ensure that a health claim for folate and NTD's can be safely implemented. However, because the safe use of the health claim is based on the concurrent implementation of the amendment to the folic acid food additive regulation, FDA is proposing that the health claim regulation not become effective until the food additive amendment is effective.

On the other hand, because of the significance of the information provided in the health claim, and because of the absence of an issue about the safe level of use of folate in foods that naturally contain this nutrient and in dietary supplements, FDA is proposing that § 101.79 would become effective for these foods 30 days after the date of publication of this final rule.

VII. Comments

Interested persons may, on or before December 13, 1993, submit to the Dockets Management Branch (address above) written comments regarding this

proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

During the comment period on this and the two related documents on folic acid, the agency intends to convene the Folic Acid Subcommittee and the Food Advisory Committee for a discussion of the issues raised in the documents. FDA also intends to request comments from the experts who participated in its November 23 and 24, 1992, meeting of its Folic Acid Subcommittee. The agency will make these comments and the views of the committees available for public review and comment as part of this rulemaking immediately after the Advisory Committee meeting is held. In addition, FDA will endeavor to have copies of the transcripts of the Folic Acid Subcommittee and Food Advisory Committee meetings available as quickly as possible as well.

VIII. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday. Because the agency is taking three actions involving folic acid, and the net effect of these actions is likely to increase the usage of folic acid, one environmental assessment has been prepared which considers all three agency actions.

IX. Economic Impact

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act and Executive Order 12291. The Regulatory Flexibility Act requires regulatory relief for small business where feasible. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking, where permitted by law. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In compliance with the Regulatory Flexibility Act (Pub. L. 96-354), FDA certifies that the proposed rule will not have a significant

impact on a substantial number of small businesses.

The agency is proposing to authorize health claims for folate and NTD's. Because no products are currently making health claims concerning folate and NTD's, the proposed rule will not adversely affect any labels currently being used. FDA believes that there are no costs associated with the proposed rule.

The allowance of a health claim for folate and NTD's will, to the extent that folate health claims appear on products and to the extent that consumers read and understand that health claim, result in an unquantifiable benefit in terms of the education of consumers about the relationship between folate, diet, health, and NTD's. Folate health claims may result in increased demand for products containing this nutrient. An increase in consumption of products containing folate is likely to result in health benefits in terms of fewer NTD's. However, FDA is not able to estimate the number of products that will bear health claims or the effect that folate health claims will have on consumer demand for products containing folic acid. FDA requests comment on these factors.

X. 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.

1. Laurence, K.M., N. James, M.H. Miller, G.B. Tennant, H. Campbell, "Double Blind Randomized Controlled Trial of Folate Treatment Before Conception to Prevent Recurrence of Neural Tube Defects," *British Medical Journal*, 282:1509-1511, 1981.
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List of Subjects in 21 CFR Part 101

Food labeling, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs, it is proposed that 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 continues to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 371).

§ 101.71 [Amended]

2. Section 101.71 *Health claims: claims not authorized* is amended by removing paragraph (c) and by redesignating paragraphs (d) through (f) as (c) through (e), respectively.

3. New § 101.79 is added to subpart E to read as follows:

§ 101.79 Health claims: folate and neural tube defects.

(a) *Relationship between folate and neural tube defects*—(1) *Definition*. Neural tube defects are serious birth defects of the brain or spinal cord that can result in infant mortality or serious disability. The birth defects anencephaly and spina bifida are the most common forms of neural tube defects and account for about 90 percent

of these defects. These defects result from failure of closure of the covering of the brain or spinal cord during early embryonic development. Because the neural tube forms and closes during early pregnancy, the defect may occur before a woman realizes that she is pregnant.

(2) *Relationship*. The available data show that diets adequate in folate may reduce the risk of neural tube defects. The strongest evidence for this relationship comes from an intervention study by the Medical Research Council of the United Kingdom that showed that women at risk of recurrence of a neural tube defect pregnancy who consumed a supplement containing 4 milligrams (mg) (4,000 micrograms (µg)) folic acid daily had a reduced risk of having a child with a neural tube defect. (Products that contain this level of folic acid are drugs.) In addition, based on its review of a Hungarian intervention trial that used a multivitamin and multimineral preparation containing 800 µg (0.8 mg) of folic acid, and its review of the observational studies that reported use of multivitamins containing 0 to 1,000 µg of folic acid, the Food and Drug Administration concluded that most of these studies had results consistent with the conclusion that folate, at levels attainable in usual diets, may reduce the risk of neural tube defects.

(b) *Significance of folate*—(1) *Public health concern*. Neural tube defects occur in approximately 0.6 of 1,000 live births in the United States (i.e., about 2,500 cases among 4 million live births annually). Neural tube defects are believed to be caused by many factors. The single greatest risk factor for a neural tube defect-affected pregnancy is a personal or family history of a pregnancy affected with a such a defect. However, about 90 percent of infants with a neural tube defect are born to women who do not have a family history of these defects. The available evidence shows that diets adequate in folate may reduce the risk of neural tube defects but not of other birth defects.

(2) *Populations at risk*. Prevalence rates for neural tube defects have been reported to vary with a wide range of factors, including genetics, geography, socioeconomic status, maternal birth cohort, month of conception, race, nutrition, and maternal health, including maternal age and reproductive history. Women with a close relative (i.e., sibling, niece, nephew) with a neural tube defect, those with insulin-dependent diabetes mellitus, and women with seizure disorders who are being treated with valproic acid or carbamazepine are at

significantly increased risk compared with women without these characteristics. Rates for neural tube defects vary within the United States, with lower rates observed on the west coast than on the east coast.

(3) *Those who may benefit*. Based on a synthesis of the results of several observational studies, the Public Health Service has estimated that about 50 percent of neural tube defect-affected pregnancies in the United States (e.g., about 1,250) may be averted annually if all women consume adequate amounts of folate daily (i.e., 0.4 mg) throughout their childbearing years.

(c) *Requirements*. The label or labeling of food in conventional food form or dietary supplements may contain a folate/neural tube defect health claim provided that:

(1) *General requirements*. The health claim for a food or supplement meets all of the general requirements of § 101.14 for health claims, except that a food or dietary supplement may qualify to bear the health claim if it meets the definition of the term "good source."

(2) *Specific requirements*—(i) *Nature of the claim*—(A) *Relationship*. A health claim that women who are capable of becoming pregnant and who consume adequate amounts of folate daily during their childbearing years may reduce their risk of having a pregnancy affected by spina bifida or other neural tube defects may be made on the label or labeling of foods in conventional food form or of dietary supplements provided that:

(B) *Specifying the nutrient*. In specifying the nutrient, the claim shall use the terms "folate," "folic acid," "folacin," "folate, a B vitamin," "folic acid, a B vitamin," or "folacin, a B vitamin."

(C) *Specifying the condition*. In specifying the health-related condition, the claim shall identify the birth defects as "neural tube defects," "birth defects, spina bifida, or anencephaly," "birth defects of the brain or spinal cord anencephaly or spina bifida," or "spina bifida or anencephaly, birth defects of the brain or spinal cord;"

(D) *Multifactorial nature*. The claim shall state that neural tube defects have many causes and shall not imply that folate intake is the only recognized risk factor for neural tube defects.

(E) *Prevalence*. In specifying the prevalence of neural tube defects among women in the general population, the claim shall state that such birth defects "which, while not widespread, are extremely significant" or " * * * birth defects * * * that, while not widespread, are extremely significant."

(F) *Reduction in risk.* The claim shall not attribute any specific degree of reduction in risk of neural tube defects, including mention of the Public Health Service estimate that 50 percent of neural tube defects may be averted annually, to maintaining an adequate folate intake throughout the childbearing years. The claim shall state that some women may reduce their risk of a neural tube defect pregnancy by maintaining adequate intakes of folic acid during their childbearing years.

(G) *Safe upper limit of daily intake.* Claims on fortified foods in conventional form and on dietary supplements that contain more than 25 percent of the RDI for folate (100 µg per serving or per unit) shall state that 1 mg folate per day is the safe upper limit of intake (e.g., "Folate consumption should be limited to 1,000 µg per day from all sources").

(H) *The claim.* The claim shall not state that a specified amount of folate (e.g., 400 µg in a dietary supplement) is more effective in reducing the risk of neural tube defects than a lower amount (e.g., 100 µg in a breakfast cereal or from diets rich in fruits and vegetables).

(ii) *Nature of the food—(A)*

Requirements. The food or supplement shall meet or exceed the requirements for a good source of folate as defined in § 101.54:

(B) *Diets adequate in folate.* The claim shall identify diets adequate in folate by using phrases such as " * * * diets that include 2 to 4 servings per day of fruits (including citrus fruits and juices), 3 to 5 servings of vegetables (including dark green leafy vegetables and legumes), 6 to 11 servings of enriched grain products (such as breads, rice, and pasta) and fortified cereals. Such diets provide many essential minerals and vitamins, including folate. Women who do not eat well-balanced diets or who may be concerned about their diets may choose to obtain folate from dietary supplements."; or "Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables and legumes, enriched grain products, including breads, rice, and pasta, fortified cereals, or a dietary supplement."; or "Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or from dietary supplements."

(C) *Dietary supplements.* Dietary supplements shall meet the United States Pharmacopeia (U.S.P.) standards for disintegration and dissolution, except that if there are no applicable U.S.P. standards, the folate in the

dietary supplement shall be shown to be bioavailable under the conditions of use stated on the product label.

(iii) *Limitation.* The claim shall not be made on foods in conventional food form or dietary supplements that contain more than 100 percent of the RDI for vitamin A as retinol or preformed vitamin A or vitamin D.

(iv) *Nutrition labeling.* The nutrition label shall include information about the amount of folate in the food. This information shall be declared after the declaration for iron if only the levels of vitamin A, vitamin C, calcium, and iron are provided, or in accordance with § 101.9 (c)(8) and (c)(9) if other optional vitamins or minerals are declared.

(3) *Optional information—(i) Risk factors.* The claim may specifically identify risk factors for neural tube defects:

(ii) *Relationship between folate and neural tube defects.* The claim may include statements from paragraphs (a) and (b) of this section that summarize the relationship between folate and neural tube defects and the significance of the relationship except for information specifically prohibited from the claim.

(iii) *Personal history of a neural tube defect-affected pregnancy.* The claim may state that women with a history of a neural tube defect pregnancy should consult their physicians or health care providers before becoming pregnant.

(iv) *Daily value.* The claim may identify the daily value level of 400 µg of folate per day as the target intake goal.

(d) *Model health claims.* The following are examples of model health claims that may be used in food labeling to describe the relationship between folate and neural tube defects:

(1) *Example 1.* Women who consume adequate amounts of folate, a B vitamin, daily throughout their childbearing years may reduce their risk of having a child with a neural tube birth defect. Such birth defects, while not widespread, are very serious. They can have many causes. Adequate amounts of folate can be obtained from diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or a supplement. Folate consumption should be limited to 1,000 µg per day from all sources.

(2) *Example 2.* Women who consume adequate amounts of folate daily throughout their childbearing years may reduce their risk of having a child with a birth defect of the brain and spinal cord. Such birth defects, while not widespread, are very serious. They can have many causes. Adequate amounts of folate, a B vitamin, can be obtained from

diets rich in fruits, dark green leafy vegetables and legumes, enriched grain products, fortified cereals, or a supplement. Women who have had a child with a spinal cord birth defect should consult a physician before becoming pregnant. Folate consumption should be limited to 1,000 µg per day from all sources.

(3) *Example 3.* Women who take steps to ensure that their folate intake is adequate throughout their childbearing years may reduce their risk of having a child with a neural tube defect. Such birth defects, while not widespread, are very serious. They can have many causes. Adequate amounts of folate, a B vitamin, can be obtained from diets rich in citrus fruits and juices, dark green leafy vegetables and legumes, enriched grain products such as breads, rice, and pasta, fortified cereal, or a supplement. Folate consumption should be limited to 1,000 µg per day from all sources.

(4) *Example 4.* Women who take steps to ensure that their folate intake is at least 400 µg daily throughout their childbearing years may reduce their risk of having a child with spina bifida or anencephaly, birth defects of the brain or spinal cord that, while not widespread, are very serious. These birth defects can have many causes. Adequate amounts of folate, a B vitamin, can be obtained from diets rich in fruits, including citrus fruits and juices, vegetables, including dark green leafy vegetables and legumes, enriched grain products, including breads, rice, and pasta, fortified cereals, or from a supplement. Women who have had a pregnancy affected with a neural tube defect should consult a physician before becoming pregnant. Folate consumption should be limited to 1,000 µg per day from all sources.

(5) *Example 5.* Some women who consume the Daily Value of folate (400 µg) throughout their childbearing years may reduce their risk of having a child affected with spina bifida or anencephaly, birth defects of the brain or spinal cord that, while not widespread, are very serious. These birth defects can have many causes. Women of childbearing age should choose well-balanced diets that include 2 to 4 servings per day of fruits (including citrus fruits and juices), 3 to 5 servings of vegetables (including dark green leafy vegetables and legumes), 6 to 11 servings of enriched grain products (such as breads, rice, and pasta) or fortified cereals throughout their childbearing years. Such diets provide many essential minerals and vitamins, including folate. Women who may be concerned about their diets may choose to obtain folate from a supplement.

Folate consumption should be limited to 1,000 µg per day from all sources.

(e) *Effective date.* For fortified foods, this regulation is effective on the date the food additive regulation on the use of folic acid that was proposed on October 14, 1993, becomes effective.

Dated: October 1, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

Note: The following tables are to the Preamble and will not appear in the annual Code of Federal Regulations.

TABLE 1.—FOLIC ACID AND NEURAL TUBE DEFECTS: COMPOSITION OF SUPPLEMENTS USED IN INTERVENTION TRIALS

Composition (vitamins and minerals)	Smithells et al., 1983 (ref. 2)	Medical research council trial (ref. 4)	Hungarian trial (ref. 24)	National research Council (ref. 123)	
				25 to 50 y	
				Female	Pregnant
Vitamin A—IU	4,000	4,000	6,000	2,660 ¹	2,660 ¹
Vitamin D—IU	400	400	500	200	400
Thiamin (B ₁)—mg	1.5	1.5	1.6	1.1	1.5
Riboflavin (B ₂)—mg	1.5	1.5	1.8	1.3	1.6
Pyridoxine (B ₆)—mg	1.0	1	2.6	1.6	2.2
Vitamin C—mg	40	40	100	60	70
Niacin (Niacinamide)—mg	15	15	19	15	17
Vitamin E—TE	0	0	15	8	8
Folic acid—mg	0.36	4 or 0 (see below)	0.8	0.18	0.40
Vitamin B ₁₂ —µg	0	0	4	2.0	2.2
Vitamin K—µg	0	0	0	65	65
Ca. pantothenate—mg	0	0	10	4 to 7 ²	
Biotin—mg	0	0	0.2	0.03 to 0.10 ³	
Mg—mg	0	0	100	280	320
Ca—mg	480 mg calcium	240 mg dicalcium	125 mg Ca	800	1,200
P—mg	phosphate	phosphate	125 mg P	800	1,200
				15	30
Fe—mg	75.6 mg Fe	120 mg ferrous sulfate	60 mg Fe	12	15
Zn—mg	0	0	7.5	1.5 to 3.0 ³	
Cu—mg	0	0	1	2.0 to 5.0 ³	
Mn—mg	0	0	1.		
I—µg	0	0	0.		
Se—µg	0	0	0.		
	Treatments: Vitamins (as above) or unsupplemented.	Treatments: (A) Ca+Fe + 4 mg folate, (B) Ca+Fe+vitamins + 4 mg folate, (C) Ca+Fe, (D) Ca+Fe+vitamins without folate.	Treatments: Multivitamin & multimineral supplement or placebo. Placebo contained Zn, Cu, and Mn as above + vitamin C (as calcium ascorbate, 7.3 mg) and lactose.		

¹ 800 RE; 1 IU vitamin A = 0.30 retinol equivalents (RE)

² ESADDI (adults)

³ TE: 1 mg alpha tocopherol = alpha tocopherol equivalent (TE)

TABLE 2.—FOLIC ACID AND NEURAL TUBE DEFECTS: DEFINITIONS OF SUPPLEMENTS WHOSE USE WAS REPORTED IN OBSERVATIONAL STUDIES

Study	Mulinare et al., 1988 (ref. 5)	Mills et al., 1989 (ref. 7)	Milunsky et al., 1989 (ref. 6)	Werler et al., 1993 (ref. 26)
Years covered.	1968 to 1980	1985 to 1987	1984 to 1987	1988 to 1991

TABLE 2.—FOLIC ACID AND NEURAL TUBE DEFECTS: DEFINITIONS OF SUPPLEMENTS WHOSE USE WAS REPORTED IN OBSERVATIONAL STUDIES—Continued

Study	Mulinare et al., 1988 (ref. 5)	Mills et al., 1989 (ref. 7)	Milunsky et al., 1989 (ref. 6)	Werler et al., 1993 (ref. 26)
Outcome	Use of vitamins was protective ...	Use of vitamins or fortified cereals was not protective..	Use of vitamins was protective	Use of vitamins was protective.
Definition of multivitamins.	Multivitamins or prenatal vitamins were not defined; compositions were unknown. Based on years of data collection (1968 to 1980), supplements could have contained 0 to 800 µg of folate/unit.	Multivitamins were defined as supplements containing the U.S. RDA of at least 4 vitamins. No further specification of compositions.	Multivitamins were not defined. A substantial majority of the preparations whose use was reported contained vitamins A, C, D, and/or E. Based on a random sample of 150 multivitamin users, daily doses of folate ranged from 100 to 1,000 µg with distribution as follows: 100 µg, 17%; 300 µg, 23%; 400 µg, 22%; 1,000 µg, 45%.	Multivitamin was defined as any supplement containing at least two vitamins, one of which was water-soluble. Most common dose of folate, 400 µg/unit.

TABLE 3.—FOLIC ACID AND NEURAL TUBE DEFECTS: REPORTED ASSOCIATIONS BETWEEN MATERNAL DIET AND RISK OF NEURAL TUBE DEFECTS

Study	Dietary observations
Laurence, 1983 (Ref. 9)	This intervention study of dietary guidance found that improvement in women's diets from "poor" to "good" led to a 50 percent reduction in recurrence of neural tube defects in a subsequent pregnancy in women at high risk of this complication. "Poor" diets were defined as diets considered to be deficient in first-class protein, usually no fruits or vegetables, and generally with excessive amounts of carbohydrates. "Good" diets were defined as diets providing good intakes of all essential foods, including protein, no excessive amounts of refined carbohydrates, sweets, and soft drinks.
Bower and Stanley, 1989 (Ref. 8) ...	The study found an association between increasing intakes of dietary folate and decreased risk of occurrence of neural tube defects. Protective effects were also observed for increasing intakes of dietary fiber, calcium, vitamin C, and carotene, markers usually associated with consumption of fruits and vegetables.
Milunsky et al., 1989 (Ref. 6)	Dietary folate intake was calculated from the diet portion of the study questionnaire for those women who were not taking a multivitamin supplement. Nonusers of supplements who had dietary folate intakes greater than 100 µg/day had a 50 percent lower incidence of neural tube defects than did nonusers of supplements whose diets provided less than 100 µg of folate per day.
Werler et al., 1993 (Ref. 26)	For nonusers of supplements, there was a statistically significant trend of decreasing risk of occurrence of a neural tube defect for quintiles of dietary folate intake. Percent reductions in risk for daily dietary folate intakes of 0.253 to 0.310 mg, 0.311 to 0.391 mg, and 0.392 to 2.195 mg were 30, 40, and 40 percent, respectively.

TABLE 4.—FORTIFICATION SCENARIOS—ESTIMATED FOLATE INTAKES FOR LOW AND HIGH CONSUMERS^{1,2,3,4}

[Goal for the target population: Intakes of low consumers should be as high as possible. Goal for nontarget population groups: Intakes of high consumers should be within the safe range (≤ 1 mg/day).]

Option	Target population						Non-target population									
	F 11 to 18 y		F 19 to 50 y		MF 1 to 3 y		MF 4 to 10 y		M 11 to 18 y		M 19 to 50 y		F 51 + y			
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High		
1. Current intakes: foods only	140	420	110	370	120	350	160	430	200	560	160	510	170	480	140	400
2. Current intakes: foods + supplements (400 µg unit)	150	700	150	700	150	470	190	720	220	810	190	760	200	750	170	710
3. Grains ² + 0.070 mg/100 g	180	490	160	430	140	390	190	490	260	600	210	560	220	540	180	450
4. Grains + 0.140 mg/100 g	220	550	190	470	160	420	230	530	310	670	260	600	260	600	210	510
5. Grains + 0.350 mg/100 g	350	770	290	680	220	520	350	730	460	980	400	920	370	810	290	690
6. Grains + 0.070 mg/100 g + supplements (400 µg)	190	730	190	750	190	500	240	780	270	900	240	830	260	790	210	770
7. Grains + 0.140 mg/100 g + supplements (400 µg)	240	770	240	790	220	540	270	830	330	950	300	880	300	840	250	800
8. Grains + 0.350 mg/100 g + supplements (400 µg)	370	970	360	970	300	670	390	1,030	490	1,180	460	1,100	420	1,050	350	980
9. Grains, juices ³ , & dairy ⁴ + 0.070 mg/100 g	280	1,110	210	810	370	1,110	400	1,110	440	1,320	280	1,080	310	940	240	810
10. Grains, juices, & dairy + 0.140 mg/100 g	420	1,840	280	1,260	590	1,960	630	1,790	660	2,250	380	1,690	400	1,540	330	1,280
11. Grains, juices, & dairy + 0.350 µg/100 g	830	4,050	480	2,650	1,230	4,550	1,300	4,020	1,230	5,040	650	3,550	670	3,240	580	2,670
12. Grains, juices, & dairy + 0.070 µg/100 g + supplements (400 µg)	320	1,250	280	1,070	450	1,250	480	1,310	470	1,480	330	1,250	360	1,140	310	1,100

1 Data bases:

A. 1987 to 1988 U.S. Department of Agriculture's Nationwide Food Consumption Survey (NFCS);

B. Only individuals with 3 days of data were selected;

C. This survey apparently underreports food intake. For example, for women 19 to 50 years, the average reported energy intake is only about 70 percent of the current average requirement (1-day data = 70 percent; 3-day average = 67 percent). See text for additional details.

2 Assumptions used for fortification scenarios—Cereal-grain products: Fortification levels of 0.07, 0.14, and 0.35 mg folic acid/100 g were applied to the following dry enriched cereal-grain products: wheat flours; corn grits; corn meals; farinas; rice; macaroni; spaghetti; and noodles.

For breakfast cereals: The majority of breakfast cereals are currently fortified with 100 µg of folic acid/serving (i.e., 25 percent per serving of the RDI for folic acid). Other breakfast cereals contain 35 to 45 percent of the RDI for folic acid, while a limited number contain 100 percent of the RDIs for many vitamins and minerals, including folic acid. The data base provided brand-specific consumption data for these cereals. For about the fifty top-selling breakfast cereals, in instances in which the current folic acid content of the cereal (identified from a review of food labels in a local supermarket) differed from the values used in the USDA data base, the USDA data base values were updated with the more recent values. Thus, values assigned to these breakfast cereals were generally reflective of what is currently in the marketplace. Note: This correction was not applied to cooked breakfast cereals because of the lack of brand-specific information.

3 Assumptions used for fortification scenarios—Juices: Fortification levels as above were applied to fruit juices (e.g., orange, grapefruit, lemon, pineapple, apple, grape, prune, peach, etc.).

4 Assumptions used for fortification scenarios—Dairy products: Fortification levels as above were applied to the following dairy products: fluid cow's milk, reconstituted dry milk, condensed, and evaporated milks; and yogurts (Note: codes for "dry milk, not reconstituted" were excluded).

Use of Dietary Supplements:

The following response categories were considered to represent supplements that might contain folic acid: "multivitamin," "multivitamin with iron or other minerals," "other combination of vitamins and minerals," or "other single vitamins/minerals." The following response categories were considered not to represent supplements that might contain folic acid: "combination of vitamin C and iron," "vitamin C," "iron", or "calcium." Currently available adult supplements contain 400 µg folic acid/unit.

A. For persons ≥ 4 years of age: Persons ≥ 4 years who reported consuming supplements that could contain folic acid (e.g., multivitamins, single vitamins) were assigned an intake value of 400 µg/day if they reported consuming supplements "every day" or "almost every day". Persons ≥ 4 years were assigned an intake value of 200 µg of folic acid daily if they indicated that they consumed supplements that might contain folic acid "every so often".

B. For persons 1 to 3 years of age: Persons 1 to 3 years who reported consuming supplements that could contain folic acid (e.g., multivitamins, single vitamins) were assigned an intake value of 200 µg/day if they reported consuming supplements "every day" or "almost every day". Persons 1 to 3 years were assigned an intake value of 100 µg of folic acid daily if they indicated that they consumed supplements that might contain folic acid "every so often".

TABLE 5.—PROS AND CONS OF FORTIFICATION OPTIONS IN WHICH CEREAL-GRAIN PRODUCTS ARE FORTIFIED WITH 70, 140, OR 350 µg FOLIC ACID/100 g¹

Options for fortification	Pros	Cons	Comments
Fortify cereal-grain products with 70 µg folic acid/100 g (Estimates #3, 6: Table 4) Estimates of results: —10 µg/serving of breakfast cereal made with fortified wheat flour or corn meal —20 µg/slice of fortified bread —30 µg/serving of noodles made with fortified flour	Low consumers in target population could consume 160 to 180 µg or more of folic acid per day (approximately 35 to 45% increase over current intakes) without supplement use (Est. #3). With supplement use (Est. #6), low consumers in target population could consume 190 µg or more folic acid per day (approximately 30% increase over current intakes). Intakes by high consumers in subgroups of adults 51+ years could be 450 to 540 µg/day without supplement use (Est. #3) and 770 to 790 µg/day with supplement use (Est. #6).	For low consumers, intakes of folate do not reach the PHS-recommended level of 400 µg/day.	Use of 1 mg/day as the maximum safe upper limit of intake is consistent with PHS recommendation. Intakes by high consumers in adult population subgroups would remain within this limit with supplement use, even when considering likely underreporting biases (underreporting of food intake and underestimation of folate content of foods).
Fortify cereal-grain products with 140 µg folic acid/100 g (Estimates #4, 7: Table 4) Estimates of results: —20 µg/serving of breakfast cereal made with fortified wheat flour or corn meal —40 µg/slice of fortified bread —60 µg/serving of noodles made with fortified flour	Low consumers in target population could consume 190 to 220 µg or more folic acid per day (approximately 60 to 80% increases over current intakes) without supplement use (Est. #4). With supplement use (Est. #7), low consumers in target population could consume 240 µg or more folic acid per day (approximately 60% increase over current intakes).	For low consumers, intakes of folate do not reach the PHS-recommended level of 400 µg/day. Folate intakes by high consumers among adults 51+ years could reach 800 to 840 µg/day with supplement use (Est. #7).	With supplement use, daily intakes of high consumers among children 4 to 10 years exceed 800 µg/day. This value is somewhat below the PHS-recommended safe upper limit without taking into account likely underreporting biases regarding food intakes and underestimation of folate content of foods.
Fortify cereal-grain products with 350 µg folic acid/100 g (Estimates #5, 8: Table 4) Estimates of results: —50 µg/serving of breakfast cereal made with fortified wheat flour or corn meal —90 µg/slice of fortified bread —150 µg/serving of noodles made with fortified flour	Low consumers in target population could consume 290 to 350 µg or more of folic acid/day without supplement use (Est. #5). With supplement use, low consumers in target population could consume 360 to 370 µg folate/day (Est. #8).	Daily intakes of folate for all consumers 11 years and older are in the range of 680 to 980 µg without supplement use and 970 to 1,180 µg with supplement use.	With supplement use, daily intakes of high consumers among children 1 to 3 years and 4 to 10 years are 670 µg and 1,030 µg, respectively, without taking into account likely underreporting biases regarding food intakes and underestimation of folate content of foods.

¹ Examples of levels of folate that could be present in typical products (i.e., breads, breakfast cereals and noodles manufactured from enriched flours) are included for reference purposes. Bread: 1 serving=1 slice=50 g; Composition: Approximately 50% flour. Folic acid content: 17.5 µg folic acid/serving with use of flour fortified with 70 µg/100 g and 35 µg folic acid/serving with use of flour fortified with 140 µg folic acid/100 g. Values rounded to 20 and 40 µg, respectively.

TABLE 6A.—EXAMPLES OF LIKELY DAILY INTAKES OF FOLATE FROM FOLIC ACID-FORTIFIED CEREAL-GRAIN PRODUCTS AND OTHER FOODS IF THE USDA FOOD PYRAMID RECOMMENDATIONS WERE FOLLOWED—LOW INTAKES

Examples of effects of fortification of cereal-grain products with folic acid

(A) Daily consumption—low intakes based on the USDA food choice pyramid with fortification of cereal-grains at:

	70 µg/ 100 g		140 µg/ 100 g		350 µg/ 100 g
	Folic acid µg		Folic acid µg		Folic acid µg
4 srvs breads @ 20 µg/srv	80	4 srvs breads @ 40 µg/srv	160	4 srvs breads @ 90 µg/srv	360
1 srv cereal	100	1 srv cereal	100	1 srv cereal	100
1 srv noodles/pasta	30	1 srv noodles/pasta	60	1 srv noodles/pasta	150
1 srv milk	5	1 srv milk	5	1 srv milk	5
1 srv cheese	20	1 srv cheese	20	1 srv cheese	20
1 srv peas	90	1 srv peas	90	1 srv peas	90
1 srv cauliflower	55	1 srv cauliflower	55	1 srv cauliflower	55
1 srv veg. w/o sig. folate	0	1 srv veg. w/o sig. folate	0	1 srv veg. w/o sig. folate	0
1 apple	5	1 apple	5	1 apple	5
1 orange	25	1 orange	25	1 orange	25
2 srvs beef	10	2 srvs beef	10	2 srvs beef	10

TABLE 6A.—EXAMPLES OF LIKELY DAILY INTAKES OF FOLATE FROM FOLIC ACID-FORTIFIED CEREAL-GRAIN PRODUCTS AND OTHER FOODS IF THE USDA FOOD PYRAMID RECOMMENDATIONS WERE FOLLOWED—LOW INTAKES—Continued

Examples of effects of fortification of cereal-grain products with folic acid

(A) Daily consumption—low intakes based on the USDA food choice pyramid with fortification of cereal-grains at:

	70 µg/ 100 g		140 µg/ 100 g		350 µg/ 100 g
	Folic acid µg		Folic acid µg		Folic acid µg
Folate µg/day	420	Folate µg/day	530	Folate µg/day	820
+ 1 supplement µg/day	400	+ 1 supplement µg/day	400	+ 1 supplement µg/day	400
Total µ/day	820	Total µ/day	930	Total µ/day	1,200
Percent of RDI	205	Percent of RDI	233	Percent of RDI	305
Percent of RDI attainable from fortified cereal-grain products 210/400 = 53%.		Percent of RDI attainable from fortified cereal-grain products 320/400 = 80%.		Percent of RDI attainable from fortified cereal-grain products 610/400 = 153%.	

The current USDA food pyramid recommends daily consumption of 6 to 11 servings from the bread, cereal, rice, and pasta group, 2 to 3 servings from the dairy group, 3 to 5 servings of vegetables, 2 to 4 servings of fruit, and 2 to 3 servings from the meat, poultry, fish, dry beans, eggs, and nuts group. The examples above show estimates of average daily intakes of folate that could result if the USDA food pyramid recommendations were followed and cereal-grain products were fortified with folic acid. Most breakfast cereals are currently fortified with 25 percent of the RDI for folate/serving (i.e., 100 µg/serving). One option regarding amendment of the food additive regulation for folic acid could permit fortification of breakfast cereals at levels up to 400 µg/serving. The estimates were calculated to show the effects on intakes with these additional sources of folic acid. The "percent of RDI" estimates use the 1980 RDA for folate of 400 µg.

TABLE 6B. EXAMPLES OF LIKELY DAILY INTAKES OF FOLATE FROM FOLIC ACID-FORTIFIED CEREAL-GRAIN PRODUCTS AND OTHER FOODS IF THE USDA FOOD PYRAMID RECOMMENDATIONS WERE FOLLOWED—HIGH INTAKES

Examples of effects of fortification of cereal-grain products with folic acid

(B) Daily consumption—high intakes based on the USDA food choice pyramid with fortification of cereal-grains at:

	70 µg/ 100 g		140 µg/ 100 g		350 µg/ 100 g
	Folic acid, µg		Folic acid, µg		Folic acid, µg
8 srvs breads @ 20 µg/srv	160	8 srvs breads @ 40 µg/srv	320	8 srvs breads @ 90 µg/srv	720
1 srv cereal	400	1 srv cereal	400	1 srv cereal	400
2 srvs noodles/pasta	60	2 srvs noodles/pasta	120	2 srvs noodles/pasta	300
2 srvs milk	10	2 srvs milk	10	2 srvs milk	10
1 srv cheese	20	1 srv cheese	20	1 srv cheese	20
1 srv peas	90	1 srv peas	90	1 srv peas	90
1 srv cauliflower	55	1 srv cauliflower	55	1 srv cauliflower	55
1 srv spinach	50	1 srv spinach	50	1 srv spinach	50
1 srv cabbage	15	1 srv cabbage	15	1 srv cabbage	15
1 srv broccoli	180	1 srv broccoli	180	1 srv broccoli	180
1 apple	5	1 apple	5	1 apple	5
3 oranges	75	3 oranges	75	3 oranges	75
2 srvs beef	10	2 srvs beef	10	2 srvs beef	10
2 srvs beans	140	2 srvs beans	140	2 srvs beans	140
Folate µg/day	1,270	Folate µg/day	1,490	Folate µg/day	2,070
+ 1 supplement µg/day	400	+ 1 supplement µg/day	400	+ 1 supplement µg/day	400
Total µg/day	1,670	Total µg/day	1,890	Total µg/day	2,470
Percent of RDI	418	Percent of RDI	473	Percent of RDI	618
Percent of RDI attainable from fortified cereal-grain products 620/400 = 155%.		Percent of RDI attainable from fortified cereal-grain products 840/400 = 210%.		Percent of RDI attainable from fortified cereal-grain products 1,420/400 = 355%.	

The current USDA food pyramid recommends daily consumption of 6 to 11 servings from the bread, cereal, rice, and pasta group, 2 to 3 servings from the dairy group, 3 to 5 servings of vegetables, 2 to 4 servings of fruit, and 2 to 3 servings from the meat, poultry, fish, dry beans, eggs, and nuts group. The examples above show estimates of average daily intakes of folate that could result if the USDA food pyramid recommendations were followed and cereal-grain products were fortified with folic acid. Most breakfast cereals are currently fortified with 25 percent of the RDI for folate/serving (i.e., 100 µg/serving). One option regarding amendment of the food additive regulation for folic acid could permit fortification of breakfast cereals at levels up to 400 µg/serving. The estimates above were calculated to show the effects on intakes with these additional sources of folic acid. The "percent of RDI" estimates use the 1980 RDA for folate of 400 µg.

TABLE 7.—ESTIMATES OF FOLATE INTAKES IF ALL BREAKFAST CEREALS WERE FORTIFIED WITH FOLIC ACID AT 100 µg/srv OR 400 µg/srv: LOW AND HIGH CONSUMERS¹

Options ¹	Target population						Non-target population									
	F 11 to 18 y		F 19 to 50 y		MF 1 to 3 y		MF 4 to 10 y		M 11 to 18 y		M 19 to 50 y		M 51+ y		F 51+ y	
	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High	Low	High
1. Current intakes: foods only	140	420	110	370	120	350	160	430	200	560	160	510	170	480	140	400
If cereals=100 µg/srv	130	390	110	360	120	340	160	410	200	500	160	460	170	420	140	370
If cereals=400 µg/srv	140	880	120	640	170	690	230	830	210	1,090	160	810	180	750	150	620
2. Current intakes: foods + supplements(400 µg/unit)	150	700	150	700	150	470	190	720	220	810	190	760	200	750	170	710
If cereals=100 µg/srv	150	670	150	690	150	460	190	690	220	760	190	730	200	720	170	700
If cereals=400 µg/srv	170	1,040	160	910	250	770	350	1,040	270	1,340	190	970	230	1,000	190	850
3. Grains ² +0.070 mg/100 g	180	490	160	420	140	390	190	490	260	600	210	560	220	540	180	450
If cereals=100 µg/srv	170	440	150	400	140	360	200	470	260	570	210	520	220	490	170	420
If cereals=400 µg/srv	190	930	160	690	200	710	270	860	280	1,150	220	850	230	800	190	660
4. Grains + 0.140 mg/100 g	220	550	190	470	160	420	230	510	310	670	260	640	260	600	210	510
If cereals=100 µg/srv	220	530	190	460	160	390	230	510	310	650	260	610	260	540	210	470
If cereals=400 µg/srv	240	970	200	730	230	790	310	900	340	1,210	270	930	290	840	220	690
5. Grains + 0.350 mg/100 g	350	770	290	680	220	520	330	730	460	980	400	920	370	810	290	690
If cereals=100 µg/srv	340	760	290	660	220	500	330	690	450	950	400	890	360	790	290	630
If cereals=400 µg/srv	380	1,220	300	890	280	870	430	1,060	520	1,390	420	1,190	410	1,040	320	840
6. Grains + 0.070 mg/100 g + supplements (400 µg)	190	730	190	750	190	500	240	780	270	900	240	830	260	790	210	770
If cereals=100 µg/srv	190	720	190	740	190	480	240	740	270	840	240	790	250	780	210	750
If cereals=400 µg/srv	230	1,090	210	950	270	790	390	1,080	320	1,390	240	1,030	280	1,040	230	900
7. Grains + 0.140 mg/100 g + supplements (400 µg)	240	770	240	790	220	540	270	830	330	950	300	880	300	840	250	800
If cereals=100 µg/srv	250	760	230	780	220	520	280	800	330	910	300	850	300	830	250	790
If cereals=400 µg/srv	270	1,140	250	980	300	810	440	1,120	380	1,440	310	1,090	330	1,060	270	950
8. Grains + 0.350 mg/100 g + supplements (400 µg)	370	970	360	970	300	670	390	1,030	490	1,180	460	1,100	420	1,050	350	980
If cereals=100 µg/srv	370	950	350	950	300	660	390	1,010	490	1,140	460	1,060	420	1,040	340	950
If cereals=400 µg/srv	430	1,300	380	1,130	380	890	550	1,280	570	1,640	480	1,290	470	1,230	390	1,090

¹ Values in the top lines of rows 1 through 8 above are the same as those shown in Table 4 and are estimates of intakes based on current consumption patterns and current marketing practices (lines 1. and 2) and estimates of intakes based on current consumption patterns and current marketing practices with cereal-grain products fortified as described above (lines 3 through 8). Examination of additional options included calculation of intakes if all breakfast cereals were fortified at 100 µg or 400 µg folic acid per serving. All such estimates were based on current consumption patterns.

² Fortification of cereal-grain products: Fortification levels of 70, 140, and 350 mg folic acid/100 g were applied to dry cereal-grain products as described in Table 4.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES**Food and Drug Administration****21 CFR Part 101**

[Docket No. 93N-0289]

RIN 0905-AD96

Food Labeling; Health Claims for Dietary Supplements**AGENCY:** Food and Drug Administration, HHS.**ACTION:** Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing not to authorize health claims relating to an association between fiber and cancer, fiber and heart disease, antioxidant vitamins and cancer, *omega*-3 fatty acids and coronary heart disease, and zinc and immune function in the elderly on the label or in the labeling of dietary supplements of vitamins, minerals, herbs, or other similar nutritional substances. The agency has tentatively determined that there is not significant scientific agreement among experts that claims on these nutrient-disease relationships are supported by the totality of publicly available scientific evidence. Thus, the agency is proposing to amend its regulations to make it explicit that health claims on these nutrient-disease relationships are not authorized for foods in conventional food form or for dietary supplements. Elsewhere in this issue of the *Federal Register* FDA is proposing to authorize a health claim with respect to the relationship of folic acid and neural tube defects on the labels and in the labeling of dietary supplements and of foods in conventional food form.

DATES: Written comments by December 13, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12340 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Judith W. Riggins, Office of Policy (HF-23), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-2831.

SUPPLEMENTARY INFORMATION:

I. Background**A. Passage of 1990 Amendments**

On November 8, 1990, the President signed into law the Nutrition Labeling

and Education Act of 1990 (the 1990 amendments) (Pub. L. 101-535), which amended the Federal Food, Drug, and Cosmetic Act (the act). The 1990 amendments, in part, authorized the Secretary of Health and Human Services (the Secretary), and FDA by delegation, to issue regulations authorizing health claims on the label or labeling of foods. Under these new health claim provisions, a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition, unless the claim is made in accordance with the procedures and standards established under sections 403(r)(3) and (r)(5)(D) of the act (21 U.S.C. 343(r)(3) and (r)(5)(D)).

The 1990 amendments also required (section 3(b)(1)(A)(ii), (b)(1)(A)(vi), and (b)(1)(A)(x)) that the Secretary issue proposed regulations to implement section 403(r) of the act. These provisions also required the Secretary to determine through rulemaking, among other things, whether claims regarding 10 nutrient-disease relationships met the requirements of the act. FDA was asked to evaluate the scientific evidence for the relationships: (1) Dietary fiber and cancer; (2) dietary fiber and cardiovascular disease (CVD); (3) folic acid and neural tube defects; (4) antioxidant vitamins and cancer; (5) zinc and immune function in the elderly; (6) *omega*-3 fatty acids and coronary heart disease (CHD); (7) calcium and osteoporosis; (8) dietary lipids and CVD; (9) dietary lipids and cancer; and (10) sodium and hypertension.

B. The 1991 Health Claims Proposals

In the *Federal Register* of November 27, 1991 (56 FR 60537), FDA proposed general requirements regarding the use of health claims on the labels of both conventional foods and dietary supplements and regarding the content of petitions requesting the use of health claims related to specific substances in food. FDA also published proposals on health claims on the 10 nutrient/disease topics listed above.

Based on its review of the available scientific information, FDA tentatively found that four relationships were supported, and it proposed to allow health claims on food labels for calcium and osteoporosis, sodium and hypertension, fat and cardiovascular disease, and fat and cancer. FDA conditionally concluded that two other claims—fiber and heart disease and fiber and cancer—required additional information. Additionally, because sufficient scientific information was lacking, FDA proposed not to permit

claims for four nutrient disease relationships: folic acid and neural tube defects; antioxidant vitamins and cancer; zinc and immune function in the elderly; and *omega*-3 fatty acids and heart disease.

C. The Dietary Supplement Act of 1992

In October 1992, the Dietary Supplement Act (the DS Act) (Pub. L. 102-571) was enacted. This statute imposed a moratorium on FDA's implementation of the 1990 amendments with respect to dietary supplements until December 15, 1993. The DS Act required FDA to issue proposed rules to implement the 1990 amendments with respect to such dietary supplements by June 15, 1993, and to publish the final rules based on these proposals by December 31, 1993. An exception to this moratorium was a provision that permitted FDA to authorize health claims for dietary supplements with respect to those nutrient-disease relationships for which the agency authorized claims on foods in conventional food form. The DS Act also amended the 1990 amendments to state that if the agency did not meet the established timeframe for issuance of final rules with respect to health claims on dietary supplements, the proposed regulations would be considered final regulations.

D. The 1993 Final Rules for Health Claims for Foods in Conventional Food Form

On January 8, 1993, FDA published final rules on the general requirements for health claims on the labels and in the labeling of foods in conventional food form (58 FR 2478) and final rules authorizing health claims on seven nutrient/disease relationships (calcium and osteoporosis; fat and cancer; saturated fat and cholesterol and CHD; fiber-containing grain products, fruits, and vegetables and cancer; fruits, vegetables and grain products that contain fiber and risk of CHD; sodium and hypertension; and fruits and vegetables and cancer).

It should be noted that of the seven health claims that FDA authorized, three were for fresh fruits and vegetables and grains, and thus these claims are not authorized on dietary supplements. FDA will be considering the nutrient-disease relationships that led the agency to authorize these claims, fiber and cancer, fiber and CHD, and antioxidant vitamins and cancer, as well as two others, *omega*-3 fatty acids and CHD and zinc and immune function in the elderly, for dietary supplements in this document. FDA will consider the evidence on folic acid and neural tube

defects in a document published elsewhere in this issue of the Federal Register.

E. The 1993 Proposed Rules for Health Claims on Dietary Supplements

In response to the 1990 amendments and the DS Act, FDA proposed in the Federal Register of June 18, 1993 (58 FR 33700), to revise its food labeling regulations to make dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances subject to a standard and procedure for the use of health claims that characterize the relationship of a substance to a disease or health-related condition on the label or in labeling that are the same as those that Congress established for foods in conventional food form.

The agency did not address the specific nutrient-disease relationships for nutrients in dietary supplements that it is required to consider under sections 3(b)(1)(A)(vi) and (b)(1)(A)(v) of the 1990 amendments and under the DS Act. It stated that it would address these relationships in the near future. It is doing so in this document and the companion document on folic acid and neural tube defects that is published elsewhere in this issue of the Federal Register.

F. Provisions of the Proposed Rule—Regulation Amended

Section 101.71(a) (21 CFR 101.71(a)) of the January 6, 1993, final rule specified that the agency had not authorized health claims on the label or in the labeling of foods in conventional food form for six nutrient-disease relationships: Fiber and cancer; fiber and heart disease; antioxidant vitamins and cancer; omega-3 fatty acids and CHD; folic acid and neural tube defects; and zinc and immune function in the elderly.

In this document, FDA is proposing to amend § 101.71(a) to state that health claims regarding five of these nutrient-disease relationships are not authorized for foods in conventional food form or for dietary supplements of vitamins, minerals, herbs, or other similar substances. Elsewhere in this issue of the Federal Register FDA is proposing to remove the sixth, folic acid and neural tube defects, from the list.

II. Dietary Fiber and Cancer

A. The 1991 Proposed Findings

In the Federal Register of November 27, 1991 (56 FR 60566), FDA published a proposal on the use of a health claim regarding the relationship of dietary fiber and cancer. After reviewing the available scientific evidence, it

tentatively found that there was not a sufficient basis to authorize the use of health claims regarding the relationship of dietary fiber and a reduction in the risk of cancer on the labels or in the labeling of foods, including dietary supplements. The agency tentatively found that while data supported an association between consumption of fiber-rich plant foods and a reduced risk of cancer, they did not establish a basis on which to find that this effect was attributable to the fiber itself.

FDA limited its review of the scientific evidence relating ingestion of dietary fiber and cancer to the topic of dietary fiber and the risk of colorectal cancer. FDA deemed this limitation appropriate because the great majority of epidemiologic and intervention studies have focused on colon cancer, as have virtually all animal studies on this topic. The strongest support and largest volume of evidence for a possible protective effect of fiber-rich diets is for colon and rectal cancers (colorectal cancer), the second leading causes of cancer deaths in the United States. FDA found that relationships between dietary fiber and the risk of cancer at other sites (for example, breast, stomach, endometrium, and ovaries) had been less extensively examined but were the focus of considerable research effort (56 FR 60566 at 60576).

In deciding whether to authorize a claim relating dietary fiber to cancer, FDA considered all available evidence on this topic, including extensive review of consensus documents like "The Surgeon General's Report on Nutrition and Health," the National Academy of Sciences' "Diet and Health, Implications for Reducing Chronic Disease Risk," and other relevant reports and other reviews by recognized scientific bodies (56 FR 60566 at 60569 and 60570) and reports in the scientific literature.

FDA cited several key factors (56 FR 60566 at 60576 and 60577) that formed a basis for its tentative conclusion that the use of a health claim relating the intake of fiber to a reduced risk of cancer was not sufficiently supported by scientific evidence. These factors included: (1) The fact that the prospective epidemiologic studies that exist are few in number and have had mixed results; (2) insufficient data exist to demonstrate that it is the total dietary fiber, or a specific fiber component, that is related to any reduction of cancer risk; (3) the need for better defined measures of dietary fiber and for standardized descriptions of the source, type, and amount of dietary fiber; and (4) a lack of composition data on the fiber content of foods that precluded

estimates of dietary intakes of total dietary fiber or fiber components in most human studies (56 FR 60566 at 60577 and 60578).

B. The January 1993 Final Rule

In the Federal Register of January 6, 1993 (58 FR 2537), FDA published a final rule that announced its decision to authorize a health claim regarding the relationship of diets low in fat and high in fiber-containing grain products, fruits, and vegetables to a reduced risk of cancer. The agency reviewed numerous authoritative documents, as well as more recent research on dietary fiber and cancer risk (58 FR 2537 at 2542 and 3543). In addition, the agency reviewed the comments that it had received on the November 1991 proposal (58 FR 2537 at 2540 and 2541). The agency concluded that the publicly available scientific evidence supports an association between diets low in fat and high in fiber-containing grain products, fruits, and vegetables and reduced risk of cancer (58 FR 2537 at 2544). FDA explained the basis for this conclusion, listed the elements that had to be addressed in any health claim, listed the circumstances in which a food would be eligible to bear a claim, provided for additional optional information that could be included as part of the claim, and set out two model health claims that could be used on labeling (58 FR 2537 at 2544 to 2545).

The agency went on to state, however, that based on the totality of the publicly available scientific evidence, including recently available evidence, there was not significant scientific agreement among qualified experts that a claim relating dietary fiber, per se, to a reduced risk of cancer was scientifically valid. FDA reviewed the new scientific evidence, including studies that focused on prior cholecystectomy as a risk factor for right-sided colon cancer (58 FR 2537 at 2542); colonic adenoma incidence based on sigmoidoscopy biopsy reports (58 FR 2537 at 2543); dietary factors in a case-control study of colonic polyp patients (58 FR 2537 at 2543); rectal cell proliferation, fecal bile acid concentration, and fecal pH (58 FR 2537 at 2543); fecal short-chain fatty acid composition in controls and patients with resected adenomatous polyps and resected colonic cancer (58 FR 2537 at 2543); and the effect of fat and cellulose fiber on the growth and biochemical characteristics of two human colon cancer cell lines implanted subcutaneously in mice (58 FR 2537 at 2543). These new studies provided data on the possible link between consumption of dietary fiber and reduced risk of colon cancer. However,

with the exception of one study that had limited applicability (see 58 FR 2537 at 2543), none of the studies provided evidence of an independent contribution of fiber itself (distinct from its presence in food) to risk reduction. Rather, the studies showed a relationship between diets rich in fiber-containing foods and a reduced risk of cancer (58 FR 2537 at 2543). In addition, preliminary results of a study on the effects of amount and type of dietary fiber on colonic bacterial enzymes and bile acids in humans supported FDA's observation that insoluble fiber has not been shown to be protective (58 FR 2537 at 2543).

In addition to these factors, the agency's decision was based on the absence of a well-defined measure of dietary fiber and of standardized descriptions of source, type, and amount of dietary fiber. The agency identified factors, including the inability of commonly used methodologies to detect variable characteristics of fiber (e.g., particle size and chemical composition), the inability to identify the characteristics among fibers that are predictive of physiological effects, and the general lack of clear evidence on the mechanisms of action of fibers, that made it difficult to establish the role of fiber in the health effects of diets that are low in fat and high in fiber-rich foods (58 FR 2537 at 2544).

The full discussion from the proposed and final rules, including the studies cited in those documents is referenced herein.

C. Summary of Comments

In issuing the final rules in January of 1993, the agency recognized that an undertaking of the magnitude of the agency's rulemaking under the 1990 amendments was bound to include certain unintended technical problems. Therefore, the agency invited comments on technical matters and addressed them in technical amendment final rules in the Federal Register of June 18, 1993 (58 FR 33700).

Two comments requested clarification of the term "without fortification" as used in the final rules. One of these comments also requested clarification that the use of fiber-containing ingredients in bakery products that already contain fiber does not constitute fortification. Another comment stated that in the agency's discussion of dietary fiber in its final rule on mandatory nutrition labeling, it equated "fortification" with "supplementation," a definition that connotes an addition to a fiber source so that the resulting level of fiber in that source exceeds the

indigenous level (58 FR 2079 at 2096, January 6, 1993). Therefore, the comment asked FDA to clarify that the combination of multiple grains in a food, each of which contains an indigenous level of fiber, is not fortification as the agency used the term in its final rule.

The questions raised in these comments specifically request clarification of the agency's criteria regarding the definition of "fortification." These comments are not relevant to the issue of whether the agency may authorize a health claim on the relationship of dietary fiber to cancer. Therefore, the agency will address these comments in a separate Federal Register document.

The agency did not receive any comments that provided any information that would support a health claim on the labels or in the labeling of dietary supplements regarding the relationship of dietary fiber and reduced risk of cancer in response to the January 6, 1993, final rule. Thus, the agency is not aware of any basis to find that a different conclusion than it reached in January 1993 is appropriate on whether to authorize a claim on fiber, specifically the fiber in dietary supplements, and the risk of cancer.

D. The Proposal

Based on the totality of the publicly available scientific evidence, FDA has tentatively concluded that there is not significant scientific agreement among qualified experts that a health claim on the labels or in the labeling of dietary supplements regarding the relationship of dietary fiber and reduced risk of cancer is scientifically valid. Numerous human and animal studies have examined the possible role of dietary fiber intake in reducing the risk of developing cancer. Most correlational and many (but not all) case-control studies show that diets high in fiber-containing foods (whole grains, fruits, and vegetables) are associated with reduced risk of colorectal cancer. These diets differ, however, in levels of many nutrients and types of dietary fiber, making it difficult to ascribe the observed nutrient and disease relationship to a single nutrient. Overall, the available data are not sufficiently conclusive or specific for fiber to justify authorization of a health claim relating the intake of dietary fiber to a reduced risk of cancer on the labels or in the labeling of dietary supplements.

Because a supplement would contain only fiber, and there is no evidence that any specific fiber itself caused the effects that were seen in studies

involving fiber-rich fruits, vegetables, and grain products, FDA tentatively finds that an appropriate basis for proposing to authorize a claim on dietary fiber and cancer on dietary supplements does not exist (56 FR 60566 and 58 FR 2537).

III. Dietary Fiber and Cardiovascular Disease

A. The 1991 Proposed Findings

In the Federal Register of November 27, 1991 (56 FR 60582), FDA published a proposal on the use of a health claim regarding the relationship of dietary fiber and cardiovascular disease. After reviewing the available evidence, it tentatively concluded that there was no basis to authorize such health claims on the labels or in labeling of foods, including dietary supplements. The agency tentatively found that while an association appeared to exist between the consumption of fiber-rich foods and a reduced risk of cardiovascular disease, the data did not provide a basis on which it could not attribute this effect to the fiber itself (56 FR 60582).

FDA limited its review of the scientific evidence related to ingestion of dietary fiber and cardiovascular disease to the topic of soluble dietary fiber and risk of developing CHD. Previous Federal government and other reviews by recognized scientific bodies and the majority of research efforts had focused on this topic. Therefore, FDA tentatively concluded that this limitation was appropriate (56 FR 60582 at 60592).

In deciding whether to authorize a claim relating dietary fiber to cardiovascular disease, FDA considered all available information on this topic, including the incidence of cardiovascular disease in the United States, current chemical information on dietary fiber and analytical methodology used to determine the biological and health consequences of dietary fiber intake, and all available information on the risk factors that contribute to CHD (56 FR 60582 at 60583). FDA also considered recent Federal government comprehensive reports, reviews, and dietary guidelines on this topic (56 FR 60582 at 60584). The agency's tentative conclusion that the totality of the evidence did not provide a sufficient basis to authorize a health claim on dietary soluble fiber and reduction in risk of developing CHD was based on its tentative finding that while many human studies showed a relationship between diets high in plant foods (e.g., fruits, vegetables, and grains) and a reduced risk of developing CHD, these diets differed in the levels of many

nutrients and in types of dietary soluble fiber, making it difficult to ascribe the observed effects to a single nutrient (56 FR 60582 at 60592).

FDA reviewed over 30 human studies published in the United States over the last several years. Under the study conditions, many investigators observed a decline in blood cholesterol levels with increasing intakes of soluble fiber. Most studies, however, were of very short duration and, therefore, could not establish long-term benefits from high soluble fiber diets. Questions of long-term effects were raised by the observation of an initial decline in blood cholesterol levels followed by a return upwards towards baseline in some of the longer studies, even when the investigators reported excellent compliance for consumption of test substances (56 FR 60582 at 60591).

Based on the studies it reviewed, FDA tentatively concluded that serum cholesterol responses were affected by a number of factors, including initial serum cholesterol level, base diet, self-initiated changes to base diet (particularly changes in intake of saturated fat and polyunsaturated fat) during the test period, body weight, exercise, medications, general health, and other lifestyle variables. These confounding factors, which were generally not well controlled within the individual studies and which made cross-study comparisons difficult, made it impossible to draw conclusions about the relationship of fiber intake to serum cholesterol levels (56 FR 60582 at 60593).

FDA cited certain additional factors that contributed to its tentative conclusion that the available data did not demonstrate that soluble dietary fiber, or a specific measurable and quantifiable subcomponent of dietary fiber, is related to lower blood cholesterol levels (56 FR 60582 at 60592). These factors included: (1) The need for better defined measures of dietary fiber and for standardized descriptions for source, type, and amount of dietary fiber; and (2) a lack of composition data on the fiber content of foods that precluded estimates of dietary intakes of total dietary fiber or fiber components in most human studies (56 FR 60582 at 60593 through 60595).

B. The January 1993 Final Rule

In the *Federal Register* of January 6, 1993 (58 FR at 2552), FDA published a final rule announcing its decision to authorize a health claim regarding the relationship of diets low in saturated fat and cholesterol and high in fruits, vegetables, and grain products that

contain dietary fiber (particularly soluble fiber) and a reduced risk of CHD. The agency reviewed numerous authoritative documents, as well as recent research on dietary fiber and CHD risk (58 FR 2552 at 2552 through 2562). In addition, the agency reviewed the comments that it received (58 FR 2552 at 2562 through 2572).

FDA concluded that the publicly available scientific evidence supports an association between diets low in saturated fat and cholesterol and high in fruit, vegetables, and whole grains that contain soluble fiber to a reduced risk of CHD (58 FR 2552 at 2572). The agency explained the basis for its conclusion and set out the elements that had to be addressed in any health claim (58 FR 2552 at 2572 through 2574).

In the same document (58 FR 2552), FDA announced its decision to not authorize the use of health claims regarding the relationship of dietary fiber and a reduced risk of CHD on the label and labeling of foods. FDA found that the available scientific evidence was not sufficiently conclusive or specific for soluble fiber to justify use of a health claim for this relationship (58 FR 2552 at 2572).

FDA reviewed new scientific evidence including studies on mildly to moderately hypercholesterolemic individuals and normocholesterolemic individuals using multiple sources of soluble fiber, including oat bran and other cereal brans, legumes, pectin, psyllium, and guar gum (58 FR 2552 at 2553 through 2558). The agency noted that the studies had significant design flaws, including very small sample sizes; inadequate control of confounding factors, such as concomitant weight losses and changes in other dietary components, that may have affected some studies; and the absence of adequate data to ensure that dietary changes other than differences in soluble fiber intakes had not occurred. The agency determined that, given inconsistencies in results among similar studies using apparently similar fibers, the physiological effects of particular fibers were not consistently predictable by an analytical definition of dietary fiber but rather varied, in some unknown way, among different sources or combinations of sources of dietary fiber. Therefore, the agency concluded that generalizing results from one type of fiber source to another in determining whether the relationship between soluble fiber and heart disease is supported by the evidence requires caution (58 FR 2552 at 2559).

The agency also reviewed new animal studies on the relationship between specific soluble fibers and plasma

cholesterol and the relationship between *beta*-glucan and plasma cholesterol (58 FR 2552 at 2559 through 2562). The agency determined that these studies provided evidence to support the likely effectiveness of soluble fibers relative to the cholesterol-lowering characteristics of diets high in some cereals. However, the animal studies, like the human studies, failed to provide adequate specifications to characterize the test fiber sources and did not provide characteristics or commercial sources of the soluble fibers used as test substances (58 FR 2552 at 2562).

Therefore, the agency concluded that, overall, the available data were not sufficient to demonstrate that it is total soluble dietary fiber, or a specific measurable and quantifiable subcomponent of that fiber, that is related to lower blood cholesterol levels (58 FR 2552 at 2562). The full discussion from the proposed and final rules, including the studies cited in those documents, is referenced herein.

C. Summary of Comments

In issuing the final rules in January of 1993, the agency recognized that an undertaking of the magnitude of the agency's rulemaking under the 1990 amendments was bound to include certain unintended technical problems. Therefore, the agency invited comments on technical matters and addressed them in technical amendment final rules in the *Federal Register* of June 18, 1993 (58 FR 33700).

The only comments that FDA received about fiber were those that it described in its discussion of fiber and cancer. The agency did not receive any comments that provided information that would support a health claim on the labels or in the labeling of dietary supplements regarding the relationship of dietary fiber and reduced risk of cardiovascular disease, including CHD, in response to the January 6, 1993, final rule. Thus, the agency is not aware of any basis to find that a different conclusion than it reached in January 1993 is appropriate on whether to authorize a claim on dietary supplements on this nutrient-disease relationship.

D. The Proposal

Based on the totality of publicly available scientific evidence, FDA has tentatively concluded that there is not significant scientific agreement among qualified experts that a health claim regarding the relationship of dietary fiber and reduced risk of cardiovascular disease on the labels or in the labeling of dietary supplements is valid

A major limitation in designing and evaluating research studies has been the need for better defined measures of dietary soluble fiber and standardized descriptions of source, type, and amount of dietary soluble fiber. Commonly used analytical methodologies do not detect many of the characteristics that may vary among fibers and that may be related to biological function. Other components associated with soluble fibers in foods may also have some ability to affect blood cholesterol levels. The inability to detect many of the differences among fibers, fiber components, and other substances in foods that contain soluble fiber, and the general lack of conclusions regarding the mechanisms of action of soluble fibers, raise questions about the ability of commonly used analytical methods to adequately predict biological actions of specific fibers. The currently available scientific evidence is not sufficiently conclusive or specific for soluble fiber to justify use of a health claim relating the intake of dietary fiber to a reduced risk of cardiovascular disease, including CHD.

Because a dietary supplement would contain only fiber, and there is no evidence that the fiber itself caused the effects that have been seen in studies of diets low in saturated fat and cholesterol and high in fruits, vegetables, and whole grains, FDA tentatively finds that an appropriate basis for proposing to authorize a claim on dietary fiber and cardiovascular disease on dietary supplements does not exist (56 FR 60582 and 58 FR 2552).

IV. Antioxidant Vitamins and Cancer

A. The 1991 Proposed Findings

In the Federal Register of November 27, 1991 (56 FR 60624), FDA published a proposal on the use of a health claim regarding the relationship of antioxidant vitamins and cancer. In deciding whether to authorize a claim, FDA examined all available information on this topic (56 FR 60624 at 60625 and 60626), including the mechanisms of carcinogenesis and its relationship to antioxidants, the interactions among antioxidants, and the associations between *beta*-carotene and risk of cancer (56 FR 60624 at 60627). The agency also considered the regulatory history of antioxidant vitamins and all comments that it had received in response to a request for scientific data and information (56 FR 60624 at 60628 and 60629).

The agency tentatively found that there was no basis to authorize such claims regarding the relationship of antioxidant vitamins and cancer on the

labels and in the labeling of foods. The agency found that strong epidemiologic evidence existed that showed that consumption of fruits and vegetables, which tended to contain higher amounts of vitamin C, were associated with reduced risk of cancers in some sites, notably the stomach and gastrointestinal tract. However, the agency also tentatively found that it was not possible to determine from the available data whether the reduced risks of cancer at specific sites were caused by the vitamin C content of the foods, by other components that were present in those foods, or by general dietary patterns that included those foods (56 FR 60624 at 60636). The agency further recognized that consumption of food sources of vitamin E was frequently, but not consistently, associated with lowered risk of cancer at a number of sites. However, the agency tentatively concluded that the data did not demonstrate that vitamin E itself was responsible for this association, and that the data did not permit identification of the other factors that might produce or prevent the effect. In addition, the agency tentatively found that the data were insufficient to determine the amount of vitamin E needed to produce the effect (56 FR 60624 at 60638).

B. The January 1993 Final Rule

In the Federal Register of January 6, 1993 (58 FR 2622), FDA published a final rule that announced its decision to authorize a health claim regarding the relationship of diets low in fat and high in fruits and vegetables (foods that are low in fat and may contain dietary fiber, vitamin A, and vitamin C) to a reduced risk of cancer. The agency reviewed numerous authoritative documents as well as new studies on the association of intake of *beta*-carotene, vitamin C, and vitamin E and the risk of cancer (58 FR 2622 at 2623 through 2627 and 2636 through 2639). The agency also reviewed the comments on this relationship that it had received (58 FR 2622 at 2627 through 2633). The agency concluded that the publicly available scientific evidence supported an association between diets high in fruits and vegetables that are good sources of two of the antioxidant vitamins (vitamin A as *beta*-carotene and vitamin C) and a reduced risk of cancer (58 FR 2622 at 2633). FDA described the information concerning *beta*-carotene, vitamin C, and fruits and vegetables that served as a basis for its decision (58 FR 2622 at 2633 and 2634) and explained the basis for the requirements that it was establishing for the health claim (58 FR 2622 at 2635 and 2636).

FDA went on to announce (58 FR 2622) its decision not to authorize the use of a health claim regarding the relationship of antioxidant vitamins and cancer on the label or labeling of foods. Based on the totality of the publicly available scientific evidence, including the recently available evidence, the agency concluded that there was not significant scientific agreement among qualified experts as to whether the observed protective effects of fruit and vegetable consumption on cancer risk were the result of a single or combined effect of the antioxidant vitamins and other nutrients with antioxidant functions (i.e., selenium), of unmeasured components of such foods such as nonnutritive components, or of displacement of other known risk components (such as fats and calories) within the total diet (58 FR 2622 at 2634). Therefore, the agency concluded that a claim relating antioxidant vitamins to reduced risk of cancer was not supported by available scientific evidence.

1. Vitamin E

FDA concluded that the available scientific data did not support that there is a relationship between vitamin E and a reduced risk of cancer. Most of the studies on the possible protective effect to vitamin E related plasma or serum levels of vitamin E (rather than food consumption) to cancer risk. FDA recognized that some evidence showed an association of low plasma serum levels of vitamin E and an increased cancer risk. The agency found, however, that the available evidence was not adequate to determine whether this association was the result of an effect specific to vitamin E or the result of other unmeasured factors that are associated with those dietary patterns that would produce such plasma serum levels (58 FR 2622 at 2633). FDA recognized that the animal data and biochemical data provided a basis on which to hypothesize a protective effect of vitamin E (*alpha*-tocopherol) in humans but found that the data from epidemiological studies, although providing some suggestion of an effect, were not sufficient to conclude that such effects were of importance in humans. Therefore, the agency concluded that, although vitamin E has been shown to have an antioxidant effect in humans, the data were not sufficient to associate such effects with protection against cancer (58 FR 2622 at 2633).

2. Beta-carotene

Based on the totality of the scientific evidence and comments that it received

relative to the available evidence, FDA concluded that the data did not support the relationship of *beta*-carotene (provitamin A) to a reduced cancer risk. Although the available scientific human data showed an association of consumption of fruits and vegetables and calculated *beta*-carotene intakes from these foods with reduced risk for some types of cancer, the agency concluded that the available scientific evidence was not sufficient to conclude that the *beta*-carotene, as opposed to some other component of these foods, was responsible for the protective effect (58 FR 2622 at 2633).

Consistent with earlier studies reviewed in the proposed rule (56 FR 60624 at 60634), the more recent studies supported findings that there was an inverse relationship between consumption of fruits and vegetables and the risk of cancer. This relationship was strongest for lung cancer. Intakes of the green and yellow vegetables had also been shown to be inversely associated with cervical cancer, but the evidence was not as consistent as with lung cancer. These studies were based on calculated intakes of nutrients from these foods. However, the agency said that it was not possible to determine from these studies what substance or substances in these foods were responsible for the results. FDA found that *beta*-carotene may have been responsible for the effect, but that its presence in these foods may simply have served as a marker for some other unmeasured substances that were responsible for the protective effect of fruits and vegetables (58 FR 2622 at 2626).

3. Vitamin C

The data reviewed by FDA in the final rule were compatible with the tentative conclusion in the proposed rule that consumption of fruits and vegetables rich in vitamin C might protect against some types of cancer (58 FR 2622 at 2626). These data also provided additional indications of a mechanism to explain the relationship between vitamin C and reduced risk of stomach cancer. The relatively small number of studies reported after the publication of the proposed rule were in agreement with earlier findings that consumption of fruits and vegetables was protective against cancer at several sites, particularly stomach cancer. The new studies, taken together with previous studies, indicated that consumption of fruits and vegetables is most consistently protective against cancers of the stomach, lung and cervix, and less consistently protective at other sites. These data, however, were not

sufficient to identify vitamin C, as opposed to other substances in these foods, as being responsible for the observed protective effect (58 FR 2622 at 2626).

FDA also recognized that the mechanistic and animal studies suggested that vitamin C may reduce the risk of cancer through the mechanism of inhibition of nitrosamine synthesis. The stomach is the likely site of highest *N*-nitroso compound exposure and is the site for which the data were the most complete. These data provided a mechanistic basis for understanding a possible protective effect of vitamin C for stomach cancer risk. However, FDA concluded that nitrosation had not been accepted by the general scientific community as a validated risk factor for stomach cancer. One of the unsolved questions was whether studies of this mechanism for the Chinese and other populations, which differ from the U.S. population in genetic, dietary, and environmental risk factors, adequately explain the etiology of stomach cancer in the United States (58 FR 2622 at 2627).

The studies showing the relationship of *N*-nitroso compounds (a class of compounds with known carcinogenicity) to stomach cancer provided evidence for a mechanism by which a specific vitamin C effect might occur for this and other cancers (e.g., esophageal and uterine cervical). When considered together, the different types of data were suggestive, but not conclusive, that vitamin C may be responsible for at least part of the reduction in risk of stomach cancer associated with consumption of diets high in fruits and vegetables in U.S. populations. Given differences in rates and likely etiologies of stomach cancer among different cultures and geographic areas, FDA concluded that there was not significant scientific agreement either that this mechanism is an etiologic factor in stomach cancer risk in the United States, or that qualitative changes in production and excretion of nitroso-compounds are a risk factor for stomach cancer (58 FR 2622 at 2634).

In order to allow the issue of intermediate or surrogate markers (such as the formation of nitroso-compounds) for cancer risk to be more fully evaluated, FDA stated that it would convene an advisory committee in the near future to make recommendations that could be applied to evaluations of data for determining the scientific basis for health claims relating antioxidant vitamin intakes to cancer risk (58 FR 2622 at 2634).

FDA summarized its considerations of all comments received (58 FR 2622 at

2630 through 2632) and recent scientific evidence (58 FR 2622 at 2633 and 2634) in its examination of the issues. The full discussion from the proposed and final rules, including the studies cited in those documents, is referenced herein.

C. Summary of Comments

In response to the January 6, 1993, final rule, FDA received comments that raised the following concerns: Two comments requested that the agency raise the threshold (percentage of Recommended Dietary Allowance (RDA)) at which a product could bear a health claim. One of these comments also requested that FDA broaden the scope of products that could bear a claim regarding relationship of antioxidant vitamins and a reduced risk of cancer.

A third comment stated that although advisory committees can be helpful in reaching scientific conclusions, the result can be predetermined depending on the persons selected. It urged the agency to make every attempt to ensure that the membership of the committee on antioxidants is balanced to encompass the spectrum of nutritional thought. Another comment stated that the agency should allow consumers to receive accurate and balanced information where there is a reasonably good chance of benefit and virtually no safety risk. Another comment objected to the agency's position in the final rule that it would not be permissible for a health claim to imply that levels clearly beyond the range attainable in the context of the total daily diet would be effective in reducing the risk of a disease or health-related condition, stating that this was an implied premise that products such as vitamins and minerals are not really foods. Another comment requested that the agency provide examples to clarify the meaning of the section of the final rule that requires that qualifying nutrients be based on natural levels in foods.

None of these comments are relevant to the issue of whether there is an appropriate scientific basis for the agency to authorize a health claim on the relationship of dietary fiber to cardiovascular disease, nor did any of them provide any additional information upon which the agency could rely to authorize a health claim for this relationship. Thus, the agency did not receive any information in these comments that would support a different conclusion on a health claim regarding the relationship of antioxidant vitamins and cancer than the one that it reached regarding a health claim on this nutrient-disease relationship for foods

in conventional food form in the January 6, 1993, final rule.

As for the matters that were raised in the comments, the latter comments relate to the standard and procedure for health claims on dietary supplements. These issues will be dealt with by FDA as part of the rulemaking instituted in June by FDA (58 FR 33700). As for the makeup of FDA advisory committees, the agency is required by the Federal Advisory Committee Act to ensure that its advisory committees are balanced, and it always endeavors to ensure that balance in fact exists. The basis on which the agency chose the level necessary to qualify for the health claim was fully explained in the final rule (see 58 FR 2622 at 2636). The comments provided no information that would cause the agency to conclude that the basis that is set out for the amount of vitamin A or vitamin C that must be present in the food for it to qualify for a health claim was not appropriate. Finally, as explained in this document, FDA has not been provided with evidence that would justify broadening the scope of products that could bear the claim.

D. The Proposal

FDA has tentatively concluded, based on the totality of publicly available scientific evidence, that there is not a sufficient basis to authorize a health claim regarding the relationship of antioxidant vitamins and cancer on the labels or in the labeling of dietary supplements. While populations with diets rich in fruits and vegetables experience many health advantages, including lower rates of some types of cancers, it is not possible to specifically determine that the two antioxidant vitamins (*beta*-carotene and vitamin C) that are contained in fruits and vegetables are responsible for this effect or to rule out the possibility of significant protective effects from nonmeasured components in these foods. Since many food substances (both nutritive and nonnutritive) coexist in fruits and vegetables, an observed correlation between a measured nutrient and a disease risk may be a surrogate for a "true" correlation between a coexistent, but a nonmeasured or an unknown, food substance. Currently, there is not significant scientific agreement as to whether the observed protective effects of fruits and vegetables are the result of a single or combined effect of the antioxidant vitamins and other nutrients with antioxidant functions (e.g., selenium), to other nutritive compounds in such foods, to unmeasured components of such diets, or to displacement of other

known risk components within the total diet.

Because a dietary supplement would contain only the antioxidant vitamins, and there is not significant scientific agreement that the antioxidant vitamins alone caused the effects that were observed in the relevant studies, FDA tentatively finds that an appropriate basis for proposing to authorize a claim on antioxidant vitamins and cancer on dietary supplements does not exist (56 FR 60624 and 58 FR 2622).

V. Zinc and Immune Function in the Elderly

A. The 1991 Proposed Findings

In the Federal Register of November 27, 1991 (56 FR 60652), FDA published a proposal on the use of the health claim regarding the relationship of zinc and immune function in the elderly. Based on its review of the available scientific evidence, the agency tentatively concluded that there was not a sufficient basis to authorize the use of a health claim regarding the relationship of zinc and immune function in the elderly on the label or in the labeling of foods. The agency stated that a specific protective role of zinc supplementation of the elderly population had not been demonstrated.

In deciding whether to authorize a claim regarding this nutrient-disease relationship, FDA reviewed all available scientific evidence on this topic, including public health aspects of zinc and immune function in the elderly, mechanisms and measures of immunity, and immune function in aging (56 FR 60652 at 60653). FDA also conducted an extensive review of consensus documents and of reports in the scientific literature (56 FR 60652 at 60653 and 60654 through 60663). In addition, FDA reviewed comments that it received on this nutrient-disease relationship (56 FR 60652 at 60654).

FDA tentatively found that the scientific evidence showed that proper dietary zinc levels are essential for adequate function of the immune system, and that dietary zinc intake, serum zinc, and cell-mediated immunity all decline with advancing age. However, the agency tentatively concluded that the available data did not provide a basis on which to find that increased zinc intake can reverse the age-related decline in immunocompetence in the general healthy elderly population in the United States. In fact, the agency noted that some evidence suggested that it may suppress immune function (56 FR 60652 at 60661).

The data evaluated by FDA included seven human studies in which elderly subjects were supplemented with zinc to determine its influence on immune system function. The results of four of the earliest published studies suggested a zinc-associated enhancement of several measures of immune function. However, FDA noted that the reliability of three of these studies was limited by the fact that they included very few individuals, and by the fact that the tested subjects were not representative of the general elderly population. Moreover, FDA noted that the results of these initial reports have not been substantiated by more recent, larger studies of more rigorous experimental design (56 FR 60652 at 60661).

B. The January 1993 Final Rule

In the Federal Register of January 6, 1993 (58 FR 2661), FDA published a final rule that announced its decision not to authorize the use of a health claim regarding the relationship of ingestion of zinc and immune function in the elderly on the labels or in the labeling of foods in conventional food form. The agency concluded that, based on the totality of the publicly available scientific evidence, there was not significant scientific agreement that increased intake of zinc enhanced immune function in the elderly.

The agency stated that zinc is considered to be relatively nontoxic, particularly if taken orally, but that adverse effects, which include impaired immune function, are known to occur with zinc intake in excess of the RDA. The agency's examination of the scientific evidence found that although it is well accepted that adequate dietary zinc is essential for normal immune function, a specific protective role of zinc supplementation of the elderly population has not been demonstrated.

Thus, FDA concluded that the publicly available data on the role of zinc in immune system function do not provide a sufficient scientific basis on which to conclude that immune function in the elderly U.S. population can be improved by zinc supplementation. On this basis, FDA decided not to authorize the use of a health claim on this nutrient-disease relationship on the label or in labeling of foods in conventional food form.

The agency summarized its consideration of the comments received (58 FR 2661 at 2662) and publicly available scientific evidence (58 FR 2662 at 2663 and 2664) in reaching its conclusion. The full discussion from the proposed and final rules, including the studies cited in those documents, is referenced herein.

C. Summary of Comments

The agency did not receive any comments regarding the relationship of ingestion of zinc and immune function in the elderly in response to the January 6, 1993, final rule.

D. The Proposal

FDA has tentatively concluded, based on the totality of publicly available evidence, that there is not significant scientific agreement that zinc supplementation will improve immune function in the elderly. Although it is well accepted that adequate dietary zinc is essential for normal immune function, a specific protective role of zinc supplementation of the elderly population has not been demonstrated. In fact, as discussed above, there is some evidence in recent well-controlled studies that high levels of zinc intake will suppress the immune function. FDA has not been presented with any evidence in the wake of its January 6, 1993, final rule on zinc and immune function in the elderly that would lead the agency to a different conclusion. Therefore, FDA is proposing to not authorize a health claim on the relationship of zinc and immune function in the elderly in the labeling of dietary supplements.

Because a dietary supplement would contain only zinc, and there is no evidence that the zinc supplementation itself plays a specific protective role in the elderly population, FDA tentatively finds that an appropriate basis for proposing to authorize a claim on zinc and immune function in the elderly on dietary supplements does not exist (56 FR 60652 and 58 FR 2661).

VI. Omega-3 Fatty Acids and Coronary Heart Disease

A. 1991 Proposed Findings

In the *Federal Register* of November 27, 1991 (56 FR 60663), FDA published a proposal on the use of a health claim regarding the relationship of *omega*-3 fatty acids and CHD. After reviewing the publicly available scientific evidence, the agency tentatively found that the evidence did not provide a basis to authorize a health claim on the label or in the labeling of foods. Examination of the epidemiological research on this topic revealed that the available studies applied only to the consumption of fish, which contain *omega*-3 fatty acids, and that it was not possible to ascribe any effects specifically to *omega*-3 fatty acids.

In deciding whether to authorize a health claim relating *omega*-3 fatty acids and CHD, FDA considered publicly available scientific evidence on the

public health significance of CHD, information on the properties of *omega*-3 fatty acids (56 FR 60663 at 60664), and comments that it had received on this topic (56 FR 60663 at 60665 and 60666). FDA reviewed consensus documents like the "Surgeon General's Report on Nutrition and Health," the National Academy of Science's "Diet and Health: Implications for Reducing Chronic Disease Risk" (56 FR 60663 at 60666), and other reports in the scientific literature, including epidemiological studies, animal studies, and other relevant information (56 FR 60663 at 60667 through 60671 and 60673 through 60676).

FDA tentatively determined that the publicly available evidence was not adequate to show that increased consumption of *omega*-3 fatty acids reduced the risk of CHD, particularly noting its lack of effect on serum cholesterol levels. FDA found that an increase in bleeding times and a decrease in platelet aggregation (which also may be associated with bleeding tendencies) had been observed consistently in normal healthy individuals, as well as in diseased persons, who consumed fish oils. The agency stated, however, that direct relationships between these effects and risk of CHD have not been established (56 FR 60663 at 60671).

The agency noted that *omega*-3 fatty acids had been shown to reduce blood pressure in hypertensive people to a small degree, which may bear on a relationship between *omega*-3 fatty acids and CHD. It stated that the effect was not of large magnitude (56 FR 60663 at 60672). Moreover, the agency also said that it had not been established that *omega*-3 fatty acids reduce blood pressure in normal subjects, and that it had not been demonstrated that the magnitude and duration of changes in blood pressure observed in short-term studies would persist during long-term consumption of *omega*-3 fatty acids. Finally, the agency noted the possibility that *omega*-3 fatty acids could increase the risk of CHD, through increases in LDL-cholesterol or apo- β -lipoprotein, among diabetics and hyperglycemics, and that *omega*-3 fatty acids might worsen control of blood glucose in diabetics. It said that these were significant safety concerns (56 FR 60663 at 60672). Given the lack of evidence that *omega*-3 fatty acids themselves reduced the risk of heart disease, specifically their lack of demonstrated effect on serum cholesterol (including LDL-cholesterol), the uncertainties about the relevance and significance of the blood pressure findings to the general populations, and the unresolved

safety concerns, the agency tentatively concluded not to authorize a health claim for *omega*-3 fatty acids and heart disease.

B. The January 1993 Final Rule

In the *Federal Register* of January 6, 1993 (58 FR 2682), FDA published a final rule that announced its decision not to authorize the use of a health claim regarding the relationship of *omega*-3 fatty acids and CHD on the label and in the labeling of foods in conventional food form.

FDA concluded that the totality of the available scientific evidence did not provide an adequate basis for a health claim. The agency said that the association between fish consumption and reduced risk of heart disease was not sufficient to establish a role for *omega*-3 fatty acids per se, versus other factors associated with dietary patterns high in fish, in achieving the desired effect. The agency noted that there was not significant scientific agreement that the physiological changes, such as increased bleeding times and a decrease in platelet aggregation, that were seen with consumption of *omega*-3 fatty acids would reduce the risk of CHD. The agency also said that the data were ambiguous because some effects of *omega*-3 fatty acids were not consistently observed, which suggested that other variables are important in determining whether an effect is seen (58 FR 2682 at 2702).

In the final rule, FDA also discussed some matters with respect to which greater agreement would be needed that the effects produced by *omega*-3 fatty acids are directly related to the risk of CHD before the agency could consider authorizing a claim. For example, many surrogate markers had been hypothesized, on the basis of limited evidence, to be related to specific diseases, including CHD, but few withstood the continued scrutiny of scientific investigation. FDA said that it could authorize a health claim only when there was significant scientific agreement, based on the totality of the scientific evidence, that a surrogate marker for a disease was a valid predictor of disease risk, specifically of heart disease risk for the general population. FDA said that evidence of such acceptance could be provided by a statement by an unbiased, nationally representative authoritative scientific or medical body (58 FR 2682 at 2705).

The agency reviewed numerous authoritative documents, the extensive comments that it had received on the proposal (58 FR 2682 at 2683 through 2699), and new scientific data, including epidemiological studies and

animal studies (58 FR 2682 at 2699 through 2705 and 2707 through 2714). Based on its review of all available information, the agency concluded that there are numerous physiological effects (e.g., increased bleeding times) of consumption of *omega*-3 fatty acids, but that at present, these endpoints are not generally accepted as being closely related to the risk of CHD. Thus the agency said that more data would be needed to show that the association between fish consumption and reduced risk of heart disease is specifically attributable to the *omega*-3 fatty acids in the fish.

The full discussion from the proposed and final rules, including the studies cited in those documents, is referenced herein.

C. Summary of Comments

In response to the January 6, 1993 final rule, the agency received two comments requesting that FDA allow voluntary inclusion of *omega*-3 fatty acid content information on food labels. These comments are not relevant to the issue of whether the agency can authorize a health claim on the relationship of *omega*-3 fatty acids and CHD. Therefore, no action on these comments is appropriate in this document. The agency points out, however, that in the *Federal Register* of June 18, 1993 (58 FR 33731 at 33736), it stated that under § 101.13(i)(3), information about the amount of a vitamin or mineral for which an RDI has not been established (e.g., vitamin K, selenium) could be declared on a food label, although not within the nutrition label, as long as the statement does not in anyway implicitly characterize the level of the nutrient and is not false or misleading in any respect. The agency notes that this provision would also apply to *omega*-3 fatty acid content information on food labels, including the labels of dietary supplements.

The agency did not receive any comments that provided any information that would support a health claim on the labels or in the labeling of dietary supplements regarding the relationship of *omega*-3 fatty acids and CHD in response to the January 6, 1993, final rule.

D. The Proposal

FDA has tentatively concluded, based on the totality of publicly available scientific evidence regarding the relationship of *omega*-3 fatty acids and coronary heart disease that there is not significant scientific agreement among experts that a claim about this relationship is scientifically valid.

There are numerous effects of *omega*-3 fatty acids that may be related to the risk of CHD, e.g., reduction in fasting and postprandial triglycerides, reductions in platelet aggregation and adhesion, and changes in the composition of lipoproteins. However, at this time, these endpoints are not generally recognized as being closely related to the risk of CHD.

Because a dietary supplement would contain only the *omega*-3 fatty acids, and there is not sufficient evidence that the *omega*-3 fatty acids alone caused the effects that were observed in studies of the effects of fish consumption on CHD, FDA tentatively finds that an appropriate basis for proposing to authorize a claim on *omega*-3 fatty acids and CHD on dietary supplements does not exist (56 FR 60663 and 58 FR 2682).

VII. The Next Steps

FDA has been diligent in developing proposed and final rules under the rigorous timeframes imposed by both the 1990 amendments and the DS Act of 1992. FDA has generally met its deadlines and is committed to completing the dietary supplement rulemakings in a timely manner. However, the agency has limited resources to both prepare the final rules that yet remain to be done under the 1990 amendments and the DS Act and to carry out the administrative activities required by the final rules under the 1990 amendments that the agency has already published. These activities include reviewing petitions, responding to inquiries, and conducting appropriate compliance activities, as well as preparing final rules in this and the five other rulemakings that are pending on dietary supplements.

The agency recognizes the emerging nature of the scientific information regarding the relationships between the intake of nutrients and disease or health-related conditions. A primary objective of FDA's administrative process is to provide a full airing of the scientific data and other relevant information on each of the nutrient-disease relationships listed in section 3 of the 1990 amendments.

FDA must consider both the validity of the link between the substance and the disease condition and the safety of the substance, especially when the purpose of the proposed health claim is to encourage intake of substance (in contrast to the claims on fat, for example, which encourage moderation in consumption). Care in reviewing safety is especially important when the claim is made for a substance in a dietary supplement because consumption of dietary supplements, in

contrast to most foods in conventional food form, is not self-limiting.

The process that FDA has engaged in with respect to folic acid and neural tube defects is an example of the agency's commitment to examine thoroughly all questions regarding a possible health claim. Initially, there was promising scientific evidence regarding a link between folic acid and the incidence of neural tube defects. However, there were also substantive safety questions in January 1993 that required further scrutiny and left the agency unable to authorize a health claim. Nevertheless, the agency did not abandon the issue but continued to address the issues by working with an expert advisory committee. Now, the agency is proposing to authorize a health claim on this nutrient-disease relationship.

The results of the rulemaking process for the five nutrient-disease relationships that the agency is initiating in this *Federal Register* document may differ. The agency may find that there is significant scientific agreement based on the totality of evidence for some of the relationships and may conclude that for other relationships, there is not such agreement. On still others, the agency may find that while evidence is promising, there are questions and concerns that must be resolved before a claim can be authorized. The agency will authorize a health claim in the first type of situation and will deny a health claim in the second type. With respect to the third type, the agency will also deny the health claim but will continue its process with respect to the relationship, with a goal of ensuring that interested persons obtain useful information that is scientifically valid and that will, in fact, be beneficial to health.

VIII. FDA's Plan for Completing a Final Rule

This proposal provides an opportunity for interested persons to submit new scientific data and comments in the five nutrient-disease relationships that are the subject of this rulemaking. The agency will review all comments received and will conduct its own literature review to obtain recent scientific evidence. In addition, FDA plans to cosponsor, with other research and health organizations, an open symposium on antioxidant vitamins to discuss the available science, to identify any unmet research needs, and to discuss ways of facilitating research to meet these needs. FDA will consider the results of this symposium in deciding whether to authorize a health claim on

antioxidant vitamins and cancer. FDA will provide notice of the meeting in the *Federal Register*. The agency intends to publish a final rule on this rulemaking in December of 1993, in accordance with the amendments to the 1990 amendments in the DS Act.

IX. Comments

Given the public health significance of cancer, CVD, and immune function in the elderly, FDA wants to make sure that its decisions in this proceeding reflect the latest scientific information. Therefore, FDA is requesting comments on any new data that have become available on the matters discussed in this document.

Interested persons may, on or before December 13, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between Monday through Friday.

X. Economic Impact

FDA has examined the economic implications of the proposed rule amending 21 CFR as required by the Regulatory Flexibility Act and Executive Order 12291. The Regulatory Flexibility Act requires regulatory relief for small businesses where feasible. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking. The agency finds that this proposed rule does not constitute a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act, FDA has explored whether these proposed rules will have a significant impact on small businesses and has tentatively concluded that they do not.

In the *Federal Register* of November 27, 1991 (56 FR 60366), FDA published a number of proposed food labeling regulations to implement the provisions of the 1990 amendments (Pub. L. 101-535). The agency also published a regulatory impact analysis which preliminarily estimated the costs and benefits of the various proposed regulations and on which FDA asked for comments.

Final regulations that implemented the 1990 amendments, except with respect to dietary supplements, were issued on January 6, 1993, including a final regulatory impact analysis (RIA) of those final regulations (58 FR 2927). In the RIA, FDA responded to the

comments regarding dietary supplements with tentative conclusions.

As described previously in this preamble, FDA is proposing to amend its food labeling regulations to state that health claims regarding the five nutrient-disease relationships are not authorized for dietary supplements. There are several different types of products which may be considered to be dietary supplements. These products include dietary supplements of vitamins, minerals, herbs, and other similar nutritional substances. In the proposals of June 18, 1993, FDA estimated that there are about 5,000 vitamin, mineral, and other dietary supplement products marketed in the United States and approximately 15,000 labels.

There are two potential costs of this regulation if implemented as proposed: Relabeling costs for those products using unauthorized health claims which must be removed from labels or labeling and the inability to market certain products based on those health claims.

The agency estimates that very few, if any, products are currently using the health claims that the agency is proposing not to authorize. Therefore, FDA does not believe that this proposed rule will not result in any significant changes in labeling. Accordingly, this regulation would result in few costs or benefits.

XI. Environmental Impact

The agency has determined under 21 CFR 25.24 (a)(11) 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.

List of Subjects in 21 CFR Part 101

Food 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 21 CFR part 101 be amended as follows:

PART 101—FOOD LABELING

1. The authority citation for 21 CFR part 101 is revised to read as follows:

Authority: Secs. 4, 5, 6 of the Fair Packaging and Labeling Act (15 U.S.C. 1453, 1454, 1455); secs. 201, 301, 402, 403, 409, 501, 502, 505, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 342, 343, 348, 351, 352, 355, 371); sec. 202(a)(2) of the Dietary Supplement Act (Pub. L. 102-571).

2. Section 101.71 is amended by revising the introductory text of paragraph (a) to read as follows:

§ 101.71 Health claims: claims not authorized.

(a) Health claims not authorized for foods in conventional food form or for dietary supplements of vitamins, minerals, herbs, or other similar substances:

Dated: October 1, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

Donna E. Shalala,

Secretary of Health and Human Services.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 136, 137, and 139

[Docket No. 91N-100S]

Food Standards: Amendment of the Standards of Identity for Enriched Grain Products to Require Addition of Folic Acid

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the standards of identity for enriched bread, rolls and buns, enriched flour, enriched self-rising flour, enriched corn grits, enriched corn meals, enriched farina, enriched rice, enriched macaroni products, enriched nonfat milk macaroni, and enriched noodle products, and, by cross-reference, the standards of identity for enriched bromated flour, enriched vegetable macaroni products, and enriched vegetable noodle products, to require the addition of folic acid. The agency is proposing to require that these products be fortified with folic acid at levels ranging from 0.43 milligrams (mg) to 1.4 mg per pound (mg/lb) or 95 micrograms (μ g) to 309 μ g/100 grams (g) of product. These values are based on a fortification level of 140 μ g/100 g (0.635 mg/lb) of the cereal-grain product. This action is proposed on FDA's own initiative. It is intended in part to help women of childbearing age comply with the recommendation by the U.S. Public Health Service (PHS) that they consume at least 0.4 mg (400 μ g) daily of folate. This action also responds to a citizen petition submitted by Glenn Scott.

DATES: Written comments by December 13, 1993. The agency is proposing that any final rule that may issue, based on

this proposal, become effective 1 year after date of publication in the *Federal Register*.

ADDRESSES: Written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Felicia B. Satchell, Center for Food Safety and Applied Nutrition (HFS-158), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-205-5099.

SUPPLEMENTARY INFORMATION:

I. Background

In September 1992, following an open meeting sponsored by the Centers for Disease Control (CDC) in Atlanta, GA (57 FR 29323) and based on reviews of the relevant scientific data, PHS recommended that all women of childbearing age in the United States consume 0.4 mg (400 µg) of folate daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 1). In discussing this recommendation, PHS raised several issues that directly bear on FDA's responsibilities under the Federal Food, Drug, and Cosmetic Act (the act). One of these issues was to identify the best approach for increasing intake of folate by women during their childbearing years. PHS identified several possible approaches by which folate intake by the target population might be increased. These approaches included: (1) Improvement of dietary habits, (2) fortification of the U.S. food supply, and (3) daily use of folate supplements by women throughout their childbearing years. The PHS recommendation also cautioned against the effects of higher intakes of folate. The recommendation stated that a widely recognized adverse effect of high intakes of folate is masking the anemia of vitamin B₁₂ deficiency and thus allowing the neurologic damage to progress untreated. PHS said that care should be taken to keep total folate consumption at less than 1 mg (1,000 µg)/day, except under the supervision of a physician (Ref. 1).

After the PHS recommendation was issued, FDA convened a subcommittee on folate of its Food Advisory Committee (hereinafter referred to as the "Folic Acid Subcommittee") to consider some of the issues raised by the recommendation. At a meeting in November 1992, the Folic Acid Subcommittee discussed approaches for ensuring that the folate intakes of women would be increased. It identified several approaches. These included: (1)

Development of a fortification scheme such that 90 percent of women of childbearing age could receive at least 400 µg of folate per day from all sources, while preventing excessively high folate intakes by nontarget groups; (2) appropriate labeling of foods, including dietary supplements; and (3) implementation of an educational program directed primarily at women of childbearing age that emphasizes the importance of folate intake before, during, and after conception and its effect on the incidence of neural tube defects. The Folic Acid Subcommittee also recommended that a surveillance and monitoring system be established to provide baseline data on vitamin B₁₂ status in subgroups of the population that might potentially be at greatest risk as a result of increased intakes of folate.

These issues and the Folic Acid Subcommittee's recommendations are fully discussed elsewhere in this issue of the *Federal Register* in a proposed rule entitled "Food Labeling; Health Claims and Label Statements: Folic Acid and Neural Tube Defects" (hereinafter referred to as the health claims proposal).

II. The Proposal

In this document, the agency is proposing to implement its tentative conclusion, discussed at length in the health claims proposal, that food fortification should be limited to cereal-grain products. Specifically, FDA is proposing to establish a fortification scheme that will assist women in the target population in increasing their daily intake of folate. This document also responds to a citizen petition (Docket No. 92P-0132), submitted by Glenn Scott, that requested that the agency amend the standards of identity for enriched cereal-grain products to include a requirement for the addition of folic acid, although the levels of addition suggested by the petitioner were lower than those that FDA is proposing to require in this document.

FDA is proposing to amend the following standards of identity to require the addition of folic acid: Enriched bread, rolls and buns (§ 136.115 (21 CFR 136.115)); enriched flour (§ 137.165 (21 CFR 137.165)); enriched self-rising flour (§ 137.185 (21 CFR 137.185)); enriched corn grits (§ 137.235 (21 CFR 137.235)); enriched corn meals (§ 137.260 (21 CFR 137.260)); enriched farina (§ 137.305 (21 CFR 137.305)); enriched rice (§ 137.350 (21 CFR 137.350)); enriched macaroni products (§ 139.115 (21 CFR 139.115)); enriched nonfat milk macaroni products (§ 139.122 (21 CFR 139.122)); and enriched noodle products (§ 139.155 (21

CFR 139.155)). FDA notes that the standards of identity for enriched bromated flour (§ 137.160 (21 CFR 137.160)), enriched vegetable macaroni products (§ 139.135 (21 CFR 139.135)), and enriched vegetable noodle products (§ 139.165 (21 CFR 139.165)) cross-reference the standards of identity for enriched flour, enriched macaroni products, and enriched noodle products, respectively, and will thus also be amended by this proposal. FDA also points out that the standard for enriched macaroni products fortified with protein is stayed and thus will not be addressed in this rulemaking.

As fully discussed in the health claims proposal published elsewhere in this issue of the *Federal Register*, FDA has tentatively decided that the fortification of the food supply is an appropriate approach for increasing the intake of folate by women in the target population. As noted by the Folic Acid Subcommittee and expert speakers who testified before the Folic Acid Subcommittee, food fortification has the advantage of reaching a great number of women in the target population before conception and during early pregnancy, when the risk of neural tube defects is greatest. It also has the advantage of providing folate in a continuous and passive manner and, thus, represents an effective means for improving the folate nutrition of women in their childbearing years.

In determining what foods would be appropriate for fortification with folic acid and at what levels, the agency used the U.S. Department of Agriculture (USDA) 1987-1988 national food consumption data (Ref. 2) to estimate daily intake of folate for the target population, as well as the general population, with fortification at different levels for cereal grains, dairy products, and juices. The agency estimated the effects of fortification using three values—0.070, 0.140, and 0.350 mg of folic acid/100 g of cereal-grain products. As discussed in the health claims proposal, the value of 0.070 mg/100 g (0.3 mg/lb) is the amount, recommended in 1974 by the Food and Nutrition Board, National Research Council, National Academy of Sciences, that would restore folate lost in the milling of cereal-grain products and represents about a four-fold increase in the level of folate that ordinarily occurs in wheat flour (Ref. 3). The value of 0.140 mg/100 g is twice that amount, and 0.350 mg/100 g is five times that amount.

The different approaches that FDA used in estimating the effects of fortification of food with these levels of folic acid are fully discussed in the

health claims proposal, published elsewhere in this issue of the *Federal Register*. In arriving at these estimates, FDA made provision for consumption of ready-to-eat cereals fortified with folic acid as well as dietary supplements containing folic acid.

In its analysis, FDA assumed likely underreporting biases in food intakes. The agency did so because national food consumption surveys generally underestimate the food intake of survey respondents. This fact is supported, in part, by the observation that when consumer-reported dietary intakes are used as a basis for designing intervention diets (not necessarily for weight reduction), subjects that follow the intervention diet frequently lose weight (Ref. 4). Further, calorie intakes that were estimated based on the survey respondents' daily reported food intake fell below the current average calorie intakes recommended by the Food and Nutrition Board. For example, in the 1987-1988 USDA Nationwide Food Consumption Survey (Ref. 2) used for these estimates, calculated median energy intakes of women 19 to 50 years of age were only about 1,500 calories, whereas the most recent recommended average energy intake for this gender/age group is 2,200 calories (Ref. 5).

FDA also took into account in performing its analysis that underestimation of folate contents of foods was likely in the analysis that had been done. Comparison of newer methods of sample preparation with older methods for determining the folate content of foods has revealed underestimates in the range of 20 percent for vegetables such as spinach and cauliflower and 50 percent for canned tuna. Thus, commonly used methods for folate analysis may significantly underestimate the folate content of foods.

As fully discussed in the health claims proposal published elsewhere in this issue of the *Federal Register*, results of FDA's analysis show that when fortification included fruit juices and dairy products in addition to cereal grain and dietary supplements, folate intakes of some nontarget group consumers exceeded 1 mg/day regardless of the fortification level examined. However, when fortification was limited to cereal-grain products at levels of 70 µg/100 g or 140 µg/100 g, daily intake levels remained below 1 mg/100 g. At fortification levels of 350 µg/100 g, the estimated daily intake could reach levels of 1,220 µg/100 g, which exceeds the recommended safe upper limit.

The agency also estimated the daily intake of folate for consumers who

follow Federal government dietary guidance, such as the U.S. Dietary Guidelines and the Department of Health and Human Services (DHHS)/USDA Food Guide Pyramid, and consume cereal-grain products fortified with folic acid, to determine whether these consumers will have daily intakes in excess of the recommended safe upper limit of approximately 1 mg/day.

These estimates, as shown in Table 7 in the health claims proposal, indicate that consumers who followed even the low end of recommendations from the DHHS/USDA Food Guide Pyramid could, without supplement use, easily consume 420 µg or more of folate per day from cereal-grain products fortified with 70 µg folic acid/100 g. Further, such consumers' daily intake could triple if such products were fortified with 350 µg folic acid/100 g.

As a result of its analysis of fortification of several cereal-grain, dairy, and juice products, FDA has tentatively concluded that fortification should be limited to cereal-grain products and not extended to dairy products and fruit juices. (The agency notes that results of its analysis are presented in Tables 4 through 7 in the health claims proposal published elsewhere in this issue of the *Federal Register*.) The agency found that intakes by very large segments of the general population would reach several milligrams per day if all of these foods were fortified with folic acid.

The agency has also tentatively decided that the appropriate fortification level for cereal-grain products is 140 µg/100 g. Based on the results of its analysis, fortification of cereal-grain products with 140 µg/100 g will provide daily intakes for the nontarget population that remain within the recommended safe upper limit of approximately 1 mg/day, while providing increased intakes of folate for women in their childbearing years. The agency notes that with supplement use, 95th percentile intakes by adults 51+ years of age could reach 840 to 860 µg/day if these enriched cereal-grain products are fortified with 140 µg/100 g. While the agency recognizes that this level approaches the recommended safe upper limit and does not take into account likely underreporting biases regarding food intakes and underestimation of folate content of foods, it tentatively concludes that fortification of cereal-grain products with 140 µg/100 g folic acid is the most appropriate fortification level of the three levels analyzed to ensure that folate intakes by the target population will increase. Fortification at a lower level of 70 µg/100 g may not provide

sufficient folate levels to that portion of the target population that have lower daily food intakes or that consume minimal amounts of cereal-grain products. For example, folate intake estimates for the 25th percentile of the target population if cereal-grain products were supplemented with 70 µg/100 g of folic acid showed levels of 160 to 180 µg/day without supplement use and 200 µg/day with supplement use.

In this document, the agency is proposing to provide for folic acid fortification of the individual enriched cereal-grain products discussed below, which are subject to standards of identity.

A. Bakery and Wheat Flour Products

1. Enriched Flour

Wheat flour products are produced in various forms, plain, self-rising, instantized, and enriched. The products may be sold directly to consumers or may be specially designed for manufacturing bakery products, i.e., breads, rolls and buns, or other specialty food products. Standards of identity for enriched forms of these products provide for addition of specified amounts of thiamin, niacin, riboflavin, and iron and, in some instances, for the optional addition of calcium and vitamin D. (FDA is providing for correction of the spelling of "thiamin" in all the food standards that it is proposing to amend.)

As stated above, FDA has tentatively concluded that it is appropriate to fortify enriched cereal-grain products with folic acid based on a fortification level of 140 µg/100 g for wheat flour. This level will provide a better opportunity for a larger portion of the target population to achieve significantly increased folate intakes.

In determining what minimum level of folate should be present in enriched wheat flour, FDA consulted the Food and Nutrition Board's report of the proceedings of a workshop entitled "Technology of Fortification of Cereal-Grain Products" conducted in May 1974 (Ref. 6) and the USDA Handbook 8-20, *Composition of Foods: Cereal Grains and Pasta, Raw, Processed, Prepared* (Ref. 7). The Food and Nutrition Board's report included a paper by Kulp that provided information on naturally occurring levels of vitamins and minerals in commercially milled wheat flour. The paper reported summary data, collected by members of the industry, academia, and the governments of the United States and Canada, on the analysis of 65 samples of various types of flours originating from mills in the

United States and Canada. The average folate content of wheat flour was shown to be 0.076 mg/lb (or 0.017 mg/100 g), with a range of 0.044 to 0.120 mg/lb (or 0.009 to 0.026 mg/100 g).

The USDA Handbook 8-20 lists values for folate content (listed as folacin) of four types of wheat flour other than whole grain flour, i.e., all purpose, bread, cake, and self-rising wheat flours. The folate values for the flour products, in order of the foregoing list, are 0.117, 0.131, 0.086, and 0.191 mg/lb (or 0.026, 0.029, 0.019, and 0.042 mg/100 grams) (Ref. 7). These values are somewhat higher than the average value, 0.076 mg/lb (range 0.044 to 0.120 mg/lb), reported for wheat flour in the Food and Nutrition Board's report (Fig. 1, p.14, Ref. 6). However, the USDA Handbook 8-20 values for folate content in wheat (before milling) and whole wheat flour, ranging from 0.171 to 0.196 mg/lb (or 0.038 to 0.044 mg/100 g), were lower than the Food and Nutrition Board's recommended restoration level of 0.3 mg/lb folic acid for milled (i.e., bran removed) wheat flour products.

Given these data, FDA has tentatively decided to use the average normally occurring level for folate content in wheat flours cited in the Food and Nutrition Board's report because it is based on a more comprehensive data base on the folate content of wheat flour. The agency is not aware of subsequent studies of this nature that would alter the findings of this study. Thus, to fortify wheat flour at a level of 140 µg/100 g (0.635 mg/lb), FDA is proposing that enriched flour contain 0.7 mg/lb of folic acid. FDA derived this value by adding the proposed fortification level of 0.635 mg/lb to the Food and Nutrition Board's folate value for unfortified flour of 0.076 mg/lb, which yields 0.711 mg/lb, and rounding this value to 0.7 mg/lb. Accordingly, based on this calculation, FDA is proposing to amend the standards of identity for enriched flour (§ 137.165) and enriched self-rising flour (§ 137.185), and by cross-reference, enriched bromated flour (§ 137.160), to require that these foods contain 0.7 mg/lb of folic acid.

2. Enriched Rolls and Buns

For consistency with the requirements for enriched flour products, FDA is proposing to amend the standards of identity for enriched bread, rolls, and buns in § 136.115 to require that these foods contain 0.43 mg/lb of folic acid. This rate of fortification is proportionally consistent with the fortification rate used for the B vitamins (thiamin, riboflavin, and niacin) when enriched flour is used in making these

foods. For example, the levels of thiamin, riboflavin, and niacin in enriched flour (§ 137.165) are 2.9, 1.8, and 24.0 mg/lb, respectively, and in enriched bread (§ 136.115) are 1.8, 1.1, and 15.0 mg/lb, resulting in a ratio of approximately 1.62 to 1. In the case of the level of folic acid, the proposed level for enriched flour is 0.7 mg/lb compared to 0.43 mg/lb for bread, resulting in a ratio 1.63 to 1. The lower level specified for the B vitamins and folic acid content in enriched bread products allows the bread products to be made from the standardized enriched flour without further fortification.

3. Enriched Farina

FDA is also proposing a fortification level for folic acid in enriched farina (§ 137.305) on the same basis as that for enriched wheat flour, i.e., 1 lb of the food would contain not less than 0.7 mg of folic acid. Both wheat flour and farina are made from the endosperm of wheat, that portion of the wheat kernel that remains after the bran layer and germ have been removed. The bran layer and germ contain most of the B vitamins, including the naturally occurring folate. Therefore, the agency tentatively finds that it is reasonable to fortify both flour and farina at the same level of 140 µg/100 g or 0.7 mg/lb.

FDA notes that, like flour, farina is not consumed directly but is prepared in some recipe. The enriched farina may be rinsed before use and is usually boiled in water. These steps are likely to dilute the levels of nutrients in the food. Because of such possible losses, the agency is also proposing an upper limit of addition (0.87 mg/lb). The upper limit for folic acid is approximately 25 percent higher to counter possible losses of the vitamin in preparation of the finished food product and is consistent with the upper levels of other B vitamins in the standard.

B. Corn and Rice Products

1. Enriched Corn Grits

USDA Handbook 8-20 data (Ref. 7) show that corn products, except for corn meals, contain significantly less folate than wheat products, ranging from a low of 0.005 mg/100 g (0.022 mg/lb) in dry corn grits to a high of 0.031 mg/100 g (0.141 mg/lb) in degermed corn meals and 0.057 mg/100 g (0.258 mg/lb) in bolted corn meals. However, because corn products are often used as substitutes for wheat based food products, FDA is proposing to amend § 137.235 to require fortification of enriched corn grits with the same level of folic acid as that proposed for enriched wheat flour products, such

that each pound of the food would contain at least 0.7 mg of folic acid. Because there may be losses from the rinsing of corn grits before cooking, FDA is also proposing an upper limit for folic acid fortification of 1.0 mg/lb, which is approximately 50 percent higher than the proposed minimum of 0.7 mg/lb, as it has done for the other B vitamins (thiamin, riboflavin, and niacin) that are required to be present in enriched corn grits.

2. Enriched Corn Meals

In the case of enriched corn meals under § 137.260, FDA is proposing a minimum folic acid level that is consistent with that for enriched flour, such that each pound of the food contains 0.7 mg. As noted above, corn products may be used as substitutes for wheat products. Thus, FDA believes that consumers expect to be able to obtain the same levels of nutrients from enriched corn meals as from enriched wheat flour. FDA is also proposing an upper limit for folic acid addition (i.e., 1.0 mg/lb which is approximately 50 percent higher than the minimum fortification level), as it has done for the added B vitamins. The upper limit on the other B vitamins is intended to prohibit addition of excessive amounts of the nutrient and to ensure uniformity in composition of corn meals. FDA tentatively finds that for the same reasons an upper limit on the addition of folic acid of 1.0 mg/lb is necessary.

3. Enriched Rice

The folic acid content of rice varies from 0.008 mg/100 g (0.036 mg/lb) for white rice to 0.020 mg/100 g (0.090 mg/lb) for brown rice (Ref. 7). FDA is proposing to amend the standard of identity for enriched rice (§ 137.350) to include a range for the folic acid fortification level, 0.7 mg/lb to 1.4 mg/lb, with the lower limit being consistent with the proposed folic acid fortification level for enriched wheat flour. FDA believes that use of the same minimum level of fortification is appropriate because it is consistent with the Food and Nutrition Board's recommendation that the same restoration level be used for wheat flour, corn products, and rice. However, as discussed above, FDA believes a level (0.635 mg/lb) that is approximately twice that of the Food and Nutrition Board's recommended level (0.3 mg/lb) is necessary to ensure that sufficient levels of folate are available to meet the dietary needs of the target population.

FDA is also proposing that the upper limit for folic acid fortification of enriched rice be twice the proposed minimum fortification level for folic

acid (0.7 mg/lb) or 1.4 mg/lb, as it has done with other added nutrients in enriched rice. This proposed upper level is based on the way that rice is fortified in this country.

In the United States rice may be enriched by addition of a powder mixture containing the added nutrients or by use of a rice premix consisting of rice kernels coated with a concentrated nutrient mix. When the powder enrichment procedure is used, the label of the package is required to state that the rice should not be rinsed before cooking or drained after cooking, so that the rice retains the added nutrients. However, there is no assurance that these instructions will be followed. In the case of the rice premix, a special coating is applied to the rice kernels, so that the added nutrients will not be washed off if the product is rinsed before cooking. The coated rice premix is blended with unenriched rice such that the finished enriched rice product will contain the required minimum levels of added nutrients. The stated range provides flexibility in the production of the enriched rice and ensures that the food, when prepared for consumption, will contain the required minimum levels of nutrients.

The agency believes that most, if not all, enriched rice is manufactured using a rice premix procedure, and that it may not be necessary to continue to provide for the range of added nutrients in the standard of identity for enriched rice (Ref. 8). If comments provide substantive information that enriched rice is generally being prepared in this manner, or that the specified level of added nutrients is maintained during cooking when the rice is prepared according to labeled instructions on the package, FDA will consider not including the upper limit of the proposed range, and establishing a single level for folic acid addition (0.7 mg/lb), in any final rule that is published in this proceeding.

C. Macaroni and Noodle Products

The standards of identity for enriched macaroni products (§ 139.115), enriched nonfat milk macaroni (§ 139.122), and enriched noodle products (§ 139.155), and the cross-referenced standards of identity for enriched vegetable macaroni products (§ 139.135) and enriched vegetable noodle products (§ 139.165), provide for significantly higher levels of nutrient addition than the related flour standards of identity because these products are usually cooked in a large amount of water that is usually discarded after cooking and before consumption of the macaroni and noodle products. FDA is proposing to

require addition of folic acid to macaroni and noodle products in the same proportion as it is proposing for use in enriched flour, except that the proposed level (expressed in terms of a range) will be approximately 25 percent higher than the proposed level of folic acid to be added to flour. This 25 percent increase is consistent with that of the other added nutrients (thiamin, riboflavin, niacin, and iron) in the enriched macaroni and noodle products standards compared to those in the standards of identity for flour products. Accordingly, FDA is proposing to require that the enriched macaroni and noodle products contain from 0.9 to 1.2 mg/lb of folic acid.

The agency requests comments on whether the proposed fortification levels discussed for the above products are appropriate. Interested persons who wish to suggest alternative fortification levels should include a rationale for such levels and data to support the suggested levels. Further, the agency requests comments on whether addition of folic acid to these cereal-grain products should be required as proposed or should be optional because increased levels of folate intake present health risks to persons with vitamin B₁₂ deficiency.

Minor editorial changes have been made in the standards of identity to achieve consistency in language format.

III. Economic Impact

FDA has examined the economic implications of this proposed rule as required by the Regulatory Flexibility Act and Executive Order 12291. The Regulatory Flexibility Act requires relief for small businesses where feasible. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In accordance with the Regulatory Flexibility Act (5 U.S.C. 601-612), FDA has also determined that this proposed rule will not have a significant adverse impact on a substantial number of small businesses.

A. Options

FDA has evaluated the following options: (1) Improve dietary practices among women of childbearing age to increase their daily folate intake, (2) change the standards of identity to require fortification of cereal-grain products with folic acid at levels of 0.14 mg of folate per 100 g of cereal-grain product, and (3) change the standards of identity to require fortification of cereal-grain products with folic acid at either 0.07 mg/100 g or 0.35 mg/100 g.

B. Costs

1. Improve Dietary Practices Among Women of Childbearing Age

Under this option, Federal and State health agencies would encourage improved dietary practices among women of childbearing age to increase their daily folate intake. This might be accomplished under any of the numerous existing programs, through government outreach programs, and physicians. This option will work in conjunction with health claims which are expected to increase the intake of folate by women of childbearing age. However, the agency is unsure of the potential cost or efficacy of this option and requests comments on it.

2. Require Fortification with Folic Acid at 0.14 mg/100 g

Excess folate intake can interfere with the diagnoses of vitamin B₁₂ deficiency at levels as low as 0.25 mg per day. There is no scientific consensus on the percentage of diagnoses of vitamin B₁₂ deficiency that would be complicated by folate intake at this level. However, the agency has tentatively determined that adverse health effects are not significant until folate intake reaches 1 mg per day. Under this option, folate intake will be below 1 mg per day for all individuals.

The cost of the folic acid that must be added to the specified cereal-grain products is estimated to be approximately \$4 million per year. The cost of analytical testing depends on how many tests are run. As an example of the costs involved, if each affected manufacturing plant tests five products for folic acid content three times per year, total testing costs would be \$2.5 million per year. The cost of required label changes is estimated to be about \$20 million.

In addition, some countries, including Canada, do not allow folic acid fortification of these products. Thus, this option would require that separate production runs be made for fortified products exported to and imported from these countries. FDA cannot estimate these costs at this time.

The total cost of this option is estimated to be \$27 million per year plus the cost of separate production runs for these products exported to and imported from certain foreign countries.

3. Require Fortification with Folic Acid at 0.07 mg/100 g or at 0.35 mg/100 g

Folic acid fortification at 0.07 mg/100 g will not raise the folate intake of consumers at risk of vitamin B₁₂ deficiency and pernicious anemia to levels greater than 1 mg per day. The

cost of the required folic acid is approximately \$2 million per year. The cost of testing is estimated to be about \$2.5 million per year and the cost of the required label changes \$20 million. Total costs of folic acid fortification at 0.07 mg/100 g are therefore estimated to be \$25 million.

Folic acid fortification at 0.35 mg/100 g will raise the folate intake of some consumers at risk of vitamin B₁₂ deficiency and pernicious anemia to levels exceeding 1 mg per day. As an example of the costs involved, a simple linear extrapolation of the results of a study that found that between 50 percent and 77 percent of patients with pernicious anemia experienced prolonged hematological remission to a dose of 5 mg of folate per day will be used (Ref. 9).

A delay in the diagnosis of vitamin deficiency can result in severe and potentially irreversible neurologic damage. The most common irreversible consequences of a delay in the diagnosis of vitamin B₁₂ deficiency are permanent paresthesia (numbness or tingling) in the hands or feet and ataxia (inability to coordinate voluntary muscular movements). Based on the number of people estimated to be at risk of pernicious anemia, and on a study dealing with the prevalence of permanent paresthesia and ataxia in cases of pernicious anemia initially diagnosed at the stage at which neurologic symptoms are present, consumers may experience health consequences valued at approximately \$1.85 billion per year under this level of folic acid fortification (Ref. 10).

The cost of the folic acid required to obtain 0.35 mg/100 g is approximately \$10 million per year. The cost of testing is estimated to be \$2.5 million and the cost of the required label changes \$20 million.

Total costs of folic acid fortification at 0.35 mg/100 g are therefore estimated to be \$1.88 billion per year plus the cost of separate production runs for these products exported to and imported from certain foreign countries.

C. Benefits

1. Improve Dietary Practices Among Women of Childbearing Age

As indicated above, the agency cannot estimate the benefit of this option at this time. FDA requests comments on the benefits of this option.

2. Require Fortification with Folic Acid at 0.14 mg/100 g.

The benefit of this option is a reduction in the incidence of infants born with neural tube defects (NTD's).

PHS has estimated that if all women of childbearing age achieved an intake of 0.4 mg folate per day the incidence of NTD's could be reduced by 50 percent.

The agency is proposing elsewhere in this issue of the *Federal Register* to allow health claims for folic acid. In order to determine the number of women whose folate intake will exceed 0.4 mg per day due to the proposed level of folic acid fortification, the increase in folate consumption due to health claims must be estimated. FDA has insufficient information to estimate the increase in folate intake due to health claims alone. As an example of the benefits involved, the following assumes that all women currently taking dietary supplements will take supplements containing 0.4 mg folic acid per day once health claims for folic acid are allowed.

NTD's are rare but serious birth defects that can result in infant mortality or serious disability. There are about 2,500 cases of NTD's each year. Based on a linear extrapolation of the PHS estimate cited above and the percentage of women whose folate intake would exceed 0.4 mg per day due to folic acid fortification at 0.14 mg/100 g, this option is estimated to eliminate about 116 NTD's each year. In 1989, NTD's accounted for 533 infant deaths. If this figure is representative, this option should prevent about 25 infant deaths each year.

There is no consensus on the value of a reduction in risk corresponding to one statistical infant life saved. If the value of a statistical life saved does not vary with life years remaining, a reasonable estimate is \$5 million. If the value of a statistical life saved does vary with life years remaining, a reasonable estimate is \$11 million (Ref. 11). The value of the infant deaths avoided each year is therefore estimated to be between \$123 million and \$260 million.

The birth defects anencephaly and spina bifida are the most common forms of NTD's and account for about 90 percent of these defects. Spina bifida is a serious condition that is associated with a variety of adverse health effects. One study of the effects of spina bifida found that 41 percent of patients born with spina bifida died before their 16th birthday (Ref. 12). Assuming that the estimated number of infant deaths are due primarily to anencephaly, the increase in life expectancy due to the elimination of the estimated number of cases of spina bifida is estimated to be about \$323 million. This study also found that 20 percent of patients with spina bifida who did not die before their 16th birthday suffered from mental retardation, 30 percent were wheelchair

bound, and 44 percent incontinent (Ref. 12). The estimated benefit from the elimination of these adverse health effects is estimated to be \$205 million per year (Ref. 11). This estimate is based on a willingness-to-pay methodology that includes, for example, cost of illness and pain and suffering. Benefit estimates based solely on cost of illness would be significantly lower. Additional adverse health effects from NTD's were also observed but were relatively rare and will not be considered here.

Total benefits of this option are therefore estimated to be approximately \$651 to \$788 million per year.

3. Require Fortification with Folic Acid at 0.07 mg/100 g or at 0.35 mg/100g

Based on the methodology discussed above, the benefit of requiring fortification of these products at 0.07 mg/100 g is estimated to be between \$326 million and \$394 million.

Based on the methodology discussed above, the benefit of requiring fortification of these products at 0.35 mg/100 g is estimated to be between \$1.63 billion and \$1.97 billion. This option is the only option that would generate health costs.

D. Conclusion

In accordance with Executive Order 12291, the agency has analyzed the economic effects of this proposed rule and has determined that this rule, if promulgated, will not be a major rule as defined by that order.

The costs of the proposed action are estimated to be approximately \$27 million per year plus the cost of separate production runs for products exported to and imported from certain foreign countries. The benefits are estimated to be from \$651 to \$788 million per year.

IV. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Because the agency is proposing to take three actions involving folic acid and the net effect of these actions is likely to increase the usage of folic acid, one environmental assessment has been

prepared which considers all three agency actions.

V. 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.

1. CDC, "Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects," *Morbidity and Mortality Weekly Reports*, 41, 1-7, 1992.

2. USDA, Nationwide Food Consumption Survey/Individual Intake—1987-1988, accession no. PB90-504044, National Technical Information Service, Springfield, VA, 1990.

3. Food and Nutrition Board, National Research Council, National Academy of Sciences, *Proposed Fortification Policy for Cereal-Grain Products*, 36 pp., National Academy of Sciences, Washington, DC, 1974.

4. Mertz, W., J. C. Tsui, J. T. Judd, and S. Reiser, et al., "What are People Really Eating? The Relation Between Energy Intake Derived From Estimated Diet Records and Intake Determined to Maintain Body Weight," *American Journal of Clinical Nutrition*, 54:291-295, 1991.

5. Food and Nutrition Board, National Research Council, National Academy of Sciences, "Recommended Dietary Allowances," 10th ed., Washington, DC, 1989.

6. Subcommittee on Food Technology, Committee on Food Protection, Food and Nutrition Board, National Research Council, National Academy of Sciences, Proceedings of a Workshop on Technology of Fortification of Cereal-Grain Products, Washington, DC, May 16-17, 1977.

7. USDA Handbook 8-20: Composition of Foods, Cereal Grains and Pasta, Raw Processed, Prepared. Rev., October 1989.

8. Hoffpauer, D.W., "Rice Enrichment for Today," *Cereal Foods World*, vol. 37, No. 10, pp. 757-759, 1992.

9. Schwartz, S. O., S. R., Kaplan, and B. E., Armstrong, "The Long-Term Evaluation of Folic Acid in the Treatment of Pernicious Anemia," *Journal of Laboratory and Clinical Medicine*, 35: 894-898, 1950.

10. Heaton, E. B., D. G. Savage, J. C. Brust, T. J. Garrett, J. Lindenbaum, "Neurologic Aspects of Cobalamin Deficiency," *Medicine*, vol. 7, No. 4, pp. 229-245, July 1991.

11. Research Triangle Institute, "Quality of Well-Being Scale in Estimating the Value of Consumers' Loss From Food Violating the FD&C Act," vol. II, Final Report, September 1988.

12. Hunt, G. M., "Open Spina Bifida: Outcome for a Complete Cohort Treated Unselectively and Followed Into Adulthood," *Developmental Medicine and Child Neurology*, vol. 32, No. 2, pp. 108-118, February 1990.

VI. Comments

Interested persons may, on or before December 13, 1993, submit to the Dockets Management Branch (address

above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy.

Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above, between 9 a.m. and 4 p.m., Monday through Friday.

During the comment period for this proposal, the agency intends to convene public meetings of the Folic Acid Subcommittee and the Food Advisory Committee for a discussion of the issues raised in this document, as well as the Health Claim document and the Standards of Identity document. FDA also intends to request comments from the experts who participated in its November 23 and 24, 1992, meeting of its Folic Acid Subcommittee. The agency will make any comments received from these experts and the views of the committees available for public review and comment immediately after the Advisory Committee meeting. In addition, FDA will endeavor to have copies of the transcripts of the Folic Acid Subcommittee and Food Advisory Committee meetings available as quickly as possible.

List of Subjects

21 CFR Part 136

Bakery products, Food grades and standards.

21 CFR Part 137

Cereals (food), Food grades and standards.

21 CFR Part 139

Food grades and standards.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs it is proposed that 21 CFR parts 136, 137, and 139 be amended as follows:

PART 136—BAKERY PRODUCTS

1. The authority citation for 21 CFR part 136 is revised to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

2. Section 136.115 is amended by revising paragraph (a)(1) to read as follows:

§ 136.115 Enriched bread, rolls, and buns.

(a) * * *

(1) Each such food contains in each pound 1.8 milligrams of thiamin, 1.1 milligrams of riboflavin, 15 milligrams

of niacin, 0.43 milligrams of folic acid, and 12.5 milligrams of iron.

* * * * *

PART 137—CEREAL FLOURS AND RELATED PRODUCTS

3. The authority citation for 21 CFR part 137 is revised to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

4. Section 137.165 is amended by revising paragraph (a) to read as follows:

§ 137.165 Enriched flour.

* * * * *

(a) It contains in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 20 milligrams of iron.

* * * * *

5. Section 137.185 is amended by revising paragraph (a) to read as follows:

§ 137.185 Enriched self-rising flour.

* * * * *

(a) It contains in each pound 2.9 milligrams of thiamin, 1.8 milligrams of riboflavin, 24 milligrams of niacin, 0.7 milligrams of folic acid, and 22 milligrams of iron.

* * * * *

6. Section 137.235 is amended by revising paragraph (a)(1) to read as follows:

§ 137.235 Enriched corn grits.

(a) * * *

(1) It contains in each pound not less than 2.0 milligrams (mg) and not more than 3.0 mg of thiamin, not less than 1.2 mg and not more than 1.8 mg of riboflavin, not less than 16 mg and not more than 24 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.0 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe).

* * * * *

7. Section 137.260 is amended by revising paragraph (a)(1) to read as follows:

§ 137.260 Enriched corn meals.

(a) * * *

(1) It contains in each pound not less than 2.0 milligrams (mg) and not more than 3.0 mg of thiamin, not less than 1.2 mg and not more than 1.8 mg of riboflavin, not less than 16 mg and not more than 24 mg of niacin or niacinamide, not less than 0.7 mg and not more than 1.0 mg of folic acid, and not less than 13 mg and not more than 26 mg of iron (Fe).

* * * * *

8. Section 137.305 is amended by revising paragraph (a)(1) to read as follows:

§ 137.305 Enriched farina.

(a) * * *

(1) It contains in each pound not less than 2.0 milligrams and not more than 2.5 milligrams of thiamin, not less than 1.2 milligrams and not more than 1.5 milligrams of riboflavin, not less than 16.0 milligrams and not more than 20.0 milligrams of niacin or niacinamide, not less than 0.7 milligrams and not more than 0.87 milligrams of folic acid, and not less than 13.0 milligrams of iron (Fe).

* * * * *

9. Section 137.350 is amended by revising paragraph (a)(1) to read as follows:

§ 137.350 Enriched rice.

(a) * * *

(1) Not less than 2.0 milligrams and not more than 4.0 milligrams of thiamin, not less than 1.2 milligrams and not more than 2.4 milligrams of riboflavin, not less than 16 milligrams and not more than 32 milligrams of niacin or niacinamide, not less than 0.7 milligrams and not more than 1.4 milligrams of folic acid, and not less than 13 milligrams and not more than 26 milligrams of iron (Fe).

* * * * *

PART 139—MACARONI AND NOODLE PRODUCTS

10. The authority citation for 21 CFR part 139 is revised to read as follows:

Authority: Secs. 201, 401, 403, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 343, 348, 371, 379e).

11. Section 139.115 is amended by revising paragraph (a)(1) to read as follows:

§ 139.115 Enriched macaroni products.

(a) * * *

(1) Each such food contains in each pound not less than 4.0 milligrams (mg) and not more than 5.0 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and not less than 13 mg and not more than 16 mg of iron (Fe);

* * * * *

12. Section 139.122 is amended by revising the first sentence of paragraph (a)(3) to read as follows:

§ 139.122 Enriched nonfat milk macaroni products.

(a) * * *

(3) Each such food contains in each pound not less than 4.0 milligrams and not more than 5.0 milligrams of thiamin, not less than 1.7 milligrams and not more than 2.2 milligrams of riboflavin, not less than 27 milligrams and not more than 34 milligrams of niacin or niacinamide, not less than 0.9 milligrams and not more than 1.2 milligrams of folic acid, and not less than 13 milligrams and not more than 16 milligrams of iron (Fe). * * *

13. Section 139.155 is amended by revising paragraph (a)(1) to read as follows:

§ 139.155 Enriched noodle products.

(a) * * *

(1) Each such food contains in each pound not less than 4 milligrams (mg) and not more than 5 mg of thiamin, not less than 1.7 mg and not more than 2.2 mg of riboflavin, not less than 27 mg and not more than 34 mg of niacin or niacinamide, not less than 0.9 mg and not more than 1.2 mg of folic acid, and not less than 13 mg and not more than 16.5 mg of iron (Fe);

* * * * *

Dated: September 13, 1993.
David A. Kessler,
Commissioner of Food and Drugs.
[FR Doc. 93-25030 Filed 10-7-93; 2:51 pm]
BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 172

[Docket No. 91N-100F]

Food Additives Permitted for Direct Addition to Food for Human Consumption; Folic Acid (Folacin)

AGENCY: Food and Drug Administration, HHS.

ACTION: Proposed rule.

SUMMARY: The Food and Drug Administration (FDA) is proposing to amend the food additive regulations to set limitations for the use of folic acid on a per serving basis in accord with the Nutrition Labeling and Education Act of 1990 (the 1990 amendments); to allow for the addition of folic acid to foods for which standards of identity exist, where such standards permit the addition of folic acid; to restrict to breakfast cereals the foods, for which standards of identity do not exist, to which folic acid may be added; to continue to permit the use of folic acid in infant formulas, dietary supplements, and foods for special dietary use; and to incorporate specifications for folic acid consistent with those in the Food Chemicals Codex.

DATES: Written comments by December 13, 1993.

ADDRESSES: Submit written comments to the Dockets Management Branch (HFA-305), Food and Drug Administration, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Dennis M. Keefe, Center for Food Safety and Applied Nutrition (HFS-206), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-254-9523.
SUPPLEMENTARY INFORMATION:

I. Background

A. Introduction

The 1990 amendments to the Federal Food, Drug, and Cosmetic Act (the act) provide in section 403(r)(1)(B) (21 U.S.C. 343(r)(1)(B)) that a product is misbranded if it bears a claim that characterizes the relationship of a nutrient to a disease or health-related condition (a "health-claim"), unless the claim is made in accordance with the procedures and standards established under the act. FDA published a final rule on general requirements for health claims on January 6, 1993 (58 FR 2478). The regulation provides that FDA will promulgate regulations authorizing health claims only when it determines, based on the totality of publicly available scientific evidence, that there is significant agreement, among experts qualified by training or experience to evaluate such claims, that the claim is supported by the scientific evidence.

The 1990 amendments required that FDA evaluate 10 nutrient-disease relationships with respect to their appropriateness for health claims; the topic of folic acid and neural tube defects was among those 10 topics. On November 27, 1991, the agency proposed (56 FR 60610) not to authorize the use of a health claim relating to an association between folic acid¹ and neural tube defects on the label or in labeling of foods, including dietary supplements. The agency tentatively concluded that there was not significant agreement among qualified experts that intakes of folic acid at levels permitted under the food additive regulation would be protective against occurrence of neural tube defects in pregnancies of women in the U.S. population.

In September 1992, while FDA's rulemaking was in progress, the U.S. Public Health Service (PHS)

¹ The term "folates" is a generic descriptor for a group of compounds that have nutritional properties and chemical structures similar to those of pterylglutamic acid, the parent form of the vitamins. Synthetic folic acid, added as a fortificant to foods, including dietary supplements, is the oxidized, monoglutamate form of the vitamin.

recommended, based on reviews of existing and newly available scientific data, that all women of childbearing age in the United States who are capable of becoming pregnant should consume 0.4 milligram (mg) (400 micrograms (μ g)) of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects (Ref. 1). The PHS recommendation noted that although all the effects of high intakes of folate are not well known, the effects do include complicating the diagnosis of vitamin B₁₂ deficiency. Therefore, the PHS recommended that care should be taken to keep total folate consumption at less than 1 mg per day except under the supervision of a physician.

On January 6, 1993 (58 FR 2606), the agency published a final rule in which it concluded that a health claim for folic acid and prevention of neural tube defects should not be authorized. The agency reaffirmed its support of the PHS recommendation that all women of childbearing age in the United States who are capable of becoming pregnant consume 0.4 mg of folic acid daily to reduce their risk of having a pregnancy affected with spina bifida or other neural tube defects. The agency noted, however, that questions about the safe use of folic acid in food remained, and the agency concluded that it could not authorize a health claim for folic acid until these questions, among others, were satisfactorily resolved.

Given the seriousness of neural tube defects and the safety and other concerns expressed in the PHS recommendation, FDA convened a subcommittee of its Food Advisory Committee to consider the issues concerning folic acid (hereinafter referred to as the "Folic Acid Subcommittee"). The Folic Acid Subcommittee met in November 1992 and in April 1993. FDA requested that the Folic Acid Subcommittee provide the agency with recommendations on several issues, including identification of the appropriate target population for a folate-neural tube defects health claim, the appropriate daily intake of folate to reduce the risk of neural tube defects, and safety concerns for the target population and the general population. One of the recommendations from the November 1992 meeting of the Folic Acid Subcommittee was that FDA attempt to design a fortification scheme that could provide 90 percent of women of childbearing age with at least 0.4 mg of folate per day from all sources, but would not result in excessively high folate intakes by nontarget groups.

At its April 1993 meeting, following expression of diverse opinions of the potential effectiveness of health claims

as an educational tool and by close votes by the Subcommittee members, the Folic Acid Subcommittee voted to support FDA actions to propose to authorize a health claim for folate and to propose to fortify cereal-grain products with folic acid. Based on the agency's discussion of the uncertainties in the intake data base and the difficulties in predicting bioavailability factors under differing conditions, the Folic Acid Subcommittee supported 1 mg as the safe daily upper limit for total folate from all sources.

The agency has now tentatively concluded, based on the totality of the scientific evidence, that there is significant scientific agreement supporting a relationship between folate and neural tube defects. The agency has also tentatively concluded that fortification of cereal-grains and breakfast cereals with folic acid is an appropriate means to increase the folate intake of women of childbearing age. Therefore, in documents published elsewhere in this issue of the *Federal Register*, FDA is proposing to: (1) Authorize the use on the label or in labeling of foods in conventional food form or of dietary supplements a claim concerning the relationship between folate and reduction in risk of neural tube birth defects (hereinafter referred to as the Health Claim proposal); and (2) require the addition of folic acid to enriched cereal-grain products (hereinafter referred to as the Standards of Identity proposal). The bases for these proposed actions and the safety issues considered by the agency are fully discussed in the Health Claim proposal.

FDA believes that if a health claim for the folate-neural tube defect relationship were authorized, food manufacturers would have an incentive to add folic acid to a wide variety of foods, which could lead to an increase in the intake of folate both by women in their childbearing years and by other segments of the general population. For example, in the *Federal Register* of January 6, 1993 (58 FR 2606), FDA presented an analysis showing that widespread fortification of the food supply with folic acid could lead to individual intakes in the range of 3 to 5 mg or more of folate per day. Because such an increase could bring with it certain risks, the agency is proposing to amend the food additive regulation for folic acid so that authorization of a health claim does not result in unsafe levels of folic acid in the diet.

B. Current Food Additive Regulation

In the *Federal Register* of August 2, 1973 (38 FR 20725), FDA published a final rule establishing safe conditions of

use for folic acid (folacin) in food and dietary supplements under § 121.1134 (21 CFR 121.1134). In determining the safe conditions of use for folic acid, the agency considered the Recommended Dietary Allowance established by the National Academy of Sciences, and other relevant information.

In 1977, § 121.1134 was recodified as § 172.345. The current food additive regulation states:

Folic acid (folacin) may be safely added to a food for its vitamin property, provided the maximum intake of the food as may be consumed during a period of 1 day, or as directed for use in the case of a dietary supplement, will not result in daily ingestion of the additive in excess of 0.4 milligram for foods labeled without reference to age or physiological state; and when age or the conditions of pregnancy or lactation are specified, in excess of 0.1 milligram for infants, 0.3 milligram for children under 4 years of age, 0.4 milligram for adults and children 4 or more years of age, and 0.8 milligram for pregnant or lactating women. (21 CFR 172.345)

The current regulation provides no guidance to manufacturers on how to comply with the stated limits. Information available to the agency, however, establishes that daily intakes of more than 1 mg of folate may place certain subpopulations at increased risk of masking the anemia associated with vitamin B₁₂ deficiencies. Other individuals that may be at risk due to increased intakes of folate include those receiving certain anticonvulsant or antifolate chemotherapies. The potential risks associated with chronic high exposure to folate are discussed in greater detail in the Health Claim proposal published elsewhere in this issue of the *Federal Register*. Thus, the current regulation is inadequate to allocate folic acid safely in the food supply.

Under section 409(c)(3)(A) of the act (21 U.S.C. 348(c)(3)(A)), the so-called "general safety clause" of the statute, a food additive cannot be approved for a particular use unless a fair evaluation of the evidence available to FDA establishes that the additive is safe for that use. FDA regulations grounded in the legislative history of the Food Additives Amendment of 1958 define "safe" as " * * * a reasonable certainty in the minds of competent scientists that the substance is not harmful under the intended conditions of use." (21 CFR 170.3(i)).

Section 409(c)(5)(A) and (c)(5)(B) of the act require the agency to consider, in determining whether a proposed use of an additive is safe, the probable consumption of the additive and the cumulative effect of the additive in the diet of man. In the Health Claim

proposal published elsewhere in this issue of the *Federal Register*, the agency tentatively concludes, based upon the evidence currently available, that 1 mg per day is the safe upper limit of folate intake for all population groups. In light of this tentative conclusion, the agency has considered how it should amend its food additive regulations to establish safe conditions of use of folic acid in the food supply and still achieve the goals recommended by the Folic Acid Subcommittee that the target population, women of childbearing age, should consume at least 0.4 mg per day of folate from all sources while preventing excessively high intakes by nontarget groups.

Given the two goals of ensuring that the target population receives enough folate and ensuring that the general population is not placed at risk, FDA is proposing to amend the food additive regulation for folic acid (folacin) (§ 172.345) to confine the foods to which folic acid may be added to breakfast cereals and foods for which the standards of identity specifically require the addition of folic acid. This proposed rule also explicitly provides for the use of folic acid in infant formulas and in foods used under medical supervision, and does not change the current limitations on the use of folic acid in dietary supplements. Finally, this proposed rule establishes specifications for folic acid for use in food.

C. Safety Issues

The potential risks that may occur if the food supply were heavily fortified with folic acid were discussed in detail by FDA in the *Federal Register* of January 6, 1993 (58 FR 2806), and in the Health Claim proposal published elsewhere in this issue of the *Federal Register*; they are also summarized briefly here.

The ability of folates to mask the anemia of vitamin B₁₂ deficiency is the most widely recognized adverse effect of high intakes of the vitamin. In the presence of excess folic acid and inadequate vitamin B₁₂, the anemia of vitamin B₁₂ deficiency may not develop. However, severe and irreversible neurologic damage may occur and continue to progress (Ref. 2). Because of this risk, FDA has required warning statements in the labeling for oral and parenteral preparations of folic acid for therapeutic use, which statements describe the potential for the masking of pernicious anemia, a manifestation of vitamin B₁₂ deficiency (45 FR 69043, October 17, 1980; 36 FR 6843, April 9, 1971).

The potential for masking the anemia of vitamin B₁₂ deficiency was recognized by the September 14, 1992, recommendation of PHS, which stated: "Because the effects of high intakes are not well known but include complicating the diagnosis of vitamin B₁₂ deficiency, care should be taken to keep total folate consumption at <1 mg per day, except under the supervision of a physician" (Ref. 1).

As discussed in the Health Claim proposal published elsewhere in this issue of the *Federal Register*, vitamin B₁₂ deficiency is not an uncommon condition in the United States, nor is its diagnosis always straightforward. In general, the population most at risk of developing pernicious anemia is the elderly (Ref. 3). However, the average age of onset is variable among different ethnic groups in the United States (Refs. 4, 5, and 6). Other populations for whom high intakes of folate may pose risks include persons with epilepsy or who are taking certain anticonvulsant medications, persons taking drugs that interfere with folate metabolism, and pregnant women. The Health Claim proposal, published elsewhere in this issue of the *Federal Register*, includes a detailed discussion of the risks presented by excessive folate intake.

The agency's overriding responsibility in this food additive rulemaking is to ensure that the amount of folate that people are reasonably expected to consume is safe. The agency has examined the currently available data on the levels of folate that are capable of masking the anemia of vitamin B₁₂ deficiency, and tentatively concludes that the safe upper limit of daily intake of folate for the general population is 1 mg. The agency also tentatively concludes that 1 mg per day is a safe upper limit for other populations at risk. These tentative conclusions are based on: (1) The scientific evidence that the "masking" effect on vitamin B₁₂ deficiency is most likely to occur at levels of folate above 1 mg (see the Health Claim proposal published elsewhere in this issue of the *Federal Register* and Refs. 7 and 8); and (2) the support by the Folic Acid Subcommittee for FDA's use of 1 mg total folate per day as a safe upper limit to guide development of fortification options (Ref. 7); and (3) the PHS recommendation that " * * * care should be taken to keep folate consumption at <1 mg per day, except under supervision of a physician." (Ref. 1). This tentative conclusion concerning the safe daily upper limit for folate intake represents the agency's best scientific judgment at this time. The agency recognizes the significance of

this proposed upper limit to its analysis of the options for fortification of the food supply. FDA further acknowledges that this value may need to be adjusted based upon comments received on the three folic acid proposals.

D. Allocation of Folic Acid in Food Supply

1. Fortification Alternatives

In evaluating various options for increasing the folate intake of women of childbearing age, while at the same time not increasing the risk to the general population, FDA assessed the effect of various fortification and supplementation options on the estimated daily intake of folate. In developing these different options, the agency considered current use of folic acid as a food additive; a possible fortification of food categories that are widely consumed by the general population, e.g., dairy products, fruit juices, and cereal-grains; and dietary supplement use. The Health Claim proposal published elsewhere in this issue of the *Federal Register* discusses in detail the fortification options considered by the agency.

The agency determined, based upon available information, that the only conventional food category that currently enjoys widespread fortification with folic acid is breakfast cereal. The majority of breakfast cereals are fortified at 100 µg per serving (25 percent of the reference daily intake (RDI)). Other breakfast cereals contain 35 to 45 percent of the RDI for folate. There are a few breakfast cereals that contain 100 percent of the RDI for folate. The agency specifically requests comments as to whether there is currently widespread folic acid fortification of other food categories.

The agency also examined current practices with respect to consumption patterns of dietary supplements containing folic acid and the amount of folic acid that is routinely contained in dietary supplements. Many nationwide surveys conducted since 1970 show that 35 to 60 percent of the U.S. population consumes vitamin and mineral supplements. Park et al., (Ref. 9) reported the median potency of folic acid in single nutrient supplements was 125 percent of the RDI (range, 57 to 250 percent). In multinutrient supplements for children, folic acid was added at a level that provides approximately 75 percent of the RDI (range, 2 to 100 percent). The corresponding median potency values for prenatal supplements was 111 percent of the RDI (range, 50 to 125 percent), and for other supplements, 100 percent of the RDI (range, 1 to 500

percent) (Ref. 9). Thus, many supplements currently contain folic acid at or near 100 percent of the RDI (i.e., 0.4 mg or 400 µg for adults). This is consistent with the report by Werler et al. (Ref. 10), who determined that the most common dose of folic acid found in a variety of supplements was 0.4 mg (400 µg or 100 percent of the RDI).

FDA has considered a number of approaches to fortifying the food supply with folic acid. In particular, as described in the Health Claim proposal published elsewhere in this issue of the Federal Register, the agency examined the effect of fortification of the following food categories: Cereal grains, dairy products and fruit juices at 70, 140, and 350 µg folic acid per 100 g of food product. The agency also considered the effect on intake of adding 100 µg or 400 µg folic acid per serving to all breakfast cereals. In addition, in conducting this evaluation, the agency assumed that all dietary supplements contain 400 µg of folic acid. (The agency anticipates that if a health claim is allowed, the majority of dietary supplements will likely contain 100 percent of the RDI for folate (i.e., 400 µg)).

2. Proposed Folic Acid Fortification Approach

Upon examining the estimated folate intakes resulting from the different fortification options and in light of the agency's tentative conclusion that 1 mg per day is the safe upper limit of folate intake for the general population, the agency determined that the fortification scenario that best achieves the two goals of safety and effective delivery to the target population was one that limited the food additive use of folic acid to: (1) Enriched cereal-grains for which there exist standards of identity which authorize the addition of folic acid at 140 µg per 100 g; (2) breakfast cereals at levels up to 100 µg per serving; and (3) dietary supplements at levels up to 400 µg per daily dose, except for those labeled with reference to age or the condition of pregnancy or lactation.

Folic acid fortification of enriched cereal-grains offers the following advantages for delivery of folic acid to the target population: (1) Added folic acid is stable in the products derived from enriched cereal-grains; and (2) consumption of products manufactured with enriched cereal-grains is widespread throughout the population, including the target population. Therefore, the agency has tentatively concluded that folic acid fortification of enriched cereal-grain products is an effective way to increase the folic acid intake of women of childbearing age. Consistent with this tentative

conclusion, in a document published elsewhere in this issue of the Federal Register, the agency is proposing to amend the regulations for the standards of identity of the following enriched cereal-grain products: enriched bread, rolls, and buns (§ 136.115); enriched flour (§ 137.165); enriched self-rising flour (§ 137.185); enriched corn grits (§ 137.235); enriched corn meals (§ 137.260); enriched farina (§ 137.305); enriched rice (§ 137.350); enriched macaroni products (§ 139.115); enriched nonfat milk macaroni products (§ 139.122); and enriched noodle products (§ 139.155).

FDA has tentatively determined that the addition of folic acid to breakfast cereals at levels up to 100 µg per serving is an appropriate means to provide added folic acid because: (1) Breakfast cereal is the only food category that currently enjoys widespread fortification with folic acid and such cereals represent a traditional source of many nutrients, including folic acid, for those who consume them; and (2) due to patterns of consumption, fortification of breakfast cereals at 100 µg folic acid per serving should not result in excessive folate intakes in the nontarget population. FDA considered, and has tentatively rejected, a proposed regulation that would have allowed for addition of up to 400 µg folic acid per serving in breakfast cereal, because this level would have resulted in the estimated daily intake of folic acid among significant portions of the population exceeding what has been tentatively identified as the safe upper limit of 1 mg per day. These excess levels would have occurred even in the absence of the fortification of enriched cereal-grains.

The agency has tentatively concluded that it should continue to allow the addition of folic acid up to 400 µg per daily dose in dietary supplements because: (1) There is a documented history of safe use of dietary supplements at this level (Ref. 9), and (2) dietary supplements containing higher levels of folic acid are not appropriate except in specific circumstances (i.e., conditions of pregnancy or lactation) because of the identified safety concerns, particularly the masking of vitamin B₁₂ deficiencies.

As noted above, in developing this proposal, the agency examined several fortification scenarios. In tentatively choosing a fortification approach, the agency's concern was the safety of the food supply. FDA recognizes that it is impossible for the agency to examine all possible fortification scenarios. The agency requests comments on possible alternative fortification approaches that

will achieve FDA's dual goals of maximizing delivery of folate to the target population and ensuring the safety of such uses of folic acid. Thus, comments on alternative fortification schemes should address issues related to the safety of the exposures that would result from the proposed alternative scheme.

E. Proposed § 172.345

In this rulemaking, the agency is proposing to: (1) Establish a limitation for the addition of folic acid to breakfast cereals, of 0.1 mg folic acid per serving; (2) retain current limitations for the use of folic acid in dietary supplements; (3) permit the addition of folic acid to foods as authorized by standards of identity established under section 401 of the act (21 U.S.C. 341); (4) explicitly allow for the use of added folic acid in infant formulas and in foods to be used under medical supervision; and (5) establish specifications for folic acid that are consistent with those in the Food Chemicals Codex (3d ed.) (Ref. 9).

1. The agency is proposing in § 172.345(d) to limit the added folic acid in breakfast cereals, as defined under 21 CFR 170.3(n)(4), to 100 µg per serving.

FDA recognizes that this proposed action will have the effect of requiring the reformulation of a small number of breakfast cereals. It is not the agency's desire to have such an effect, but it appears to be unavoidable given the data and information currently available to the agency. The agency is prepared to reconsider this approach for breakfast cereals if interested persons submit comments that provide data or other information demonstrating that even with higher fortification of breakfast cereals, folate consumption can be kept within safe limits.

The agency is particularly interested in obtaining substantive comments on the fortification option tentatively chosen by the agency. In addition, FDA expressly seeks: (1) Comments on the use of 1 mg per day total folate as a safe upper limit for establishing restrictions on food additive uses of folic acid; (2) comments that address issues related to folic acid intake and adverse effects; and (3) comments that provide information pertaining to the proposed limitations of 100 µg per serving of folic acid in breakfast cereals.

FDA recognizes that some may find an inequity in the agency's treatment of dietary supplements, with respect to which the agency is proposing to allow continued marketing of a 400 µg folic acid supplement, as compared to the agency's treatment of breakfast cereals, with respect to which FDA is proposing to establish a 100 µg per serving limit

for folic acid. FDA has tentatively determined that this approach is appropriate because supplements tend to be used to supplement the diet for specific purposes, while breakfast cereals are used more generally as part of the overall diet. However, the agency specifically requests comments on this issue. Although comments may suggest alternate approaches, such comments will be most useful if they explain how the suggested approach will ensure that total dietary intake of folate will remain within what are shown to be safe levels.

The agency finds that current limitations based on daily intake levels for added folic acid are impractical and require clarification, especially if a health claim is authorized. In light of the recent establishment of new food labeling format requirements (58 FR 2079, January 6, 1993), FDA also finds that establishing limitations based on a "per serving" basis would be more consistent with the new food labeling format and more informative because it would provide the consumer with a consistent basis upon which the nutritive value of food products can be compared. Therefore, the agency is proposing to amend the language of its regulation to establish use limitations on a "per serving" basis.

2. In § 172.345(f), the agency is proposing to maintain current limitations on the use of folic acid in dietary supplements. As discussed in the Health Claim proposal published elsewhere in this issue of the **Federal Register**, the agency has concluded that the current limitation of 400 µg per daily dose in supplements labeled without reference to age or physiological status is safe and the agency does not anticipate that unsafe intakes of folate will occur if the current limitation is maintained.

3. In § 172.345(c), the agency is proposing to amend the current food additive regulation to allow for addition of folic acid in accordance with standards of identity established under section 401 of the act. In the Standards of Identity proposal published elsewhere in this issue of the **Federal Register**, the agency is proposing to amend the standards of identity for a number of cereal-grain products to require folic acid fortification at a level of 140 µg per 100 g.

4. In § 172.345(e), the agency is proposing to amend the current food additive regulation by explicitly permitting addition of folic acid to infant formulas, consistent with section 412 of the act and regulations promulgated thereunder.

5. In § 172.345(g), the agency is proposing to amend the current food

additive regulation by exempting foods used under medical supervision from limitations, other than good manufacturing practices, on the amount of folic acid that may be added.

6. In § 172.345(b), the agency is proposing to amend the current food additive regulation by incorporating by reference specifications for folic acid added to food to make the regulation consistent with the Food Chemicals Codex specifications (Ref. 11).

The agency tentatively concludes that this proposed rule provides a reasonable certainty of no harm because, as discussed above and in the Health Claim proposal, the estimated daily intakes of folate in the population do not exceed 1 mg per day, which is the level that has been tentatively identified as the safe upper limit of exposure.

II. Environmental Impact

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

Because the agency is proposing three actions involving folic acid and the net effect of these actions is likely to increase the use of folic acid, one environmental assessment has been prepared, which considers all three proposed actions.

III. Economic Impact

FDA has examined the economic implications of the proposed rule as required by the Regulatory Flexibility Act and Executive Order 12291. The Regulatory Flexibility Act (Pub. L. 96-354) requires regulatory relief for small businesses where feasible. Executive Order 12291 compels agencies to use cost-benefit analysis as a component of decisionmaking, where permitted by law. The agency finds that this proposed rule is not a major rule as defined by Executive Order 12291. In compliance with the Regulatory Flexibility Act, FDA certifies that the proposed rule will not have a significant impact on a substantial number of small businesses.

The agency is proposing to restrict the use of folic acid as a food additive only to breakfast cereals, dietary supplements, foods for special dietary use, infant formula, and any standardized foods which are required to contain folic acid. If the proposed

rule is finalized, some products that currently contain folic acid as an ingredient will have to be reformulated because they do not fall into the categories listed above. The agency does not have information on how many products will have to be reformulated. However, as far as FDA is aware, the only intended technical effect of adding folic acid to food is to supplement the nutritional content of the food. Thus, the reformulation should not be costly nor should it have any measurable adverse impact on the consumer demand for the products. FDA estimates the cost of the proposed rule to be minimal.

FDA is proposing to take this action in order to prevent health risks associated with high intakes of folate in the event that the standards of identity for enriched grain products are amended to require the addition of folic acid and that a health claim is permitted for folates and neural tube defects. FDA is not able to quantify the benefit of the proposed rule because it is not able to estimate the extent to which folate health claims will be made or the effect that claims will have on consumer demand for products containing added folic acid.

IV. Comments

During the comment period for this proposal, the agency intends to convene public meetings of the Folic Acid Subcommittee and the Food Advisory Committee for a discussion of the issues raised in this document, as well as the Health Claim proposal and the Standards of Identity document. FDA also intends to request comments from the experts who participated in its November 23 and 24, 1992, meeting of the Folic Acid Subcommittee. The agency will make any comments received from these experts available for public review and comment. In addition, FDA will endeavor to have copies of the transcripts of the Folic Acid Subcommittee and Food Advisory Committee meetings available as quickly as possible.

Interested persons may, on or before December 13, 1993, submit to the Dockets Management Branch (address above) written comments regarding this proposal. Two copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the docket number found in brackets in the heading of this document. Received comments may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

V. 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.

1. Centers for Disease Control, "Recommendations for the Use of Folic Acid to Reduce the Number of Cases of Spina Bifida and Other Neural Tube Defects," *Morbidity and Mortality Weekly Reports*, 41:1-7, 1992.

2. Butterworth, C. E., and T. Tamura, "Folic Acid Safety and Toxicity: A Brief Review," *American Journal of Clinical Nutrition*, 50:353-358, 1989.

3. Herbert, V., N. Coleman, and E. Jacob, "Folic Acid and Vitamin B₁₂," in *Modern Nutrition in Health and Disease*, 6th ed., edited by Goodhart, R. S. and M. Shils, Lea and Febiger, Philadelphia: pp. 249-250, 1980.

4. Carmel, R., and S. C. Johnson, "Racial Patterns in Pernicious Anemia: Early Age at Onset and Increased Frequency of Intrinsic Factor Antibody in Black Women," *New England Journal of Medicine*, 296:647-650, 1978.

5. Solanki, D. L., R. J. Jacobson, and R. J. Green, et al., "Pernicious Anemia in Blacks: A Study of 64 Patients From Washington, DC and Johannesburg, South Africa," *American Journal of Clinical Pathology*, 75:96-99, 1981.

6. Sinow, R. M., C. S. Johnson, and D. S. Karnaze, et al., "Unsuspected Pernicious Anemia in a Patient With Sickle Cell Disease Receiving Routine Folate Supplementation," *Archives of Internal Medicine*, 147:1828-1829, 1987.

7. Transcript of meeting of the Food Advisory Committee, Subcommittee on Folic Acid, November 23-24, 1992.

8. Transcript of meeting of the Food Advisory Committee, Subcommittee on Folic Acid, April 15, 1993.

9. Park, Y. M., I. Kim, and E. A. Yetley, "Characteristics of Vitamin and Mineral Supplement Products in the United States," *American Journal of Clinical Nutrition*, 54:750-759, 1991.

10. Werler, M. M., S. Shapiro, and A. A. Mitchell, "Periconceptional Folic Acid

Exposure and Risk of Occurrent Neural Tube Defects," *Journal of the American Medical Association*, 269:1257-1261, 1993.

11. Food Chemicals Codex, 3d ed., pp. 125 and 126, Washington, DC: National Academy Press, 1981.

List of Subjects in 21 CFR Part 172

Food additives, 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 21 CFR part 172 be amended as follows:

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

1. The authority citation for 21 CFR part 172 continues to read as follows:

Authority: Secs. 201, 401, 402, 409, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 341, 342, 348, 371, 379e).

2. Section 172.345 is revised to read as follows:

§ 172.345 Folic acid (folacin).

Folic acid (CAS Reg. No. 59-30-3), also known as folacin or folate, may be safely used in food as a nutrient in accordance with the following prescribed conditions:

(a) Folic acid is the chemical N-[4-[[[(2-amino-1,4-dihydro-4-oxo-6-pteridiny)]methyl]amino]benzoyl]-L-glutamic acid.

(b) Folic acid meets the specifications of the Food Chemicals Codex, 3d Ed. (1981), pp. 125 to 126, which is incorporated by reference in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from the National Academy Press, 2101 Constitution Ave. NW., Washington, DC 20418, or may be examined at the Office of the Federal Register, 800 North Capitol St. NW., suite 700, Washington, DC.

(c) Folic acid may be added to foods as authorized by standards of identity established under section 401 of the act.

(d) Folic acid may be added, at levels not to exceed 100 micrograms (µg) per serving, to breakfast cereals, as defined under § 170.3(n)(4) of this chapter.

(e) Folic acid may be added to infant formula in accordance with section 412(i)(2) of the Federal Food, Drug, and Cosmetic Act (the act) or with regulations promulgated under section 412(b)(1) of the act.

(f) Folic acid may be added to a dietary supplement that is a food, other than in conventional food form, that supplies a component with nutritive value to supplement the diet by increasing the total dietary intake of folic acid, provided that the maximum intake as directed for use will not result in daily ingestion of the additive in excess of 400 µg for foods labeled without reference to age or physiological state; and when age or conditions of pregnancy or lactation are specified, daily ingestion of folic acid may not exceed 100 µg for infants, 300 µg for children under 4 years of age, 400 µg for adults and children 4 or more years of age, and 800 µg for pregnant or lactating women.

(g) Folic acid may be added to special dietary foods that are intended for use solely under medical supervision to meet nutritional requirements in specific medical conditions and that comply with the requirements of part 105 of this chapter. Folic acid may be used in such foods at levels not to exceed the amount reasonably required to accomplish its intended nutritive effect.

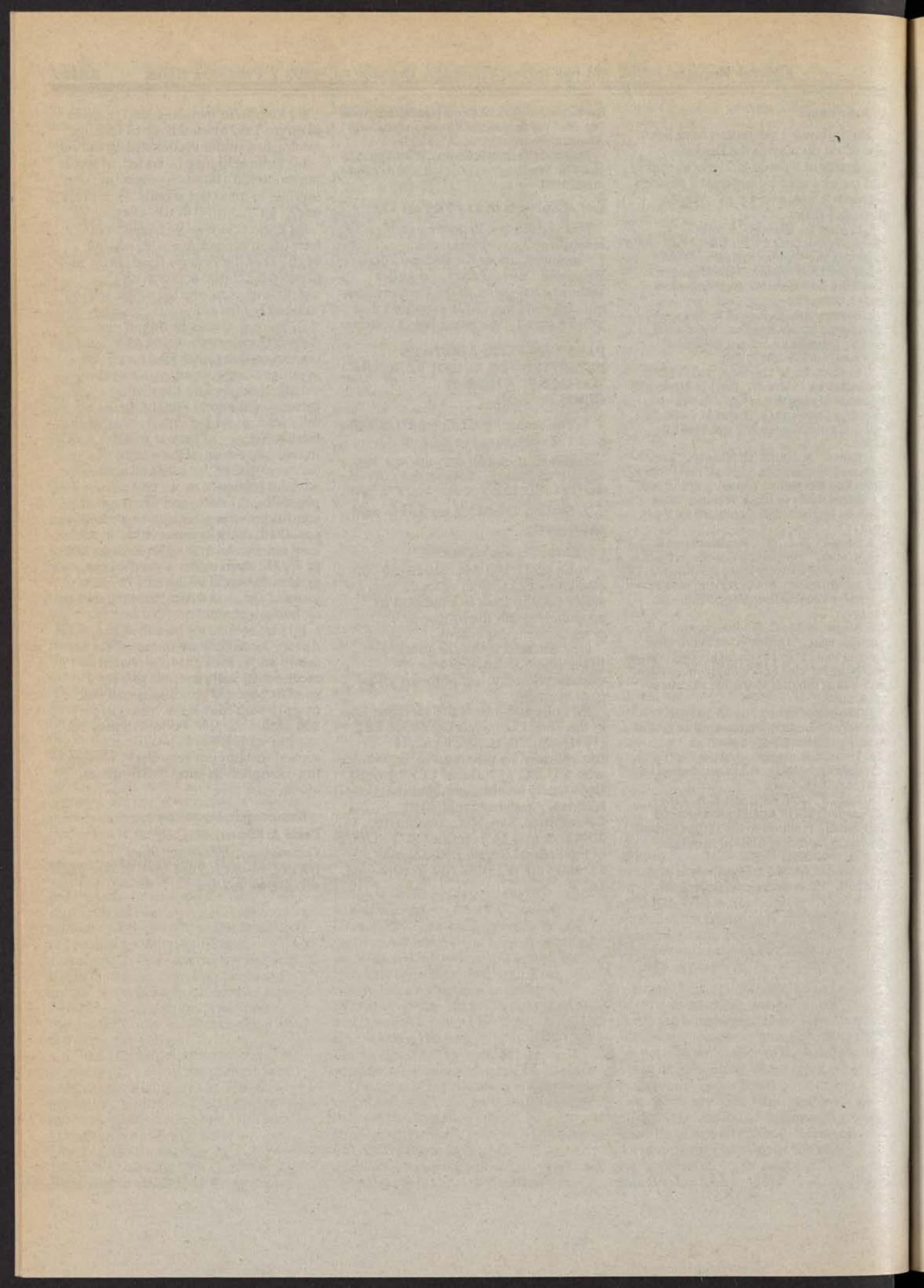
Dated: September 13, 1993.

David A. Kessler,

Commissioner of Food and Drugs.

[FR Doc. 93-25028 Filed 10-7-93; 2:51 pm]

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federal register

Thursday
October 14, 1993

Part IV

Department of Commerce

**National Oceanic and Atmospheric
Administration**

**50 CFR Parts 215, 216, and 222
Protected Species Special Exception
Permits; Proposed Rule**

DEPARTMENT OF COMMERCE

National Oceanic and Atmospheric Administration

50 CFR Parts 215, 216, and 222

[Docket No. 930404-3104; I.D. 122492C]

RIN 0648-AD11

Protected Species Special Exception Permits

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

ACTION: Proposed rule and request for comments.

SUMMARY: NMFS is proposing to amend the regulations for permits to: Take or import marine mammals for the purposes of scientific research, public display, or enhancing the survival or recovery of a marine mammal species or stock (enhancement) under the Marine Mammal Protection Act of 1972 (MMPA); take, import, export, or carry out any other otherwise prohibited act concerning endangered or threatened species for scientific purposes or to enhance the propagation or survival of the affected species (enhancement) under the Endangered Species Act of 1973 (ESA); and take, import, export, possess, or transport North Pacific fur seals for educational, scientific, or exhibition purposes under the Fur Seal Act of 1966 (FSA). These proposed revisions would update and consolidate existing permit regulations that have been promulgated for these purposes under the MMPA, ESA, and FSA (the Acts), implement amendments to the MMPA enacted November 23, 1988, and clarify when a permit is required and the scope and extent of permit authority under the Acts. Provisions would be added regarding permits under the MMPA and ESA to take, import, export or carry out other activities that would otherwise be prohibited concerning protected species (i.e., marine mammals and endangered or threatened species) for the purpose of enhancement. Further revisions would include permit-specific and generally applicable terms and conditions, clarified permit requirements and review procedures, amendments to the criteria for deciding whether to issue or deny permits, and revised administrative requirements and procedures. These revisions are intended to provide a comprehensive regulatory foundation for these special exception permits and to make administration of the NMFS permit program more efficient, consistent, and

predictable. NMFS is proposing to consolidate these permit regulations under a single part of title 50 CFR.

DATES: Comments on this proposed rule must be postmarked or received by December 13, 1993. Notice of the dates and time, and location of public hearings will be published in the Federal Register. A public briefing will be held on November 3, 1993, 1 p.m. to 5 p.m.

ADDRESSES: Comments on this proposed rule may be mailed to the Permits Division; Office of Protected Resources; National Marine Fisheries Service, NOAA; 1315 East-West Highway, SSMC III; Silver Spring, MD 20910. The public briefing will be held at the NOAA Auditorium; 1305 East-West Highway, SSMC IV; Silver Spring, Maryland 20910.

FOR FURTHER INFORMATION CONTACT: Art Jeffers or Ann Terbush, Permits Division, Office of Protected Resources, National Marine Fisheries Service, Silver Spring, Maryland, 301/713-2289. If you need accommodations to attend the public briefing or public hearings, please call Ann Hochman on 301/713-2289 (voice). People who are deaf or hearing impaired may place a call through the Maryland Relay Service on 1-800-735-2258.

SUPPLEMENTARY INFORMATION:

General Background and Statutory Information

The MMPA (16 U.S.C. 1361 *et seq.*) sets forth as one of its purposes the protection and management of marine mammal populations and establishes, with limited exceptions, a moratorium on the taking of marine mammals by persons subject to U.S. jurisdiction. The MMPA also prohibits importation of marine mammals except under specific circumstances. On November 23, 1988, extensive amendments to the MMPA were enacted (Pub. L. 100-711). Among other things, the amendments modified the requirements for issuing permits for the take or import of marine mammals for scientific research and public display purposes, and added new provisions for the issuance of permits for enhancing the survival or recovery of a species or stock (enhancement).

The ESA (16 U.S.C. 1531 *et seq.*) sets forth as its purpose the conservation of endangered species, threatened species, and the ecosystems upon which these species depend. The ESA makes it unlawful, with limited exceptions, for persons subject to U.S. jurisdiction to import, export, take, or engage in interstate or foreign commerce affecting endangered species, or to violate any regulation promulgated under the ESA

pertaining to such species or to any threatened species. Limited exceptions include activities authorized by permits for scientific purposes or by permits to enhance the propagation or survival of the affected species (enhancement).

The FSA (16 U.S.C. 1151 *et seq.*) makes it unlawful, with limited exceptions, for any person or vessel subject to U.S. jurisdiction to take, import, export, offer for sale, or possess North Pacific fur seals or their parts. Limited exceptions include activities authorized by permits to take, import, export, transport, or possess fur seals or their parts for educational, scientific, or exhibition purposes, and takings for subsistence use under limited conditions.

Permits may be issued under each of the Acts for purposes of scientific research and under both the MMPA and ESA for purposes of enhancement. Permits may be issued for purposes of public display under both the MMPA and the FSA.

(Note: North Pacific fur seals (Pribilof Island population) have been designated as depleted under the MMPA, and as a consequence, NMFS will not issue permits to capture North Pacific fur seals (Pribilof Island population) from the wild for purposes of public display until they have recovered and are no longer designated as depleted.)

NMFS is proposing to consolidate regulations for permits for these purposes under 50 CFR part 216 and replace corresponding permit sections in 50 CFR parts 215 and 222 with references to 50 CFR part 216.

The term "protected species" refers to species subject to the jurisdiction of NMFS under the Acts. These species include marine mammals (including North Pacific fur seals), marine species determined to be endangered under the ESA, and species determined to be threatened under the ESA for which prohibitions, restrictions, or other protective measures have been established through regulation.

(Note: Captive maintenance provisions are proposed to be generally applicable to marine mammals under the Acts, and are proposed to have strictly limited applicability to other endangered or threatened species under the ESA; for example, endangered or threatened species of marine and anadromous fish or marine reptiles.)

Permit Program Review

Because of numerous issues and questions arising from approximately 17 years of administration of the permit program and the 1988 amendments to the MMPA, NMFS initiated a comprehensive Permit Program Review in March 1989 (54 FR 13099, March 30,

1989). At that time, a discussion paper ("Permit Policies and Procedures for Scientific Research and Public Display under the Marine Mammal Protection Act and the Endangered Species Act," Office of Protected Resources and Habitat Programs, NMFS) was released for public distribution along with a request for comments on the issues raised in the paper. The objectives of the Permit Program Review were to:

1. Clarify and confirm the policies that should govern the overall direction of the permit program;
2. Develop criteria and procedures that are clear, consistent, and responsive to applicant and public concerns;
3. Determine what documentation is needed for all permits to satisfy the requirements of the National Environmental Policy Act (NEPA);
4. Establish administrative procedures that result in a more streamlined and efficient process; and
5. Revise existing permit regulations in order to implement these improvements and the 1988 amendments to the MMPA.

Seven working sessions were held between October 1989 and January 1990. The topics for discussion were the definition of public display, scientific research permits, care and maintenance of captive marine mammals, education and conservation programs for the public display of marine mammals, and NEPA.

These working sessions provided an opportunity for permit holders in the scientific and public display communities, as well as members of the public interested in protected species, to actively participate in Permit Program Review discussions. Representatives of the Marine Mammal Commission (MMC), the U.S. Fish and Wildlife Service (FWS), and the Animal and Plant Health Inspection Service (APHIS) participated in the working sessions, submitted comments on the Discussion Paper, and were consulted concerning specific aspects of the permit program.

The results of the working sessions, together with 312 letters received in response to the discussion paper, helped NMFS identify areas of the permit program in the greatest need of improvement. These areas include NMFS' administrative tools and procedures, changes to which would not require revisions to permit regulations, such as the Instructions to Applicants, communication with applicants, and database management. NMFS also identified policy and procedural areas in need of improvement that would require revision of existing permit regulations. In considering these needed improvements and revisions, NMFS

reexamined the Acts and their legislative histories to ensure that any proposed revisions were consistent with their respective purposes, policies, and provisions. Review of the MMPA and its legislative history was a particular emphasis in this reexamination.

During the Permit Program Review and reexamination of the Acts, NMFS identified a number of major issues that should be addressed through revised regulations. As a result of extensive discussion and analysis during the Permit Program Review, NMFS developed proposed policies that became the goals for the revised regulations. These proposed policies and goals are discussed in the following section.

Issue Analysis

I. General Goals

1. Establish Basic Permit Conditions and Reporting Requirements Common to all Permits

The existing regulations do not include basic permit conditions and reporting requirements. The conditions and reporting requirements that are included in existing permits as both special and general conditions have not always been clearly understood by permit holders or been administered consistently by NMFS. For example, two permits authorizing identical activities may contain different special conditions affecting reporting, other administrative requirements, and how the permitted activity may be conducted. While the general permit conditions have been essentially consistent in the past, they have frequently been a source of permit holder confusion as to how these general conditions apply to their particular permitted activity. Also, because of the lack of specificity in many of the existing general conditions, and the resulting frequent case-by-case manner in which NMFS has been compelled to interpret them, they have not been administered or enforced in a consistent or predictable fashion. The existing general permit conditions were developed without public review and comment and, in a time of increased public scrutiny of the permit program, NMFS has received numerous questions and criticisms regarding their specificity and adequacy.

The proposed regulations include provisions for standard permit-specific conditions and would allow the creation of supplementary permit-specific conditions that would be tailored to the circumstances of each permit. The proposed regulations also contain general conditions and reporting

requirements that would be applicable to all existing and future permits. Improved permit holder understanding and consistent permit program administration should facilitate compliance with permit terms and conditions.

2. Establish Clear Issuance Criteria and Terms and Conditions Specific to Public Display, Scientific Research, and Enhancement Permits

The existing regulations do not clearly distinguish between terms, conditions, and issuance criteria generally applicable to all types of permits from those specific to public display, scientific research, or enhancement permits. This has sometimes proven confusing to permit applicants trying to discern what information and other requirements are applicable to a proposed activity. It has also sometimes resulted in delays in the review and processing of applications, both because of the frequent need to assist applicants in discerning what requirements are applicable and because applications must frequently be returned because they lack information or the information submitted is inappropriate. Additionally, permit holders have been forced to sort through all generally applicable terms and conditions and decide for themselves which of these conditions are not applicable; an incorrect decision in this regard involves significant risk of permit violation.

NMFS is proposing to correct these problems by separating generally applicable permit requirements from those that are specific to a particular type of permit. Therefore, in these proposed regulations, permit issuance criteria, restrictions, and conditions generally applicable to all permits are presented separately from those specific to public display, scientific research, or enhancement permits. In addition, in order to enhance readability, permit terms and conditions have been grouped into separate sections in a manner reflecting their different procedural and substantive purposes; see §§ 216.36 through 216.39 of the proposed regulations and the amendment procedures of § 216.40 discussed in section I.5. of this preamble.

3. Establish Eligibility Requirements for Permit Applicants and Holders

Due to an absence of clear eligibility criteria for permit applicants in the existing regulations, questions frequently arise over who is an appropriate permit applicant. The absence of guidance has resulted in NMFS providing sometimes conflicting

information to potential applicants as to whether they are appropriate candidates for a permit. To try to minimize these problems in the future, these proposed regulations contain "eligibility criteria" for applicants.

NMFS is proposing that eligible applicants for public display permits would be limited to facilities. Related to this limitation, a definition of "facility" is proposed. In the past, NMFS allowed any person to apply for a public display permit to take or import marine mammals, regardless of whether that person owned and controlled or was responsible for management and operation of the public display facility, or simply had custody of marine mammals that were displayed at facilities owned by others. This led to differing administration of public display permits held by individuals and by facilities. For example, some permit holders maintaining marine mammals at more than one facility would move marine mammals between facilities without NMFS' knowledge, which has caused difficulties in ensuring that transfer/transport is properly authorized. Not surprisingly, this has also made it difficult to monitor the location and movement of marine mammals. Further, it has caused problems in ensuring that individual permit holders with the responsibility for captive marine mammals provide proper care and maintenance when those individuals do not control the facility at which the marine mammals are displayed. NMFS has concluded that, since all public display activities involve captive maintenance of marine mammals, the most efficient and effective way to avoid the problems of the past is to restrict eligible public display permit applicants to facilities (see the proposed definitions of public display and facility discussed under II.1. and II.4. of this preamble).

For scientific research and enhancement permits, NMFS is proposing that eligible applicants would be the principal investigator or, under certain circumstances, the appropriate institution, governmental entity, or corporation responsible for the supervision of the principal investigator. If the research involves co-investigators, a single principal investigator, who will be primarily responsible for the special exception activity, would be identified as the applicant. The reason for these limitations on eligible applicants is to ensure accountability for activities conducted under the authority of a permit. By making the principal investigator or the entity responsible for the supervision of the principal

investigator the permit holder, it is hoped that care will be exercised by the permit holder when choosing others to conduct activities on the permit holder's behalf. Co-investigators, such as the principal investigator's on-site representative, could be designated as agents in the permit and would thus also be responsible for the special exception activity authorized by the permit. Persons or groups of people totally removed from and not responsible for conducting the actual proposed scientific research or enhancement activities would not be eligible applicants.

Consistent with the "facility" approach for public display permits, where the proposed scientific research or enhancement activity involves captive maintenance in a facility, temporary pen, or other temporary enclosure, the permit application would be required to include a supporting statement from the person responsible for the facility or other temporary enclosure.

4. Establish a Process to Ensure that the Requirements of the National Environmental Policy Act of 1969 (NEPA) are Addressed During Permit Application Review and the Decision-Making Process

NMFS has reexamined the manner in which applicable NEPA requirements are addressed during the special exception permit decision-making process—including whether categorical exclusions (CEs) apply, or whether environmental assessments (EAs) or environmental impact statements (EISs) are required. This reexamination stemmed in part from two Federal court decisions—*Jones v. Gordon*, 621 F.Supp. 7 (D. Alaska 1985), modified 729 F.2d 821 (9th Cir. 1986); *Greenpeace, U.S.A. v. Evans*, 688 F. Supp. 579 (W.D. Wash. 1987). Under the MMPA, NMFS had issued permits authorizing captures of killer whales (*Orcinus orca*) for public display and scientific research purposes and authorizing scientists to collect biopsy samples from killer whales in Puget Sound. The issuance of these permits was challenged on the grounds that NMFS had failed to address NEPA concerns adequately. The courts discussed NMFS' blanket determination that the issuance of the permits qualified for CEs from the NEPA requirement to prepare an EA or an EIS because the issuance of permits, as a class of actions, does not have a significant effect on the human environment. The courts disagreed with NMFS' determination, finding that NMFS had violated NEPA by failing to

prepare an EA or EIS in light of the controversy over the potential environmental effects of the proposals. The courts found that the elements of controversy surrounding the environmental effects of the proposals indicated that they might not be eligible for a CE, especially in the absence of any evidence that NMFS had addressed the potential environmental effects of the proposals in a reasoned manner.

These two decisions made it clear that, while the issuance of permits under section 104 of the MMPA and section 10 of the ESA may often qualify for a CE, such is not always the case. Where factors such as unusual controversy over potential environmental effects exist, NMFS must have enough information to make a reasoned decision as to whether the proposed activity qualifies for a CE or requires the preparation of an EA or EIS. Such a decision must be explained in the administrative record.

This reassessment resulted in two major NEPA considerations being reflected in these proposed regulations. The first is that an initial decision consistent with the requirements of NEPA would be made before publication of the notice of receipt of a permit application in the Federal Register and the opening of the public comment period. This initial NEPA analysis would result in a decision either that a permit decision is categorically excluded from further environmental impact assessment under NEPA, an EA has been prepared resulting in a finding of no significant impact, or an EIS has been completed on the proposed issuance of a permit.

The reason for proposing to reach a CE decision or prepare an EA/EIS before publishing the notice of receipt of a complete permit application in the Federal Register is to comply with the time constraints of the MMPA and those established in existing ESA regulations. Section 104(d)(2) of the MMPA and 50 CFR 222.24(a) of the existing ESA permit regulations state that, upon publication of the notice of receipt of the application in the Federal Register, a 30-day public comment period begins. Section 104(d)(5) of the MMPA requires the Assistant Administrator for Fisheries, NOAA (AA), to make a decision either to issue or deny issuance of a permit within 30 days of the close of a public hearing, or, if no hearing is held, within 30 days of the close of the public comment period. 50 CFR 222.24(c) of the existing ESA regulations requires the AA to issue or deny issuance of a permit within 30 days of the close of the public hearing or as soon as practicable after the close of the

30-day public comment period. If, during the public comment period or as a result of a public hearing, it became evident that more NEPA analysis is required, there would be no practicable way to obtain and analyze the necessary information within the 30-day decision window. Since the AA would not have the necessary information to allow a decision to issue a permit within the statutory time period in the case of the MMPA or the regulatory time period in the case of existing ESA regulations, the AA would be forced to deny issuance of a permit. This time problem caused by the requirements of section 104(d) of the MMPA, and 50 CFR 222.24(c) of existing ESA regulations, can be avoided if the necessary NEPA analysis has been completed before the 30-day public comment period begins. If, however, after publishing a notice of receipt with an initial NEPA determination that the proposed activity is categorically excluded from the requirement to prepare an EA or an EIS, or that an EA had been prepared resulting in a finding of no significant impact, the AA determines on the basis of new information regarding the impact of the proposed activity on the human environment that an EA or EIS must be prepared, the AA must deny the permit; unless an EA is prepared and a finding of no significant impact is made before the AA must make a decision to issue or deny the permit. If a permit is denied under these circumstances, the application may be resubmitted with information sufficient to prepare the required EA or EIS, and will be processed as a new application.

The second NEPA consideration reflected in the proposed regulations is that the applicant for a permit would be responsible for submitting information adequate for NMFS to address NEPA concerns and, where NMFS determines that additional information is necessary, the applicant would be responsible for providing that information. NMFS believes the permit applicant is in the best position to describe the proposed activity. In planning the activity, the applicant should have obtained information regarding the status of the species and stock of protected species and the associated marine ecosystem to be affected by the proposed activity, other activities affecting or that may affect the same protected species and associated marine ecosystem, and the likely individual and cumulative effects of the proposed activity. This information is necessary to ensure that an applicant's proposed activity is designed in consideration of these factors and that the taking of protected

species proposed is only that required to meet the objectives of the activity. NEPA also provides that an agency may require an applicant to submit environmental information for use by that agency in complying with NEPA requirements.

5. Develop a Straightforward, Predictable Permit Amendment Procedure

In the past, different procedures have been followed depending on the circumstances of each "modification" request to make changes in the terms or conditions of permits; such as extending the time period for which a permit is valid, adding species or increasing numbers of protected species authorized to be taken or imported, changing scientific sampling methods, and other non-punitive, administrative alterations. However, section 104(e) of the MMPA discusses "modification" of permits only in cases where violations of the terms and conditions of the permit have occurred, or where circumstances have changed due to the promulgation of subsequent regulations. Section 104(e) does not suggest that permits can be "modified" for non-punitive reasons that do not respond to newly promulgated regulations.

During the Program Review, it was recognized that a straightforward permit amendment procedure was needed to address non-punitive, administrative alterations in permit terms and conditions. Under these proposed regulations, the "modification" procedure would be limited to the two types of situations listed in section 104(e) of the MMPA (also see 15 CFR part 904). Pursuant to the authority granted by section 112(a) of the MMPA to "prescribe such regulations as are necessary and appropriate to carry out the purposes of [the MMPA]" and section 10(a)(1) of the ESA that "[t]he Secretary may permit, under such terms and conditions as he shall prescribe * * *," NMFS is proposing a permit amendment procedure that distinguishes between major amendments that would require public notice and comment equivalent to that for a permit application, and minor amendments that would not require public notice and comment.

This proposed mechanism would designate as major amendments those alterations to permits that involve changes in permit-specific conditions regarding (1) the numbers or species of protected species authorized to be taken or imported, (2) changes in the type or level of take that could result in increased jeopardy to protected species or protected species populations, (3) the

location in which the take is to occur or from/to which the import/export is to be made, or (4) time extensions of more than 12 months. Essentially, major amendments would be changes to fundamental permit-specific terms and conditions. For permits under the MMPA, these fundamental terms and conditions are listed in section 104(b)(2) of the MMPA. Just as the MMPA and ESA require a formal process of public review and comment for permit applications, NMFS is proposing that major amendments also should be subject to the same level of formal public review and input.

Minor amendments would be any change to a permit that is not a major amendment and would not require a formal opportunity for public review and comment. NMFS is proposing that minor amendments involve only permit changes that do not alter the permit-specific conditions that NMFS considers fundamental elements of a special exception permit and which, for permits under the MMPA, are listed in section 104(b)(2) of the MMPA.

Both major and minor amendments would be authorized by the AA only if it were determined that the amendment is consistent with the applicable Acts and all applicable regulations. Amendments could either be requested by a permit holder or proposed by the AA. As discussed previously, procedures similar to those used for processing permit applications would apply to major amendments, including public notice and comment, public hearings where warranted, and, for MMPA permits, review by the MMC. Minor amendments requested by permit holders could be approved or denied by the AA. However, for MMPA permits, the AA would consult with the MMC prior to approving or denying a minor amendment in the case of scientific research and enhancement permits.

Major amendments proposed by the AA would also go through a public notice and comment process similar to that for permit applications, giving both the permit holder and the public the ability to request hearings and seek judicial review of decisions to make or deny major amendments. Minor amendments proposed by the AA would afford the permit holder the right to submit written objections and to request a hearing. A hearing could be held at the discretion of the AA, either with or without a request from the permit holder.

6. Develop Reasonable, Appropriate Fees Charged for Permits and Permit-Related Activities

Section 104(g) of the MMPA directs the Secretary of Commerce (Secretary) to "establish and charge a reasonable fee for permits issued under this section." No further guidance as to what is "reasonable" appears in the MMPA or its legislative history. Section 10(a)(1) of the ESA states simply that the Secretary may issue permits "under such terms and conditions as he shall prescribe," and a provision for a "reasonable fee" is included in ESA regulations that presently implement this section of the law (50 CFR 222.23(d)(8)). The FSA, in section 104, provides that the Secretary shall permit special exception activities "subject to such terms and conditions as he deems desirable."

The fees that are presently charged for permits (i.e., \$25 for scientific research permits and \$200 for public display permits) have remained essentially unchanged for approximately 20 years. Fee receipts are deposited directly to the General Fund of the United States Treasury and are not used in the direct support of permit program administration. NMFS considered many types and amounts of permit fees to be proposed in these regulations, including fees linked to, for example, per animal charges, fair market value, percentage of gate/attendance receipts, type of take, or administrative processing time. NMFS is requesting comments on alternative methods for establishing reasonable permit fees.

For the purpose of soliciting comments, and as a proposed reasonable basis and mechanism for assessing permit fees, NMFS is proposing fees that, while they would not offset the costs of permit program administration, reasonably reflect the variation in the complexity involved for reviewing and processing different types of permit applications. In general, the proposed fees are based on the five permit categories reflected in appendix A to subpart D of these proposed regulations. The categories of permits and proposed fees roughly factor in the degree of risk to protected species and the associated potential for impact on wild stocks, and, as a result, the relative level of difficulty of administrative review and processing associated with that type of permit application and the relative likelihood that the proposed activity would require preparation of an EA or EIS.

These revised fees are presented in the form of a modified "fee schedule" for scientific research and enhancement permits, with a proposed range from

"no charge" up to \$1,000. Proposed fees for public display permits would be assessed dependent on the type of activity proposed and whether the applicant already is a public display permit holder and would range from \$1,000 to \$2,500. These proposed fees would also serve to inform applicants of the most likely fees when submitting their permit application. See § 216.42 for the permit issuance and permit-related administrative fees proposed in these regulations, and appendix A to subpart D of these proposed regulations for related information.

Relatively smaller fees are proposed to be assessed for the issuance of major amendments to applicants who already hold a public display permit. This reflects the fact that certain aspects of the applicant's qualifications and facility characteristics have already been evaluated, and review of a subsequent major amendment request generally would merely involve updating information supplied in the past. Thus, the effort involved in reviewing and processing such a major amendment request is not as great as the effort required to review and process a permit application from a previously unknown applicant.

Permit administrative fees would also be charged for certain administrative activities associated with permits, such as amendments and authorizations for the transfer of animals between permit holders. Major amendments requested by scientific research or enhancement permit holders that involve increases in levels of jeopardy, risk of adverse impacts, or levels of harassment would be charged administrative fees that reflect the type and level of take authorized after the amendment to the permit. For example, if a scientific research or enhancement permit that initially authorized a take with a corresponding permit issuance fee of \$150 was amended to authorize a take with a corresponding issuance fee of \$1,000, the administrative fee charged for the major amendment would reflect the difference in the relevant issuance fees, or \$850. For a major amendment requested by the permit holder that does not involve increased levels of jeopardy, risk of adverse impact, or levels of harassment, an administrative fee of \$100 would be charged, except for certain permits involving only non-intrusive, non-contact harassment, for which \$50 would be charged. No administrative fee would be charged for major amendments initiated by the AA or for minor amendments. In proposing these administrative fees for major amendments requested by permit holders, NMFS has considered the fact

that, in many cases, the levels of administrative processing involved for major amendments will be similar to those required to process a permit application.

If NEPA documentation were needed, the AA might require that the permit applicant bear the cost of developing an EA or EIS in the form of supplemental fees that would be included in the permit issuance fee. Supplemental fees to be either included in the permit issuance fee or assessed as administrative fees would be also be charged for costs such as transportation, lodging, and per diem associated with inspections of foreign facilities, and for the costs associated with placing observers on vessels engaged in a permitted activity, if the AA or a Regional Director, NMFS, determines that an observer is required.

Fees could be reduced or waived if the applicant is a Federal agency or if the AA determined that such a waiver or reduction is in the public interest consistent with the policies and objectives of the Acts. An example of circumstances in which fees could be reduced or waived for a non-Federal applicant would be for activities that the AA has determined are essential to the enhancement of the survival or recovery of a protected species or stock. Also fees could be reduced for activities involving salmon or sturgeon species listed as endangered or threatened taking into consideration the life stage affected (e.g., smolts), the type of take or otherwise prohibited activity involved, and the related risk or impact on stocks.

7. Provide for a Smooth Transition From the Current Regulatory Scheme to the Proposed Regulatory Scheme

These regulations, as proposed, would alter the administration of the permit program. Consequently, NMFS is proposing a number of actions to ease the transition to the new system. This transition scheme is proposed in § 216.43. The transition process would differ depending on the type of permit involved and on whether the affected entity is a facility or an individual. The effective date of final regulations will be 30 days after the date the final rule is published in the *Federal Register*. This date is referenced in brackets in the proposed regulations as "[the effective date of the final rule]." On the effective date of the final rule, the current general permit conditions would be replaced by the revised general permit terms and conditions proposed in these regulations. The 1-year to 18-month transition periods for permit adjustment or application submission are provided to ease the administrative burden of the

transition on both holders of permits or other authorizing documents and NMFS.

a. *Public Display/Facilities.* NMFS is proposing that, within 1 year of the effective date of the final rule, NMFS would adjust all public display permits previously issued before the effective date of the final rule and associated with facilities for purposes of public display to reflect the status quo for the species and numbers of marine mammals held at that facility as of the effective date of the final rule.

NMFS is proposing that, within 18 months of the effective date of the final rule, public display permits that were issued before the effective date of the final rule and associated with a multiple facility aggregation, or that are otherwise not facility-specific, would also be adjusted. These permits would become separate permits specific to each individual facility. These separate permits would reflect each facility's status quo, and each separate permit would provide a reasonable allowance for the transfer of marine mammals between the separate facilities comprising multiple facility aggregations. Until the facility-specific permit transition is completed for any particular multiple facility aggregation, inter-facility transfers among the component facilities could continue without additional NMFS authorization.

NMFS would notify facilities that are holding marine mammals for public display, but that have not been issued public display permits, that they need a permit to continue holding marine mammals for public display purposes. Within 6 months of this notification, but not more than 1 year from the effective date of the final rule, these facilities would be required to submit a complete permit application. If, after going through the normal permit process, the facility meets the criteria proposed in these regulations, a public display permit would be issued. If the facility could not meet the criteria, NMFS would work with that facility and other permit holders to relocate the marine mammals to permitted facilities.

b. *Public display/individuals.* NMFS is proposing to notify individuals who currently hold marine mammals for purposes of public display, either under permit or other authorizing documents, that within 1 year of the effective date of the final rule, they would be required to arrange, either with the facility where the marine mammals are currently held or with another facility, to have those marine mammals brought under the authority of that facility's permit.

c. *Scientific research/facilities or individuals.* Scientific research permits

issued before the effective date of the final rule involving marine mammals would not be greatly affected by these proposed regulations, except that, on the effective date of the final rule, the general permit terms and conditions of these proposed regulations would supersede the existing general conditions. Within 1 year from the effective date of the final rule, the reporting requirements of the proposed regulations would apply to all scientific research permits involving marine mammals. Within 1 year of the effective date of the final rule, scientific research permits issued before the effective date of the final rule that authorize research on captive marine mammals in a facility other than a public display facility would be adjusted once, to reflect the status quo at that facility. Any intrusive research being conducted under authority of a public display permit on the effective date of the final rule would be allowed to continue for up to 1 year from the effective date of the final rule; but must then be authorized under a separate scientific research permit. Any intrusive research begun after the effective date of the final rule, either at a public display facility or elsewhere, would be required to be specifically authorized under a scientific research permit.

Scientific research permits issued before the effective date of the final rule that authorize research on protected species other than marine mammals (e.g., endangered or threatened species of marine and anadromous fish or marine reptiles) will not be affected by these regulations.

8. Establish a Process Through Which Beached and Stranded Marine Mammals Taken for Rehabilitation May Be Used for Purposes of Public Display, Scientific Research, or Enhancement After Rehabilitation

Section 109(h) of the MMPA allows Federal, State or local officials, or persons designated by the AA through a section 112(c) agreement, to take marine mammals for the protection or welfare of the mammal. Pursuant to this statutory authority, beached and stranded marine mammals are recovered and rehabilitated. During and after rehabilitation, some of these marine mammals have been publicly displayed or involved in scientific research or an enhancement activity. On November 4, 1992, the Marine Mammal Health and Stranding Response Act (MMHSRA) was enacted (Pub. L. 102-587), which amended the MMPA to require that by November 4, 1994, NMFS, in consultation with the Secretary of the Interior, the MMC, and others, develop

and implement objective criteria to determine at what point a marine mammal undergoing rehabilitation is returnable to the wild. Until this process occurs, NMFS is proposing both a basic regulatory framework within which such releasability decisions would be made and the requirements that would apply for the use of rehabilitated beached and stranded marine mammals for public display, scientific research, or enhancement purposes. These requirements include that such activities would first have to be specifically authorized by NMFS, and that they be conducted in accordance with the public display, scientific research, or enhancement provisions of these regulations.

Section 109(h)(3) of the MMPA requires that steps be taken to return marine mammals taken under section 109 to their natural habitat, where feasible. Consistent with section 109(h)(3), the proposed regulations would require the release of the rehabilitated marine mammals to the wild, if feasible. Under these proposed regulations, release is considered to be feasible if: (1) The release of the marine mammal to the wild is likely to be successful; and (2) the marine mammal to be released is determined by the AA not to be a suitable substitute for a marine mammal of the same species and characteristics for which a permit has been issued for capture from the wild or for acquisition from captive stock. These requirements would be used on an interim basis to be revised consistent with, and may be used as a starting point for, the objective criteria required by the MMHSRA for determining when rehabilitated marine mammals are returnable to the wild.

NMFS is proposing various provisions to ensure marine mammals are released, if feasible, and to prevent a situation where a marine mammal being rehabilitated remains in captivity in an indeterminate status for an extended period of time. For example, NMFS is proposing that a marine mammal be released within 6 months, unless the attending veterinarian has determined that the release to the wild is not likely to be successful or that additional time is needed to make a releasability determination. If the attending veterinarian makes such a determination, the Regional Director could either concur with that determination not to release the marine mammal to the wild or require the marine mammal's release after an independent assessment of the feasibility of release by the Regional Director or his or her agents.

In no case would a marine mammal be held for more than 2 years without a final determination as to releasability. Within 30 days of a determination that the release of the marine mammal is not likely to be successful, the holder would be required to request authorization to retain or transfer custody of the marine mammal, or carry out other disposition. For example, such marine mammals would have to be held under an existing, amended, or newly issued special exception permit if they were to be used for purposes of public display, scientific research, or enhancement. Consequently, under such circumstances, the holder of the marine mammal may need to apply for a special exception permit or request a major amendment to an existing permit, or to transfer custody to an acceptable permit holder. First consideration would be given to retention of the marine mammal by the facility that bore the cost of rehabilitation. Additionally, provisions are included in the proposed regulations allowing for the retention or transfer of custody of such rehabilitated marine mammals pending the processing of such permit applications or requests for major amendments, if necessary.

In the past, for purposes of public display, scientific research, or enhancement, NMFS has authorized retention or transfer of some marine mammals originally taken for rehabilitation under section 109(h) of the MMPA by issuing Letters of Agreement. The process for reviewing requests for such Letters of Agreement has been less structured than the process for reviewing applications for public display permits. One of the reasons for issuing Letters of Agreement to authorize the holding of rehabilitated non-releasable marine mammals has been to minimize the burden borne by rehabilitation facilities. There are significant costs involved in the maintenance of animals after they have been rehabilitated pending approval of a permit application. However, to make treatment of these situations more consistent with the treatment of other situations under the MMPA, during the last few years NMFS has been requiring that any facility receiving marine mammals for the first time must have a permit, even if the marine mammals were originally removed from the wild for rehabilitation under section 109(h) of the MMPA. The proposed regulations include a specific procedure for accomplishing the transition from the status of a beached or stranded marine mammal taken under section 109 of the MMPA for rehabilitation to the status of

a marine mammal taken under section 104 for purposes of public display, scientific research, or enhancement.

II. Public Display Goals

1. Define the Term "Public Display"

Many issues were considered during the Program Review in formulating the definition of "public display." The MMPA imposes a general moratorium on taking or importing marine mammals, except in limited and specific situations. One exception is for public display purposes. However, the term "public display" is not defined in the MMPA or in existing regulations. One of the major issues considered was whether public display includes activities in the wild, such as marine mammal observation, feeding or swimming with marine mammals, documentary or other film-making, or photography for educational/conservation purposes.

The statutory language and legislative history of the MMPA make it clear that public display activities were understood and intended by Congress to be conducted only in captive settings. For instance, the public display permit provisions of section 104(c)(2), most recently amended in 1988, discuss public display activities only in terms of activities at land-based facilities.

The reasons for limiting public display activities to captive settings were discussed and considered during the course of processing one application requesting a public display permit to conduct marine mammal feeding activities in the wild; the permit was ultimately denied after extensive comments from the public and scientific community. It was determined that terms and conditions that can be applied to public display activities in captive settings cannot readily be applied to activities conducted in the wild. For instance, while captive maintenance of marine mammals can be required to meet NMFS, APHIS, or other regulatory standards, such standards are written for, and do not apply outside of, captive settings. Further, because wild animals are unpredictable, activities conducted in the wild that depend on the ability to attract or closely approach marine mammals for success or profitability could result in unnecessary harassment or injury to wild marine mammals. Wild marine mammals that could be habituated toward careful persons operating under a public display permit could not be prevented, regardless of any protective terms or conditions included in any permit, from approaching other, perhaps less careful, persons. This increases the risk of

harassment, injury and death of marine mammals in the wild. Interaction in the wild between marine mammals and qualified and experienced personnel conducting bona fide scientific research or enhancement activities under a section 104 permit is provided for under the MMPA. Attempts to authorize activities involving the interaction of wild marine mammals and the general public, where such activities are likely to result in substantial risk of adverse impact to a species, stock, or individual protected species, no matter how carefully or responsibly attempted, poses unacceptable risks to animals and the public.

Consideration of all the information gained in processing and rejecting the permit application to conduct public display activities in the wild, along with review of the language of the MMPA and its legislative history, have led NMFS to the conclusion that observation or direct interaction by the public with marine mammals in their natural habitat does not fall within the intended meaning of public display in the MMPA. Therefore, public display permits authorizing such activities cannot be issued under the MMPA. Observation/whale watching, film-making, feeding, swimming and other activities conducted in the wild must be conducted in a manner so as not to take (e.g., harass) marine mammals. NMFS published a notice reflecting this policy not to accept or consider applications to conduct public display activities in the wild because such activities are not encompassed in the term "public display" as it is used in the MMPA (55 FR 35336, August 29, 1990).

In a related matter, NMFS in 1991 amended the regulatory definition of take to clarify that feeding marine mammals in the wild is a form of take. That action was challenged by a commercial dolphin feeding cruise operator, and on October 29, 1992, the Federal District Court for the Southern District of Texas in *Strong v. United States* (Civil Action No. C-91-083), enjoined NMFS from applying that definition of "take" as it relates to dolphins. The court also enjoined NMFS from enforcing the policy against considering applications for public display permits authorizing activities conducted in the wild, discussed above, on the grounds that the policy was actually a regulation that had not been subject to public notice-and-comment rulemaking under the Administrative Procedure Act (APA). While NMFS is appealing the courts ruling, these proposed regulations, most specifically the proposed definition of the term "public display," would address that

courts concerns about adopting agency policy without complying with the APA.

A second major issue NMFS considered when defining public display was whether the definition includes interactive programs and activities conducted in captive settings, such as petting, "swim-with," or feeding programs. After careful review, NMFS believes that many of these interactive programs can be conducted consistent with the MMPA's guidance on public display. In an effort to assess the compatibility between public display and swim-with interactive programs, four facilities are currently authorized to conduct "swim-with-the-dolphin" programs on an experimental basis. Whether NMFS will authorize the continued conduct of these or additional swim-with interactive programs will depend on the review of these experimental programs. Regardless, interactive activities, by their nature, involve a considerable risk of conveying attitudes and values to the participating public that are inconsistent with the goal of protecting and improving public understanding of wild marine mammals and the marine ecosystem. Certain interactive programs could also involve an increased risk to the health and welfare of the participating marine mammals. Consequently, such programs would be evaluated on a case-by-case basis. If found acceptable, they would have to be specifically authorized in the permit.

As a result of the assessment of issues associated with public display, definitions of "public display" and "interactive program" are proposed at § 216.3.

The permit holder's staff referred to in the definition of "interactive program" includes persons contracted to, or volunteers supervised by, the permit holder, where such contractors or volunteers are necessary for the performance of the animal and facility support functions noted in the definition. NMFS recommends that, if a permit holder or other person is uncertain as to whether a proposed activity falls within this definition, they should check first with NMFS.

2. Clarify That Captive Holding Is a Form of Take Under the MMPA

Reexamination of the language of the MMPA, its legislative history, and the existing regulatory definition of take during the Program Review has led NMFS to the conclusion that holding a marine mammal captive is, in itself, a take under the MMPA. This take of a marine mammal occurs regardless of whether such captive holding is directly

associated with and immediately preceded by a capture of the marine mammal from the wild (also see the discussion regarding captive-born marine mammals in IL.6. of this preamble). As a result, captive maintenance needs to be permitted for the purpose of public display, scientific research, or enhancement under section 104 of the MMPA.

Section 3(12) of the MMPA states that "take" means to harass, hunt, capture, or kill, or attempt to harass, hunt, capture, or kill any marine mammal. NMFS' existing regulatory definition of "take," found at 50 CFR 216.3, lists some of the activities that constitute a take:

Take means to harass, hunt, capture, collect, or kill, or attempt to harass, hunt, capture, collect, or kill, any marine mammal. This includes, without limitation, any of the following: The collection of dead animals, or parts thereof; the restraint or detention of a marine mammal, no matter how temporary; tagging a marine mammal; the negligent or intentional operation of an aircraft or vessel, or the doing of any other negligent or intentional act which results in disturbing or molesting a marine mammal; and feeding or attempting to feed a marine mammal in the wild.

NMFS' regulatory definition of take has included the concepts of restraint or detention of marine mammals, no matter how brief or long the duration, since December 21, 1972 (37 FR 28177). In 1981, Congress expressly reviewed and approved NMFS' present regulatory definition of take that prohibits restraint or detention of marine mammals, or the doing of any other intentional or negligent act that results in harassment. The Supreme Court has found persuasive evidence of Congressional approval of an agency interpretation of statutory language, where Congress subsequently reviews the agency's interpretation and does not overturn it (*Young v. Community Nutrition Inst.*, 476 U.S. 974, 983 (1986)). Holding a marine mammal in captivity is a take via restraint or detention, and thus must be authorized by a section 104 permit. Other interpretations in this regard cannot be reconciled with the text of the MMPA or of the intent of Congress as expressed in the statute's legislative history.

While taking a marine mammal by capture may be limited to only the initial act of removing the marine mammal from the wild, the existing regulatory definition of take also encompasses the activities of "restraint or detention," which include prolonged holding of the marine mammal. Holding a marine mammal captive is a take by restraint or detention that may be, but

is not necessarily, related to the capture of a marine mammal from the wild; and is prohibited under sections 3, 101, and 102 of the MMPA and the existing definition of take at 50 CFR 216.3. For the purposes of public display, scientific research, and enhancement, such a take may be authorized only by a permit under section 104 of the MMPA.

In addition to providing the basis for consistent and predictable decision-making, the most immediate consequence of this determination is that the captive holding of all marine mammals presently being held for purposes of public display, scientific research, or enhancement would be required to be authorized by a permit under section 104 of the MMPA. Most facilities holding marine mammals for purposes of public display have been issued a public display permit at some time in the last 20 years. However, as it concerns these and other facilities, NMFS has used instruments besides section 104 permits during this period to authorize captive holding and routine inter-facility transfers. These letters, agreements, or other authorizing documents have primarily been based upon the general provisions of section 112(c) of the MMPA. However, after analysis, NMFS believes that the use of section 112(c) alone as a statutory basis for authorizing captive holding, transport/transfer, purchase or sale activities, or other disposition of marine mammals for purposes of public display, scientific research, or enhancement may not give appropriate consideration to the requirements of sections 102 and 104 of the MMPA. For this reason, Letters of Agreement would no longer be used as a basis for authorizing a facility to hold a marine mammal. All authorizations for transport/transfer, purchase or sale activities, or other disposition of marine mammals would be consistent with and linked to a permit.

In this regard, for an applicant (non-permit holder) who wishes to import or capture a marine mammal from the wild and subsequently maintain it in captivity for public display, scientific research, or enhancement purposes, a single section 104 permit could be issued that would authorize all of the taking activities to be conducted by the applicant in the terms and conditions of the permit. For an applicant that seeks to simply hold a marine mammal captive for public display, scientific research, or enhancement purposes, but would not need to import or capture the marine mammal from the wild (i.e., would obtain the marine mammal from captive stock), a section 104 permit

could be issued to an applicant solely to authorize the taking of the marine mammal by captive holding. For permit holders that wish to import or capture marine mammals in the wild in addition to marine mammals already held under an existing permit, a major amendment could be issued for the import or capture activity and to, as necessary, authorize their subsequent captive maintenance (i.e., if the existing permit does not already authorize sufficient species and numbers of marine mammals to encompass the additional animals to be imported or captured).

3. Delineate the Scope of NMFS' Jurisdiction and Authority Under the MMPA for the Captive Maintenance of Marine Mammals; and Explain How the MMPA and the Animal Welfare Act (AWA) Apply to Captive Maintenance

Section 104(b)(2) of the MMPA directs NMFS to specify in the terms and conditions of a permit the number and species of marine mammals, the location and manner in which they may be taken, and the period during which the permit is valid. Further, section 104(c)(1) directs NMFS to specify requirements for the methods of capture, supervision, care, and transportation that must be observed while conducting activities authorized by the permit. The MMPA thus provides NMFS with clear and independent jurisdiction and responsibility for establishing care and maintenance standards for captive marine mammals. Concurrently, the terms of the AWA apply to captive maintenance of marine mammals.

Following enactment of the MMPA in 1972, as required by section 104(c), each permit issued by NMFS for public display purposes included detailed terms and conditions regarding the captive care, supervision, and transportation of marine mammals. Seven years later, in 1979, after interagency consultation with NMFS, FWS, and the MMC, APHIS promulgated standards under the AWA for the care and maintenance of captive marine mammals. At that time, in the interest of avoiding duplication in regulation or enforcement, NMFS both modified all permits to incorporate these new care and maintenance standards and entered into a formal interagency agreement with FWS and APHIS concerning respective functions, responsibilities, and authorities among NMFS, APHIS, and the FWS.

Since 1979, NMFS has discharged its statutory duty under the MMPA by incorporating the basic standards promulgated by APHIS as terms and conditions of special exception permits

involving captive marine mammal care, supervision, or transport. During this period, issues have arisen and incidents have occurred involving the care, maintenance, or transport of captive marine mammals. Both the independent jurisdiction provided NMFS and FWS under the MMPA and the interagency agreement between these agencies have proven important in addressing these issues and resolving a number of these incidents. Also, during the course of the Permit Program Review, a number of concerns were raised by animal welfare groups, conservation organizations, the MMC, and NMFS regarding the adequacy of the present AWA/APHIS care and maintenance standards for marine mammals and the adequacy of APHIS enforcement of these standards. NMFS, the MMC, and FWS plan to work with APHIS to address the problem areas identified and to revise the marine mammal captive maintenance standards as necessary.

Until these standards are revised, and pursuant to the existing Agreement among NMFS, APHIS, and FWS, the current AWA/APHIS standards are referenced in these proposed regulations (see § 216.37). A violation of the AWA/APHIS standards, therefore, would also be considered a violation of the MMPA permit. In addition, NMFS may exercise its independent statutory duty concerning marine mammals to supplement APHIS's captive maintenance standards, if NMFS finds such action necessary.

4. Establish a System of Facility-Specific Periodically Renewed Permits for Purposes of Public Display Which Can Be Implemented Fairly and Consistently (Also See I.3. of This Preamble)

In the past, NMFS has not required all facilities or persons to comply with the same requirements and standards. Some facilities and persons have been required to comply with certain administrative requirements prior to conducting an activity, while others have conducted the same type of activity without having to comply with similar requirements. Part of the inconsistency resulted from the lack of a regulatory definition to determine what constitutes a "facility." The sometimes disparate treatment of separate facilities also has been due, in part, to single corporate ownership or other affiliation of multiple facilities. For example, transfers of marine mammals between separately owned facilities have required explicit prior authorization from NMFS before proceeding, while transfers of marine mammals between facilities owned by the same entity have proceeded with no

prior authorization. Consequently, NMFS frequently has been unable to monitor the transport or location of marine mammals.

This situation caused NMFS to reexamine its policies to search for mechanisms with which to ensure equal treatment for all facilities, regardless of ownership, and to improve administrative efficiency and information flow between NMFS and the facilities. The proposed regulations describe a single set of requirements that would be applicable to all facilities and persons. This is done in large part through a proposed new definition of the term "facility," included at § 216.3.

This definition of facility refers to enclosures not necessarily located on a contiguous parcel of land but grouped nearby; for example, separate "satellite" enclosures for medical or other purposes. Seasonal traveling facilities, such as temporary exhibits that use one facility for traveling and another for "permanent off-season" care of marine mammals, would be considered two separate facilities, unless the same "traveling" facility is used during the "off-season" as a semi-permanent exhibit.

The proposed regulations have been developed with the idea that the ownership of one or multiple facilities is irrelevant to the question of whether each must be permitted, and is irrelevant to the manner in which they are treated by the regulations. Under the definition of facility, NMFS would require that each separate facility, regardless of size, affiliation, or corporate structure, comply with the requirements and standards of the regulations. Each one of multiple facilities under single corporate ownership or management would be subject individually to the same requirements as facilities owned by different entities. For example, each separate facility would be required to hold a permit, and transfers of marine mammals among all facilities would require prior authorization. This uniform application of the regulations is necessary to ensure that all permits and conditions, requirements and privileges, are administered consistently, and would allow NMFS to monitor all transfers and facility-specific activities and maintain accurate data concerning them, neither of which has been possible to date.

NMFS policy has been to limit the valid period of scientific research permits to a maximum of 5 years. Scientific research involving a period greater than 5 years generally required a new permit to be obtained, even if all other aspects of the research activity

remained unchanged. At the same time, in permits issued for the purpose of public display, NMFS has consistently identified the valid period for importation or certain types of taking and related activities, including captures from the wild or acquisition of marine mammals from captive stock. These valid periods have usually been identified as a few years, with NMFS generally adhering to a policy limiting extensions of these valid periods to no more than 5 years. However, these same public display permits have not explicitly identified a valid period for the subsequent captive holding of these marine mammals. At most, public display permits have included a statement that the terms and conditions of the permit apply as long as the marine mammals are held captive. Under these circumstances, an indefinite valid period for the captive holding of marine mammals under the permit has been implied.

Section 104(b) requires, among other things, that any special exception permit specify the period during which the permit is valid. As discussed extensively in this preamble, marine mammals may be held captive for purposes of public display, scientific research, or enhancement only if such taking is authorized under a special exception permit. Consequently, NMFS has determined that a valid period must be specified for such captive holding. An indefinite valid period for a permit authorizing the captive holding of marine mammals is unacceptable for a number of reasons. Most importantly, periodic review and renewal of permits are necessary to ensure that the permit holder continues to comply with the terms and conditions of the permit. Also, over time, the circumstances associated with the captive holding of marine mammals may change. An indefinite valid period for permits is equivalent to a prohibition on periodic public review and comment concerning a taking of marine mammals under the MMPA, regardless of changing circumstances. Such an opportunity for public review and comment regarding special exception permits is given considerable weight in the MMPA. As a result, NMFS has concluded that an indefinite valid period for permits authorizing the captive holding of marine mammals would be contrary to the requirements of the MMPA.

NMFS is proposing a 5-year limitation on the valid period of any special exception permit, including public display permits. Extensions of this valid period would be allowed by major amendment (see L5. of this preamble). The valid period of each such major

amendment would also be limited to 5 years. Additionally, this proposed allowance for an extension of the valid period of a permit by major amendment would also apply to scientific research permits, dropping the present requirement that an entirely new permit be issued every 5 years even if all aspects of the research remain unchanged. New scientific research permits would continue to be required for new or significantly changed research protocol or objectives. To provide some essential flexibility in the administration of this provision, NMFS is also proposing to allow, at the discretion of the AA in response to a request by the permit holder, a one-time allowance for the extension of the initial valid period of the permit of no more than 12 months by minor amendment. This would allow the initial valid period of the permit to be extended up to a period of 6 years before a major amendment would be required for further extension.

5. Incorporate the 1988 Amendments to the MMPA Requiring an Education or Conservation Program and Regularly Scheduled Public Access as Requirements for Public Display Permits

The 1988 amendments to the MMPA added requirements for public display permits. A requirement was added to section 104(c)(2) that applicants must offer an education or conservation program that, based on professionally recognized standards of the public display community, is acceptable to the Secretary. During the Permit Program Review it became clear that the phrase "based on professionally recognized standards of the public display community" did not refer to any standards already established by the public display community. Until the public display community establishes uniform comprehensive standards on which specific issuance criteria could be based, NMFS proposes to use the basic education or conservation program issuance criteria and permit terms and conditions proposed in these regulations to determine whether applicants' education or conservation programs are acceptable.

In determining whether an education or conservation program offered by an applicant is acceptable, NMFS is proposing that the AA consider: (1) Whether an education or conservation program has clearly stated objectives and has been designed and will be administered by a professional staff; (2) whether the basic messages of the program are consistent with the policies and objectives of the MMPA; and (3) whether the program effectively conveys

accurate information to the public about the life history, behavior, sensory capabilities, conservation, or other aspects of marine mammals, such as their role in the marine ecosystem. These standards would also be included as a permit term or condition in any permit issued. These standards reflect the interim policy on education and conservation programs published in the Federal Register on May 22, 1989 (54 FR 22001), and a distillation of the numerous comments and recommendations on this subject received during the Permit Program Review.

As stated in the existing interim policy on education and conservation programs, given the diversity of public display facilities, NMFS recognizes that the content of education and conservation programs will vary, as will the techniques used to communicate with the public. However, NMFS is proposing in these regulations that regardless of the type or content of such programs, they must effectively convey accurate information about marine mammals and their role in the marine ecosystem. It is not the intent of NMFS to regulate educational content other than to require that the information be accurate, current, and understandable, and that the overall message be consistent with the purpose and policies of the MMPA, resulting in an improved understanding of marine mammals and their role in the marine ecosystem. NMFS will encourage public display facilities to conduct programs that foster positive attitudes toward the marine mammals being displayed, that improve public understanding of marine mammals and support for protection and conservation of marine mammals in the wild and the marine ecosystem of which they are a part, and that are attuned to the interests and backgrounds of the varied public to which the education and conservation programs are directed, including visitors to the display facility. Following the issuance of final regulations, NMFS will continue to work with the public display community, education professionals, and interested members of the public to facilitate development of "professionally recognized standards" for education and conservation programs.

Other requirements added to section 104(c)(2) of the MMPA by the 1988 amendments were that public display facilities must be open to the public on a regularly scheduled basis and that access to the facilities must not be restricted other than by an admission fee. These requirements would be incorporated in the proposed

regulations as permit restrictions and permit issuance criteria. These permit issuance criteria and restrictions are not intended to require permit holders to relinquish any rights or obligations held by them as business proprietors concerning the safety of their patrons and premises. For example, the requirement that access not be restricted other than by the charging of an admission fee would not preclude a public display facility from exercising reasonable discretion in removing disruptive or unruly patrons who either interfere with facility operations or pose a threat to the health or welfare of the marine mammals held at the facility.

6. Delineate the Authority of the MMPA and the Jurisdiction of NMFS Concerning Captive-Born Marine Mammals, Including "Pre-Act Progeny"

Over the years, NMFS has been presented with the argument that the only activity other than importation that NMFS may issue a permit for under section 104 is the taking of marine mammals in the wild, including capturing marine mammals from the wild, and that, therefore, the only captive marine mammals over which NMFS has jurisdiction under section 104 are those captured from the wild. It has been argued further that once a NMFS-authorized capture has been completed, NMFS jurisdiction concerning the captured animal ceases. Thus, some argued, conditions of captivity for those marine mammals, and any activities (including captive holding or transportation) involving marine mammals born in captivity are outside the scope of the MMPA, and consequently not subject to NMFS' jurisdiction to regulate. However, NMFS' review of the MMPA and its legislative history does not support that argument; it indicates that NMFS has a statutory mandate to regulate the methods of care, supervision, and transport of marine mammals, regardless of whether the marine mammal arrived in captivity through capture from the wild or through birth into captivity. This is even more clear since, as discussed previously, captive holding of marine mammals is a take.

Section 104(e) of the MMPA allows NMFS to modify, suspend, or revoke permits for violations of their terms or conditions. If permit terms and conditions applied only to capture activities, then revocation of a permit for substandard captive maintenance of the previously captured marine mammal would have no impact on the permit holder because the activity authorized in the permit terms and conditions (i.e., the capture) would

already have occurred. Such an interpretation would also ignore NMFS' duty under section 104(c)(1) to prescribe in the terms and conditions of the permit the methods (and to monitor a permit holder's compliance with the prescribed methods) of supervision, care, and transportation of marine mammals after captures. Further, it would ignore the terms of section 102(a)(2)(B) prohibiting any person from using any place under the jurisdiction of the United States for any purpose in any way connected with the taking or importation of marine mammals unless authorized by a section 104 permit in the context of public display, scientific research, or enhancement activities. Finally, an interpretation that NMFS permit terms and conditions apply only to capture activities would ignore the section 102(a)(4) prohibition on purchase, sale, or transport activities involving any marine mammals (not only those captured from the wild), unless authorized under a section 104 permit in the context of public display, scientific research, or enhancement activities.

During the Program Review, it also became clear that if captive-born marine mammals are not subject to the jurisdiction, and thereby the protection, of the MMPA, facilities or individuals could hold these marine mammals obtained from other facilities without the authorization of a permit. This would mean that NMFS could not sanction facilities for substandard care of these captive-born marine mammals, which would be contrary to the intent of Congress, as reflected in the following passages:

Additionally, during the moratorium, permits may be issued for the taking or importation of marine mammals for scientific research or for display in public or privately owned oceanariums. However, strict regulations are to be imposed by this legislation on such practices. (S. Rep. No. 863, 92d Cong., 2d Sess. 7 (June 15, 1972)).

And the section-by-section analysis accompanying the MMPA states:

Scientific research permits or permits for the display of marine mammals by profit and non-profit institutions must be issued by the Secretary subject to his requirements as to the manner in which those animals may be captured, transported and cared for. (118 Cong. Rec. H9405 (daily ed. Oct. 10, 1972)).

These statements indicate a strong Congressional intent to authorize the Secretary of Commerce to oversee the conditions of captivity for marine mammals, without any indication that captive-born marine mammals should be treated differently from marine mammals originally captured from the wild.

Based on this interpretation that captive-born marine mammals are encompassed under the permitting authority of section 104, these proposed regulations provide for the regulation by NMFS of the care, supervision, and transport of marine mammals captive-born after December 21, 1972, including the authority to revoke a permit for substandard care of captive-born marine mammals. The proposed regulations would subject a facility to control and sanctions to ensure proper care of marine mammals, even if the only marine mammals held at the facility were captive-born.

Section 102(e) of the MMPA states: "This Act shall not apply with respect to any marine mammal taken before the effective date of this Act * * *." Thus, marine mammals taken (e.g., captured from the wild and/or held captive) prior to the effective date of the MMPA are specifically exempt from the terms of the statute. Marine mammals in captivity prior to the effective date of the MMPA are commonly referred to as having "pre-Act" status and their offspring, if born after the effective date of the MMPA, have been called "pre-Act progeny." The proposed regulations would apply to pre-Act progeny. There is no indication in the legislative history of the MMPA that section 102(e) was intended to include any marine mammal born in captivity after the effective date of the MMPA whose ancestry could be traced to a marine mammal "taken" prior to the effective date of the MMPA. Pre-Act progeny are subject to the jurisdiction of the MMPA, just as are progeny born in captivity to post-Act parents.

The plain language of the MMPA makes clear that all marine mammals, except those in captivity before December 21, 1972, fall under the jurisdiction of the MMPA. Section 101(a) imposes a moratorium on the taking of all marine mammals except as authorized under the MMPA, e.g., by a section 104 public display, scientific research, or enhancement permit. As previously discussed, captive holding is a take and, therefore, the section 101 moratorium applies to the captive holding of marine mammals. Further, section 102(a)(4) makes it unlawful to transport, purchase, sell or offer to purchase or sell any marine mammal (including those born in captivity) or marine mammal product unless such activity is authorized under a section 104 public display, scientific research, or enhancement permit. There are no exceptions, either from the section 101 moratorium or from the section 102(a)(4) prohibitions, for captive-born offspring of marine mammals regardless

of whether one or both parents is "pre-Act." NMFS' interpretation of the applicability of the MMPA to captive-born marine mammals in this regard, as reflected in NMFS regulations since December 21, 1972, was reiterated in a Federal Register notice on September 5, 1991 (56 FR 43887).

7. Explain That Marine Mammals Held Under Permits May Be Transported/Transferred as Authorized Under the Terms and Conditions of a Permit, and That a Separate Permit for Each Transport/Transfer of Marine Mammals Is Not Required Under the MMPA

From time to time, NMFS has been urged to require separate permits for the transport of marine mammals, including transfers of marine mammals between permit holders. During the Permit Program Review, NMFS considered this issue and reexamined the language of the MMPA and its legislative history to determine whether the MMPA requires separate permits. This review has led NMFS to the conclusion that the MMPA does not require separate permits for every transfer of marine mammals between permit holders, including transport of marine mammals between permitted facilities. While the MMPA requires that the transfer or transport of a marine mammal held under authority of a section 104 permit be specifically authorized by NMFS, a separate permit specifically for transport/transfer alone is not required.

In the context of public display, scientific research, and enhancement permits, section 102(a) prohibits certain specified activities involving marine mammals, including the take or transport of a marine mammal, except as authorized under section 104. A marine mammal must be "taken" (e.g., captured from the wild and/or held captive) before it can be transported, and the "taking" activities must be authorized by a section 104 permit. Section 104(b)(2)(D) directs NMFS to specify any permit terms or conditions that NMFS deems appropriate, and section 104(c)(1) further directs NMFS to specify methods of transportation in the permit terms and conditions. It is clear from this language that Congress envisioned some transport of marine mammals held under special exception permits.

The public is on notice from the time an applicant requests a permit that transfers and transport of marine mammals may occur if a permit is issued. There is ample opportunity to address the issues of potential transfers and transportation during the public comment period that precedes the issuance of every permit. Once a permit

is issued, permitted activities (including the transport of marine mammals) may be conducted in compliance with the terms and conditions of the permit (which may require prior authorization from NMFS) without going through another public comment period. A separate permit procedure for transfers or other transport of marine mammals between permit holders would impose an unnecessary administrative burden on both NMFS and permit holders. However, if a transfer/transport of a marine mammal requires a major amendment to the receiving facility's permit to add a species or increase the numbers of marine mammals authorized to be held, then the major amendment would be processed in accordance with the same public review and comment procedures as for a permit application, as noted in the permit amendment discussion (see I.5. of this preamble).

Any actual transfer/transport of a marine mammal may be authorized in accordance with the terms and conditions of the permit under which the marine mammal is captured, held, or under which it will be held. Therefore, pursuant to the authority granted to NMFS by section 104(b)(2)(D), transfers of marine mammals would be from permit holder to permit holder in accordance with the terms and conditions of the permits held by both the transferring and the receiving permit holders.

8. Incorporate a Mechanism for the Authorization of Purchase and Sale Transactions Involving Captive Marine Mammals

During the administration of the permit program, questions have been raised regarding the many purchase and sale transactions involving living marine mammals since December 21, 1972. During the Program Review, NMFS looked carefully at the issue of purchase and sale transactions involving living marine mammals. NMFS started from the premise that captive holding and other "takings" of living marine mammals by any person are prohibited by the moratorium imposed by section 101(a) of the MMPA. Congress' authority for enacting a law imposing such a moratorium is its constitutionally conferred power to regulate interstate commerce. Congress specifically noted the relationship between interstate commerce and activities involving marine mammals in section 2(5) of the MMPA.

Under this authority, Congress has prohibited taking (e.g., captive holding), purchase, or sale activities involving marine mammals through section 102 of the MMPA, unless, for purposes of

public display, scientific research, or enhancement, prior authorization from the AA is obtained in accordance with section 104. Pursuant to section 104, authority to hold marine mammals captive is conditional, and the permit that authorizes such a taking is subject to revocation at any time. Further, purchase and sale transactions involving marine mammals are prohibited by section 102 unless authorized consistent with the terms and conditions of a section 104 permit, or under certain other sections of the MMPA. Persons issued permits to hold marine mammals in captivity are not, by virtue of the authorization to conduct that single activity, also authorized to purchase, sell, offer to purchase or sell, or to transport marine mammals (see section 102(a) of the MMPA). In this sense, section 104 authorization to hold marine mammals in captivity is no different from section 104 authorization to harass marine mammals in the wild; both are merely grants of conditional authority to conduct otherwise prohibited activities. Marine mammals are subject to management and protection as a national resource in the broad regulation of commerce by Congress, and Congress has prohibited all purchase or sale transactions involving marine mammals, except as authorized and conditioned by NMFS through the provisions of section 104 of the MMPA.

NMFS authorizes purchase or sale transactions in its statutorily mandated role as public trustee for marine mammals. Custody of a marine mammal, i.e., the authority to hold a marine mammal, is revocable at any time by NMFS. To simplify the authorization of purchase and sale transactions, and to minimize the administrative burden on all parties, NMFS is proposing that, when authorizing a permit holder to obtain custody of a marine mammal from captive stock (e.g., a transfer between public display facilities), this authorization would also "automatically" include authorization for purchase and sale transactions involving that marine mammal. NMFS is not undertaking to regulate what price in cash, goods, or services the purchaser and seller agree upon. Insofar as NMFS is concerned, the relevant issue is whether the purchase and sale transaction is authorized in accordance with the requirements of the MMPA and these proposed regulations, and not the consideration exchanged in the transaction.

NMFS is further proposing to authorize purchase and sale transactions solely under the authority of section 104

of the MMPA. Past reliance upon section 112(c) as authority to effect these transactions may not have given appropriate consideration to the provisions of sections 102 and 104 of the MMPA. Explicitly addressing this issue through the terms and conditions of a permit issued under section 104 of the MMPA is in the interests of all concerned.

III. Scientific Research Goals

1. Define "Bona Fide" Scientific Research

The MMPA provides an exception to the section 101 general moratorium on taking or importing marine mammals to allow the take or import of marine mammals for bona fide scientific research purposes. The requirement that scientific research be bona fide was added to the MMPA by Congress in 1988. While NMFS uses the "bona fide" standard as general guidance in evaluating the validity of both MMPA and ESA scientific research proposals (existing 50 CFR 216.31(c) and 222.23(c)(4)), neither the MMPA, the ESA, or the existing regulations define the term. NMFS is proposing a definition of bona fide scientific research in these revised regulations at § 216.3.

Under this definition, only scientific research on or benefiting protected species could be authorized under a special exception permit. In section 2(3) of the MMPA, Congress notes that "there is inadequate knowledge of the ecology and population dynamics of such marine mammals and of the factors which bear upon their ability to reproduce themselves successfully". In section 2(6), Congress stresses that "marine mammals * * * should be protected and encouraged to develop to the greatest extent feasible commensurate with sound policies of resource management and that the primary objective of their management should be to maintain the health and stability of the marine ecosystem." In section 3(2), Congress then clarifies that "conservation" and "management" mean "the collection and application of biological information for the purposes of increasing and maintaining the number of animals within species and populations of marine mammals * * *". Such terms include the entire scope of activities that constitute a modern scientific resource program * * *." Similar provisions are found in the ESA. Thus, in the context of the purposes and policies of the MMPA and ESA, research that is not on, or that does not otherwise benefit, protected species would not be considered to fall within

the "bona fide" requirement of section 104 of the MMPA or the scientific purposes requirement of section 10(a)(1)(A) of the ESA. Although such research would not be eligible for a section 104 permit under the MMPA, or a section 10(a)(1)(A) permit under the ESA, sections 101(a)(3)(A) and 101(a)(5)(A) of the MMPA and section 10(a)(1)(B) and, for Federal agency actions, section 7 of the ESA, provide mechanisms for authorizing the take of protected species incidental to research that is not on or benefiting protected species.

2. Develop Objective Standards to Determine Whether an Activity Conducted in the Wild is Likely to Involve a Take of a Protected Species and to Facilitate Reporting

The existing regulations lack clear standards for determining whether and to what extent takes of protected species occur during activities conducted in the wild. This has posed difficulties for the implementation of the requirements of section 104 of the MMPA, section 10 of the ESA, and for the administration of the permit program.

For example, section 104(b) of the MMPA requires NMFS to specify the location and manner in which takes can occur, as well as how many marine mammals can be taken. Section 104(c)(1) requires permit holders to submit reports on all activities conducted under the authority of a permit. Similarly, section 10(d) of the ESA requires NMFS to find that the special exception activity will not operate to the disadvantage of the affected species and will be consistent with the purposes and policies of section 2 of the ESA. Without objective standards to determine whether an activity constitutes, or is likely to constitute, a take, neither NMFS nor permit holders can fully comply with the requirements of section 104 of the MMPA or section 10 of the ESA.

Presently, the NMFS permit database consists of data derived from permit reports, which include assessments of take based on the judgment of the permit holders. While many qualified and experienced investigators conducting bona fide research on protected species in the wild are capable of assessing whether a protected species has been harassed, each of these investigators applies a different subjective criterion to determine whether and to what extent such a take has occurred. Consequently, without a consistently applied objective standard for reporting purposes (for reference purposes at the very least), the validity and utility of the reported take data are

of questionable value. For these reasons, NMFS has concluded that the present exclusive reliance on such ad hoc subjective data is not acceptable.

During the Program Review it was suggested that NMFS could use existing guidelines developed by the NMFS Regional Offices as a rough standard for determining when takes are likely and, if conducted under a special exception permit under the Acts, need to be reported to NMFS. However, these regional guidelines are not an acceptable alternative to a uniform objective standard for this purpose. This is because these guidelines vary from region to region and, as a result, cannot be administered in a consistent manner, provide a basis for consistent data and comparable reporting, or be administered in an equitable fashion. This is especially the case where activities conducted under a special exception permit occur in more than one region. In addition, much of the scientific community and the public are not aware of either the existence of regional "guidelines" or the need and reasons for approach standards/restrictions. These factors make a uniform objective standard even more important.

NMFS has also concluded that an objective standard for determining when a take is likely is important, not only for determining whether a permit is needed, but also as a reference guide for establishing the type and manner of an authorized take and the number to be taken. Such an objective standard would also improve NMFS' ability to assess likely and actual takes, as well as how they are reported by collecting essential data on permitted activities in the wild. The data would have utility in assessing individual or cumulative levels of harassment associated with authorized scientific research, public display (e.g., capture), or enhancement activities in the wild.

To meet this need for an objective standard, at least for marine mammals, NMFS is proposing the recommended approach standards included as appendix B to 50 CFR part 216, subpart D, of these proposed regulations. NMFS recommends that an application be submitted for a special exception permit if a person intends to conduct, or may conduct, an activity for a special exception purpose that may involve an approach of marine mammals closer than the recommended minimum distance standard or will be conducted contrary to the recommended activity limitations or operating procedures described in appendix B. The recommended approach standards of appendix B are also the standards that

would be used for reporting purposes for activities conducted in the wild under a special exception permit.

Importantly, the approach standards recommended in appendix B are limited to the approach of, or other activities directed at, marine mammals. If a marine mammal elects to approach a vessel or person that has made every effort to comply with the recommended approach and activity limitations described here, and such a person or vessel does not otherwise take the marine mammal, then such an approach by the marine mammal cannot by itself be considered harassment or another type of take under the Acts. In that case, the activity is not prohibited under the Acts and a special exception permit is not required to conduct the activity.

There are several important differences between the approach standards recommended in appendix B and the proposed regulations and guidelines for approaching cetaceans and pinnipeds published in the *Federal Register* on August 3, 1992 (57 FR 34101 and 34121) and subsequently withdrawn on March 29, 1993 (58 FR 16519). A number of commenters voiced serious concerns regarding these now withdrawn proposed approach regulations. Although, importantly, the approach standards recommended in appendix B are guidelines and are not regulatory requirements, NMFS has nonetheless considered fully these serious concerns and prepared appendix B accordingly. The recommended approach standards of appendix B establish, as guidance, a "threshold" beyond which the risk of harassment is unlikely and which, if exceeded by an approaching person or vessel, the risk of harassment becomes likely. The approach standards recommended in appendix B are guidelines intended to benefit permit applicants and permit holders, as well as improve the efficiency and consistency of permit administration and reporting; whereas, the proposed approach regulations would have established specified distances to maintain when approaching marine mammals, a requirement applicable to the public in general. In addition to this fundamental distinction between recommendations and requirements, NMFS acknowledges explicitly in appendix B that actions on the part of the marine mammal to approach a person or vessel cannot be controlled, and marine mammals may "bow ride" or otherwise approach a person or vessel independent of any action on the part of that person or vessel. As a result, such actions on the part of a marine mammal independent of any action on the part of a person or

vessel cannot be construed to constitute a take of such a marine mammal. The recommended approach standards proposed in appendix B would meet the immediate needs of NMFS, permit holders, and potential permit applicants as objective standards for determining when takes are likely and, as a result, are proposed to be used for purposes of reporting and permit program administration.

The approach standards recommended in appendix B would be applicable to scientific research and enhancement permits for activities conducted in the wild. Because the approach standards recommended in appendix B would be applicable only to activities conducted in the wild, they would apply to public display permits only where the taking authorized under a public display permit involved chase and capture activities conducted in the wild. Additionally, their use would be limited to marine mammals; NMFS would establish objective standards to address these concerns for other protected species, i.e., endangered or threatened marine species other than marine mammals, on a species-specific basis.

During the Permit Program Review, discussion of this issue frequently focused on the lack of a specified definition of the term "harass;" accompanied by claims that this has contributed to confusion on the part of the public and permit applicants. Confusion was expressed regarding what activities conducted in the wild constitute a take and therefore are either prohibited or may be conducted only for certain excepted purposes. In addition, in deciding the case *Strong v. United States*, discussed under II.1. of this preamble, the district court raised several issues and concerns regarding the term "harass." The FWS has defined the term "harass" at 50 CFR 17.3. NMFS is proposing a definition of the term "harass" under the MMPA that is modeled on the FWS regulatory definition of this term.

3. Categorize Various Types of "Take" of Protected Species, Particularly for Activities Conducted in the Wild

On a matter that is closely related to the issues discussed in III.2. of this preamble, categorization of the various types of take is necessary for the same reasons discussed in III.2.; i.e., to allow NMFS, permit holders and permit applicants to comply fully with the requirements of section 104 of the MMPA and section 10 of the ESA. After determining whether particular activities result in takes, the next step would be to categorize takes to increase

the efficiency of processing permit applications. Efficiency would be increased through categorization by allowing NMFS to sort permit applications according to type of take and the corresponding levels of effort involved in review and processing, and by allowing NMFS to assess early in the review process a proposed activity's relative complexity and anticipated impact on protected species.

For activities involving takes in the wild, NMFS is proposing to break the term "take" down into the three major categories of activities in the statutory definition—kill, capture, and harass. Each of these three major categories would then be further subdivided to reflect more accurately the major types of activities that commonly involve the take of protected species in the wild. For example, harassment encompasses takes ranging from acts likely to result in a significant change in behavior to injury of the protected species. These takes may occur without the capture or killing of a protected species. Capture encompasses takes that range from short-term capture-and-release to the permanent removal of protected species from the wild. Depending on the nature of the proposed activities, more than one type of take, as well as different levels of each type of take, may be involved. For example, capture of a protected species from the wild necessarily involves harassment, but does not necessarily involve killing. Conversely, killing normally involves harassment of protected species, but does not necessarily involve capture. In appendix A to subpart D of the proposed regulations at 50 CFR part 216, types of take are broken down by the major categories of harassment, capture, and kill. These types of take are then subdivided further into subcategories such as non-intrusive/non-contact (close approach) harassment, intrusive/contact (close approach with physical contact) harassment, temporary capture/removal, and permanent capture/removal (indefinite captive maintenance or lethal take).

4. Separate Authorized Research Activities From Unauthorized Commercial and Recreational Activities

During the history of the permit program, as well as during the Permit Program Review, questions have been raised regarding the commercial use of photographs or other material obtained while conducting scientific research authorized by a scientific research permit issued under the MMPA or ESA, sections 104 and 10, respectively. The most significant concern in this regard

is the commercial incentive that is created to harass the subject protected species for reasons unrelated to the purpose authorized by the permit. Commercial use of a research product that involves the financial gain of the permit holder also creates an incentive to harass/take the subject protected species to a degree greater than may otherwise be required to collect data to further scientific research.

NMFS believes that most members of the scientific research community, regardless of such a commercial gain incentive, limit harassment of protected species to levels authorized and necessary to carry out permitted scientific research. However, such self-restraint may not be exercised by everyone. During the last several years, NMFS believes that some individuals may have used scientific research permits as a subterfuge for conducting unauthorized commercial activities. Such real or potential permit abuses cannot be reconciled with the purposes and policies of the Acts.

The authorization granted by a scientific research permit issued under the Acts does not extend to commercial or recreational activity. A scientific research permit is a grant of a privilege to conduct certain otherwise prohibited activities, not the grant of a license or exclusive right to a commercial activity or product. The primary purpose of the MMPA is to protect and manage marine mammals for their benefit and the health and stability of the marine ecosystem. Similarly, the primary purpose of the ESA is the conservation of endangered and threatened species and the ecosystems on which they depend. Commercial and recreational activities, while not necessarily otherwise prohibited by the general moratorium established under the MMPA or prohibitions established under the ESA, are not properly the subject of scientific research permits issued under the Acts.

To ensure that activities conducted under the authority of a scientific research permit are limited to only those activities necessary for the conduct of bona fide scientific research and consistent with the Acts, these proposed regulations would prohibit the sale of photographs or other marketable products obtained during authorized scientific research, unless such marketable products were obtained in a manner or for a purpose essential to the conduct, presentation, or publication of the research, or for a few other limited purposes. This limitation is intended to address concerns regarding misuse of permit authority for commercial rather than scientific research purposes.

A proposed definition of "marketable products" is included in the revised regulations at § 216.3. This proposed definition is intended to assist in the separation of authorized bona fide scientific research from the most significant commercial incentive for the abuse of the research privileges, thereby minimizing the potential for increased risk of adverse impacts to the subject protected species. The proposed regulation provides a mechanism by which photographic or other marketable products obtained consistent with a scientific research permit can be made available to the public free of charge, with the permission of the permit holder. Additionally, NMFS has made it clear that the definition of the term "marketable product" does not include intellectual property (e.g., knowledge and experience) gained in the conduct of a permitted activity or an otherwise marketable product obtained in the course of an activity conducted outside the context of a permitted activity and that does not involve the take of a protected species in the wild. Also, protected species parts and products are not included in this definition.

As stated in III.2. of this preamble, the proposed approach standards of appendix B to subpart D of the proposed regulations are recommended standards for approaches of marine mammals by vessels or persons, a "threshold" beyond which (i.e., if maintained) the risk of harassment is unlikely and within which (i.e., if exceeded by an approaching person or vessel) the risk of harassment becomes likely, and for certain vessel operations likely to harass marine mammals. Importantly, as also noted in III.2. of this preamble, these approach standards would not preclude a marine mammal from approaching a photographer, vessel, or individual closer than the recommended approach limit. It would be likely that, by following these recommended approach standards, commercially lucrative photography/filming and observation of marine mammals could be conducted without taking marine mammals. The important point is that, to avoid a likely take of marine mammals, commercial or recreational activities must be conducted, and any marketable products must be obtained, consistent with these objective standards. If such activities were conducted without taking marine mammals, and were separate from any activities conducted under a scientific research permit, any marketable products obtained during these activities could be used for any purpose.

These proposed limitations would not prohibit or restrict such commercial/

recreational activities more than NMFS believes necessary to minimize the risk of harassment to protected species. Except for certain reasonable exceptions, NMFS has determined that activities involving the take of protected species in the wild for commercial or recreational purposes are outside the scope of, and cannot be authorized by, scientific research permits issued under the Acts.

5. Delineate Permit Requirements for Scientific Research Activities That Involve Marine Mammals Held Under Public Display Permits

NMFS is proposing that some research could be conducted involving marine mammals held under a public display permit without additional authorization. The terms and conditions of the public display permit would include authorization for research other than intrusive research that is conducted in a humane manner consistent with the proposed captive maintenance standards, and does not interfere with the activities for which the public display permit was issued. Intrusive research (as opposed to husbandry, care, maintenance, or medical treatment activities), which by definition is likely to involve a risk to the health or welfare of a captive marine mammal, would need to be specifically authorized under a scientific research permit.

The purpose of takes that occur during intrusive research is scientific research, not public display. The reason for requiring a separate permit for intrusive research is that intrusive research involves taking/harassment of marine mammals beyond the simple captive maintenance normally associated with public display. As a result, such intrusive research should only be authorized after public notice and review of the merits of the proposal by the scientific community, the public, and the MMC consistent with the purposes and policies of the Acts. The most appropriate mechanism under the MMPA for the authorization of intrusive research on marine mammals held under a public display permit is the scientific research permit application process. For these reasons, a proposed definition of "intrusive research" is included in these revised regulations at § 216.3.

This proposed definition of intrusive research is not intended to include procedures conducted for training or demonstration/performance purposes, if they are conducted in compliance with the captive maintenance requirements as set forth in these proposed regulations.

6. Explain That Funding Is Not a Prerequisite for Issuance of a Scientific Research Permit, But That Research Must Be Conducted as It Is Permitted, Unless Otherwise Specifically Authorized

Permits are issued with the understanding that the permit activities will be conducted as proposed in the application and as authorized by the permit. This is particularly true for scientific research permits. If permitted research is modified for any reason, including funding considerations, such a change could require an amendment to the permit. The proposed regulations provide a permit amendment procedure, discussed in I.5. of this preamble, for such situations.

IV. Enhancement Goals

Clarify that enhancement permits will be issued only for the conduct of special exception activities concerning living protected species or protected species parts that are necessary to accomplish the enhancement purpose.

The 1988 amendments to the MMPA added section 104(c)(4) to authorize taking or importing marine mammals for the purpose of enhancing the survival or recovery of a species or stock (enhancement). The proposed regulations provide for the issuance of enhancement permits applicable only to living protected species or protected species parts that are necessary for the enhancement of the survival, recovery, or propagation of the affected species or stock. Moreover, enhancement permits would authorize only management-type activities such as projects to increase stock sizes in the wild, establishing experimental protected species communities, or reintroduction of protected species in areas they previously occupied. Protected species parts would include, in this regard, clinical specimens or other biological samples required for the conduct of breeding programs or the diagnosis or treatment of disease.

These activities in most cases do not fall cleanly into the category of scientific research and could therefore not be appropriately authorized under scientific research permits. Section 104(c)(4) was added to fill this critical gap that could not be adequately addressed by the provisions for public display and scientific research permits. The understanding that enhancement permits are limited to living marine mammals and marine mammal parts necessary to accomplish the enhancement purpose is reflected in the types of activities discussed and the

conditions placed on them in section 104(c)(4).

This approach differs somewhat from the approach taken in the past under the enhancement provision of the ESA (section 10(a)(1)(A)). In some instances, the ESA enhancement provision has been used to allow import and possession of "trophies," or parts of dead endangered species, based on the argument that big game hunting and commercial trade in parts of endangered species provided revenue with which conservation and management programs could be financed. One problem with this approach is that it may create commercial trade opportunities and an incentive for poaching because it is difficult, from an enforcement standpoint, to tell permitted parts from poached parts. Limiting enhancement permits to living protected species and protected species parts necessary to accomplish the enhancement purpose would avoid this type of problem that has been observed in the administration of the ESA enhancement provision.

An example of a typical enhancement activity that reflects the applicability of section 104(c)(4) of the MMPA and section 10(a)(1)(A) of the ESA is the Hawaiian Monk Seal Head Start Program. When it was initiated in 1985, it was authorized by a scientific research permit to explore the feasibility of taking abandoned or weakened monk seal pups, rehabilitating them, and then releasing them back into the wild. During the course of the Head Start Program, it was learned that the experimental techniques worked, and the activities moved away from an experimental status to a proven method of assisting in the survival and recovery of the Hawaiian monk seal. Such an activity is more appropriately authorized by an enhancement permit than a scientific research permit.

Classification

NMFS prepared an EA for this action and concluded that this proposed rule will not significantly affect the human environment, and, as a result, preparation of an EIS on this action is not required by section 102(2) of the National Environmental Policy Act (NEPA) or its implementing regulations. Copies of the EA are available on request (see ADDRESSES). NEPA requirements as they pertain to individual permits that may be issued under these proposed regulations will be addressed on a case-by-case basis.

The AA has determined that this rule is not a "major rule" requiring a regulatory impact analysis under E.O. 12291. The present action will not have a cumulative effect on the economy of

\$100 million or more, nor will it result in a major increase in costs to consumers, industries, government agencies, or geographical regions. No significant adverse effects on competition, employment, investments, productivity, innovation, or competitiveness of U.S.-based enterprises are anticipated.

An Initial Regulatory Flexibility Analysis was prepared by NMFS and is available upon request [see ADDRESSES], in accordance with the Regulatory Flexibility Act (RFA) (5 U.S.C. 601 *et seq.*). The projected economic impact of the proposed revisions on affected small business entities is a combination primarily of paperwork burden costs, permit fees, and bond costs. NMFS believes that it is unlikely that significant economic impact will result from the requirements of the proposed regulations beyond the economic impacts associated with the paperwork requirements, associated permit administration, and similar requirements imposed under existing regulations. However, sufficient financial and other economic information concerning affected entities is not available for an in-depth analysis of the economic impact of the proposed regulations on small business entities. Sufficient financial data on permit holding entities, when available, could demonstrate such significant economic impacts. As a result, NMFS is soliciting information through this proposed rule regarding its economic impacts on small business entities, and will consider any information submitted in preparation of a Final Regulatory Flexibility Analysis, if warranted, prior to publication of a final rule.

This proposed rule contains collections of information subject to the Paperwork Reduction Act that have been submitted to the Office of Management and Budget for approval. The public reporting burden for collection of this information is estimated to average 29 hours per response for permit applications and major amendment requests, 3 hours for minor amendment/authorization requests, and 8 hours per response for reporting. Please send comments regarding these burden estimates, or any other aspect of this collection of information, including suggestions for reducing this burden, to the National Marine Fisheries Service, (F/PR1), 1315 East-West Highway, Silver Spring, MD 20910; and to the Office of Information and Regulatory Affairs, Office of Management and Budget, Washington, DC 20503 (Attn: Paperwork Reduction Act Projects 0648-0084).

This proposed rule does not contain policies with federalism implications sufficient to warrant preparation of a federalism assessment under E.O. 12612.

NOAA has determined that these proposed regulations do not directly affect the coastal zone of any State with an approved coastal zone management program.

List of Subjects

50 CFR Part 215

Administrative practice and procedure, Marine mammals, Penalties, Pribilof Islands, Reporting and recordkeeping requirements.

50 CFR Part 216

Administrative practice and procedure, Imports, Indians, Marine mammals, Penalties, Reporting and recordkeeping requirements, Transportation.

50 CFR Part 222

Administrative practice and procedure, Endangered and threatened species, Exports, Imports, Reporting and recordkeeping requirements, Transportation.

Dated: October 5, 1993.

Nancy Foster,

Acting Assistant Administrator for Fisheries.

For reasons set forth in the preamble, 50 CFR parts 215, 216, and 222 are proposed to be amended as follows:

PART 215—PRIBILOF ISLANDS

1. The authority citation for part 215 is revised to read as follows:

Authority: 16 U.S.C. 1151-1175, 1361 *et seq.*

2. Section 215.1 is revised to read as follows:

§ 215.1 Purpose and scope.

The purpose of these regulations is to implement the provisions of the Fur Seal Act of 1966, as amended. These regulations apply to the administration of the Pribilof Islands; the take of fur seals; and permits for the take, transportation, importation, exportation, or possession of fur seals or their parts for educational, scientific, or exhibition purposes.

3. In § 215.2, (f) is revised to read as follows:

§ 215.2 Definitions.

* * * * *

(f) *Public display* means the same as defined in § 216.3 of this chapter.

* * * * *

4. Subpart B is revised to read as follows:

Subpart B—Permits for Scientific Research and Public Display

§ 215.11 Permits for scientific research and public display purposes.

In accordance with the provisions of part 216, subpart D, of this chapter, the AA may issue permits for the taking, transportation, importation, exportation, or possession of fur seals or their parts for scientific research or public display purposes.

PART 216—REGULATIONS GOVERNING THE TAKING AND IMPORTING OF MARINE MAMMALS

5. The authority citation for part 216 continues to read as follows:

Authority: 16 U.S.C. 1361 *et seq.*, unless otherwise noted.

6. In part 216, all references to "Act" are revised to read "MMPA".

7. In § 216.3, the definition of *Act* is removed, new definitions of *Acts*, *bona fide scientific research*, *custody*, *ESA*, *facility*, *FSA*, *harass*, *humane*, *interactive program*, *intrusive research*, *marketable product*, *MMPA*, *protected species*, *public display*, and *rehabilitation* are added, in alphabetical order, and the definition of *take* is revised to read as follows:

§ 216.3 Definitions.

* * * * *

Acts means, collectively, the Marine Mammal Protection Act of 1972, 16 U.S.C. *et seq.*, the Endangered Species Act of 1973, 16 U.S.C. 1531 *et seq.*, and the Fur Seal Act of 1966, 16 U.S.C. 1151 *et seq.*

* * * * *

Bona fide scientific research:

(1) Means scientific research on or otherwise benefiting protected species, the results of which:

(i) Likely would be accepted for publication in a peer-reviewed scientific journal; or

(ii) Are likely to contribute to understanding the basic biology or ecology of the species or stock, or to identifying, evaluating, or resolving possible conservation problems. (Note: This includes, for example, long-term assessment and management studies necessary to identify or determine how to resolve conservation problems; studies to monitor the effects of human activities on protected species or the effectiveness of conservation measures; or the inclusion of protected species parts in a properly curated, professionally accredited scientific collection); or

(iii) Are necessary to fulfill a critically important research need. (Note: This is intended to include, particularly for

marine mammals that are designated as depleted under this part and marine species designated as endangered under part 222 of this chapter or threatened under part 227 of this chapter, research to identify factors contributing to the decline of the species or stocks, or to the destruction or adverse modification of critical habitats, or to identify and evaluate measures for stopping and reversing population declines and habitat degradation. Also, this may include research on protected species that would likely contribute significant results essential to understanding or solving a critical problem affecting human health.)

(2) Research that is not on or that does not otherwise benefit protected species, but that may incidentally take protected species, is not included in this definition (see sections 101(a)(3)(A) and 101(a)(5)(A) of the MMPA and section 10(a)(1)(B) of the ESA).

* * * * *

Custody means the holding of a living marine mammal pursuant to the conditional authority granted under a special exception permit, and the responsibility therein for captive maintenance of the marine mammal. This definition does not apply to the term "custody" in 50 CFR 216.78.

* * * * *

ESA means the Endangered Species Act of 1973, 16 U.S.C. 1531 *et seq.*

* * * * *

Facility:

(1) Means:

(i) One or more permanent primary enclosures used to hold marine mammals captive (e.g., pools, lagoons) and associated infrastructure (e.g., equipment and supplies necessary for the care and maintenance of marine mammals) where these enclosures are either located within the boundaries of a single contiguous parcel of land and water, or are grouped together within the same general area within which enclosure-to-enclosure transport is expected to be completed in less than 1 hour; or

(ii) A traveling display/exhibit, where the enclosure(s) and associated infrastructure is transported together with the marine mammals.

(2) This definition is specific to the term "facility" and is applicable to the term "facilities" only when the context clearly is specific to captive marine mammals.

* * * * *

FSA means the Fur Seal Act of 1966, 16 U.S.C. 1151 *et seq.*

* * * * *

Harass in the definition of "take" in the MMPA means an intentional or

negligent act or omission that results in, or is likely to result in, an injury to a marine mammal, a disruption in the behavior that a marine mammal was exhibiting prior to the act or omission, or a significant effect on the normal behavioral patterns of a marine mammal, including, but not limited to, breeding, feeding, sheltering, or migration patterns.

Humane means the method of taking, import, export, or conduct of an otherwise prohibited activity involving a protected species that involves the least possible degree of pain and suffering practicable to the animal involved.

Interactive program means a program that allows a member of the public to touch, feed, share an enclosure with, physically contact, or directly interact with a captive marine mammal, from within or outside of its enclosure. Examples of interactive activities include, but are not limited to, petting, feeding, or swimming, snorkeling, or SCUBA diving with a marine mammal. For the purpose of this definition, a member of the public means any person other than the permit holder's staff whose functions concern the training, supervision, handling, care and maintenance, treatment, or transportation of marine mammals or maintenance of associated facilities, or an authorized agent under the permit.

Intrusive research means a procedure conducted for bona fide scientific research involving: A break in or cutting of the skin or equivalent, insertion of an instrument or material into an orifice, introduction of a substance or object into the animal's immediate environment that is likely either to be ingested or to contact and affect directly animal tissues (e.g., chemical substances), or a stimulus directed at animals that may involve a risk to health or welfare or that may have an impact on normal function or behavior (e.g., audio broadcasts directed at animals that may affect behavior). Provided that, for captive animals, this definition does not include:

(1) A procedure conducted by the professional staff of the holding facility or an attending veterinarian for purposes of animal husbandry, care, maintenance, or treatment, or a routine medical procedure that, in the reasonable judgment of the attending veterinarian, would not constitute a risk to the health or welfare of the captive animal; or

(2) A procedure involving either the introduction of a substance or object (i.e., as described in this definition) or a stimulus directed at animals that, in the reasonable judgment of the attending veterinarian, would not involve a risk to the health or welfare of the captive animal.

Marketable product means a product obtained in the course of an activity conducted in the wild under a special exception permit that is or may be of commercial value. This includes photographs, film, video or audio recordings, or other audio-visual products. This definition does not include intellectual property (e.g., knowledge and experience) gained in the conduct of a permitted activity or an otherwise marketable product obtained in the course of an activity conducted outside the context of a permitted activity and that does not involve the take of a protected species in the wild. Protected species parts and products are not included in this definition, but are addressed elsewhere in this part.

MMPA means the Marine Mammal Protection Act of 1972, 16 U.S.C. 1361 et seq.

Protected species means those species subject to the jurisdiction of the National Marine Fisheries Service (NMFS) under the Acts. These species include marine mammals (including North Pacific fur seals), marine and anadromous species determined to be endangered under the ESA, and marine and anadromous species determined to be threatened under the ESA for which prohibitions, restrictions, or other protective measures have been established through regulation.

Public display means an activity that provides opportunities for the public to view and otherwise appreciate and learn about living marine mammals, conducted in a manner consistent with the goals and objectives of the MMPA, under the direction of professional staff, and at a facility holding marine mammals captive that offers an education or conservation program acceptable to the AA that contributes to public appreciation and understanding of marine mammals and their role in the marine ecosystem.

Rehabilitation means the treatment of beached and stranded marine mammals taken under section 109(h)(1) of the MMPA or rendering medical treatment otherwise unavailable to marine mammals imported under section 109(h)(2) of the MMPA, with the intent of restoring the marine mammal's health

and, if necessary, behavioral patterns, such that the marine mammal is reasonably expected to survive when returned to its natural habitat. Marine mammals are considered rehabilitated upon completion of such treatment.

Take means to harass, hunt, capture, collect, or kill, or attempt to harass, hunt, capture, collect, or kill any marine mammal. This includes, without limitation, any of the following: The collection of dead animals, or parts thereof; the restraint or detention of a marine mammal, including holding a marine mammal captive, no matter how temporary; tagging a marine mammal; or feeding or attempting to feed a marine mammal in the wild.

8. In § 216.22, paragraph (c)(8)(i) is revised to read as follows:

§ 216.22 Taking by State or local government officials.

(c) * * *

(8) * * *

(i) The transfer is a temporary transfer to a laboratory or research institution within the United States so that analyses can be performed for the person salvaging the specimen; or

9. In subpart C, new §§ 216.27 and 216.28 are added to read as follows:

§ 216.27 Emergency authorization.

(a) Under the authority of sections 109(h) and 112(c) of the MMPA, the AA may grant an emergency research or enhancement authorization to take or import marine mammals or marine mammal parts for purposes of bona fide scientific research or enhancing the survival or recovery of the species or stock (enhancement), if the AA determines that such taking or importation is necessary for the protection or welfare of marine mammals or a marine mammal stock. An emergency authorization may be granted in consultation with the Marine Mammal Commission and Committee of Scientific Advisors on Marine Mammals only if necessary to respond to an emergency, such as a sudden and unforeseen event presenting a significant threat to a marine mammal stock, for example an environmental disaster or a major mortality event.

(b) To obtain an emergency research or enhancement authorization, a signed written request must be submitted, including the following information:

- (1) The location and nature of the emergency;
- (2) The objectives of the proposed research or enhancement activity;

(3) The nature of the take or import requested;

(4) The principal applicant and any other persons to be responsible for conducting or supervising the proposed research or enhancement activity; and

(5) Current or past scientific research or enhancement permits issued to the applicant or under which the applicant was designated as a co-investigator/agent.

(c) In order to grant an emergency authorization, the AA must find that:

(1) The proposed activity is necessary for the protection or welfare of marine mammals or a marine mammal stock because of an emergency as described in paragraph (a) of this section;

(2) The proposed activity is bona fide scientific research or an enhancement activity;

(3) The activity cannot otherwise be authorized under the MMPA within the period of time required by the emergency; and

(4) The person proposed to be principally responsible for conducting or supervising the proposed research or enhancement activity either:

(i) Currently holds, has held, or has been designated as a co-investigator/agent under, a scientific research or enhancement permit for the species in question; or

(ii) Is under the direct supervision of a qualified person designated by the AA in consultation with the Marine Mammal Commission and Committee of Scientific Advisors on Marine Mammals.

(d) Emergency authorizations shall be in writing and shall specify the authorized level and methods of take or import and any appropriate conditions, including reporting requirements. The AA may amend, modify, suspend, or revoke an emergency authorization at any time.

(e) The AA shall publish a notice of issuance of an emergency authorization in the Federal Register within 10 days of issuance.

(f) An emergency authorization may be granted for an initial period of up to 60 days. This initial authorization period may be extended up to an additional 60 days if the AA finds that the criteria in paragraph (c) of this section continue to apply.

(g) The AA may extend an emergency authorization beyond 120 days if an application for a scientific research or enhancement permit has been submitted before or during the period of emergency authorization and found initially complete under § 216.34. In this case, the period of authorization may be extended until the scientific

research or enhancement permit is either issued or denied.

§ 216.28 Release or other disposition of rehabilitated marine mammals.

(a) *Release requirements.* (1) Any marine mammal held for rehabilitation must be released within 6 months of the date of capture or import unless the attending veterinarian determines:

(i) That the marine mammal might transmit a contagious disease to marine mammals in the wild;

(ii) That the release of the marine mammal to the wild is not likely to be successful, considering both the physical condition and behavior of the marine mammal; or

(iii) That more time is needed to determine whether the release of the marine mammal to the wild is likely to be successful.

(2) In the case of beached and stranded pinnipeds, the person with authorized custody of the marine mammal must notify the appropriate NMFS Regional Director (Regional Director) at least 15 days in advance of the proposed release. The Regional Director shall forward such release notifications for beached and stranded pinnipeds to the AA to provide the AA an opportunity to require disposition in accordance with paragraph (b)(4) of this section and § 216.44.

(3) In the case of beached and stranded cetaceans or imported marine mammals, the person with authorized custody of the marine mammal must notify the AA at least 30 days in advance of the proposed release.

(4) The release notifications required by paragraphs (a)(2) and (a)(3) of this section must include:

(i) A description of the marine mammal, including its physical condition and estimated age;

(ii) The proposed date and location of release; and

(iii) The proposed method and duration of transport.

(5) The Regional Director (in the case of pinnipeds) or the AA (in the case of cetaceans or imported marine mammals) may:

(i) Require additional information before the marine mammal may be released;

(ii) Require a change in the date, location, method or duration of transport or release;

(iii) Place additional requirements on the release to improve the likelihood of success or to monitor the success of the release; or

(iv) Require other disposition of the marine mammal.

(6) All marine mammals must be released near wild populations of the

same species, unless a waiver is granted by the Regional Director or the AA, as appropriate.

(7) All marine mammals to be released must be tagged in a manner acceptable to the Regional Director or the AA, as appropriate. The tag number must be reported to the Regional Director following release. The results obtained from a radio, satellite or other type tag following release must be submitted as a part of the annual report required in paragraph (c) of this section.

(b) *Other disposition.* (1) A determination by the attending veterinarian under paragraph (a)(1) of this section must be forwarded, along with supporting documentation, to the Regional Director, who shall forward a copy to the AA.

(2) If the Regional Director (in the case of pinnipeds) or the AA (in the case of cetaceans or imported animals) concurs with the attending veterinarian's determination that more time is needed, the continued rehabilitation of the marine mammal may be authorized subject to a new release determination at least every 6 months. If the Regional Director or AA disagrees with the attending veterinarian's determination that more time is needed or that the release of the marine mammal is not likely to be successful, he/she may require the release of the marine mammal, the continued rehabilitation of the marine mammal subject to a new release determination at least every 6 months, or require other disposition. In any case, after 24 months of continued rehabilitation from the date of capture or import it will be presumed that the release of the marine mammal is not likely to be successful.

(3) Except in the case of paragraph (b)(2) of this section, no later than 30 days after an attending veterinarian's determination that the release of the marine mammal is not likely to be successful, the person with authorized custody of the marine mammal must request authorization to retain or transfer custody of the marine mammal in accordance with § 216.44 or carry out other disposition of the marine mammal.

(4) Notwithstanding any of the provisions of § 216.28, the AA may, subject to the provisions of § 216.44(b), require that a rehabilitated marine mammal be used as a substitute for a marine mammal of the same species for which a special exception permit has been issued under subpart D of this part to capture from the wild or obtain from captive stock.

(c) *Reporting.* In addition to the report required under § 216.22(b), the person with authorized custody of marine

mammals held for rehabilitation must submit an annual report to the Regional Director regarding release or other disposition. This report must include, for each marine mammal held for rehabilitation: An assessment (medical assessment if a veterinarian was involved) of and, if applicable, reason for the animal's condition at the time of capture/import; location of release or description of other disposition; tag data following release, if any; date of death, release, or other disposition; and, if the animal died (or was euthanized), a copy of a necropsy report or the cause of death (if a veterinarian is available) or the likely cause of death (if veterinarian is not available). Where applicable, this annual report must be provided in the form specified by the Regional Director.

§ 216.40 [Redesignated as § 216.50]

10. Section 216.40 is redesignated as § 216.50 of subpart E.

11. Subpart D is revised to read as follows:

Subpart D—Special Exception Permits

Sec.

- 216.30 General.
- 216.31 Definitions.
- 216.32 Scope.
- 216.33 Is a special exception permit required?
- 216.34 Permit application, review, and decision procedures.
- 216.35 Issuance criteria.
- 216.36 Permit restrictions.
- 216.37 Captive maintenance.
- 216.38 Permit conditions.
- 216.39 Reporting.
- 216.40 Permit amendment, modification, suspension, or revocation.
- 216.41 Penalties.
- 216.42 Fees.
- 216.43 Applicability/transition.
- 216.44 Use for special exception purposes of marine mammals taken or imported for rehabilitation.

Appendix A to Subpart D—Examples of Activities That Require a Special Exception Permit

Appendix B to Subpart D—Approach Standards Recommended for Activities Conducted in the Wild

Appendix C to Subpart D—Permit Application Information

Subpart D—Special Exception Permits

§ 216.30 General.

(a) *Purpose.* The regulations in this subpart set forth procedures and criteria for the issuance of special exception permits:

(1) To authorize the taking and importation of marine mammals or marine mammal products for purposes of scientific research, public display, or enhancing the survival or recovery of a

species or stock (enhancement), under the MMPA;

(2) To authorize persons subject to U.S. jurisdiction to import, export, take, engage in interstate or foreign commerce, or conduct any other act otherwise prohibited, concerning fish and wildlife under the jurisdiction of NMFS and listed as endangered, or, where similarly regulated, threatened (see § 222.21 of this chapter), for scientific purposes or to enhance the propagation or survival of the affected species (enhancement) under the ESA; and

(3) To take, import, export, transport, or possess North Pacific fur seals or their parts for educational, scientific, or exhibition purposes under the FSA.

Note: North Pacific fur seals (Pribilof Island population) have been designated as depleted under the MMPA and, therefore, while depleted, North Pacific fur seals (Pribilof Island population) may not be taken for purposes of public display/exhibition.

(b) *Terms of reference.* (1) For the purposes of this subpart, the permits listed under paragraph (a) of this section are referred to as "special exception permits" to distinguish them from "general permits" issued under section 104(h) of the MMPA or "incidental taking" permits issued under section 10(a)(1)(B) of the ESA.

(2) The term "special exception activity" refers to activities affecting protected species and otherwise prohibited under the Acts for which a special exception permit is required; for example, take, importation, export, transport, purchase or sale (interstate or foreign commerce only under the ESA), possession (FSA), or otherwise prohibited activity under any of the Acts or their respective regulations.

Note: Captive maintenance provisions are generally applicable to marine mammals under the Acts, and have strictly limited applicability to other endangered or threatened species under the ESA; for example endangered or threatened species of marine and anadromous fish or marine reptiles.

(c) *Objectives.* The objectives of the Special Exception Permit Program are to ensure that:

(1) Permitted special exception activities will have the least practicable adverse effects on protected species populations or stocks;

(2) Permitted special exception activities, including the care and maintenance of marine mammals in captivity, will be humane and in accordance with applicable requirements of the Acts and the Animal Welfare Act;

(3) Permitted special exception activities will contribute to an improved

scientific or public understanding of the ecology, population dynamics, biology, reproduction, and behavior of protected species in the wild and in captivity, and an enhanced public appreciation for and understanding of the marine ecosystem and the need for protected species conservation both in the United States and worldwide; and

(4) Available data on protected species are accessible as a basis for informed policy decisions, effective management, and the protection of protected species populations and marine ecosystems.

§ 216.31 Definitions.

Wherever a term defined in § 216.3 of this part is also defined in 50 CFR part 215 or part 217, the definitions in 50 CFR part 215 shall apply to special exception permits involving North Pacific fur seals and the definitions in 50 CFR part 217 shall apply to special exception permits involving species listed as endangered or threatened under the ESA, except for marine mammals. Terms not defined in § 216.3 of this part but defined in 50 CFR part 215 or part 217, shall apply to this subpart as applicable (i.e., wherever a special exception permit involves North Pacific fur seals or endangered or threatened species).

§ 216.32 Scope.

(a) *Marine mammals and marine mammal parts.* Except as provided in paragraph (b) of this section:

(1) Unless otherwise specified, the regulations of this subpart apply to all marine mammals or marine mammal parts, including any marine mammal born in captivity after December 21, 1972, regardless of parentage.

(2) The regulations of this subpart do not apply to or otherwise affect any marine mammal or marine mammal part taken before December 21, 1972 (pre-Act marine mammals or marine mammal parts), provided that:

(i) The AA receives adequate documentation from the holder that establishes the "pre-Act" status of the marine mammal or marine mammal part, including a description of the manner in which the subject marine mammal or marine mammal part is marked such that it is distinguishable from any other marine mammal or marine mammal part; and

(ii) For marine mammals—
(A) The AA receives prior notification from the holder and intended recipient of their intent to hold captive, transport, transfer or obtain custody of, sell, purchase, or otherwise convey or acquire an interest in, or otherwise dispose of or obtain such pre-Act

marine mammals; and the dates, method, persons involved, and any other arrangements pertaining thereto; and

(B) Such pre-Act marine mammals are not held together with marine mammals of the same species that are subject to the regulations of this subpart (i.e., if a single facility holds both post-Act and pre-Act marine mammals of the same species, such facility must comply with the requirements and conditions applicable in such circumstances set forth at §§ 216.36(a)(7) and 216.38(b)(19)).

(3) The regulations of this subpart do not apply to any marine mammal being taken or imported under the authority of section 109(h) of the MMPA unless the marine mammal is:

- (i) Placed on public display during rehabilitation or before disposition has been completed under § 216.44; or
- (ii) Subjected during rehabilitation to an intrusive research procedure as defined in § 216.3.

(b) *Endangered or threatened species and endangered or threatened species parts.* Unless otherwise specified in parts 217 through 229 of this chapter, the regulations of this subpart apply to all protected species and protected species parts determined to be endangered under part 222 of this chapter or threatened under part 227 of this chapter.

(c) *Permit applicants*—(1) *Public display.* The applicant must be the public display facility where the marine mammals will be held and displayed to the public. Each public display facility must apply separately for a special exception permit (i.e., public display permits are facility-specific, except as provided in § 216.37(g) and (h)).

Temporary holding of marine mammals at a different facility (e.g., because of an emergency, facility renovations, or for acclimation and transition training following wild capture) may be authorized if the applicant submits as a part of the application a letter from the temporary holding facility indicating agreement to hold the marine mammals temporarily in accordance with the provisions of this subpart.

(2) *Scientific research.* (i) The applicant must be the principal investigator conducting the scientific research or be the appropriate institution, governmental entity, or corporation responsible for the supervision of the principal investigator, if the research:

(A) Involves a periodic change in the responsible principal investigator (e.g., long-term monitoring studies or the curation of protected species parts in a permanent scientific collection); or

(B) Is otherwise controlled by and dependent upon the institution, governmental entity, or corporation.

(ii) If the research involves a number of co-investigators, a single principal investigator who will be primarily responsible for the taking, importation, export, or otherwise prohibited activity involving protected species, and any related activities under the permit, must be identified as the applicant. Co-investigators may be designated as agents in the permit (i.e., the principal investigator's on-site representative also responsible for the special exception activity authorized by the permit); see § 216.38(d)(1).

(iii) Where the proposed scientific research involves captive maintenance in a facility, temporary pen, or other temporary enclosure, the application must include a supporting statement from the person responsible for the facility or other temporary enclosure.

(3) *Enhancement.* The applicant must be the person, institution, governmental entity, or corporation responsible for implementing the proposed enhancement activity and responsible for the take, importation, or export of, or conduct of an otherwise prohibited activity involving, the protected species.

§ 216.33 Is a special exception permit required?

(a) *Public display.* A public display permit is required to take or import for public display purposes any marine mammal subject to this subpart, including rehabilitated marine mammals. Only living marine mammals may be taken or imported under the authority of public display permits.

(b) *Scientific research.* A scientific research permit is required to:

(1) Take or import for bona fide scientific research purposes any marine mammal or marine mammal part subject to this subpart, including an intrusive research procedure involving a marine mammal held captive under the authority of a public display or enhancement permit or under other authority of this part (e.g., for rehabilitation); or

(2) Take, import, export, or conduct any otherwise prohibited activity, for bona fide scientific research purposes any endangered or threatened species or species part subject to this subpart.

(c) *Enhancement.* (1) An enhancement permit is required to: (i) Take or import, for purposes of enhancing the survival or recovery of a species or stock, any marine mammal or marine mammal part subject to this subpart; or

(ii) Take, import, export, or conduct any otherwise prohibited activity, for enhancement purposes, any endangered

or threatened species or part of such species subject to this subpart.

(2) Only living protected species and protected species parts necessary for enhancement of the survival, recovery, or propagation of the affected species or stock may be taken or imported under the authority of enhancement permits. Protected species parts include, in this regard, clinical specimens or other biological samples required for the conduct of breeding programs or the diagnosis or treatment of disease.

(d) *Guidelines and examples.* (1) The most common activities that require a special exception permit are included in appendix A to this subpart. In addition, for marine mammals in the wild, an activity that exceeds or is conducted in a manner contrary to the recommended approach standards described in appendix B to this subpart will likely require a special exception permit. These appendices are provided as guidance in determining whether a permit is required to conduct an activity for a special exception purpose and should not be construed as all-inclusive.

(2) An activity not described in appendix A or appendix B to this subpart, but that may involve a take, import, or export of, or otherwise prohibited activity affecting, a protected species or protected species parts for the purposes of public display, scientific research, or enhancement, may require a special exception permit. On the basis of an adequate description of the proposed activity by an applicant, the AA will determine whether a special exception permit is required under this subpart.

(e) *Export of marine mammals or marine mammal parts.* The export of a marine mammal or marine mammal part taken or imported under the authority of a special exception permit requires authorization under the conditions of the holder's permit or, if a person is proposing to export a marine mammal part and is not a permit holder, then the export of the marine mammal part must be authorized by the AA. If the marine mammal or marine mammal part to be exported is a species listed as endangered or threatened under the ESA, a permit is required authorizing that activity.

§ 216.34 Permit application, review, and decision procedures.

(a) *Application submission.* An original signed by the applicant and two copies of the completed signed application for a special exception permit must be submitted to the AA at the address listed in the application instructions referred to in paragraph (c) of this section.

(b) *Applications involving the export of living protected species.* Applications to take and export living protected species from the United States for a special exception purpose, including applications from persons not subject to U.S. jurisdiction under the Acts (e.g., a foreign facility), must:

(1) Be submitted to the AA through the Convention on International Trade in Endangered Species management authority of the foreign government and, if different, the appropriate agency or agencies of the foreign government that perform functions and activities similar to the functions performed by NMFS under the Acts.

(2) Include a certification from the foreign government:

(i) That the information set forth in the application is accurate;

(ii) That the laws and regulations of the government involved allow enforcement of the terms and conditions of the permit, should it be issued, and that the government, including the affected Convention on International Trade in Endangered Species management authority, will enforce such terms and conditions, including an annual inspection of the foreign facility equivalent to U.S. facility inspections conducted by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture (also see § 216.38(b)(22)); and

(iii) That the government concerned will afford comity to a decision by the AA to amend, modify, suspend, or revoke a permit.

(3) Demonstrate that the foreign applicant/facility meets all standards and regulations applicable to applicants that are subject to U.S. jurisdiction.

(c) *Application instructions and information requirements.*

(1) Applications must be in the format and include the information described in the Application Instructions for a Special Exception Permit (application instructions). The basic information required is included in appendix C to this subpart. The application instructions may be requested from the Director, Office of Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910. Persons requesting application instructions should identify the protected species involved and the special exception purpose for which the application will be submitted—scientific research, public display, or enhancement—and if scientific research or enhancement, whether the proposed activity will involve captive holding of protected species.

(2) The AA may require an elaboration of the information submitted

by an applicant or may require the submission of any additional information.

(d) *Initial application review.* (1) The AA will inform applicants of receipt of applications.

(2) During the initial review of the application, the AA will determine:

(i) Whether the application is complete, taking into consideration the applicable information requirements set out in appendix C of this subpart, and the application instructions.

(ii) Whether the proposed special exception activity is for purposes of public display, bona fide scientific research, or enhancement, as applicable.

(iii) If the proposed activity is for the purpose of enhancement, whether the species or stock identified in the application is in need of enhancement for its survival or recovery and the proposed activity is likely to succeed in its objectives.

(iv) Whether the activities proposed are to be conducted consistent with the permit restrictions as described in § 216.36.

(v) Whether sufficient information is included regarding the environmental impact of the proposed activity to enable the AA:

(A) To make an initial determination under the National Environmental Policy Act (NEPA) as to whether the preparation of an environmental assessment (EA) or environmental impact statement (EIS) is appropriate or necessary (i.e., whether the activity proposed is categorically excluded from preparation of further environmental documentation); and

(B) To prepare an EA or EIS if an initial determination is made by the AA that the activity proposed is not categorically excluded from such requirements.

(3) Where marine mammals are concerned, the AA may consult with the Marine Mammal Commission and the Committee of Scientific Advisors on Marine Mammals in making these initial determinations.

(4) Applications determined to be incomplete, for a special exception purpose different than that proposed in the application, proposing activities contrary to permit restrictions, or in need of additional information necessary for compliance with NEPA, will be returned to the applicant for revision. If the applicant fails to correct the deficiency within 60 days following the date of notification, the application shall be considered withdrawn by the applicant.

(5) Applications determined to be for purposes other than public display, bona fide scientific research, or

enhancement, will be returned to the applicant and not further considered.

(e) *Notice of receipt and application review.* (1) Upon completing the initial review, the AA will publish a notice of receipt of the application in the Federal Register:

(i) If the application is initially determined to be complete, for a special exception purpose consistent with that proposed, and includes information sufficient for compliance with NEPA; and

(ii) Following the preparation of any NEPA documentation that has been determined initially to be required.

(2) The Federal Register notice of receipt will:

(i) Include a summary of the application, including:

(A) The purpose of the request;

(B) The species and number of marine mammals or endangered or threatened species proposed to be taken, imported, exported, or affected by an otherwise prohibited activity;

(C) The type(s) and manner of special exception activity proposed;

(D) The location(s) in which the protected species are proposed to be taken, from which they are proposed to be imported, and to which they are proposed to be exported, as applicable;

(E) Whether, and in what manner, marine mammals proposed to be taken, imported, or exported for public display purposes are proposed to be used in interactive programs; and

(F) The proposed period of the permit.

(ii) List the locations in which the application is available for review.

(iii) Invite interested parties to submit written comments concerning the application within 30 days of the date of the notice.

(iv) Include a NEPA statement that an initial determination has been made that the activity proposed is categorically excluded from the requirements to prepare an EA or EIS, that an EA was prepared resulting in a finding of no significant impact, or that a final EIS has been prepared and is available for review.

(3) Where marine mammals are concerned, the AA will send a copy of the complete application to the Marine Mammal Commission and request that their recommendations, including those of the Committee of Scientific Advisors on Marine Mammals, be submitted within 30 days of receipt of the application by the Commission. If within 45 days of receipt of the application (or such longer time as the AA may establish) the Commission and the Committee do not recommend that the permit be issued, this will be

considered a recommendation that the permit be denied.

(4) The AA may consult with any other person, institution, or agency concerning the application.

(5) Within 30 days of publication of the notice of receipt in the Federal Register, any interested party may submit written comments or may request a public hearing on the application.

(6) If the AA determines that a public hearing would be advisable, the AA may, within 60 days of publication of the notice of receipt in the Federal Register, hold a public hearing. Notice of the date, time, and place of the public hearing will be published in the Federal Register not less than 15 days in advance of the public hearing. Any interested person may appear in person or through representatives and may submit any relevant material, data, views, or comments. A summary record of the hearing will be kept.

(7) If the AA determines that a public hearing would not be advisable, the AA may extend the period during which any interested party may submit written comments. Notice of the extension must be published in the Federal Register within 60 days of publication of the notice of receipt in the Federal Register.

(f) *Issuance or denial of a permit.* (1) Within 30 days of the close of the public hearing or, if no public hearing is held, within 30 days of the close of the public comment period, the AA will issue or deny a special exception permit, except as provided in subpart D of 15 CFR part 904.

(2) In making a decision to issue or deny issuance of a special exception permit, the AA will consider all comments received during the comment period in light of applicable issuance criteria and any other information or data that the AA determines are relevant in making such a decision, including, but not limited to:

(i) How the applicant's needs, program, and facilities compare and relate to proposed and ongoing projects and programs;

(ii) Whether the expertise, facilities, or other resources available to the applicant appear adequate to accomplish successfully the objectives stated in the application;

(iii) Opinions or views of scientists or other persons or organizations knowledgeable of the protected species that is the subject of the application or of other matters germane to the application; and

(iv) If a live animal is to be held captive or transported, the applicant's qualifications for the proper care and maintenance of the protected species

and the adequacy of the applicant's facilities, equipment, and personnel.

(3) Notice of the decision of the AA shall be published in the Federal Register within 10 days after the date of permit issuance or denial and shall indicate where copies of the permit, if issued, may be reviewed or obtained. If the permit issued involves protected species listed as endangered or threatened under the ESA, the notice shall include a finding by the AA that the permit:

(i) Was applied for in good faith;

(ii) If exercised, will not operate to the disadvantage of such endangered or threatened species; and

(iii) Is consistent with the purposes and policy set forth in section 2 of the ESA.

(4) The applicant for a permit or any party opposed to such permit may obtain judicial review of the terms and conditions of any special exception permit issued or of a decision to deny such a permit. Such review may be initiated by filing a petition for review, within 60 days of the date of permit issuance or denial, in the U.S. district court for the district wherein the applicant for a permit resides, or has its principal place of business, or in the U.S. District Court for the District of Columbia.

(5) If, after publishing a notice of receipt, the AA determines on the basis of new information regarding the impact of the proposed activity on the human environment that an EA or EIS must be prepared, the AA must deny the permit; unless an EA is prepared and a finding of no significant impact is made before the AA must make a decision to issue or deny the permit as required under paragraph (f)(1) of this section. If a permit is denied under these circumstances, the application may be resubmitted with information sufficient to prepare the required EA or EIS, and will be processed as a new application.

(6) The AA may waive the 30-day public comment period required under the ESA in an emergency situation where the health or life of an endangered animal is threatened and no reasonable alternative is available to the applicant; but notice of such waiver shall be published in the Federal Register within 10 days following the issuance of the special exception permit. Note: This provision would apply to endangered marine mammals only where the AA has authorized a taking or importation under the provisions of section 109(h) of the MMPA.

§216.35 Issuance criteria.

(a) *General.* For the AA to issue any special exception permit, the applicant must demonstrate the following:

(1) The proposed taking, importation, export, or otherwise prohibited activity is humane and does not present any unnecessary risks to the health and welfare of protected species.

(2) The proposed special exception activity is consistent with the applicable restrictions of § 216.36.

(3) Any proposed taking, importation, export, or otherwise prohibited activity involving the captive maintenance of a protected species will be conducted in accordance with the applicable requirements of § 216.37, and the applicant's qualifications and record for the care and supervision of protected species support a reasonable expectation of compliance with captive maintenance requirements. If the applicant has had a pattern of non-compliance with captive maintenance requirements or permit conditions of §§ 216.37 and 216.38, the applicant must have demonstrated, in a manner and for a period acceptable to the AA, a pattern of compliance with such requirements and conditions; such period to be not less than 1 year, during which at least two consecutive inspections conducted at least 4 months apart must have been completed documenting the applicant's full compliance with the requirements and conditions.

(4) Granting any requested import or export is not likely to result in a take of protected species or protected species parts other than that authorized by the permit (e.g., the import or export is not likely to result in replacement takes or otherwise increase demand for protected species or protected species parts resulting in takes to meet such anticipated demand).

(5) If the proposed take or import involves holding marine mammals captive (other than short-term capture and release activities associated with a capture from the wild), the applicant has:

(i) either committed to posting a surety bond(s) acceptable to the AA as required in § 216.38(b)(8)(v) and (b)(27)(i)(D), prior to obtaining custody by transfer or capturing from the wild the subject marine mammals, respectively, or made arrangements acceptable to the AA (i.e., contingency planning and assurances of adequate funding arrangements) for the disposition of the marine mammal, if and when the applicant's permitted activity terminates; and

(ii) Committed to accepting temporary custody of seized or abandoned marine

mammals on a space available basis, except where acceptance of temporary custody would involve, in the written opinion of the attending veterinarian, a risk to the health or welfare of marine mammals held by the applicant. Seized or abandoned marine mammals in this context are marine mammals held under a special exception permit for purposes of public display, scientific research, or enhancement, that either have been abandoned by the permit holder with custody or seized by NMFS under the terms of this part or of 15 CFR part 904, and for which a request to assume custody has not been received by NMFS from any permit holder within 15 days from the date of notification of all such permit holders by NMFS. The AA may exempt an applicant from the requirements of paragraph (a)(5) of this section if it is in the interest of the health and welfare of the marine mammal(s) concerned and if there is no reasonable alternative (e.g., alternative facility at which the subject marine mammal could be held/transferred).

(6) If a protected species is proposed to be held captive, a commitment to maintain or contribute data to a stud book, and, if the protected species has been determined to be depleted under the MMPA or listed as endangered or threatened under the ESA, a commitment to participate in a cooperative breeding program.

(7) The proposed special exception activity, if it involves protected species determined to be endangered or threatened under the ESA, will be conducted consistent with the purposes and policy set forth in section 2 of the ESA.

(b) *Public display.* For the AA to issue a public display permit, the applicant must demonstrate the following:

(1) The source of the proposed taking or importation of living marine mammals is one that will present the least practicable effects on wild populations.

(2) Any proposed permanent removal from the wild:

(i) Is consistent with any applicable quota established by the AA; or

(ii) Where there is no quota in effect, will not have, by itself or in combination with all other known takes and sources of mortality, a significant direct or indirect adverse effect on the protected species or stock, based on the best available information on cumulative take for the species or stock, including information provided by the applicant concerning the status of the species or stock (e.g., population survey data).

(3) The education or conservation program offered by the applicant is acceptable to the AA, considering:

(i) Whether an education or conservation program with clearly stated objectives has been designed and is being, or will be, conducted and evaluated by a professional staff; and

(ii) Whether the basic messages and purposes of the program are consistent with the policies and objectives of the MMPA, whether they include accurate information about the life history, behavior, sensory capabilities, conservation or other aspects of marine mammals, such as their role in the marine ecosystem, and whether they are being, or are likely to be, conveyed to the participating public in an effective manner.

(4) For any interactive program:

(i) All measures determined by the AA to be necessary for the health and welfare of the participating marine mammals will be taken;

(ii) The program is conducted for the purpose of education or conservation as a part of an education or conservation program determined acceptable under paragraph (b)(3) of this section, and is consistent with the policies and objectives of the MMPA; and

(iii) Any aspect of the program that involves a marine mammal/public interaction prohibited in the wild is clearly presented as such, with an explanation of why such a prohibition is necessary for the protection of marine mammals in the wild.

(5) The taking/capture of any marine mammal proposed for importation was, or will be, consistent with the same requirements, restrictions, criteria, and conditions as those applicable to the taking/capture of a marine mammal subject to U.S. jurisdiction.

(c) *Scientific research.* For the AA to issue a scientific research permit, the applicant must demonstrate the following:

(1) The proposed special exception activity does not involve unnecessary duplication of research. If similar research on the same or comparable species has been done in the past or has been authorized, the proposed research must either:

(i) Be necessary to verify (i.e., replicate) the results of this previous or authorized research; that is, results cannot be reasonably and accurately predicted from the body of scientific knowledge currently available in the scientific literature or from the likely results of ongoing studies; or

(ii) Be likely to contribute significant data to the scientific literature or provide new insight.

(2) If the lethal taking of protected species is proposed, non-lethal methods for conducting the research are not feasible.

(3) For species or stocks not designated, or proposed to be designated, as depleted under the MMPA, and not listed as endangered or threatened or not proposed to be listed as endangered or threatened under the ESA:

(i) The proposed research, by itself or in combination with other activities (i.e., all other takes and known sources of mortality), is not likely to have a significant adverse impact on the species or stock; and

(ii) Any proposed permanent removal from the wild either:

(A) Is consistent with any applicable quota established by the AA; or

(B) Where there is no quota in effect, will not have, by itself or in combination with all other takes and known sources of mortality, a significant direct or indirect adverse effect on the protected species or stock, based on the best available information on cumulative take for the species or stock, including information provided by the applicant concerning the status of the species or stock.

(4) For species or stocks designated, or proposed to be designated, as depleted by the AA under the MMPA, or listed as endangered or threatened or proposed to be listed as endangered or threatened under the ESA:

(i) The proposed research cannot be accomplished using a species or stock that is not depleted, proposed for designation as depleted, listed as endangered or threatened, or proposed to be listed as endangered or threatened;

(ii) The proposed research, by itself or in combination with other activities (e.g., all other takes and known sources of mortality), is not likely to have a long-term direct or indirect adverse impact on the species or stock; and

(iii) The proposed research will either:

(A) Address a research need/objective identified in a species recovery or conservation plan or, if there is no conservation or recovery plan in place, a research need/objective identified by the AA in light of the factors that would be addressed in a conservation or recovery plan;

(B) Be likely to contribute significantly to understanding the basic biology or ecology of the species or stock, or to identifying, evaluating, or resolving conservation problems for the species or stock; or

(C) Contribute significantly to fulfilling a critically important research need; and

(iv) If the proposed scientific research involves a lethal taking of marine mammals, the results will directly benefit that species or stock, or will fulfill a critically important research need.

(5) The proposed research is not likely to have significant adverse effects on any other component of the marine ecosystem of which the affected species or stock is a part.

(d) *Enhancement.* For the AA to issue an enhancement permit, the applicant must demonstrate the following:

(1) The proposed activity is likely to contribute significantly to maintaining or increasing distribution or abundance, or enhancing the health or welfare of the species or stock, necessary to ensure the survival or recovery of the affected species or stock in the wild.

(2) The proposed activity is consistent with an approved conservation plan developed under section 115(b) of the MMPA or recovery plan developed under section 4(f) of the ESA for the species or stock; or, if there is no conservation or recovery plan, the proposed activity is consistent with the AA's evaluation of the actions required to enhance the survival or recovery of the species or stock in light of the factors that would be addressed in a conservation or recovery plan.

(3) Any proposed public display of marine mammals will be consistent with the applicable criteria of paragraph (b) of this section, and the restrictions and conditions of §§ 216.36 and 216.37, unless specifically exempted by the AA based on a determination that such an exemption is necessary for the attainment of survival or recovery objectives.

(4) Any proposed scientific research will be consistent with the applicable criteria of paragraph (c) of this section, and the applicable restrictions and conditions of §§ 216.36 and 216.37, unless specifically exempted by the AA based on a determination that such an exemption is necessary for the attainment of survival or recovery objectives.

§ 216.36 Permit restrictions.

(a) *General.* The following restrictions are requirements of all special exception permits:

(1) The taking, importation, export, or conduct of an otherwise prohibited activity involving protected species, including the methods of capture, transportation, supervision, handling, care and maintenance, and treatment, must comply at all times with the regulations of this subpart.

(2) The valid period for any special exception permit issued, or any major

amendment granted, is limited to 5 years from the effective date of such permit or major amendment. In accordance with the provisions of § 216.40, the valid period of a permit may be extended by a minor amendment up to 12 months beyond that established in the original permit (i.e., a maximum possible initial permit period of 6 years before a major amendment is required to extend the valid period of the permit further).

(3) Any protected species or protected species part imported under the authority of a special exception permit must not have been taken or imported in a manner deemed inhumane by the AA, in violation of the Acts, or in violation of the law of another country having jurisdiction over the taking or importation. Importation of protected species and protected species parts is subject to the provisions of 50 CFR part 14.

(4) Special exception permits do not authorize the permit holder or any other person to take protected species in waters under the jurisdiction of any country without the consent of such country. The permit holder is responsible for securing such consent and complying with any applicable laws and regulations of that country.

(5) The permit holder is responsible for the activities of any individual who is operating under the authority of the permit including, but not limited to, the capture, transportation, supervision, handling, care and maintenance, treatment, health and welfare, or export of any protected species or protected species part.

(6) All individuals conducting an activity under the authority of the permit must possess qualifications (e.g., education or experience) commensurate with their duties and responsibilities, or must be under the direct supervision of a person with such qualifications. All professional staff and any authorized agent under the permit who require state or Federal licenses to practice their profession must be duly licensed while conducting any activities under the permit.

(7) Marine mammals held under the authority of a special exception permit may not be held with pre-Act marine mammals of the same species unless such pre-Act marine mammals are held by the permit holder in accordance with the provisions of this subpart (see § 216.32(a)(2)).

(8) Special exception permits must not be transferred or assigned to any other person. However, certain limited rights of succession by certain persons may be authorized in accordance with § 220.26 of this chapter and, in the case

of a change in ownership of a public display facility, the public display permit may be transferred in accordance with § 216.38(c)(5).

(9) The original or a notarized copy of any special exception permit must be in the possession of the permit holder or designated agent during the time of the authorized special exception activity, any transit that is incident to such special exception activity, and any other time while the protected species or protected species part is in the possession of the permit holder or agent. A duplicate copy of the permit must be physically attached to the container, package, enclosure, or other means of containment, in which the protected species or protected species part is placed for purposes of storage, transit, supervision, or care; except, for protected species held captive and protected species parts in storage, original or duplicate copies of permits may be kept on file at the location of captive holding or storage.

(10) Marketable products obtained in the course of an activity conducted in the wild under a special exception permit may not be sold, offered for sale, or exchanged directly or indirectly for any product or service of value, unless such marketable products were obtained in a manner or for a purpose essential to:

(i) The conduct of permitted bona fide scientific research or enhancement activities, or the publication or presentation of the results of such activities;

(ii) The development or conduct of a public display education or conservation program, where such material has been obtained incidental to permitted activities; or

(iii) The take of protected species in the wild, where such use of marketable products is specifically authorized under the terms and conditions of the permit (e.g., using photographs or video of protected species to assess remotely their health and identify animals for capture, minimizing harassment and stress associated with wild capture).

(11) Purchase and sale transactions may only be authorized if the purchaser is a holder of a special exception permit that authorizes the holding of the subject species, or a consortium of special exception permit holders where all members of the consortium are authorized to hold marine mammals captive and at least one member of the consortium holds a special exception permit authorizing the holding of the subject species.

(b) *Public display.* The following restrictions are requirements of all public display permits:

(1) Only living marine mammals may be taken or imported under the authority of a public display permit.

(2) Public display facilities must be designed and activities must be conducted in a way that ensures humane treatment of, prevents injury to, and protects the health and welfare of captive marine mammals.

(3) The permit holder must exhibit the marine mammals to the public on a regularly scheduled basis, with access not limited or restricted other than by the charging of an admission fee.

(4) No marine mammal may be taken or imported under the authority of a public display permit that is:

(i) From a species or stock designated as depleted or proposed by the AA to be designated as depleted under the MMPA, unless the marine mammal to be taken or imported is captive born and the provisions of paragraph (d)(2)(i) of this section are met; or

(ii) At the time of taking, pregnant, lactating, or either unweaned or less than 8 months old, whichever occurs later, unless the AA determines that such taking or importation is necessary for the protection or welfare of the animal.

(c) *Scientific research.* The following restrictions are requirements of all scientific research permits:

(1) Scientific research activities must be conducted as described and referenced in the permit.

(2) Research results must be published or otherwise be made known to the scientific community in a reasonable period of time.

(3) Activities conducted under the authority of a scientific research permit may only be conducted under the direct supervision of the principal investigator or a co-investigator specifically identified in the permit.

(4) The take of living protected species in the wild under the authority of a scientific research permit must be conducted independent and separate from activities conducted for commercial or recreational purposes.

(Note: This provision is intended to prevent the abuse of using a scientific research permit to take a protected species in the wild for a purpose other than scientific research (e.g., for commercial or recreational purposes)).

In this context, commercial or recreational activities include any activity for which, or in connection with which, payment in cash, product, in-kind services, or other consideration is involved. However, participation of research personnel that meets the requirements of paragraphs (a)(6) and (c)(5) of this section is not an activity

conducted for commercial or recreational purposes, whether such research personnel directly or indirectly reimburse the principal investigator for their participation in the permitted research or otherwise fund or support the permitted research. Similarly, bona fide scientific research conducted on a protected species taken incidental to a commercial activity, where such incidental take has been authorized under the MMPA or ESA, as applicable, is considered to be research conducted independent and separate from such commercial activity. In a similar manner, research conducted incidental to an enhancement activity authorized under the MMPA or ESA is considered to be research conducted independent and separate from commercial or recreational activity, regardless of whether the enhancement activity is conducted in association with a commercial or recreational activity. Also, in this context, the sale, offer for sale, or direct or indirect exchange for any product or service of value of marketable products obtained consistent with the requirements of paragraph (a)(10) of this section are not activities conducted for commercial purposes.

(5) All personnel involved in the conduct of any activity conducted under the authority of a scientific research permit (i.e., principal investigator, co-investigators/agents, and support personnel) during which a protected species is, or may be, taken, imported, exported, or affected by an otherwise prohibited activity, must:

(i) Perform a function directly supportive of and necessary for the permitted research activity (i.e., other than direct or indirect funding or payment); or

(ii) Be one of a reasonable number of support personnel included for the purpose of training or as back-up personnel for persons described in paragraph (c)(5)(i) of this section.

(6) Any protected species part imported under the authority of a scientific research permit must not have been obtained as the result of a lethal taking that would otherwise be prohibited under the Acts.

(d) *Enhancement.* The following restrictions are requirements of all enhancement permits:

(1) Only living protected species and protected species parts necessary for enhancement of the survival, recovery, or propagation of the affected species or stock may be taken, imported, exported, or affected by an otherwise prohibited activity under the authority of an enhancement permit. Protected species parts would include in this regard clinical specimens or other biological

samples required for the conduct of breeding programs or the diagnosis or treatment of disease.

(2) An enhancement permit may authorize the captive maintenance of a protected species from an endangered, threatened, or depleted species or stock only if the AA determines that:

(i) The proposed captive maintenance is likely to contribute directly to the survival or recovery of the species or stock by maintaining a viable gene pool, increasing productivity, providing necessary biological information, or establishing animal reserves required to support directly these objectives; and

(ii) The expected benefit to the species or stock outweighs the expected benefits of alternatives that do not require removal of protected species from the wild.

(3) Any protected species or its progeny held in captive maintenance under an enhancement permit must be returned to its natural habitat as soon as feasible, consistent with the objectives of an approved conservation or recovery plan or the evaluation by the AA under § 216.35(d)(2). In accordance with section 10(j) of the ESA, the AA may authorize the release of any population of an endangered species or a threatened species outside the current range of such species if the AA determines that such release will further the conservation of such species.

(4) The AA may authorize the public display of marine mammals held under the authority of an enhancement permit only if:

(i) The public display is incidental to the authorized captive maintenance;

(ii) The public display will not interfere with the attainment of the survival or recovery objectives;

(iii) The marine mammals will be held consistent with all requirements and standards that would otherwise be applicable to if the marine mammals were held under the authority of a public display permit, unless the AA determines that an exception is necessary to implement an essential enhancement activity; and

(iv) The marine mammals will be excluded from any interactive program and will not be trained for performance.

(5) The AA may authorize non-intrusive scientific research to be conducted while a protected species is held under the authority of an enhancement permit, only if such scientific research:

(i) Is incidental to the permitted enhancement activities; and

(ii) Will not interfere with the attainment of the survival or recovery objectives.

§216.37 Captive maintenance.

Paragraphs (e) through (l) of this section are applicable only to marine mammals under the Acts and do not apply to other protected species; for example, marine and anadromous fish or marine reptiles.

(a) Protected species may be held captive for a special exception purpose only if such taking is authorized under a special exception permit issued under this subpart. Protected species may be held captive for other purposes only if authorized under other provisions of the Acts or other statutory authority that specifically exempts such otherwise prohibited activity from the provisions of the Acts, as applicable (e.g., 10 U.S.C. 7524).

(b) Permit holders are responsible for the supervision, handling, care and maintenance, treatment, health and welfare, and transportation of protected species held under a special exception permit, unless otherwise specifically authorized by the AA.

(c) The methods of supervision, handling, care and maintenance, treatment, and transportation of protected species held under a special exception permit must be humane and must comply with applicable regulations and standards under the Animal Welfare Act (9 CFR parts 1, 2, and 3) and of this subpart, unless otherwise specifically authorized by the AA. Supplemental standards for the supervision, handling, care and maintenance, treatment, and transportation of protected species may be specified in the special exception permit.

(d) Failure to comply with the applicable captive maintenance requirements of this section and any supplemental standards of the permit is considered a violation of these regulations and the permit and may be the basis for amending, modifying, suspending, or revoking a permit, or denying future permits. If the AA determines there is a reasonable basis to believe that a permit holder is not complying with the applicable captive maintenance requirements of this section or any supplemental standards of the permit, to ensure the protection or welfare of the protected species held by the permit holder, the AA may, upon notice of the permit holder of this determination, seize the protected species pending completion of an investigation or resolution of any charges that may result from such an investigation (see 15 CFR part 904).

(e) Except as provided in paragraph (f) of this section, public display permit holders in the United States must be licensed or registered under the Animal

Welfare Act by the Animal and Plant Health Inspection Service.

(f) A special exception permit may be issued for activities involving captive maintenance of marine mammals at a facility before construction of all or part of the facility is completed only if the plans for the facility and the proposed program of captive maintenance are found to comply with the requirements and standards of this section.

Authorization to obtain custody of marine mammals from captive stock or to capture from the wild will be withheld until construction has been completed and the facility is determined to be in compliance with all applicable standards and requirements.

(g) The AA may authorize limited temporary holding (i.e., less than 6 months) in a facility different than that listed on the permit, if:

(1) Either an emergency exists in which the health or welfare of a captive marine mammal is in imminent jeopardy; or a short-term transfer of a marine mammal is necessary to repair, renovate, or improve the facility listed on the permit in a manner benefitting the health or welfare of the marine mammal.

(2) The transfer follows the applicable procedures of § 216.38(b)(8), unless specifically waived by the AA in the interest of the health or welfare of the marine mammal.

(3) The marine mammal is held in compliance with the requirements of this section, and only until:

(i) The emergency is resolved or facility renovation is completed and the marine mammal is transferred back;

(ii) Custody of the marine mammal is transferred to the permit holder temporarily holding the subject marine mammal pending the resolution of the emergency or completion of facility renovation; or

(iii) Custody of the marine mammal is transferred to another permit holder under § 216.38(b)(8).

(4) Detailed reports are submitted on the condition of the marine mammal and the status of the emergency or renovation at intervals not greater than 60 days.

(5) Such limited temporary holding does not exceed a 6-month period.

(6) Custody is shared jointly if the temporary holding facility is also a permit holder, meaning the marine mammal will be held at the temporary holding facility under the authority of the permit holder experiencing the emergency or conducting facility renovations and consistent with any applicable terms and conditions of the temporary holding facility's special exception permit; or custody is retained

by the permit holder if the temporary holding facility is not also a permit holder.

(h) A marine mammal captured from the wild under the terms and conditions of a special exception permit may be held temporarily in another facility for the purpose of acclimation and transition training for a period not greater than 6 months, either:

(1) Under the authority, terms, and conditions of the temporary holding facility's special exception permit, with custody being held by the temporary holding facility; or

(2) If the temporary holding facility does not hold a special exception permit, under the terms and conditions of the permit under which the marine mammal was captured, with custody being retained by the permit holder, provided that:

(i) The marine mammal is to be held temporarily only until, in the reasonable judgment of the attending veterinarian, acclimation and transition training has progressed sufficiently for the marine mammal to be transferred;

(ii) The temporary holding facility's sole purpose is the acclimation and transition training of marine mammals captured from the wild; and

(iii) The temporary holding facility is in compliance with all applicable standards of these regulations.

(i) If the 6-month limit on temporary holding under paragraph (g) or (h) of this section is exceeded, each day it is exceeded shall constitute a separate violation of these regulations.

(j) Under the terms and conditions of the special exception permit, following the capture of a marine mammal from the wild, such a marine mammal may be held in a temporary pen or other temporary enclosure located adjacent to or near the capture site only if:

(1) The marine mammal is held in the temporary enclosure for the minimum period of time necessary:

(i) For the attending veterinarian to assess the health and behavior of the marine mammal and determine whether the marine mammal should be held and transferred consistent with the purpose and terms of the permit or released to the wild; and

(ii) To arrange for transportation to the permit holder's facility or to a temporary holding facility under paragraph (h) of this section.

(2) The marine mammal is held in the temporary enclosure for no longer than 30 days, unless one or more extensions in increments no greater than 15 days each are specifically authorized by the AA, based on a determination by the attending veterinarian that the health of

the marine mammal would be endangered by transfer or release.

(3) The temporary enclosure is able to withstand inclement weather and is in compliance with Animal Welfare Act standards for primary enclosures; except that any single aspect of the minimum space requirements (e.g., volume, length, width, depth) may be reduced by no more than one half if the attending veterinarian determines such a reduction is necessary to make the determination in paragraph (j)(1)(i) of this section.

(k) Marine mammals held under the authority of a special exception permit must be held together with marine mammals of the same species, except for the purposes of short-term (i.e., several days) medical treatment by an attending veterinarian or as authorized by the AA. The AA may authorize holding a marine mammal in isolation from other marine mammals of the same species:

(1) If such isolation is necessary to fulfill the purpose or objectives of the activity for which the scientific research or enhancement permit was issued and is authorized specifically under the permit;

(2) For periods not to exceed 6 months, if the permit holder provides a statement from the attending veterinarian:

(i) Explaining how such isolation is in the interests of the health and welfare of the marine mammal concerned (e.g., social incompatibility, special medical condition, consistency with known patterns of social interaction for the species, for example, because of breeding status, sex, age, or other equivalent factors, an extended period of isolation would be consistent with that otherwise found in the wild); and

(ii) Identifying any alternatives available for minimizing the social isolation of the marine mammal, including the transfer of the marine mammal to another facility; or

(3) If the marine mammal is held together with one or more marine mammals of a different species, where the multi-species aggregation mimics multi-species aggregations found in the wild.

(1) Whenever known to occur in social units in the wild, marine mammals held under special exception permits must be held with other marine mammals of the same species in a manner and composition that in number, sexual ratio, and age structure provides the closest practicable approximation of the known fundamental (i.e., minimum) social unit found in the wild, with due consideration given to the limitations and health and welfare concerns uniquely applicable to captive

maintenance (e.g., breeding status). Exceptions to this requirement may be made by the permit holder, if:

(1) The permit holder, as a part of the annual report required under § 216.39, provides:

(i) A statement that an exception is necessary to fulfill the purpose or objectives of the activity for which the scientific research or enhancement permit was issued; or

(ii) A certification from the attending veterinarian that such an exception is necessary in the interests of the health and welfare of the marine mammals concerned and noting, for each, the reason for such an exception (e.g., social incompatibility, special medical condition, seasonal/breeding status concerns, etc.) and the period of time such exception will be necessary during the upcoming 12 months; or

(iii) A statement that an exception is necessary due to the captive maintenance limitations of the facility in which the subject marine mammals are held and the absence of a reasonable alternative to such holding facility.

(2) The AA concurs with the need for such an exception. The concurrence of the AA will be presumed unless the AA:

(i) Concurs with such an exception for a specified period less than 1 year, pending review of additional information requested from the permit holder regarding the need for an exception; or

(ii) Informs the permit holder that an exception is denied.

§ 216.38 Permit conditions.

(a) *Permit-specific conditions.* Permits issued under this subpart will contain specific terms and conditions deemed appropriate by the AA, including, but not limited to:

(1) The number and species of marine mammals, endangered species, or threatened species that are authorized to be taken, imported, exported, or affected by an otherwise prohibited activity;

(2) The manner in which these protected species may be taken (according to type of take and authorized level of harassment, including harassment during capture);

(3) The location(s) in which the protected species may be taken, from which they may be imported, or to which they may be exported, as applicable, and, for endangered or threatened species to be imported/exported, the port of entry/export;

(4) Whether, and in what manner, marine mammals proposed to be taken, imported, or exported, for public display purposes may be used in interactive programs;

(5) The period(s) during which the permit is valid;

(6) Any special terms or conditions that the AA deems appropriate; and

(7) For protected species other than marine mammals:

(i) The methods of transportation, care and maintenance to be used with live protected species; and

(ii) The sale or other disposition of the protected species, its progeny, or the protected species product.

(b) *General conditions.* All special exception permits are subject to the following general conditions.

(1) The permit is effective upon the permit holder's signing of the permit. In signing the permit, the permit holder agrees to comply with the terms and conditions of the permit, the regulations of this part, other applicable regulations, and, as applicable, the Acts. The holder also acknowledges and accepts that the authority or privilege to conduct certain activities specified in the permit does not arise or become effective unless and until the AA specifically authorizes such activities. The AA may or may not authorize such activities consistent with the terms and conditions of the permit, the permit holder's compliance with such terms and conditions, the regulations of this part, other applicable regulations, or, as applicable, the Acts.

(2) The permit holder may not initiate the special exception activities authorized by the permit until the AA acknowledges receipt of any required permit fee, except where another payment date is specifically authorized.

(3) The permit holder must provide the appropriate NMFS Regional Director with at least 3 weeks advance notice of the dates on and locations of:

(i) The take of protected species in the wild; or

(ii) Intrusive research involving captive protected species.

(4) The permit holder must provide the Regional Director with at least 1 week advance notice of the date, approximate time, and port of entry/export for import/exports.

(5) Except in the case of an emergency, the permit holder must provide the Regional Director at least 1 week advance notice of the dates and location of departure, transfer points (if any), and destination for the transport of living marine mammals; whether such transport is for the transfer of custody between facilities, the transport of marine mammals in a traveling display or exhibit to a different location, or a short-term transport outside a facility for medical purposes as determined necessary by the attending veterinarian. In the case of an emergency involving the imminent jeopardy of the health or welfare of a marine mammal, the permit holder must notify the Regional Director

as soon as practicable, but no later than the second business day after such an emergency transport, and include, in addition to the information noted above, a detailed description of the nature of the emergency.

(6) A permit holder shall not deliver, receive, carry, transport, or ship in interstate or foreign commerce, by any means whatsoever and in the course of a commercial activity, or sell or offer for sale in interstate or foreign commerce, any endangered species or threatened species (see parts 222 and 227 of this chapter) except with the prior approval of the AA and subject to any terms or conditions the AA may prescribe.

(7) A permit holder shall not transport, transfer, obtain custody of, sell, purchase, or otherwise convey or acquire an interest in, or otherwise dispose of or obtain any marine mammal subject to this subpart (see § 216.32(a)), except with the prior approval of the AA and subject to any terms or conditions the AA may prescribe. Except as a part of a specifically authorized capture activity, the release to the wild of a marine mammal held under a special exception permit is considered "other disposition" and must be specifically authorized by the AA.

(8) The AA may authorize the transfer of custody of marine mammals between permit holders if:

(i) Both permit holders request authorization of such transfer of custody, describing the marine mammals to be transferred (e.g., species, sex, age, identifying number and name, condition) and the permits under which the subject marine mammals are being and are to be held, respectively. Such requests must be received by the AA at least 3 weeks prior to the proposed transfer date, except where the health or welfare of a marine mammal requires otherwise.

(ii) Both permit holders identify the permit holder responsible for the actual transport of the marine mammal and the point at which the receiving permit holder will assume custody and captive maintenance responsibility.

(iii) The permit holder responsible for the actual transport identifies the proposed method (i.e., including, but not limited to, a detailed description of the containers/devices to be used and any special care required before, during, and after transportation), modes (e.g., aircraft/truck), duration (including any transfer points), date of transport, the name and qualifications of the common carrier or agent, if any, and the attending veterinarian, or professional staff of the permit holder knowledgeable in the area of marine mammal care for

the species concerned, who will accompany the marine mammal.

(iv) The supervising or attending veterinarian for the permit holder responsible for the actual transport certifies that the transport will be conducted in compliance with the captive maintenance requirements of § 216.37.

(v) The receiving permit holder submits a copy of an Animal and Plant Health Inspection Service inspection report conducted within the preceding 6 months that documents the compliance of the permit holder with the captive maintenance requirements of § 216.37 or, if such inspection documents violations or required corrective actions, either:

(A) The receiving permit holder has certified to the satisfaction of the AA that such violations have been resolved and any required corrective actions have been taken;

(B) The receiving permit holder has certified to the AA that the violations will be resolved and corrective actions taken within a period acceptable to the AA; or

(C) The AA determines that timely transfer is in the interests of the health and welfare of the marine mammal.

(vi) The receiving permit holder has either posted a surety bond acceptable to the AA in the amount of \$10,000 for each marine mammal for which custody is to be transferred, or made other arrangements acceptable to the AA for the disposition of such marine mammals, if and when the permit holder's permitted activity terminates (i.e., advance planning and assurances of adequate funding arrangements)(see § 216.35(a)(5)).

(vii) The receiving permit holder's special exception permit authorizes the take of the species for which custody is to be transferred and, in obtaining custody of the marine mammal, will not exceed the number of marine mammals of that species authorized under the permit.

(9) The AA's authorization for a transfer of custody under paragraph (b)(8) of this section will be limited to a specified period of time, not to exceed 30 days. If the transfer does not occur during the period initially authorized, the AA may extend the authorized period in increments of no greater than 30 days.

(10) Unless otherwise specified, the AA authorizes, concurrent with the authorization for a transfer of custody under paragraph (b)(8) of this section, the purchase by the transferee and sale by the transferor of all interests held by the transferor in the subject marine mammal.

(11) The AA may authorize an export of a living marine mammal only to the holder of a special exception permit that authorizes the take of the species that is to be exported, and only if the number of marine mammals of that species authorized under the permit will not be exceeded.

(12) The permit holder, or subsequent authorized recipient of protected species parts under the terms of paragraph (b)(12) of this section, may transfer protected species parts initially taken or otherwise obtained under the authority of a special exception permit to another person if:

(i) The person transferring the part does not receive remuneration for the protected species part;

(ii) The person receiving the protected species part is:

(A) An employee of NMFS, the U.S. Fish and Wildlife Service, or any other Federal agency with jurisdiction and conservation responsibilities in marine shoreline areas receiving the part in the course of their official duties;

(B) A holder of a special exception permit that authorizes the take, import, or other otherwise prohibited activity involving possession of a protected species part of the same species as the subject part; or

(C) In the case of marine mammals parts from a species that is not depleted, endangered, or threatened, a person authorized under section 112(c) of the MMPA and subpart C of this part to take or import marine mammals or marine mammal parts;

(iii) The protected species part is transferred for the purpose of scientific research, maintenance in a properly curated, professionally accredited scientific collection, or education; provided that, for transfers for educational purposes, the recipient is a museum, educational institution or equivalent that will ensure that the part is available to the public as part of an educational program that is conducted regularly with access not limited other than by an admission fee;

(iv) A unique number assigned by the permit holder (i.e., the holder of the special exception permit under which the part was taken or imported) is marked on or affixed to the protected species part or container;

(v) The person receiving the protected species part agrees that, as a condition of receipt, subsequent transfers will be conducted in compliance with the provisions of paragraph (b)(12) of this section; and

(vi) Within 30 days of the transfer, the person transferring the protected species part notifies the Regional Director of the transfer, including a description of the

part (e.g., species, specimen type, method of preservation, and the unique number assigned), the person to whom the part was transferred, the purpose of the transfer, certification that the recipient has agreed to comply with the requirements of paragraph (b)(12) of this section for subsequent transfers, and, if applicable, the recipient's permit number; or

(vii) The transfer is to any person other than those identified in paragraphs (b)(12)(ii)(A) through (C) of this section and is specifically authorized by the Regional Director consistent with the conditions listed under paragraphs (b)(12)(i) and (iii) through (vi) of this section.

(13) The permit holder or subsequent authorized recipient of protected species parts under paragraph (b)(12) of this section may loan protected species parts to another person for the purpose described in paragraph (b)(12)(iii) of this section, without the agreement and notification required under paragraphs (b)(12)(v) and (vi) of this section, if:

(i) The loan is for not more than 1 year and a record of the loan is maintained; and

(ii) For the period of the loan, the part will be included in a properly curated, professionally accredited scientific collection.

(14) The export of marine mammal parts for species determined not to be depleted under the MMPA and not to be endangered or threatened under the ESA must be authorized by the AA. Except as otherwise provided in this chapter, parts of protected species determined to be endangered or threatened under the ESA may be exported only for purposes of scientific research or enhancement under a special exception permit issued under this part. A permit holder or subsequent authorized recipient of marine mammal parts under paragraph (b)(12) of this section may export marine mammal parts if:

(i) The permit holder or other person exporting the marine mammal part does not receive remuneration for the marine mammal part;

(ii) The marine mammal part is exported for the purpose of scientific research, maintenance in a properly curated, professionally accredited scientific collection, or education; provided that, for transfers for educational purposes, the recipient is a museum, educational institution or equivalent that will ensure that the part is available to the public as part of an educational program that is conducted regularly with access not limited other than by an admission fee;

(iii) A unique number assigned by the permit holder is marked on or affixed to the marine mammal specimen or container; and

(iv) The marine mammal part is exported in compliance with other applicable U.S. and international law (e.g., ESA and the Convention on International Trade in Endangered Species).

(15) Unless other disposition is specified in the permit, a holder of a special exception permit may retain protected species parts, including, for example, parts removed from a captive animal or parts not destroyed or otherwise disposed of during or after a scientific research or enhancement activity or following the death of a marine mammal held for purposes of public display, if such protected species parts are:

(i) Maintained as part of a properly curated, professionally accredited collection;

(ii) Made available for purposes of scientific research or enhancement at the request of the AA; and

(iii) If the permit holder displays such protected species parts to the public, the part is made available to the public as a part of an educational program that is conducted regularly with access not limited other than by an admission fee.

(16) Upon request by the AA, the permit holder must provide information regarding, and must allow any employee of the National Oceanic and Atmospheric Administration or any other person designated by the AA to inspect or observe the permit holder's records, facilities, protected species, protected species parts, and activities insofar as such records, facilities, or activities pertain to those activities authorized under, or species subject to, a special exception permit, or pertain to the AA's responsibilities under the Acts.

(17) The AA may require that the permit holder submit, or the permit holder may submit voluntarily, a copy of any marketable product (see definition at § 216.3) obtained under the authority of a special exception permit. The AA will hold such material confidential unless and until the permit holder requests its release. Once the permit holder has requested the release of a marketable product submitted to the AA, a copy of the marketable product will be made available by the AA to any person upon request. In providing such material, the AA must notify the recipient that the material is non-exclusive (i.e., will be provided to any person that requests it) and will require that the recipient, in any use of the material, clearly credit the permit holder or other appropriate person and

reference the NMFS permit under which it was obtained. The AA may charge the recipient a fee to cover the costs of duplication and processing.

(18) The permit holder may sell, offer to sell, or directly or indirectly exchange for any product or service of value, marketable products obtained consistent with the requirements of § 216.36(a)(10), if:

(i) The permit holder submits information sufficient to demonstrate to the AA that the subject marketable product(s) was obtained in a manner or for a purpose essential to activities identified in § 216.36(a)(10) (i) through (iii); and

(ii) The AA authorizes the transaction.

(19) The permit holder may not obtain custody of a pre-Act marine mammal if such marine mammal is to be held at the same facility with marine mammals of the same species being held under a special exception permit, except with the prior authorization of the AA and consistent with the terms and conditions of the permit (e.g., the number of marine mammals of the subject species that the permit holder is authorized to hold).

(20) Living protected species held under the authority of a special exception permit must be individually marked in a uniquely identifiable manner and with a unique number, code, or other marking determined acceptable by the AA. Such marking or tagging must be humane and be by electronically encoded tag or an equivalent tagging method, freeze-branding, tattooing, or other long-term method acceptable to the AA that uniquely identifies the protected species in a manner that, upon examination of the animal, would be definitively apparent to persons other than the permit holder or the permit holder's staff. The AA may authorize a permit holder to hold or release protected species without such marking if the protected species are captured or captive bred for purposes of scientific research or enhancement and either held for only a short period of time or are in a life stage during which such marking is not practical (e.g., smolt), or they are marine mammals captured from the wild for purposes of public display but released immediately following capture.

(21) The permit holder must not take in the wild any marine mammal that at the time of taking is unweaned or less than 8 months old, whichever occurs later, or is a part of a mother-calf/pup pair, unless such take in the wild is specifically authorized in the special conditions of the special exception permit. Additionally, the permit holder

must not import any marine mammal that at the time of taking was or will be pregnant, lactating, or is unweaned or less than 8 months old, whichever occurs later, unless such import is specifically authorized in the special conditions of the special exception permit. In the same manner, the permit holder must not conduct intrusive research on a marine mammal held captive under a permit if, at the time of the intrusive research, the condition of the marine mammal is as described for importation in paragraph (b)(21) of this section, unless such intrusive research is specifically authorized by the AA. See also § 216.36(b)(4).

(22) Foreign permit holders that hold living marine mammals taken in and exported from the United States under a special exception permit must reimburse any reasonable and relevant costs (i.e., transportation, lodging, and per diem) for an inspection as provided under paragraph (b)(16) of this section. A foreign permit holder will be responsible for the costs associated with no more than one such inspection every 3 years, unless such an inspection documents the permit holder's non-compliance with any applicable requirement or captive maintenance standard of this subpart, in which case the foreign permit holder will be responsible for the costs associated with no more than one such inspection during any 12-month period until compliance is documented.

(23) A violation of any of the terms and conditions of a special exception permit issued under this subpart by the permit holder or any person operating under the authority of the permit may subject any such permit holder and person(s) committing such violation to penalties provided for in the Acts or implementing regulations, specifically section 105 or 106 of the MMPA and implementing regulations (see § 216.41 and 15 CFR part 904); section 11 of the ESA and implementing regulations; or section 304 of the FSA and implementing regulations, as applicable.

(24) If activities authorized under a special exception permit have unforeseen effects on the affected protected species or, for activities conducted in the wild, any other component of the ecosystem of which they are a part, the permit holder must suspend permitted activities and notify the Regional Director, and, if marine mammals are involved, the AA, of the circumstances and any relevant observations and recommendations. The permit holder shall not continue such permitted activities until specifically authorized by the Regional Director or,

if marine mammals are involved, the AA.

(25) The AA may require an immediate cessation of permitted activities on the basis of new information that demonstrates that the permitted activities may have an adverse effect on the protected species, on the species or stock, or on the marine ecosystem, that was not anticipated at the time of permit issuance; or establishes that any part of the statements or information submitted by the permit holder as a part of, or subsequent to, the permit application is not accurate or complete. Permitted activities may be resumed upon specific authorization by the AA, and subject to any terms or conditions that the AA determines necessary, consistent with the provisions of § 216.40.

(26) All living protected species must be taken, imported, or exported in a humane manner, and the conduct of any otherwise prohibited activity authorized under a special exception permit involving a living protected species must be humane. In the event the AA determines that any method of taking, import, export, or conduct of an otherwise prohibited activity authorized by a special exception permit is not humane, any such special exception activity conducted by such method must cease immediately upon notification. Such special exception activity may resume if an alternate humane method for the conduct of the special exception activity is prescribed by the AA.

(27) The permit holder must request authorization by the AA prior to importing or initiating a capture activity for long-term or permanent captive maintenance (i.e., other than short-term capture and release) of a living marine mammal. The AA may authorize such importations or captures, if:

(i) The permit holder:

(A) Requests authorization to import or capture at least 30 days prior to the proposed importation or capture date;

(B) Provides the proposed dates and, for imports, country of origin, port of entry, description of the marine mammals to be imported, and any other information otherwise required under paragraph (b)(8) of this section, and, for captures, the locations for the capture and associated taking;

(C) Identifies the proposed method, including, but not limited to, a detailed description of the containers/devices to be used and any special care required, modes (e.g., aircraft, truck, other), duration (including any transfer points), and date of transport, and the attending veterinarian, or professional staff of the permit holder knowledgeable in the area

of marine mammal care for the species concerned, who will accompany the marine mammal;

(D) Provides a copy of an Animal and Plant Health Inspection Service inspection report conducted within the preceding 6 months, and, if such inspection documents violations or required corrective actions, a certification to the satisfaction of the AA that such violations have been resolved and any required corrective actions have been taken, or that the violations will be resolved and corrective actions taken within a period specified by the AA; and

(E) Submits evidence that the permit holder has either posted a surety bond acceptable to the AA in the amount of \$10,000 for each marine mammal to be imported or captured, or made other arrangements acceptable to the AA for the disposition of such marine mammals if and when the permit holder's permitted activity terminates (i.e., advance planning and assurances of adequate funding arrangements) (see § 216.35(a)(5)); and

(ii) The responsible veterinarian certifies that the transport will be conducted in compliance with the captive maintenance requirements of § 216.37; and

(iii) The permit holder's special exception permit authorizes the importation or the take of the species to be captured and, in obtaining custody of the marine mammal, the number of marine mammals authorized under the permit will not be exceeded.

(28) The AA's authorization for an importation or capture from the wild under paragraph (b)(27) of this section will be limited to a specified period of time, not to exceed 30 days, and may include additional terms or conditions restricting or otherwise controlling the importation or methods, personnel, equipment, or location of the capture activity. The date and port of entry/specific location of the importation or capture activity, as well as whether a NMFS observer must be present, also may be determined by the Regional Director following the 1-week advance notification required for imports under paragraph (b)(4) of this section or the 3-week advance notification required for captures from the wild under paragraph (b)(3) of this section. If the importation or capture does not occur during the period initially authorized, the AA may extend the authorized period in increments of no greater than 30 days.

(c) *Public display general conditions.* All public display permits are subject to the following general conditions:

(1) Except as a part of an interactive program specifically authorized under

the special conditions of the permit, the permit holder must not allow a member of the public to engage in an interactive activity without specific authorization from the AA.

(2) The permit holder must conduct the education or conservation program in accordance with the program determined acceptable by the AA at the time of permit issuance, renewal (i.e., major amendment extending the valid period of the permit), or as modified and enhanced after permit issuance/renewal and determined acceptable. Deletion of any significant element of an education or conservation program that has been determined acceptable by the AA requires prior authorization by the AA. Unless and until notified otherwise, the permit holder may presume that substantial additions to or significant improvements in an education or conservation program are acceptable to the AA, if:

(i) A complete description of the education or conservation program as substantively supplemented or significantly improved is provided in the annual report; and

(ii) The substantial additions to or significant improvements in the education or conservation program are consistent with issuance criteria of § 216.35(b)(3) and any applicable guidelines or standards established by the AA.

(3) Except for intrusive research or research requiring the conduct of an interactive program, which must be specifically authorized by the AA, the permit holder is authorized to conduct bona fide scientific research involving marine mammals held under a public display permit, provided such scientific research is conducted in a humane manner consistent with the captive maintenance requirements of § 216.37, and is incidental to and does not interfere with the public display purposes for which the marine mammal is held captive.

(4) All captive births must be reported in accordance with § 216.39. Where a major amendment to a facility's public display permit is made necessary as a result of a captive birth (i.e., an increase in the number of marine mammals authorized to be held under the permit), the permit holder must submit a request for a major amendment within 1 year following the date of the birth.

(5) Public display permits may be transferred only in the case of a change in ownership of the public display facility. The AA may authorize transfer of the permit to a proposed new facility owner/permit holder, with any additional terms and conditions that the

AA has determined necessary, provided that:

(i) Prior to the change in ownership, both the present permit holder and the proposed new facility owner request that the AA transfer the permit to the new owner effective upon the change in facility ownership;

(ii) The proposed new facility owner submits any information deemed necessary by the AA, including information needed to ensure that the transfer of the permit will be consistent with the criteria and restrictions of §§ 216.35 through 216.38; and

(iii) The AA determines that the proposed new facility owner meets the criteria and restrictions of §§ 216.35 through 216.38 and that all reports have been submitted in compliance with § 216.39.

(d) *Scientific research general conditions.* All scientific research permits are subject to the following general conditions:

(1) The AA must approve any change in the principal investigator, except where the AA specifically authorizes notification rather than prior authorization of a change in the principal investigator. The AA must approve the addition or change of any co-investigator (i.e., the principal investigator's on-site representative(s) also responsible for the special exception activity authorized by the permit) from those designated as agents in the permit. A request to add or change an agent listed under the permit must be submitted by the permit holder and include a description of the activity to be conducted by the proposed agent, the manner in which such activity is a part of the permitted activity, and information regarding the proposed agent equivalent to that required for the principal investigator in the application.

(2) The permit holder must notify the AA of any change in research objectives, protocol, principal personnel, scope, methods or other significant aspect of the research described in the application, including any change in equipment or sample size of significance to the research. Such notification must be received at least 30 days prior to the proposed date on which the permit holder intends to implement the proposed change. If the proposed change requires either a major or minor amendment to the permit, specific authorization by the AA is required in accordance with § 216.40.

(3) Marine mammals held under a scientific research permit, and not also held under a public display permit, may not be subject to public display, included in an interactive program or

activity involving the public, or trained for performance unless:

(i) Such activities are necessary to address the objectives of the scientific research and have been specifically authorized by the AA under the scientific research permit;

(ii) Are conducted incidental to and do not in any way interfere with the permitted scientific research; and

(iii) Are conducted in a manner consistent with the criteria, restrictions, and conditions of §§ 216.35, 216.36, and 216.38(c) applicable to public display, except where exceptions are specifically authorized by the AA.

(e) *Supplemental general conditions.* Any other terms or conditions that the AA deems appropriate and applicable to a type or category of special exception permit may be specified for such permits as supplemental general conditions; either at the time such permit is issued or subsequently as an amendment to such permit in accordance with § 216.40.

(f) *Amendments to general conditions.* Permit holders are required to comply with the terms and conditions of the permit. Activities conducted in any manner inconsistent with the terms or conditions of a special exception permit are prohibited, unless the permit is amended to allow for such activities in accordance with § 216.40.

§ 216.39 Reporting.

(a) *Annual reports.* All permit holders must submit annual reports.

(1) *General.* Annual reports must be submitted to the AA on or before the date specified in the permit.

(i) The annual report submission date is the date 30 days after the reporting period identified in paragraph (a)(1)(ii) of this section; or, if requested by the applicant/permit holder and authorized by the AA, a date consistent with, but not later than, 30 days after the permit holder's fiscal year; or, for scientific research or enhancement activities dependent upon a well-defined annual field season, up to 90 days following the end of the field season as specified in the permit.

(ii) Annual reports shall cover the 12-month continuous period(s) identified in the permit, except the first annual report may cover a period of less than 12 months but no greater than 15 months.

(2) *Captive maintenance.* (i) For permits involving captive maintenance of protected species, the annual report must include:

(A) An updated protected species report, including a description of any protected species exported. Any changes to protected species report data,

other than new information, must be explained.

(B) An updated facility profile.

(C) Information regarding any changes to the animal care staff or animal care programs.

(ii) Only that information necessary to update the information provided in the permit application or as updated in earlier reports must be submitted to comply with paragraph (a)(2)(i) of this section. Information requirements for protected species and facility profile reports are summarized in appendix C to this subpart and are described specifically in application instructions.

(3) **Public display.** For public display permits, the annual report must include:

(i) A summary of the education or conservation program conducted by the permit holder, including a complete description of any substantive supplements to or significant improvements in the program, a summary of the results of any program evaluations conducted during the reporting period, and a description of the number and type of persons participating.

(ii) An estimate of the number of persons that visit the facility and observe the marine mammals annually, and, where practicable, a categorization of this information by type of visitation (e.g., general public, school group, special activities, etc.).

(iii) A summary report of any interactive program conducted by the permit holder, including participant information (both persons and marine mammals).

(iv) A summary report of research involving marine mammals held under the permit, except intrusive research conducted under a scientific research permit (see paragraph (a)(4) of this section). This summary report must include, for each such research program conducted, a statement of objectives and, as appropriate, the hypothesis(es) tested, the marine mammals involved, the principal investigator responsible for the conduct of the research, a brief description of the methods used, and an indication of where and when the research findings are expected to be published.

(4) **Scientific research and enhancement.** For scientific research and enhancement permits, the annual report must include:

(i) The species, number, identification (i.e., for living protected species, age/size/sex/reproductive condition, to the extent to which such can be determined, and, for protected species parts, description of part), date, location, and method by or manner in which

protected species, individually or as part of a discrete group were:

(A) Taken (e.g., harassed, captured, or killed), imported, exported, or affected by an otherwise prohibited activity authorized under the special exception permit (see appendix A to this subpart); and, where protected species are tagged, the dates/time periods of actual tracking effort and the duration of tag attachment (where known);

(B) If marine mammals, approached within the recommended approach standards described in appendix B to this subpart; and

(C) Affected physically or responded behaviorally to the taking, importation, export, or otherwise prohibited activity authorized under the special exception permit and described in paragraph (a)(4)(i)(A) of this section or, if marine mammals, the approach described in paragraph (a)(4)(i)(B) of this section. Wherever possible, for marine mammals taken in the wild by some type of harassment (see appendix A to this subpart), describe behavior before, during, and after the conduct of research procedures and the nature of any and all incidents where behavior may have changed in response to research activity, and whether and how behavioral responses varied by time, location, and nature of approach (i.e., an educated assessment, short of formal analysis).

(ii) The persons and vessels involved in the conduct of the permitted research or enhancement and their respective functions.

(iii) The number of attempts at accomplishing the research or enhancement objective (e.g., photo-ID, biopsy, or tagging) and number of successes; number of times any given individual or group was approached; where capture of the animal was not a part of the research or enhancement activity, the actual distance required to obtain results (e.g., biopsy, tagging, or photograph suitable for identification); and, where biopsy, tagging, or equivalent intrusive procedure short of capture was conducted, a description of the information and rationale used to conclude that each animal subjected to such actual or attempted intrusive procedure was not inadvertently harmed and upon which the decision was made to proceed with subsequent intrusive research or enhancement activity.

(iv) An evaluation of and summary of the results of the research or enhancement program conducted to date as it relates to the research or enhancement objectives.

(v) Activities planned to be conducted in the upcoming year.

(vi) What steps have been taken to coordinate proposed activities with other researchers or, if applicable, enhancement activities, so as to minimize disturbance and avoid possible duplicative research.

(vii) Any steps taken during the reporting period or proposed to be taken to minimize or avoid adverse effects.

(viii) Where the authorized take or import involves a species or stock designated, or proposed to be designated, as depleted under the MMPA or as endangered or threatened under the ESA, the permit holder must submit an assessment of whether and how the scientific research or enhancement activity contributed to the achievement of any recovery objectives established for the species or stock.

(ix) Where marine mammals designated as depleted, endangered, or threatened are held captive under an enhancement permit, the report must describe the manner in which the captive maintenance has contributed directly to the survival or recovery of the species or stock.

(x) A description of any public display of marine mammals conducted incidental to research or enhancement activities.

(xi) Any copies of marketable products that the permit holder has been required by the AA to submit as part of an annual report.

(b) **Final reports.** All permit holders must submit final reports.

(1) **Public display.** Public display permit holders must submit a final report within 90 days of the closing of the holder's facility or the transfer of the permit in accordance with § 216.37(c)(5). The final report must include a final protected species report describing the status of all marine mammals formerly held by the permit holder at the time of disposition and the disposition of each. The final report must include any updated information that may be necessary to supplement the special report submitted in accordance with paragraphs (c)(1)(i) through (iii) or paragraph (c)(2)(i) of this section.

(2) **Scientific research and enhancement.** Scientific research and enhancement permit holders must submit a final report 120 days after the submission of the last annual report for activities conducted during the valid period of the permit. This final report must include:

(i) A summary of protected species, personnel, and activity information for the conduct of the entire research or enhancement program (i.e., summary of annual report information required under paragraph (a)(4) of this section);

(ii) A statement of the objectives of the research or enhancement program and, for scientific research, the hypothesis(es) tested, and a brief description of the methodology used (with specific notations wherever these differ from that described in the original or, where applicable, amended application, and the reasons for such variation);

(iii) An evaluation and summary of results and the manner in which such results relate to the research or enhancement objectives;

(iv) For scientific research, an indication of where and when the research findings are to be published or otherwise made available to the public or scientific community;

(v) For enhancement, a description of the manner in which the enhancement program contributed significantly to maintaining or increasing distribution or abundance, or enhanced the health or welfare of the species or stock, necessary to ensure the survival or recovery of the affected species or stock in the wild; and an assessment of the need for additional enhancement, along with specific recommendations; and

(vi) A description of the disposition of any protected species parts, including an identification of the part and the manner of disposition.

(c) *Special Reports.* Special reports must be submitted by permit holders in accordance with the following.

(1) *Captive maintenance.* (i) Within 30 days of the birth, transfer of custody, importation, or export of any marine mammal, the permit holder must submit an updated protected species report reflecting this new information. Where the duration of enclosure-to-enclosure transport of a marine mammal was greater than 1 hour, this information must include: The date(s), mode(s), method(s), and duration of the transport, including number of transfer points; attending veterinarian or professional staff; the date and time the receiving permit holder assumed custody; any problems or unusual events encountered during transport; and a post-transport assessment by an attending veterinarian of the health of the marine mammal and the degree to which the marine mammal has acclimated initially to the new facility/ enclosure, where such assessment is made no earlier than 2 weeks following the transport.

(ii) The AA must be notified within 2 business days of births or deaths of marine mammals, including still-births and euthanasia. This notice must include the species, sex, identification number, and, where applicable, name of the marine mammal or, for still-births,

the sex of the marine mammal; and, for births, an assessment of apparent health; and, for deaths, any immediately apparent indication of physical injury, distress, or behavioral factors that may have contributed to the cause of death or were reasons for euthanasia (e.g., a summary of preliminary gross necropsy results) and any steps to be taken to reduce the potential for additional mortalities. If this notice is provided by telephone, a follow-up written notice must be provided by facsimile or letter postmarked within 4 business days of the birth or death. All birth and death records and related documentation, including necropsy records, are subject to review in accordance with § 216.38(b)(16).

(iii) A final necropsy report must be submitted within 30 days of the date of the death of a marine mammal. This report must include a summary clinical history of the marine mammal in a form consistent with accepted veterinary medical practice, any histopathology reports, and any conclusions reached by the veterinary pathologist or attending veterinarian regarding the cause of the death, including any contributing physical or behavioral factors. Alternatively, if information is insufficient for the completion of a final necropsy report, the permit holder may submit an interim necropsy report providing: Information developed to date and any preliminary conclusions; a status report on the development of a final necropsy report, describing the outstanding information required and including an estimate of the time needed to complete a final report (e.g., laboratory analysis of tissue samples); and a request for an extension of time to submit the final report. After receiving a satisfactory interim necropsy report, the AA may grant an extension of time of up to 60 days for submission of a final necropsy report (i.e., up to 90 days from the date of death).

(iv) When releases to the wild have been authorized under a special exception permit, reporting requirements for such releases shall be included as special permit-specific or supplemental general conditions to the permit, as appropriate.

(v) When limited temporary holding has been authorized by the AA for purposes described in § 216.37(g), detailed reports must be submitted on the condition of the marine mammal being temporarily held and the status of the emergency or renovation at intervals not greater than 60 days.

(2) *Permanent removals from the wild* (i.e., live captures and intentional, inadvertent, or assumed lethal take).

(i) Where the authorized special exception activity involves a capture from the wild, the permit holder must submit a report within 30 days of the capture or collection activity authorized under the permit, describing the time and specific location (e.g., latitude/longitude) of the capture from the wild, including the number and, to the extent possible, ages/sizes, sex, and reproductive condition of protected species encircled, temporarily held and released, and removed/collected, and, if the protected species taken are marine mammals, the marine mammals chased or approached within the approach distance standards described in appendix B to this subpart; and any deaths, injuries, or complications that arose in connection with the taking. The AA may waive this reporting requirement when the capture or collection activity involves species other than marine mammals.

(ii) Where a lethal take is authorized as a part of permitted activities, the permit holder must submit a report within 30 days of the actual lethal take. Where a lethal take occurs, inadvertently, incidentally, or otherwise, or is presumed to have occurred as a result of permitted activities, the permit holder must notify the AA within 2 business days of the actual or presumed lethal take. This lethal take report or notification, as applicable, must describe the date, time, location, number, and, to the extent possible, age/size, sex, and reproductive condition of each animal killed, and, for accidental or presumed mortalities, the circumstances accompanying the incident and identification of actions taken or to be taken to reduce the potential for additional occurrences. In the event of an unanticipated lethal take, the provisions of § 216.38(b)(24) also apply.

(3) *Importation of protected species parts.* Within 30 days of the importation of protected species parts, the permit holder must submit a report including a description of the part (e.g., species, specimen type, method of preservation) and the unique number assigned to the part.

(4) *Transfer or export of protected species parts.* Within 30 days of the transfer or export of a protected species part, the permit holder, or other person authorized to hold a protected species part, must notify the Regional Director of the transfer or export, including: A description of the part (e.g., species, specimen type, method of preservation, and the unique number assigned), the person to whom the part was transferred or exported and, if applicable, the recipient's permit number; the purpose

of the transfer or export; and, for transfers, a certification that the recipient has agreed to comply with the requirements of § 216.38(b)(12) for subsequent transfers.

(5) *Other.* If the permit holder experiences or observes an unusual or unexpected event that affects significantly, or is likely to have a significant effect upon, the health or welfare of the living protected species that is the subject of the permitted special exception activity, or, for activities conducted in the wild, any other directly-related component of the marine ecosystem of which they are a part, the permit holder must submit a brief report describing the circumstances concerned and any relevant observations or recommendations (also see § 216.38(b)(24)).

(d) *Reporting format.* Following notice of permit holders by the AA that a format for one or more reports has been established by NMFS, permit holders must submit such reports in the format established.

§ 216.40 Permit amendment, modification, suspension, or revocation.

(a) Special exception permits may be amended by the AA if he or she determines that the amendment is consistent with the Acts and complies with the applicable provisions of this subpart. Such amendment may be made by the AA in response to, or independent of, a request from the permit holder for an amendment to the terms or conditions of the permit.

(b) Requests by a permit holder for an amendment must be submitted in writing and include the following:

(1) The purpose and nature of the requested amendment;

(2) Information sufficient for the AA to determine whether the amendment is a major amendment as described under paragraph (c) of this section;

(3) Information, not previously submitted as a part of the permit application or subsequent reports, required to determine whether the proposed change meets the applicable criteria and restrictions of §§ 216.35 and 216.36; and

(4) Any additional information determined by the AA to be necessary to make the determination in paragraph (a) of this section.

(c) An amendment will be considered a major amendment if it would change the permit-specific conditions (see § 216.38(a)) regarding:

(1) The number and species of marine mammals, endangered species, or threatened species that are authorized to

be taken, imported, exported, or affected by an otherwise prohibited activity;

(2) The manner in which these protected species may be taken, imported, exported, or subjected to an otherwise prohibited activity, considering, where applicable, type of take and authorized level of harassment, including harassment during capture, if the proposed change may result in an increased level of take, jeopardy, or risk of adverse impact;

(3) The location(s) in which the protected species may be taken, from which they may be imported, and to which they may be exported, as applicable;

(4) Whether, and in what manner, marine mammals taken or imported for purposes of public display or scientific research may be used in interactive programs; or

(5) The period(s) during which the permit is valid, if the proposed extension is greater than 12 months beyond that established in the original permit.

(d) The notice of receipt, review, and decision-making provisions of § 216.34(e) and (f) applicable to permit applications will also apply to major amendments.

(e) For major amendments proposed by the AA, the permit holder will be notified by registered mail, return receipt requested, concurrent with publishing the Federal Register notice announcing the proposed major amendment and a summary of the reasons therefor.

(f) Minor amendments, i.e., amendments that do not change the terms of the permit specific conditions as stated in paragraph (c) of this section, will be made according to the following procedures:

(1) For minor amendments requested by a permit holder, the AA will notify the permit holder of the decision, specifying the minor amendment, if made, or specifying the reasons for any denial. If the minor amendment involves an extension of the valid period of the permit of 12 months or less beyond that established in the original permit, notice of such a minor amendment will be published in the Federal Register within 10 days from the date of the AA's decision.

(2) For minor amendments proposed by the AA:

(i) The permit holder shall be notified by registered mail, return receipt requested, of the proposed minor amendment and a summary of the reasons therefor. The notice will also specify that the permit holder is entitled to submit an objection to the proposed minor amendment and request a hearing

thereon, if such objection or request for such a hearing is received by the AA within 10 days after receipt of the notice or such other date specified in the notice.

(ii) If no objection to the proposed minor amendment is made during the time specified in the notice to the permit holder, and no hearing is held, the minor amendment will become effective the day following the date specified in the notice. If the minor amendment involves an extension of the valid period of the permit of less than 12 months from that established in the original permit, notice of such a minor amendment will be published in the Federal Register within 10 days from the effective date of the minor amendment.

(iii) The AA may hold a hearing on the proposed minor amendment in response to an objection and request for a hearing submitted in accordance with paragraph (f)(2)(i) of this section or independent of such an objection and request by the permit holder. Notice of the time and place for the hearing will be given to the permit holder by registered mail, return receipt requested, and published in the Federal Register not less than 10 days prior to the date of the hearing. The hearing shall be open to the public and the permit holder and any other person may submit any relevant material, data, views, or comments. A summary record of the hearing will be kept.

(iv) If an objection to the proposed minor amendment is made during the time specified in the notice to the permit holder or a hearing is held, the AA will make a decision as soon as practicable after the close of the hearing, or if no hearing is held, after the date specified in the notice to the permit holder. The AA's decision regarding the proposed amendment shall be published in the Federal Register within 10 days from the date of the decision.

(3) The Marine Mammal Commission and the Committee of Scientific Advisors on Marine Mammals will be afforded an opportunity to comment on proposed minor amendments to scientific research or enhancement permits for the take or importation of marine mammals. The AA will forward to the Commission and Committee a copy of a permit holder's request for a minor amendment or a copy of the minor amendment proposed by the AA and summary of reasons therefor. If the Commission or the Committee does not provide comments within 10 days from the receipt of a proposed minor amendment, such non-response shall be considered a recommendation from the

Commission and the Committee that the AA proceed with a decision on the minor amendment without comment from the Commission or Committee.

(g) In any case in which a violation of the terms and conditions of the permit is found, the AA may modify, suspend, or revoke, in whole or in part, the special exception permit in accordance with the provisions of subpart D of 15 CFR part 904.

(h) In order to make permits for the take or importation of marine mammals consistent with any change made after the date of permit issuance with respect to any regulation prescribed under section 103 of the MMPA, the AA may modify, suspend, or revoke, in whole or in part, any special exception permit involving marine mammals in accordance with the following:

(1) The permit holder will be notified by registered mail, return receipt requested, of any proposed modification, suspension, or revocation. Such notice will specify:

(i) The action proposed to be taken, with a summary of the reasons therefor;

(ii) The steps that the permit holder may take to demonstrate or achieve compliance with all lawful requirements; and

(iii) If a written request for a hearing is received by the AA within 10 days after receipt of the notice or such other date specified in the notice, the AA must hold a public hearing.

(2) The permit holder will be notified of the time and place for a public hearing by registered mail, return receipt requested, and a notice of the public hearing will be published in the Federal Register not less than 15 days prior to the date of the public hearing. Any person may submit relevant material, data, views, or comments. A summary record of the public hearing will be kept.

(3) The AA will issue a decision regarding a proposed modification, suspension, or revocation, as soon as practicable after the close of the public hearing, or, if no hearing is held, after the date specified in the notice to the permit holder referred to in paragraph (h)(1) of this section. Notice of the modification, suspension, or revocation shall be published in the Federal Register within 10 days from the date of the AA's decision.

(4) The permit holder, or any other person, may obtain judicial review of a decision to modify, suspend, revoke, or issue a major amendment to a special exception permit. Such review, pursuant to chapter 7 of title 5 U.S.C., may be initiated by filing a petition for review in the U.S. district court for the district wherein the permit holder

resides or has its principal place of business, or in the U.S. District Court for the District of Columbia, within 60 days of the date on which the notice of the AA's decision to modify, suspend, revoke, or issue a major amendment to the permit is published in the Federal Register.

§ 216.41 Penalties.

(a) Any person who violates any provision of this subpart is subject to civil penalties, permit sanctions and/or denial, written warnings and/or seizure and forfeiture of vessels, in accordance with 16 U.S.C. 1174(b), 1375(a), 1540(a), and 15 CFR part 904.

(b) Any person who knowingly violates any provision of this subpart is subject to criminal prosecution and criminal penalties in accordance with 16 U.S.C. 1174(a), 1375(b), and 1540(b).

§ 216.42 Fees.

(a) A reasonable fee may be charged for the issuance of a special exception permit, an amendment requested by the permit holder, or an authorization required by the special or general permit conditions. Categories I through V listed in appendix A to this subpart, approximate the difficulty of administrative review and processing complexity normally associated with a permit application for the listed type of activity. Consequently, where appropriate and applicable, these categories have been used below in establishing fees.

(b) *Public display permits.* (1) A fee of \$1,000 will be charged a non-permit holder for issuance of a permit to hold marine mammals captive indefinitely for purpose of public display, where the marine mammals are to be obtained from captive stock.

(2) A fee of \$2,500 will be charged a non-permit holder for issuance of a combined permit to import or capture from the wild and hold indefinitely marine mammals for purpose of public display.

(3) A fee of \$1,500 will be charged a permit holder for issuance of a major amendment to import or capture from the wild marine mammals for purpose of public display. This fee includes any associated amendment to the permit holder's public display permit that may be necessary to authorize the captive holding of these new marine mammals.

(4) A fee of \$250 will be charged for a major amendment to a permit requested by a permit holder for the purpose of authorizing new species or an increased number of marine mammals to be held by the facility.

(5) A fee of \$500 will be charged for a major amendment to a permit

requested by a permit holder for the purpose of authorizing an interactive program.

(6) A fee of \$150 will be charged for an authorization to transfer the custody of marine mammals between permit holders, where a major amendment of the permit is not necessary to increase the number or add species to those authorized.

(7) A fee of \$1,500 will be charged a permit holder for an authorization to export a living marine mammal. A fee of \$2,500 will be charged a non-permit holder for issuance of a permit to capture from the wild and export marine mammals for purposes of public display.

(8) No fee will be charged for major amendments proposed by the AA or for minor amendments.

(c) *Scientific research and enhancement permits.* (1) The following basic permit fees will be charged for issuance of a scientific research or enhancement permit:

Category I	No charge.
Category II	\$150.
Category III	\$400.
Category IV	\$700.
Category V	\$1,000.

A description of Category I-IV permits is provided in appendix A to this subpart.

(2) For a major amendment requested by the permit holder that increases the category of the permit (i.e., authorizing a change in the manner in which a protected species may be taken involving an increased level of jeopardy, risk of adverse impact, or level of harassment), a fee will be charged equal to the difference in the fee charged for the existing permit and that which would be charged for the amended permit (e.g., a major amendment changing a category II permit to a category III permit would be charged a fee of \$250).

(3) For a major amendment requested by the permit holder that does not increase the category of the permit, a fee of \$50 will be charged for Category I permits and a fee of \$100 will be charged for all other permits.

(4) For permits that involve captive holding, major amendments and authorizations requested by the permit holder for the purposes described in paragraphs (a)(4) through (6) of this section will be charged the same fee as established for public display permit holders in paragraphs (a)(4) through (6) of this section.

(5) A fee of \$700 will be charged a permit holder for an authorization to export a living marine mammal. A basic

fee of \$1,200 will be charged a non-permit holder for issuance of a permit to capture from the wild and export marine mammals for purposes of scientific research or enhancement.

(6) No fee will be charged for major amendments proposed by the AA or for minor amendments.

(d) *Supplemental NEPA fee.* The AA may charge a supplemental fee to cover the costs to the Federal government associated with the preparation of an EA or EIS that the AA has determined to be required under NEPA. The AA may also charge a supplemental fee for issuance of a permit belonging to a class of permits for which documentation has been prepared in accordance with the provisions of NEPA or any associated National Oceanic and Atmospheric Administration requirements or procedures.

(e) *Observer fee.* At the discretion of the AA or the Regional Director, an observer may be placed on board a vessel engaged in a permitted activity in the wild. The permit holder may be assessed an observer fee not to exceed \$100 per day for each day that the observer accompanies the permit holder in the conduct of such an activity.

(f) *Waiver of fees.* Fees may be waived or reduced by the AA if the applicant is a Federal agency or if the AA determines that such a waiver or reduction is in the public interest consistent with the policies and objectives of the Acts, as applicable.

§ 216.43 Applicability/Transition.

(a) *General.* (1) The regulations of this subpart are applicable to all persons, including persons holding permits or other authorizing documents issued before [date 30 days from date of publication of the final rule, hereafter referenced as "the effective date of the final rule"], by NMFS for the take, import, export, or conduct of any otherwise prohibited activity involving a protected species or protected species part for special exception purposes. The manner and timing in which this subpart applies to such permit holders and persons holding other authorizations, including authorizations to hold marine mammals captive (e.g., letters of agreement), are discussed in this section.

(2) Beginning [the effective date of the final rule], the provisions of this subpart, particularly permit terms and conditions (see § 216.30(c) and §§ 216.36 through 216.39, and the amendment provisions of § 216.40), apply to all public display and scientific research permits and to other authorizing documents issued before [the effective date of the final rule] by

NMFS under which marine mammals are held for public display or scientific research purposes. However, holders of public display and scientific research permits and other authorizing documents may elect to follow the reporting requirements of § 216.39 or those specified in their permits or other authorizing documents, until one of the following first occurs:

(i) The permit holder requests an amendment to or authorization under his/her permit or other authorizing document, or the permit is adjusted in accordance with paragraph (b)(1) or (c)(1) of this section, at which time the permits or other authorizing document will be amended to incorporate the reporting requirements of § 216.39.

(ii) The AA determines that the reporting requirements of § 216.39 should apply to the permit or other authorizing document and proposes a minor amendment to this effect in accordance with § 216.40.

(iii) Beginning [date 1 year after the effective date of the final rule], the reporting requirements of § 216.39 apply to all permits and other authorizing documents.

(b) *Public display.* (1) Consistent with the schedule established in paragraphs (b)(2) through (5) of this section, all facilities holding marine mammals for public display purposes must hold a public display permit consistent with the provisions of this subpart. Public display permits issued before [the effective date of the final rule] must undergo a one-time adjustment; other authorizing documents will be superseded by new or adjusted permits in accordance with paragraphs (b)(2) through (5) of this section. Permit adjustments are effective upon publication of a notice of the permit adjustment in the Federal Register. This notice will include the adjusted permit-specific conditions as described under § 216.38(a), and will provide for a 30-day public comment period.

(2) *Single facility permit holders.* A public display permit issued before [the effective date of the final rule] to a facility that holds marine mammals at one facility must undergo a permit adjustment to authorize the number and species of marine mammals that were held and/or authorized to be captured from the wild or imported as of [the effective date of the final rule]. This permit adjustment will:

(i) Be made upon the request of the facility, at the time the permit is otherwise amended, at the time of any authorization required under their permit or any other authorizing document, or on [date 1 year after the

effective date of the final rule], whichever occurs first; and

(ii) Supersede all other permits and other authorizing documents under which the marine mammals were formerly held.

(3) *Multiple facility permit holders.* Public display permits issued before [the effective date of the final rule] to a multiple facility (i.e., more than one facility under single ownership/control), without regard to the specific facility in which the marine mammals taken under the permit(s) are held, will be separated into facility-specific public display permits. This permit adjustment will establish separate facility-specific public display permits that authorize the number and species of marine mammals held on, and/or authorized to be captured from the wild or imported as of [the effective date of the final rule], plus a limited "allowance" for the transfer of marine mammals between the facilities that make up the multiple facility, in accordance with the following provisions:

(i) The facility-specific permit adjustments will be made upon the request of the multiple facility, at the time the permit is otherwise amended, at the time of any authorization required under the permit or other authorizing document, or on [date 18 months after the effective date of the final rule], whichever occurs first.

(ii) The "allowance" for each facility-specific permit may include any species of marine mammal held at the facility in the 5-year period prior to [the effective date of the final rule], and a number of marine mammals of each such species greater than that held by the facility on [the effective date of the final rule], necessary to accommodate anticipated or recently completed inter-facility transfers between facilities that make up the multiple facility, provided that the number for any facility-specific permit does not exceed any of the following:

(A) Seventy-five percent of that facility's capacity for the subject species as calculated in accordance with applicable space standards (see particularly the captive maintenance standards applicable to marine mammals promulgated by the Animal and Plant Health Inspection Service at 9 CFR parts 1, 2, and 3, and referenced in § 216.37);

(B) Fifty-percent increase above the number held on [the effective date of the final rule], for the following species: Killer whales (*Orcinus orca*), false killer whales (*Pseudorca crassidens*), pilot whales (*Globicephala melana* or *G. macrorhynchus*), or belugas (*Delphinapterus leucas*);

(C) Twenty-five percent increase above the number held on [the effective date of the final rule], of species other than those referenced in paragraph (b)(4)(ii)(B) of this section;

(D) An increase of one for any species held in isolation at the time of the facility-specific permit adjustment (see paragraph (b)(3)(i) of this section). An increase of more than one may be allowed if adequately justified on the basis of fundamental social unit requirements of the species (see § 216.37(l)); or

(E) For a seasonal facility, the species and greatest number of marine mammals that have been held in the 2-year period prior to [the effective date of the final rule].

(iii) Transfers between facilities that make up the multiple facility that are authorized under a permit or other authorizing document issued before [the effective date of the final rule] may continue without additional authorization under this subpart until the date of facility-specific permit adjustment.

(iv) The facility-specific permits will supersede all other permits and other authorizing documents under which the marine mammals were formerly held.

(4) *Facilities not holding a permit.* A facility that is holding marine mammals for public display purposes, but that does not hold a public display permit, must submit an application for a public display permit in accordance with this subpart and reflecting the marine mammals held by the facility on [the effective date of the final rule]. The facility must submit this application within 6 months of receiving notification that a public display permit is required, or by [date 1 year after the effective date of the final rule], whichever occurs first. A public display permit issued to the facility will supersede all other authorizing documents under which the marine mammals were formerly held.

(5) *Persons (other than facilities) holding marine mammals.* Persons (other than facilities) holding marine mammals under a permit or other authorizing documents may continue to hold the marine mammals under such documents until [date 1 year after the effective date of the final rule], in compliance with the requirements of paragraphs (b)(5)(i) and (ii) of this section. After [date 1 year after the effective date of the final rule], a public display permit issued to a facility is required for continued holding of marine mammals for public display purposes.

(i) By [date 60 days after the effective date of the final rule], persons (other

than facilities) holding marine mammals under a permit or other authorizing document must notify the AA of the identity of the marine mammals and the facilities at which the marine mammals were held on [the effective date of the final rule], were held on the date of notification, and will be held during the 1-year period following [the effective date of the final rule].

(ii) Not later than [date 1 year after the effective date of the final rule], the person must either:

(A) Arrange to include the marine mammals as a part of the one-time permit adjustment or permit application provided for in paragraph (b)(2), (3), or (4) of this section; or

(B) Make arrangements with a facility to apply for a major amendment to its public display permit to authorize the holding of the marine mammals.

(iii) The adjusted permit, new permit, or major amendment referenced in paragraph (b)(5)(ii) of this section will supersede all other permits and other authorizing documents under which the marine mammals were formerly held.

(c) *Scientific research.* (1) Scientific research permits issued before [the effective date of the final rule] that authorize research on captive marine mammals at a facility other than a public display facility must undergo a one-time adjustment to authorize the number and species of marine mammals held as of [the effective date of the final rule]. The permit adjustment will:

(i) Be made upon the request of a permit holder, at the time the permit is otherwise amended, at the time of any authorization required under the permit, or on [date 1 year after the effective date of the final rule], whichever occurs first; and

(ii) Become effective upon publication of a notice of the permit adjustment in the *Federal Register*. This notice will include the adjusted permit specific conditions as described under § 216.38(a), and will provide for a 30-day public comment period.

(2) Intrusive research being conducted on captive marine mammals may continue to be conducted under the authority of a public display permit until [date 1 year after the effective date of the final rule], after which the intrusive research, as defined in § 216.3, must be authorized under a scientific research permit. Any intrusive research initiated after [the effective date of the final rule], must be authorized under a scientific research permit.

(3) Scientific research permits issued before [the effective date of the final rule], that authorize research on protected species other than marine mammals (e.g., endangered or

threatened species of marine and anadromous fish or marine reptiles) are not affected by these regulations.

(d) *Other transition provisions (public display and scientific research).* (1) Permit adjustments or applications provided for in paragraphs (b) and (c) of this section will not include marine mammals being held for rehabilitation under section 109(h) of the MMPA.

(2) Permit adjustments provided for in paragraphs (b) and (c) of this section will not authorize numbers of marine mammals that exceed the capacity of the facility as determined by the captive maintenance requirements of § 216.37.

(3) Major amendments to adjusted permits must be applied for, and will be issued, in accordance with § 216.40.

(4) A facility holding marine mammals as of [the effective date of the final rule], will be exempted from the requirement in § 216.37(l) to approximate the fundamental social unit of marine mammal species until January 1, 1998, provided that the facility complies with the notification provisions of § 216.37(l)(1).

(5) Facilities or persons (other than facilities) that hold pre-Act marine mammals must either submit documentation adequate to establish the "pre-Act" status of the marine mammals in accordance with § 216.32(a)(2), or must include the pre-Act marine mammals in any permit adjustment or application provided for or required in this section.

§ 216.44 Use for special exception purposes of marine mammals taken or imported for rehabilitation.

(a) Upon receipt of a determination that the release of a rehabilitated marine mammal is not likely to be successful or a release notification in accordance with § 216.28, the AA may authorize the retention or transfer of custody of the marine mammal for a special exception purpose consistent with this section.

(b) The AA will first consider requests from the person/facility with authorized custody of the marine mammal for rehabilitation. The AA may authorize such person/facility to:

(1) Retain custody of the marine mammal under a special exception permit that authorizes the person/facility to hold such a marine mammal;

(2) Retain custody pending a major amendment or issuance of a permit, in accordance with paragraph (c) of this section, whichever is necessary, to authorize the person/facility to hold such a marine mammal;

(3) Transfer custody of the marine mammal to a holder of a special exception permit that authorizes the person/facility to hold such a marine

mammal, subject to the requirements of paragraph (d) of this section; or

(4) Transfer custody of the marine mammal to a holder of a special exception permit pending a major amendment, in accordance with paragraph (c) of this section, to authorize the person/facility to hold such a marine mammal, subject to the requirements of paragraph (d) of this section.

(c) The AA may authorize the person/facility to retain custody of the marine mammal pending a major amendment or issuance of a permit, or may authorize the transfer of the marine mammal to a holder of a special exception permit pending a major amendment, authorizing the person/facility to hold such a marine mammal, only if:

(1) A request for a major amendment under § 216.40, or, if necessary, an application for special exception permit under § 216.34, has been submitted to the AA and has been found complete;

(2) The person/facility agrees to hold the marine mammal in conformance with all requirements and standards applicable to special exception permits under this subpart and any additional terms or conditions determined by the AA to be appropriate, including that such a marine mammal shall not be included in an interactive program or subjected to intrusive research; and

(3) The person/facility acknowledges that the marine mammal is subject to seizure by the AA:

(i) If, at any time pending issuance of the major amendment or permit, the AA determines that seizure is necessary in the interest of the health or welfare of the marine mammal;

(ii) If the major amendment or permit is denied; or

(iii) If the person/facility is issued a notice of violation and assessment, or is subject to permit sanctions, in accordance with 15 CFR part 904.

(d) In transferring custody of the marine mammal under paragraphs (b) (3) and (4) of this section, the person/facility and the receiving permit holder are not authorized to purchase or sell any interest in the subject marine mammal. However, the receiving permit holder may reimburse the person/facility for any and all costs, direct or indirect, associated with the rehabilitation (i.e., care, treatment, and supervision) and transport of the marine mammal.

(e) Marine mammals undergoing rehabilitation or pending disposition under this section must not be subject to public display unless such activities are specifically authorized by the Regional Director or the AA and conducted consistent with the criteria,

restrictions, and conditions applicable to public display permits (see §§ 216.35 through 216.38). Such marine mammals must not be trained for performance or be included in any aspect of an interactive program.

(f) Marine mammals undergoing rehabilitation must not be subject to intrusive research, unless such activities are specifically authorized by the AA in consultation with the Marine Mammal Commission and Committee of Scientific Advisors on Marine Mammals and are conducted consistent with the criteria, restrictions, and conditions applicable to scientific research permits (see §§ 216.35 through 216.38).

(g) Any rehabilitated beached or stranded marine mammal placed on public display following a releasability determination under § 216.28(a) and pending disposition under paragraphs (a) through (d) of this section, or any marine mammal imported for medical treatment otherwise unavailable placed on public display after such medical treatment is concluded and pending disposition, must be held in captive maintenance consistent with all requirements and standards applicable to special exception permits for public display purposes, and must not be included in an interactive program.

Appendix A to Subpart D—Examples of Activities That Require a Special Exception Permit

The outline in this appendix is a summary description of different types of take/activity that require a special exception permit, with each type of take/activity annotated with the category assigned by NMFS for administrative purposes. An explanation of terms used in the annotated outline follows, except for the terms used under Import/Export that are self-explanatory.

Note: Applicants must consider all applicable types of activity—there may be more than one type of applicable activity. Additionally, the export of marine mammals or marine mammal parts, for species not listed as endangered or threatened under the ESA, requires authorization, not a permit. NMFS categories (I) through (V) reflect, approximately, the level of administrative review and processing complexity normally associated with a permit application for this type of activity. Consequently, these categories are used by NMFS in determining the applicable permit fee (see 50 CFR 216.42).

ANNOTATED OUTLINE

Type of take/activity	NMFS category
A. Parts collection	
1. Not Directly From a Live Animal.	(I).
2. Directly From a Live Animal.	(II or III).

ANNOTATED OUTLINE—Continued

Type of take/activity	NMFS category
B. Harassment/non-capture	
1. Non-intrusive	
a. Non-intrusive/Non-Contact	(I).
b. Non-intrusive/Contact	(II).
2. Intrusive	
a. Intrusive/Non-Contact	
(i) Low Risk/Impact	(II).
(ii) High Risk/Impact ...	(III).
b. Intrusive/Contact	
(i) Low Risk/Impact	(II).
(ii) High Risk/Impact ...	(III).
C. Harassment/Capture	
1. Temporary Capture/Removal	
a. Short-Term	
(i) Low Risk/Impact	(III).
(ii) High Risk/Impact ...	(IV).
b. Long-Term	(IV).
2. Permanent Removal/Captive Holding	(V).
D. Kill	
1. Lethal Take	(V).
E. Import/Export	
1. Protected Species Import.	(IV).
2. Protected Species Part Import.	(II).
3. Protected Species Export.	(V).
4. Protected Species Part Export.	(II).

Explanation of Terms

A. *Parts collection* includes the following:

1. *Parts collection not directly from a live animal* includes the collection of any hard or soft part, obtained in a manner other than directly from a living animal. The collection of any part from a dead animal also may be authorized under the applicable permit conditions or, for dead beached and stranded marine mammals, under 50 CFR 216.22; and, certain hard parts from marine mammals may also be collected from the beach under 50 CFR 216.26.

2. *Parts collection directly from a live animal* includes the collection of any hard or soft part directly from a live animal (which requires specific authorization under a permit); usually conducted in conjunction with another type of take.

B. *Harassment/Non-capture* includes harass, pursue, harm, wound, hunt, and shoot. Within this category:

1. *Non-intrusive* applies to activities conducted in the wild only. Generally, NMFS recommends a permit be obtained to conduct an activity that, for marine mammals, exceeds or is conducted in a manner contrary to the recommended approach standards of appendix B to this subpart, or that involves the harassment of other endangered or threatened species of marine and anadromous fish or marine reptiles. *Non-intrusive/Non-contact* applies to activities involving a close approach (e.g., risk of behavior impacts or inadvertent/incidental harassment), but that does not involve contact with the subject animal(s). *Non-*

Intrusive/Contact applies to activities involving intentional, simple non-intrusive contact, such as touching, petting, pushing, or other simple contact that does not restrain or otherwise restrict movement or mobility.

2. *Intrusive* applies to activities conducted in the wild or, for activities conducted for scientific research or enhancement purposes, living protected species held captive in a facility (see 50 CFR 216.3). *Intrusive/Non-contact* includes, for example, a stimulus directed at an animal that may involve a risk to the health and welfare of the subject animal(s) (see 50 CFR 216.3). The terms low risk/impact and high risk/impact are included under both *Intrusive/Non-contact* and *Intrusive/Contact*. *Low risk/impact* includes activities involving a low risk of injury or mortality, an established proven procedure, a short-term impact on subject animals' normal function and/or behavior, etc.; applicable primarily to take in the wild (see 50 CFR 216.3). *High risk/impact* includes activities involving a high risk of injury or mortality, a new or high risk procedure, a long-term impact on the subject animals' normal function, etc.

C. *Harassment/Capture* includes capture, trap, and collect. Within this category:

1. *Temporary capture/removal* includes activities involving a capture from the wild and holding captive for a finite period. *Short-term* includes activities involving capture and release, including encircling or restricting an animals' movement or mobility by a structure or device. The terms low risk/impact and high risk/impact are included under *Short-term*. *Low risk/impact* includes activities involving a low risk of injury or mortality, an established proven procedure, a short-term impact on subject animals' normal function, etc. *High risk/impact* includes activities involving a high risk of injury or mortality, a new or high risk procedure, a long-term impact on the subject animals' normal function, etc. *Long-term* includes activities involving holding an animal captive for weeks or months; includes both "long-term" removals, after which an animal is released to the wild, and temporary "short-term" removals, after which an animal is released, but is not released either in the company of the social group of which it was formerly a part, among the stock from which it was removed, or at the location of capture during the same time of the year in which it was initially captured.

2. *Permanent Removal/Captive Holding* is the captive holding of a protected species for an indefinite period of time, including the capture of an animal from the wild and subsequent indefinite captive holding of that animal.

D. *Kill or Lethal Take* includes activities that involve the directed, intentional, or likely killing of a protected species.

E. *Import/Export* is self-explanatory.

Appendix B to Subpart D—Approach Standards Recommended for Activities Conducted in the Wild

Under the Acts, harassment or other take of marine mammals is prohibited except under certain circumstances. Activities involving the harassment or other take of marine mammals may be permitted under

subpart D of 50 CFR part 216 for a special exception purpose. Since certain activities are likely to harass or otherwise result in the taking of marine mammals, NMFS has developed the following minimum approach distance guidelines and other recommendations for activities conducted in the wild. If a person follows these recommended approach distance standards and related recommended activity restrictions recommended in II. through IV. of this appendix, then it is reasonable to assume that such a person is not likely to harass or otherwise take a marine mammal in the wild. However, if a person or vessel approaches marine mammals within these recommended distance standards or does not follow these recommended operating procedures, such activities have a high likelihood of harassment or other taking of marine mammals in the wild.

Importantly, NMFS recognizes that, if a person or vessel closely approaches a marine mammal in the wild or conducts another activity that has a high likelihood of harassing or otherwise taking the marine mammal, but there is no change in the behavior of the marine mammal and the marine mammal has not been physically contacted in any way, then there is no observable indication that the marine mammal has been harassed or otherwise taken. Nonetheless, in the interest of the protection of marine mammals in the wild consistent with the purpose and objectives of the Acts, NMFS believes that guidance regarding activities likely to result in the harassment or other take of marine mammals in the wild is appropriate and helpful. At a minimum, such guidance is necessary as a standard for use by persons in determining whether a permit is advisable for their proposed activity in the wild, and by permit holders for reporting purposes.

NMFS recommends that an application be submitted for a special exception permit under subpart D of 50 CFR part 216 if a person intends to conduct, or may conduct, an activity for a special exception purpose that may involve an approach of marine mammals closer than the recommended minimum distance standards or will be conducted contrary to the recommended activity limitations or operating procedures as described in II. through V. of this appendix. The approach distances and other recommendations in II. through V. of this appendix are also the standards by which take in the wild shall be reported as a condition of a permit issued under subpart D of 50 CFR part 216 (see § 216.39(a)(4)(i)(B)).

The recommendations of this appendix are limited to the approach of, or other activities directed at, marine mammals. If a marine mammal elects to approach a vessel or person that has made every effort to comply with the recommended approach and activity limitations described in this appendix, and such a person or vessel does not otherwise take the marine mammal, then such an approach by the marine mammal cannot by itself be considered harassment or other take under the Acts. In this case, the activity is not prohibited under the Acts and a special exception permit is not required to conduct the activity. This and other exceptions to the

recommended approach standards and recommended operating procedures are included to clarify the intended limited scope of this appendix.

I. General Recommended Approach Standards

The following are generally applicable recommended minimum approach distances and recommended vessel operation restrictions for approaching marine mammals, and are recommended because of the likelihood such a close approach or activity will result in the harassment or other take of marine mammals in the wild. NMFS recommends that a person proposing to conduct an activity for a special exception purpose within these recommended minimum approach distances, or involving vessel operations contrary to the recommended vessel operation restrictions, apply for a permit under subpart D of 50 CFR part 216. (Note: Whales, for purposes of this appendix, include all baleen whales (*Mysticeti*) and toothed whales (*Odontoceti*) including sperm whale (*Physeter macrocephalus*), beluga whale (*Delphinapterus leucas*), killer whale (*Orcinus orca*), pilot whales (*Globicephala melus* and *G. macrorhynchus*), narwhal (*Monodon monoceros*), and all beaked whales. Dolphins and porpoise, for purposes of this appendix, include all members of the families Delphinidae, Phocoenidae, Monodontidae, and Physeteridae that are not listed under whales.)

(1) Operate an aircraft within 1,000 feet (305 m) of any marine mammal or attempt to encircle any marine mammal with an aircraft;

(2) Approach a marine mammal in a vessel or by any other means, including, but not limited to, swimming or diving, or cause a vessel or other object to approach a marine mammal within:

- (i) One hundred yards (91 m) of whales or pinnipeds on land;
- (ii) Fifty yards (46 m) for dolphins and porpoise or pinnipeds in the water; or
- (iii) Fifty feet (15 m) for pinnipeds hauled out on a fixed structure. The term fixed structure includes a pier, wharf, dock, buoy, or other similar stationary structure, but does not include a jetty, breakwater, or similar structure surfaced with a substrate similar to natural haul-out areas favored by pinnipeds or any structure located within or adjacent to a breeding rookery; or

(3) Operate a vessel or aircraft or carry out an activity in a manner that disrupts the normal movement or behavior of a marine mammal. A disruption of behavior may be manifested by, but is not restricted to, the following: A rapid change in direction or speed; escape tactics, such as prolonged diving or fleeing into the water from a haulout or rookery, underwater course changes, underwater exhalation, or evasive swimming patterns; interruptions of feeding or migratory activities; aggressive postures or charges directed at intruders; attempts by a marine mammal to shield a calf or pup from a vessel or human observer; the abandonment of a previously frequented area; or other stress-related behavior including, but not limited to, vocalizations, finning, tail lobbing, tail raking, or breaching.

II. Regional Recommended Approach Standards

The following are regionally-specific recommended minimum approach distances and recommended activity restrictions for approaching marine mammals. Note: The following recommendations specific to humpback whales in Hawaii are modeled after the special prohibitions found at subpart D of 50 CFR 222 that restrict the approach of humpback whales in Hawaii.

(1) Hawaii—humpback whales.

(i) In areas designated as cow/calf waters for humpback whales in III.(1)(ii) of this appendix, do not:

(A) Approach any humpback whale by any means within 300 yards (274 m); or

(B) Cause a vessel or other object to approach any humpback whale within 300 yards (274 m);

(ii) The following areas are designated as cow/calf waters in Hawaii:

(A) Adjoining the island of Lanai—all waters within 2 nautical miles (nm) (3.7 km) of the mean high-water line along the north and east coast between lines extending perpendicular from the coast between Keana Point and Kamaiki Point; and

(B) Adjoining the island of Maui—all waters inshore of the following boundary: Beginning at the shoreline of the southwestern tip of Puu Olai Point, then, by an azimuth measured clockwise from True South, 082 degrees for a distance of 2 nm (3.7 km); 141 degrees for a distance of 19 nm (35 km); 164 degrees for a distance of 3 nm (5.5 km); 184 degrees for a distance of 4.3 nm (7.9 km); then 295 degrees to Hawea Point; and

(2) Hawaii—Hawaiian monk seals.

(i) In the Northwestern Hawaiian Islands, do not:

(A) Approach monk seals, on land or in water, closer than 100 yards (91 m); or

(B) Pass between a mother and pup monk seal, separate them or disturb them in any way.

(ii) The following precautions should be taken in certain locations, such as French Frigate Shoals, Kure, and Midway, where a 100-yard (91-m) minimum approach distance may not be possible to maintain:

(A) Walk near or behind the vegetation line or beach crest to pass monk seals hauled out on the beach near the water's edge. Follow the reverse procedure when passing monk seals hauled out high on the beach or into the vegetation.

(B) Remain out of sight of the seals when passing them.

III. Recommended Operating Procedures

The following are recommended operating procedures that should be followed to avoid harassment or other take of marine mammals in the wild:

(1) When a vessel underway approaches or is approached by a marine mammal within the approach standards described in I. and II. of this appendix, the operator of that vessel should take all possible precautions to minimize disturbance of the animal, consistent with safe operating procedures for that vessel. These actions include, but are not limited to, maintaining speed and direction and avoiding low-speed maneuvering such as reversing direction, using bow thrusters, or sudden changes in propeller pitch.

(2) Avoid a "head-on" approach.

(3) When it is necessary for safe navigation to approach a marine mammal within the approach standards described in I. and II. of this appendix, vessels underway should be operated only at a reduced constant rate of speed (displacement speeds for smaller vessels) sufficient to maintain steerage and, to the extent practicable, in a manner consistent with the procedures recommended in paragraph III.(1) of this appendix.

IV. Exceptions to Recommended Approach Standards

Exceptions to the recommended approach standards and recommended operating procedures described in I. through III. of this appendix include:

(1) When operating a vessel in restricted bays or shipping lanes where the overall safe operating area precludes vessels from maneuvering to avoid marine mammals, and an alternative route safe for navigation is not practicable, the vessel operator should conduct a safe, continuous transit of the area while minimizing disturbance to any marine mammals present. When operating a vessel in such a restricted area, responsible actions of the vessel operator required for safe navigation may encroach on the recommended minimum approach distances described in I. and II. of this appendix.

(2) When required for the safe departure or approach of an aircraft during take-off or landing or when an alternative flight path is not feasible due to other circumstances that preclude safe operations, such as weather or an emergency, it may be necessary for an aircraft to fly lower than 1,000 feet (about 300 m) over marine mammals.

(3) Except for pinniped pups or pinniped aggregations of more than 50 animals, or, for harbor seals, more than 20 animals, pinnipeds that are located adjacent to a fixed structure, whether in the water or hauled out, may be approached within the length of the animal if the person approaching remains on the fixed structure.

(4) A person or vessel may be approached by a marine mammal even though every effort has been made to comply with the recommended approach standards and recommended operating procedures described in I. through III. of this appendix. If the person or vessel does not otherwise take the marine mammal, the approach of a person or vessel by a marine mammal cannot, by itself, be considered harassment or other take under the Acts.

Appendix C to Subpart D—Permit Application Information

The following is a description of the basic or minimum information required for permit applications. Additional information may be required, depending on the type of permit concerned and the proposed activity. Before submitting a permit application, applicants should closely examine NMFS's Application Instructions for a Special Exception Permit (application instructions). These application instructions describe in detail the information required and the format for a permit application. Application instructions specific to the type of activity proposed may be requested from the Director, Office of

Protected Resources, National Marine Fisheries Service, 1335 East-West Highway, Silver Spring, MD 20910. Requests for application instructions should identify the anticipated special exception purpose for which the application will be submitted (i.e., public display, scientific research, or enhancement (enhancing the survival or recovery of a species or stock (MMPA) or to enhance the propagation or survival of the affected species (ESA)) and, if for scientific research or enhancement, whether the proposed activity will involve the captive holding of protected species.

Where information has remained unchanged or needs to be updated/supplemented, an applicant that has previously submitted a permit application may, where applicable, simply reference the earlier application (by date) and state that this information remains unchanged or provide the updated information. This is particularly the case concerning the protected species inventory report and facility profile information described in III. of this appendix. However, curriculum vitae should be submitted anew for each application. Information required of applicants proposing an activity involving the take and export of living protected species is described in § 216.34(b).

I. General

The following information is required of all applicants.

(1) The date of the application.

(2) The identity and qualifications of the applicant and any other persons to be directly involved in the taking or importation, and, as applicable, export. Curriculum vitae must be submitted for principal personnel. An address and phone number for the applicant is required.

(3) The purpose for which a permit is being requested (i.e., public display, scientific research, or enhancement) and a description of the proposed activity, including the manner in which such activity involves the taking, importation, or export of, or conduct of an otherwise prohibited activity involving, protected species or protected species parts. The applicant must demonstrate that such a special exception activity will be consistent with the purposes of the applicable Acts, and, for marine mammals, any applicable regulations established under section 103 of the MMPA—see applicable application instructions.

(4) The dates and locations of the proposed taking or importation, and, as applicable, export. Both dates and locations should be identified as specifically as possible; including the dates on, locations from/to, and ports of entry/export through which protected species or protected species parts are to be imported/exported.

(5) The proposed duration of the permit. In the case of a permit that involves captive maintenance of protected species, the applicant must identify both the proposed duration of permit authority to capture from the wild or obtain from captive stock and the proposed duration of permit authority to hold such protected species.

(6) A description of the protected species or protected species parts to be taken and/or

imported and, as applicable, exported. The description must include the species (common and scientific names) and number of each to be taken or imported and, as applicable, exported. In addition, the age/size, sex, and reproductive condition of living protected species must also be identified along with other animal-specific information listed under V. of this appendix. Marine mammal parts to be taken or imported, and endangered or threatened species part to be taken, imported, exported, or obtained or used in an otherwise prohibited manner, must be described as specifically as possible. See the application instructions regarding specific information required for the taking, importation, or export of protected species parts. Such information must include, for example, in addition to the above, the number or code to be assigned to the part and any identifying number or coding where such parts have been labeled or have otherwise been marked previously, original source (e.g., beached or stranded, captive animal, obtained in the wild, imported, or unknown), location and date of original collection, and the name/identity of the collector.

(7) A description of the manner in which protected species or protected species parts identified in I.(6) of this appendix are to be taken, imported, or exported (see appendix A of this subpart). Where a taking of protected species or protected species parts in the wild is involved, describe techniques and equipment to be used to approach, capture, restrain, mark, tag, and/or collect tissues and other samples. For example, indicate the kinds, numbers, and sizes of samples to be taken and sampling method; the marks, tags, or other instruments to be used, including their dimensions, weights, method of application and location of attachment, expected duration of attachment, etc.; the kinds, dosages, and methods of administering any drugs or other substances; and/or the method, frequency and period of time each protected species may be restrained or otherwise taken. Clearly indicate if any protected species will be taken more than once or in more than one manner. If the proposed activity is to involve more than one type of taking or multiple takes of the same animal, the number of animals proposed to be taken must be specifically requested by type and number of takes. In this regard, the applicant should identify the maximum number of individual animals that may be taken in a given manner, the number of times each may be subject to such a take, and the number that are to be taken in more than one manner (i.e., animals that will be subjected to more than one type of take). In addition, where living protected species are concerned, the application must describe any alternatives considered to the proposed manner of taking, importation, export, or conduct of an otherwise prohibited activity, and state why the proposed method is humane (see § 216.3).

(8) A description of the effects of the proposed taking, importation, export, or otherwise prohibited activity, by itself or in combination with other known or suspected taking, importation, export, or otherwise prohibited activities. This description must

include the anticipated effects or impacts on the individual animals concerned, the relevant species or stock, the human environment, and the marine ecosystem; and be sufficiently detailed to enable the preparation of any necessary documentation required under NEPA (e.g., an EA, EIS, or documentation to support a determination that the activity is such that it is categorically excluded from requirements under NEPA to prepare an EA or EIS). If the proposed activity involves removing a protected species from the wild and a captive stock of the species concerned is being held at the time of the permit application (including stranded animals undergoing rehabilitation in preparation for release to the wild), the applicant must explain why the animal cannot be obtained from such captive stock.

(9) A summary of the best available information concerning the status of the affected species or stock(s) and factors known to be affecting this status. Where a permit application is for a public display permit, or scientific research permit involving marine mammals being held under a public display permit, and is otherwise exclusively concerned with captive stocks in the United States (i.e., does not involve a take of a marine mammal in the wild or an importation) the affected stock shall be the captive stock of the marine mammal species concerned.

(10) If issued previous permits for the taking, importation, or export of, or otherwise prohibited activity involving, protected species and a final report is not yet due, submit an update to the last annual report required.

(11) If the permitted activity involves the taking or importation of protected species parts or captive maintenance of protected species, describe what arrangements have been made, if any, for the disposition of protected species parts. For example, describe arrangements made with a museum or other institutional collection to ensure that hard and soft tissues of present or potential future interest will remain available for scientific research or enhancement purposes, or for other disposition as provided in 50 CFR 216.38(b) (11) through (14).

(12) Signature of applicant and certification that the application information submitted is accurate and that the applicant has read the permit regulations found at subpart D of 50 CFR part 216 and the applicable sections of the MMPA, the ESA, and implementing regulations at 50 CFR parts 217 through 227, and the FSA.

Note: Failure to provide a complete description of what, when, where, how, and how many protected species may be taken, and detailed information regarding the effects of such activities, often requires that the applicant be contacted to obtain additional information and is one of the most common causes of delays in processing applications. Additionally, if an applicant is a previous permit holder or is listed as an agent on a permit issued previously, the application will not be processed until all required reports for such permit(s) have been submitted.

II. Public Display

The following information is required of all applicants for a public display permit.

(1) A description of the public display program for which the marine mammals will be used; including a description of the manner or type of display (e.g., passive viewing, performance, interactive programs, etc.), and, for each type of display, how often (number of times) and how long (hours) per day/week the marine mammals will be on public display.

(2) Describe public access to the facility, including any regularly scheduled hours and any restrictions to public access other than an admission fee. Estimate the number of persons who visit the facility and observe the marine mammals annually, where practicable categorizing this information by type of visitation (e.g., general public, school group, special activities, etc.).

(3) Describe current and proposed education or conservation programs, including the program's purpose; objectives; basic information, concepts, and values to be conveyed; methods and techniques for implementation and evaluation; and identifying which aspects of the program are intended to be conveyed to which segments of the public. Also identify and provide curriculum vitae for the professional education or conservation staff who has designed and will conduct and evaluate the program.

(4) Describe any interactive programs, their purpose and whether any aspect of the program involves a marine mammal/public interaction otherwise prohibited in the wild.

(5) Where the proposed activity involves the importation of living marine mammals, state whether the marine mammals have been, or will be, taken in a manner consistent with the same requirements as those applicable to the take of a marine mammal subject to U.S. jurisdiction (i.e., whether the take of the marine mammals proposed for importation could have been authorized under the MMPA).

(6) If a marine mammal is proposed to be pregnant, lactating, or either unweaned or less than 8 months old, whichever occurs later, at the time of capture from the wild or when obtained from captive stock by transfer/transport, describe why such taking is necessary for the protection or welfare of the marine mammal.

(7) Provide the captive maintenance information listed in V. of this appendix.

III. Scientific Research

The following information is required of all applicants for a scientific research permit.

(1) Describe the research objectives; including, as appropriate, the hypothesis(es) to be tested.

(2) Provide the rationale and a detailed description of the proposed research. Indicate when, where, how, and why, as well as what research is to be done, including a brief review of relevant literature (include citations) and an explanation of the rationale for the methodology and sampling sizes proposed. The description should include the expected nature and significance of research results.

(3) If the research involves a species or stock designated as depleted under the

MMPA, or listed as endangered or threatened under the ESA, indicate why the proposed research cannot be conducted using an alternative species or stock and explain how the expected research results would benefit the species or stock or contribute significantly to fulfilling a critically important research need.

(4) If the proposed research will or may cause stress, pain, or suffering, or would require lethal taking, explain why there are no feasible alternative methods for obtaining the data or information being sought. Describe any measures to be taken to minimize such adverse effects of the research and to ensure that the taking or other permitted activity will be conducted in a humane manner.

(5) Describe the qualifications and experience of both principal and co-investigators (i.e., designated agents) relevant to the respective aspects of the research proposed to be conducted by these personnel. Curriculum vitae for each should be provided, including a list of publications relevant to the objectives, methodology, or other aspects of the proposed research. If applicable, the names and addresses of cooperating institutions and individuals should be included.

(6) Submit a copy of the formal research proposal, grant, or contract, if such has been prepared.

(7) State whether any special equipment or logistical support is necessary to conduct the research, whether it has been secured, and, if not, what steps are being or will be taken to secure it.

(8) Indicate where and, if possible, when the research results are expected to be published or otherwise made available to the public and the scientific community.

(9) List research previously undertaken under a permit issued under the MMPA, ESA, or FSA, whether or not the applicant was a previous permit holder or performed such research as a co-investigator or participated in a supporting capacity.

(10) Describe any similar research that has been or is being conducted on the same or comparable species or stock. If such research has been or is being conducted, explain why the research proposed will not be duplicative.

(11) Describe any commercial or recreational activities to be conducted in conjunction with proposed research activities (i.e., permitted research). If permitted research activities are anticipated to produce marketable products, describe what type and how many such marketable products are likely to be produced (see definition of "marketable products" at § 216.3).

(12) If protected species are to be held captive, provide the captive maintenance information listed in V. of this appendix.

IV. Enhancement

The following information is required of all applicants for an enhancement permit.

(1) Describe the proposed enhancement program, including the enhancement objective and a detailed description of when, where, how, and why, as well as what enhancement is to be done, including a brief review of relevant literature (include

citations) and an explanation of the methods and natural resource (wildlife or habitat) management techniques proposed. The description must demonstrate that the proposed taking, import, or export, or other otherwise prohibited activity, is likely to contribute significantly to maintaining or increasing distribution or abundance, or enhancing the health or welfare of the species or stock, necessary to ensure the survival or recovery of the affected species or stock in the wild.

(2) Describe the manner in which the proposed enhancement program is consistent with or differs from any applicable recovery or conservation plan for the subject species or stock.

(3) If the research involves a species or stock designated as depleted under the MMPA, or listed as endangered or threatened under the ESA, indicate the urgency of the proposed enhancement effort and whether the proposed enhancement program is a generally accepted enhancement approach (i.e., tested and proven) applicable to the subject species or stock.

(4) If the proposed enhancement program will or may cause stress, pain, or suffering, or would require lethal taking, explain why there are no feasible alternative methods for obtaining the results being sought. Describe any measures to be taken to minimize such adverse effects of the enhancement program on individual animals and to ensure that the taking will be conducted in a humane manner.

(5) Describe the qualifications and experience of all personnel involved in the proposed enhancement program. Curriculum vitae for each should be provided, including a list of publications and any experience relevant to the objectives, methodology, or other aspects of the proposed enhancement program. If applicable, the names and addresses of cooperating institutions and individuals should be included.

(6) Submit a copy of the formal proposal, grant, or contract, if available.

(7) State whether any special equipment or logistical support is necessary to conduct the enhancement effort, whether it has been secured, and, if not, what steps are being or will be taken to secure it.

(8) List of any activities previously undertaken under a permit issued under the Acts (i.e., scientific research, public display, or enhancement), whether or not the applicant was a previous permit holder, co-investigator, or participated in such a permitted activity in a supporting capacity.

(9) Describe any similar enhancement program that has been or is being conducted on the same or comparable species or stocks. If such an enhancement program has been or is being conducted, explain the manner in which such previous enhancement efforts have been considered in the development of the proposed enhancement program or how coordination with such other on-going enhancement efforts will be accomplished.

(10) If captive maintenance of a depleted, endangered, or threatened species or stock is proposed, describe how such captive maintenance will contribute directly to the survival, propagation, or recovery of the species or stock by maintaining a viable gene

pool, increasing productivity, providing necessary biological information, or establishing and maintaining animal reserves or experimental populations required to directly support these objectives. And explain why and how the expected benefit of such captive maintenance to the affected species or stock outweighs the expected benefits of alternatives that do not require removal of animals from the wild.

(11) If the purpose of all or part of the proposed activity is the establishment and maintenance of animal reserves or experimental populations of endangered or threatened species, provide any information necessary for NMFS to make the determinations required under section 10(j) of the ESA.

(12) If protected species are to be held captive, provide the captive maintenance information listed in V. of this appendix.

V. Captive Maintenance

The following information is required of all applicants proposing an activity involving captive maintenance. (However, applicants proposing a special exception activity involving the captive maintenance of protected species other than marine mammals (i.e., endangered or threatened species of marine and anadromous fish or marine reptiles) must submit only the information required under V.1., V.2., V.8., and V.14. of this appendix.)

(1) Provide a copy of a license or registration (required for public display permits; if available for scientific research and enhancement permits) issued by the Animal and Plant Health Inspection Service of the U.S. Department of Agriculture, any outstanding variances granted by the Animal and Plant Health Inspection Service, and a copy of the latest Animal and Plant Health Inspection Service inspection report, as applicable. If such inspection documents violations or required corrective actions, the applicant must certify to the satisfaction of the AA that such violations have been resolved and any required corrective actions have been taken, or that the violations will be resolved and corrective actions taken within a period specified by the AA.

(2) If the facility is not required to be licensed or registered under the Animal Welfare Act (e.g., non-registered research facilities), provide sufficient information for the AA to determine compliance with all applicable captive maintenance requirements in 50 CFR 216.37.

(3) Facilities under construction must submit facility plans and demonstrate that the facility and its proposed program of care and treatment will comply with applicable marine mammal captive maintenance requirements when construction is completed.

(4) Applicants for a permit to take and export a marine mammal in a facility outside U.S. jurisdiction must submit the information described in 50 CFR 216.34(b), including information sufficient to determine compliance with the captive maintenance requirements of 50 CFR 216.37. Such an applicant must also submit a copy of a facility inspection report prepared by a government agency with inspection/

monitoring responsibilities equivalent to that of Animal Plant Inspection Service that documents compliance with standards no less than the captive maintenance standards of, or referred to in, 50 CFR 216.37.

(5) State that either:

(i) The facility and its marine mammal species care program is in compliance with all applicable captive maintenance requirements of 50 CFR 216.37 and will not exceed or be in conflict with applicable standards if a permit is issued or amended as requested; or

(ii) Marine mammals are to be held for scientific research or enhancement purposes and maintained in a manner not in full compliance with applicable standards, describing each such exception specifically, with an explanation of why such an exception is necessary to accomplish the objectives of the research or enhancement activity (e.g., for scientific research activities, provide a copy of the research protocol review by the university's or institution's animal care committee).

(6) Identify the animal care staff, including curators, trainers, veterinarians, and other personnel responsible for the supervision, care, and maintenance of marine mammals and describe their respective functions/duties, qualifications, and experience; curriculum vitae are preferred.

(7) Describe the facility's program for animal care. Include:

(i) The diet, amount and type, for all animals and how and under what conditions food is stored.

(ii) Water supply, quality, and characteristics, including coliform counts (method, frequency, recent results), chemicals added (method, frequency, amounts, standards, measurement techniques/frequency), pH level, salinity, and temperature (standards, method of control, measurement technique/frequency).

(iii) Frequency of pool and food preparation area cleaning and sanitization, including provisions for pest control.

(iv) Emergency animal care plan addressing both facility and personnel needs. Include provisions that ensure that all marine mammals will be adequately maintained under all reasonably foreseeable circumstances, such as loss of power or water, or natural disasters. The plan should include arrangements for adequate care in the event of a strike or illness of personnel. Specify if there are laws prohibiting strikes by animal care staff. Describe emergency sources of water and power; and include minimum requirements for critical animal care stores (i.e., food, supplements, medicine, water quality, equipment, chemicals/materials, etc.).

(8) Submit an up-to-date protected species report. Specific information requirements for protected species reports may be found in the application instructions. The protected species report must include information for each protected species held by the applicant, including, for example, various animal-specific characteristics (e.g., species, sex, name/number, date of birth (estimated/actual), length and weight (estimated/actual), captive status, distinguishing natural markings, applied markings, parentage, wild

capture or historical information, dates and manner of death or other disposition/transfer/release (death/necropsy, release, or transfer information), captive purpose, and, for marine mammals, animal-specific enclosure information, health or medical condition, summary of medical treatment and research history, husbandry behaviors (optional), etc.). In the case of protected species held by the applicant other than marine mammals and in a life stage which precludes or complicates the submission of animal-specific characteristics, the protected species report may include only that actual or estimated information reasonable under the circumstances (e.g., smolt).

(9) Other than short-term capture and release activities associated with a capture from the wild, either state an intention to post a surety bond(s) as described in 50 CFR 216.38(b) (7) and (26), or describe other arrangements acceptable to the AA (i.e., contingency planning and assurances of adequate funding arrangements) for the disposition of the marine mammal if and when the applicant's permitted activity terminates. Also state a willingness to accept temporary custody of seized or abandoned marine mammals on a space available basis, except where acceptance of temporary custody would involve, in the written opinion of the attending veterinarian, a risk to the health or welfare of marine mammals held by the applicant. Seized or abandoned marine mammals in this context are marine mammals that either have been abandoned by a permit holder or seized by NMFS under the terms of this part or of 15 CFR part 904. An exemption from this requirement to accept temporary custody of seized or abandoned marine mammals on a space available basis may be granted if it is in the interest of the health and welfare of the marine mammal(s) concerned and if there is no reasonable alternative.

(10) Provide a facility profile (i.e., a description of the facility, its infrastructure and associated equipment, including detailed enclosure-specific information). Specific information requirements for a facility profile may be found in the application instructions. A facility profile includes, for example, an identification of the principal persons with responsibility and authority for the facility's infrastructure and equipment, supervision of the facility's animal care staff (i.e., applicant) and any principal support personnel in this regard; qualifications and experience of principal staff (curriculum vitae are preferred); type of facility (e.g., permanent, travelling, seasonal); species held; season dates; facility purpose (e.g., public display, scientific research, and/or rehabilitation); enclosure(s) description; etc.

(11) Provide transport/transfer information for each transport proposed, including, but not limited to, methods, equipment, and personnel, as follows:

(i) The proposed method (i.e., including, but not limited to, a detailed description of the containers/devices to be used and any special care required before, during, and after transportation), modes (e.g., aircraft, truck, other), duration (including any transfer points), and date of transport, and the attending veterinarian, or professional staff of

the permit holder knowledgeable in the area of marine mammal care for the species concerned, who will accompany the marine mammal;

(ii) A certification from the responsible veterinarian for the applicant that the transport will be conducted in compliance with the captive maintenance requirements of 50 CFR 216.37; and

(iii) If marine mammals are to be obtained from captive stock, identify:

(A) The marine mammals (e.g., species, sex, age, identifying number and name), if known, and the permit under which the subject marine mammals are being held, if any; and

(B) The facility, permit holder, or other person from which the marine mammals are to be obtained and a request from such facility, permit holder, or other person for authorization to transfer custody to the applicant; and

(C) The permit holder or other person to be responsible for the actual transport of the marine mammal, the name and qualifications of the common carrier or agent, if any, and the point at which (i.e., before, during, or after transport) the applicant will assume custody and captive maintenance responsibility.

(12) If marine mammals are to be held temporarily at a facility different than the proposed permitted facility, or are to be held in a temporary pen/enclosure following capture, state the reasons for such temporary holding, the manner in which such temporary holding is consistent with the applicable captive maintenance requirements of 50 CFR 216.37, and the information required in paragraphs V.(1) through (13) of this appendix, as applicable, for the temporary holding facility or pen/enclosure.

(13) Provide a written certification from the responsible veterinarian stating that the facilities and methods of care and maintenance are adequate, and that the methods of transport and, if applicable, capture, will be adequate to ensure the well-being of the marine mammals.

(14) Provide a written commitment to maintain or contribute data to a stud book, and, if the protected species has been determined to be depleted under the MMPA or listed as endangered or threatened under the ESA, a commitment to participate in a cooperative breeding program.

VI. Importation/Export

The following information is required of all applicants proposing an activity involving the importation or export of protected species or protected species parts.

(1) The country of origin (i.e., the country from which the protected species or protected species part is imported) or, for exports, the destination country.

(2) A copy of any laws of the country of origin/destination identified in VI.(1) of this appendix applicable to the taking of protected species or protected species parts and a description of any protected species management and protection programs of that country.

(3) The manner the protected species or protected species parts to be imported have been taken in the country of origin identified

in VI.(1) of this appendix, and, if marine mammals, whether marine mammals so taken were, at the time of taking, pregnant, lactating, or either unweaned or less than 8 months old, whichever occurs later. If the protected species was captured or captive born, or if the protected species part was first taken, in a country different from the country of origin, also identify this source country and the date on, manner in, and circumstances under which the protected species or protected species part was taken and subsequently imported into the country of origin.

(4) If the protected species part to be imported or exported was obtained as a result of a lethal taking that, for marine mammals, occurred after December 21, 1972, or, for endangered or threatened species, after December 28, 1973, describe the circumstances of such lethal taking.

(5) A statement and, to the extent practicable, documentation concerning whether the protected species to be imported was captured, or the protected species part was taken, and is presently being held in compliance with the laws of the country of origin.

(6) A statement whether taking of protected species will occur in order to replace the protected species or protected species part to be imported or exported; or whether the proposed import or export will result in an increased demand for protected species or parts.

(7) If the importation or export is necessary for protection or welfare of the protected species, discuss the circumstances involved and any alternatives considered.

PART 222—ENDANGERED FISH OR WILDLIFE

12. The authority citation for part 222 is revised to read as follows:

Authority: 16 U.S.C. 1531 et seq.

13. Section 222.23 is revised to read as follows:

§ 222.23 Endangered species, state laws and regulations, and permits for scientific purposes or to enhance propagation or survival.

(a) The species listed as endangered under either the Endangered Species Conservation Act of 1969 or the Endangered Species Act of 1973 and currently under the jurisdiction of the Secretary of Commerce are: Shortnose sturgeon (*Acipenser brevirostrum*), Totoaba (*Totoaba macdonaldi*=*Cynoscion macdonaldi*), Snake River sockeye salmon (*Oncorhynchus nerka*), Gray whale (*Eschrichtius robustus* (glaucus gibbosus)), Blue whale (*Balaenoptera musculus*), Humpback whale (*Megaptera novaeangliae*), Bowhead whale (*Balaena mysticetus*), Right whales (*Eubalaena* spp.), Fin or finback whale (*Balaenoptera physalus*), Sei whale (*Balaenoptera borealis*), Sperm whale (*Physeter catodon*), Gulf of California harbor porpoise/Cochito (*Phocoena sinus*), Chinese river dolphin (*Lipotes vexillifer*), Indus River dolphin (*Platanista minor*), Caribbean monk seal (*Monachus tropicalis*), Hawaiian monk seal (*Monachus schauinslandi*), Mediterranean monk seal (*Monachus monachus*), Leatherback sea turtle (*Dermodochelys coriacea*), Pacific hawksbill sea turtle (*Eretmodochelys imbricata bissa*), Atlantic hawksbill sea turtle (*Eretmodochelys imbricata imbricata*), Kemp's ridley sea turtle (*Lepidochelys kempii*), Green sea turtle (*Chelonia mydas*) breeding colony

populations in Florida and on the Pacific coast of Mexico and the Olive ridley sea turtle (*Lepidochelys olivacea*) breeding colony population on the Pacific coast of Mexico. Of these, NMFS has sole agency jurisdiction over sea turtles while the turtles are in the water and the U.S. Fish and Wildlife Service has jurisdiction over sea turtles while the turtles are on land.

(b) Within the jurisdiction of a state, more restrictive state laws or regulations in regard to endangered species shall prevail in regard to taking. Proof of compliance with applicable state laws will be required before a permit will be issued.

(c) In accordance with the provisions of part 216, subpart D of this chapter, the AA may issue permits for scientific purposes, or to enhance the propagation or survival of the affected endangered species, that authorize, under such terms and conditions as he/she may prescribe, taking, importation, export, or certain other acts with respect to endangered or threatened species otherwise prohibited by section 9 of the Act; except for application procedures for permits involving sea turtles, in which case the applicant shall follow the application procedures set out in 50 CFR part 220 subpart E.

§ 222.24 [Amended]

14. Section 222.24 is amended by removing paragraph (d) and redesignating paragraph (e) as paragraph (d).

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Part V

Department of Education

Special Studies Program; Notice Inviting
Applications for New Awards for Fiscal
Year 1994

DEPARTMENT OF EDUCATION

[CFDA No.: 84.159]

Special Studies Program; Notice Inviting Applications for New Awards for Fiscal Year (FY) 1994

Purpose of Program: To support studies to evaluate the impact of the Individuals with Disabilities Education Act (IDEA), including efforts to provide a free appropriate public education to children and youth with disabilities and early intervention services to infants and toddlers with disabilities.

This notice supports the National Education Goals by improving understanding of how to enable children and youth with disabilities to reach higher levels of academic achievement.

Eligible Applicants: State educational agencies are eligible for awards under these competitions. Also, those State agencies designated by the Governor in each State for the purpose of administering an early intervention program under Part H of the Individuals with Disabilities Education Act (IDEA) are also eligible for awards under these competitions.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 75, 77, 80, 81, 82, 85, and 86; and (b) The regulations for this program in 34 CFR part 327.

Priorities: Under 34 CFR 75.105(c)(3) and 34 CFR 327.10(c) and 327.40(a) the Secretary gives an absolute preference to applications that meet the following priorities. The Secretary funds under these competitions only applications that meet one or more of these absolute priorities:

Absolute Priority 1—State Agency—Federal Evaluation Studies Projects (CFDA 84.159A)

This priority supports cooperative agreements that assess the impact and effectiveness of programs, policies, and procedures assisted under the Individuals with Disabilities Education Act (IDEA) in accordance with sections 618(d)(1) and (2) of the Act. An award under this competition provides not more than 60 percent of the total cost of the project, and the State agency receiving the award provides an amount

not less than 40 percent of the total cost of the project.

Invitational Priority

Within the absolute priority specified in this notice, the Secretary is particularly interested in applications that meet the following invitational priorities. However, under 34 CFR 75.105(c)(1) an application that meets one or more of these invitational priorities does not receive competitive or absolute preference over other applications:

The Secretary particularly invites projects that evaluate the impact and effectiveness of—

- (1) Management and regulatory flexibility that encourages innovative management of schools to expand opportunities for the inclusion of children with disabilities;
- (2) Student outcomes and performance of comprehensive, community-based, family-oriented systems of education and support;
- (3) Community-supported schools focusing on family participation in activities and services;
- (4) Reconfigured relationships and responsibilities of regular and special education staff, and redesigned programs that train personnel for work in schools, for the continued development of all regular and special education personnel in the education of children with disabilities; or
- (5) Expanded multi-agency solutions to the collaborative delivery of services for individual children with disabilities and their families.

Absolute Priority 2—State Agency—Federal Evaluation Studies Projects (CFDA 84.159F)

This priority supports cooperative agreements that assess the impact and effectiveness of programs, policies, and procedures assisted under the Individuals with Disabilities Education Act (IDEA) in accordance with sections 618(d)(1) and (2) of the Act. An award under this competition provides not more than 60 percent of the total cost of the project, and the State agency receiving the award provides an amount not less than 40 percent of the total cost of the project.

Invitational Priority

Within the absolute priority specified in this notice, the Secretary is

particularly interested in applications that meet the following invitational priority. However, under 34 CFR 75.105(c)(1) an application that meets this invitational priority does not receive competitive or absolute preference over other applications:

The Secretary particularly invites projects that perform feasibility studies that develop the conceptual framework for an evaluation study about a specific issue or question concerning the impact and effectiveness of special education and related services, and determine if the conceptual framework is workable. Feasibility studies identify topics that have significant potential for evaluation, but that require preliminary study to determine feasibility related to identification of the issue, study designs, measurement, and analysis. While collection and reporting of generalizable impact and effectiveness data are not expected for feasibility studies, the Secretary particularly encourages pilot tests of data collection instruments and procedures to determine the implications of these results for the study design, measurement and analysis. The Secretary particularly encourages projects that address the feasibility of designs to evaluate the impact and effectiveness of:

- (1) Management and regulatory flexibility that encourages innovative management of schools to expand opportunities for the inclusion of children with disabilities;
- (2) Student outcomes and performance of comprehensive, community-based, family-oriented systems of education and support;
- (3) Community-supported schools focusing on family participation in activities and services;
- (4) Reconfigured relationships and responsibilities of regular and special education staff, and redesigned programs that train personnel for work in schools, for the continued development of all regular and special education personnel in the education of children with disabilities; or
- (5) Expanded multi-agency solutions to the collaborative delivery of services for individual children with disabilities and their families.

SPECIAL STUDIES PROGRAM
[Application Notices for Fiscal Year 1994]

Title and CFDA No.	Applications available	Deadline for transmittal of applications	Available funds	Estimated size of awards	Estimated No. of awards	Project period in months
State Agency—Federal Evaluation Studies Projects (84.159A).	11/22/93	03/25/94	\$400,000	¹ \$80,000	5	Up to 24.
State Agency—Federal Evaluation Studies Projects (84.159F).	11/22/93	03/25/94	200,000	² 50,000	4	Up to 12.

¹\$80,000 is the estimated average size of award for the first 12 months (year) of the project. Projects are likely to be level funded in the second year unless there are increases in costs attributable to significant changes in activity level.

²\$50,000 is the estimated average size of award for the *entire* project period (up to 12 months).

Note: The Department is not bound by any estimates in this notice.

For Technical Information Contact:
Susan Sanchez, U.S. Department of Education, 400 Maryland Avenue, SW., room 3528, Switzer Building, Washington, DC 20202-2640. Telephone: (202) 205-8998. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m. Eastern time, Monday through Friday.

For Applications and General Information Contact: Requests for applications and general information should be addressed to: Darlene Crumblin, U.S. Department of Education, 400 Maryland Avenue, SW., room 3525, Switzer Building, Washington, DC 20202-2641. Telephone (202) 205-8953. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-

800-877-8339 between 8 a.m. and 8 p.m. Eastern time, Monday through Friday.

Program Authority: 20 U.S.C. 1418.

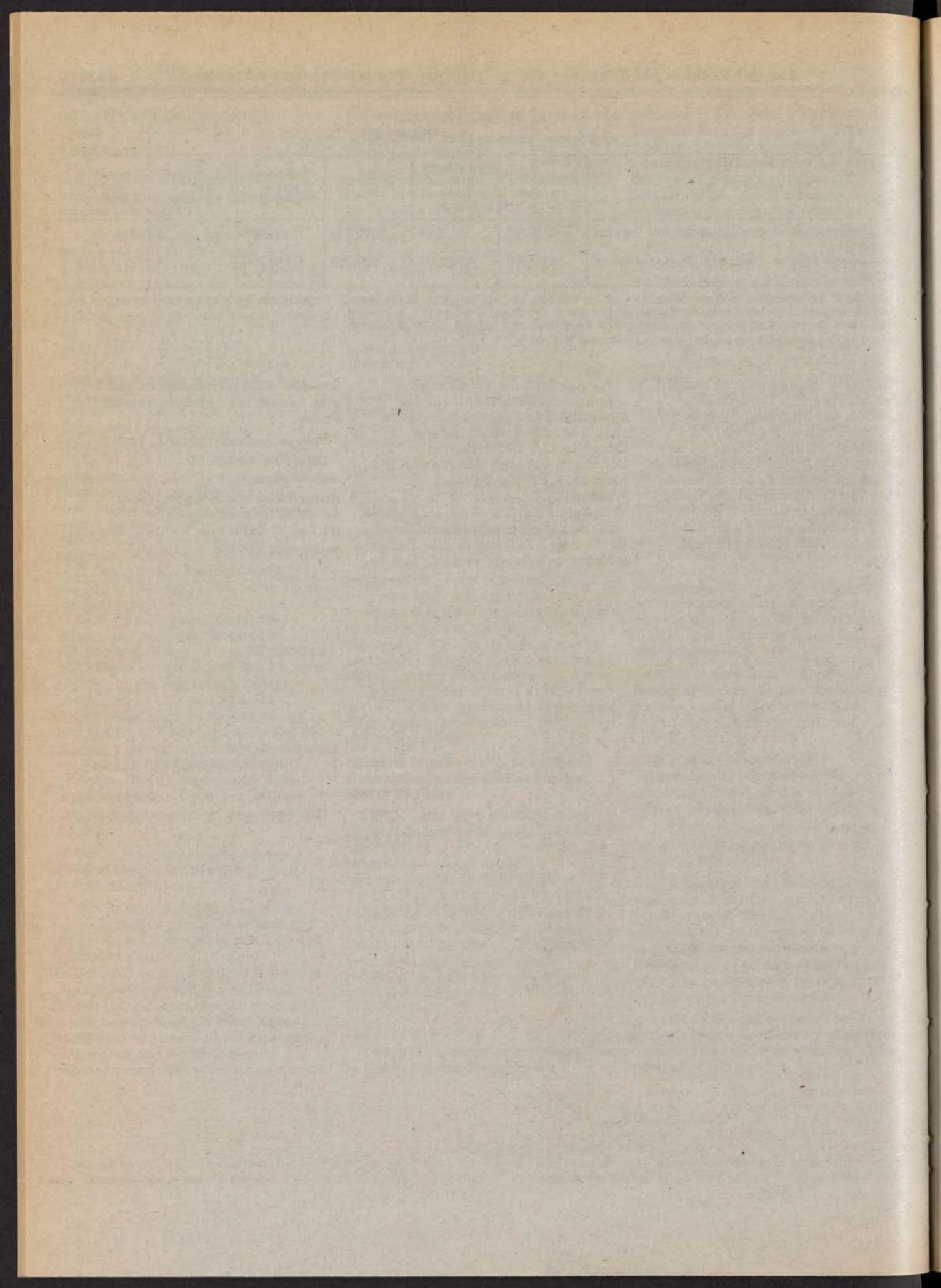
Dated: October 7, 1993.

Andrew Pepin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 93-25148 Filed 10-13-93; 8:45 am]

BILLING CODE 4000-01-U



Federal Register

Thursday
October 14, 1993

Part VI

Department of Education

Children and Youth With Serious
Emotional Disturbance: Final Priorities for
Fiscal Years 1994 and 1995 and Inviting
Applications for New Awards for Fiscal
Year 1994; Notices

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services Program for Children and Youth With Serious Emotional Disturbance

AGENCY: Department of Education.

ACTION: Notice of final priority for fiscal years 1994-1995.

SUMMARY: The Secretary announces a final priority for the Program for Children and Youth with Serious Emotional Disturbance to ensure effective use of program funds and to direct funds to areas of identified need during fiscal years 1994 and 1995.

EFFECTIVE DATE: This priority takes effect either 45 days after publication in the *Federal Register* or later if the Congress takes certain adjournments. If you want to know the effective date of this priority, call or write the Department of Education contact person.

FOR FURTHER INFORMATION CONTACT:

Linda Glidewell, U.S. Department of Education, 400 Maryland Avenue, SW., room 3524, Switzer Building, Washington, DC 20202-2641. Telephone: (202) 205-9099. Individuals who use a telecommunications device for the deaf may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION: The Program for Children and Youth with Serious Emotional Disturbance provides assistance for projects designed to improve special education and related services to children and youth with serious emotional disturbance (SED). Types of projects that may be supported under the program include, but are not limited to, research, development, and demonstration projects. Funds may also be used to develop and demonstrate approaches to assist and prevent children with emotional and behavioral problems from developing serious emotional disturbance.

On July 7, 1993, the Secretary published a notice of proposed priority for this program in the *Federal Register* (58 FR 36580).

This priority supports the National Education Goals by improving our understanding of how to enable children and youth with disabilities to reach the high levels of academic achievement called for by the Goals.

Note: This notice of final priority does not solicit applications. A notice inviting applications under this competition is published in a separate notice in this issue of the *Federal Register*.

Analysis of Comments and Changes

In response to the Secretary's invitation in the notice of proposed priority, seven parties submitted comments. An analysis of the comments and of the changes in the proposed priority follows. Technical and other minor changes—and suggested changes the Secretary is not legally authorized to make under the applicable statutory authority—are not addressed.

Comment: Three commenters recommended that the project period should be of enough duration to assess long term outcomes of proposed interventions.

Discussion: The project period is not included in the final priority. The notice inviting applications under this priority indicates that the estimated project period for awards is for up to 48 months. The Secretary believes that this will provide the necessary time for applicants to implement, refine, and measure the effects of proposed approaches.

Changes: None.

Comment: One commenter suggested that a "one year planning time" be built into the project period.

Discussion: The priority as written does not specify the amount of time that an applicant may devote to planning during the project period. Given the variability among potential applicants, the Secretary believes that some applicants will incorporate substantial planning into the development of their proposals thus limiting the need for planning time during the project period. Ultimately, it is the responsibility of applicants to justify time needed for planning in their proposals.

Changes: None.

Comment: One commenter suggested that a crosswalk of project requirements with selection criteria would be helpful to both applicants and application reviewers. The commenter further suggested that this information could be provided in the application package.

Discussion: In previous years, the application package that is provided to all potential applicants has provided clarification between requirements contained in a specific priority and the selection criteria that is used to evaluate applications. The Secretary believes that the application package is the appropriate vehicle for providing that type of information and intends to continue the practice.

Changes: None.

Comment: One commenter indicated the importance of "early screening and early intervention (i.e., pre-school to grade 3 range)" as important components of any prevention strategy.

A second commenter indicated the importance of programs designed for youth.

Discussion: The priority as written does not specify any grade or age range. The Secretary agrees with the commenter on the importance of early screening, early intervention, and programs for youth and believes that the priority as written allows applicants to address the broad spectrum of grades and ages.

Changes: None.

Comment: One commenter suggested the priority "should emphasize systematic and comprehensive research efforts that acknowledge and consider the interaction between regular and special education."

Discussion: The Secretary agrees with the commenter on the importance of the interaction between regular and special education.

Changes: Paragraph (e) under "Priority" is changed to read: "(e) Implement interventions that involve the active participation of a broad range of constituents, including school personnel, parents, and community agencies, and that acknowledge and consider the interaction between regular and special education."

Comment: One commenter indicated that interventions that consider and address a variety of factors that contribute to the development of emotional disturbance are especially needed. This commenter suggested that the priority include contributing biological, physiological and sensory processing factors within the requested conceptual framework of proposals.

Discussion: The Secretary believes that the priority as written allows an applicant to consider a broad range of factors that may contribute to the development of serious emotional disturbance.

Changes: None.

Comment: One commenter stated that the use of the term "interventions" in the proposed priority has the potential to be interpreted narrowly by both applicants and reviewers. The commenter suggested that the breadth of the meaning of the term as used in the priority should be clarified. Further, the commenter suggested that the word "test" may be "denotatively and connotatively" restrictive and that "assess, evaluate or study" might be more appropriate.

Discussion: The priority as written states: "School-based research that incorporates the demands of the environment is needed to design and test interventions * * *," and "this proposed priority would support research projects that implement and

test innovative interventions *enabling schools to provide positively oriented instruction, curricula, and support services needed* * * * (underlining is added for emphasis). The Secretary believes that the context within which the term "interventions" is used in the priority appropriately captures the intended breadth of the term. However, the Secretary agrees with the commenter's view of the possible restrictiveness of the word "test" and believes the word "assess" would be more appropriate.

Changes: The word "test" has been replaced with the word "assess" in both the Background and paragraph (d) of the priority.

Comment: One commenter suggested that prevention of serious emotional disturbance is possible only by working on the positive, and that it is crucial to avoid giving any encouragement to the deficit model.

Discussion: The Secretary believes that the priority as written firmly establishes the need for a positive, proactive approach to prevention.

Changes: None.

Comment: One commenter indicated that we don't have validated assessment technologies that assist teachers in their efficient and effective use of extant interventions nor implementation and personnel training strategies for the large scale use of these interventions. Also, the commenter suggested that efforts focused on prevention and early intervention must consider interventions that emphasize: (a) effective and positive school-based behavioral and educational support; (b) individual, classroom, and school-wide contexts; and (c) achievement of long term and generalized effects.

Discussion: The Secretary believes that the priority as written allows applicants to consider all of the approaches and issues suggested by the commenter.

Changes: None.

Priority: Under 34 CFR 75.105(c)(3) the Secretary gives an absolute preference to applications that meet the following priority. The Secretary will fund under this competition only applications that meet this absolute priority:

Absolute Priority—Preventing the Development of Serious Emotional Disturbance Among Children and Youth with Emotional and Behavioral Problems

Background

Improving the academic performance of our Nation's students is a major focus of educational reform initiatives.

However, academically focused reform initiatives may potentially divert, not strengthen, the ability of schools to meet the psychological, social, and behavioral needs of students. Schools often do not provide specific educational experiences that promote the personal and social development of youth, complemented, if necessary, with programs and services to prevent children with emotional and behavioral problems from developing serious emotional disturbance.

Our Nation's schools need a reorientation of the fundamental approach to addressing the diverse and complex patterns of psychological and social behavior presented by students, including those with serious emotional disturbance. Approaches are needed that focus on the positive outcomes desired, rather than negative outcomes to be eliminated. Schools must be responsible and accountable for ensuring that, rather than develop serious emotional disturbance, students with emotional and behavioral problems achieve positive academic, personal, and social outcomes. School-based research that incorporates the demands of the environment is needed to design and assess interventions that would enhance the personal and social development of students with emotional and behavioral problems, so as to prevent the development of serious emotional disturbance.

This priority supports research projects that implement and assess innovative interventions enabling schools to provide positively oriented instruction, curricula, and support services needed to prevent students with emotional and behavioral problems from developing serious emotional disturbance. The research will study how to assist schools in preparing these students to meet the personal and social demands of post-school environments.

Priority

To be considered for funding under this priority, a project must—

(a) Provide a conceptual framework for the preventive approach. The conceptual framework must reflect findings from multi-disciplinary research, as well as, validated interventions and strategies relevant for promoting personal and social development of children with emotional and behavioral problems;

(b) As part of the conceptual framework—

(1) Address the challenge and diversity of mental health, psychological, and social characteristics so as to assist children with emotional and behavioral problems from

developing serious emotional disturbance;

(2) Identify and define the outcomes related to personal and social development that would comprise the basis for the design of the proposed preventive components;

(3) Document the rationale for each outcome construct; and

(4) Describe means for measuring these outcomes;

(c) Provide interventions that (1) are comprehensive and positive; (2) promote the social and emotional development of students with emotional and behavioral problems; and (3) provide the cornerstone for building school-wide capacity for meeting the social and emotional needs of children with emotional and behavioral problems. The interventions must encompass an array of experiences that ensure that children with emotional and behavioral problems acquire and demonstrate in various settings the competencies needed to achieve the measurable desired outcomes related to personal and social development;

(d) Provide and assess interventions within the general education environment and expand these to include home-based and community-based components appropriate to the approach;

(e) Implement interventions that involve the active participation of a broad range of constituents, including school personnel, parents, and community agencies, and that acknowledge and consider the interaction between regular and special education;

(f) Assess the efficacy of the interventions for improving personal and social outcomes for students with emotional and behavioral problems; and

(g) Evaluate the implementation of the interventions to enhance the personal and social adjustment of students with emotional and behavioral problems across school environments.

A project must budget for two trips, annually, to Washington, DC, for (1) a two-day Research Project Directors' meeting; and (2) another two-day meeting to meet with the project director of the Office of Special Education Programs and the other projects funded under this priority to share their approaches, designs, and experiences, and to design collaborative products.

Intergovernmental Review

The Program for Children and Youth with Serious Emotional Disturbance is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR Part 79. The objective of the

Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Department's specific plans and actions for this program.

Applicable Program Regulations: 34 CFR part 328.

Program Authority: 20 U.S.C. 1426. (Catalog of Federal Domestic Assistance Number 84.237, Program for Children and Youth with Serious Emotional Disturbance)

Dated: October 7, 1993.

Andrew Pepin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 93-25149 Filed 10-13-93; 8:45 am]

BILLING CODE 4000-01-U

DEPARTMENT OF EDUCATION

[CFDA No.: 84.237F]

Program for Children and Youth With Serious Emotional Disturbance; Notice Inviting Applications for New Awards for Fiscal Year (FY) 1994

Purpose of Program: To support projects, including research projects, for the purpose of improving special education and related services to children and youth with serious emotional disturbance, and demonstration projects to provide

services for children and youth with serious emotional disturbance.

This notice supports the National Education Goals by improving understanding of how to enable children and youth with disabilities to reach higher levels of academic achievement.

Eligible Applicants: Institutions of higher education, State and local educational agencies, and other appropriate public and private nonprofit institutions or agencies are eligible for awards under this competition.

Applicable Regulations: (a) The Education Department General Administrative Regulations (EDGAR) in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, and 86; and (b) The regulations for this program in 34 CFR part 328.

Applications Available: November 5, 1993.

Deadline for Transmittal of Applications: January 7, 1994.

Deadline for Intergovernmental Review: March 8, 1994.

Available Funds: \$350,000

Estimated Average Size of Awards: \$175,000 for the first 12 months of the projects. Multi-year projects are likely to be level funded unless there are increases in costs attributable to significant changes in activity level.

Estimated Number of Awards: 2.

Note: The Department is not bound by any estimates in this notice.

Project Period: up to 48 months.

Priority: The priority Preventing the Development of Serious Emotional Disturbance Among Children and Youth

with Emotional and Behavioral Problems in the notice of final priority for this program, published elsewhere in this issue of the Federal Register applies to this competition.

For Technical Information Contact: Dr. Helen Thornton, U.S. Department of Education, 400 Maryland Avenue, S.W., room 3520, Switzer Building, Washington, DC 20202-2841. Telephone: (202) 205-5910. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m. Eastern time, Monday through Friday.

For Applications and General Information Contact: Requests for applications and general information should be addressed to: Darlene Crumblin, U.S. Department of Education, 400 Maryland Avenue, SW, room 3525, Switzer Building, Washington, DC 20202-2641. Telephone: (202) 205-8953. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m. Eastern time, Monday through Friday.

Program Authority: 20 U.S.C. 1426.

Dated: October 7, 1993.

Andrew Pepin,

Acting Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 93-25150 Filed 10-13-93; 8:45 am]

BILLING CODE 4000-01-U

Federal Register

Thursday
October 14, 1993

Part VII

**Department of the
Interior**

Bureau of Indian Affairs

**Special Tribal Court Funds; Availability
for Fiscal Year 1994; Notice**

DEPARTMENT OF THE INTERIOR

Bureau of Indian Affairs

Availability of FY 1994 Special Tribal Court Funds

AGENCY: Bureau of Indian Affairs, Interior.

ACTION: Notice of availability of FY 1994 Special Tribal Court Funds.

SUMMARY: The Bureau of Indian Affairs (BIA) invites applications for its Fiscal Year (FY) 1994 Special Tribal Court discretionary funds program to enhance the administration of justice on Indian reservations and insure the expeditious and impartial adjudication of violations of tribal law and resolution of civil disputes. FY 1994 Special Tribal Court Fund grants will be awarded to: (1) Assist tribes with the planning and development of new judicial systems; (2) enhance the operation and management of existing tribal courts; and, (3) develop community-based dispositional alternatives including traditional or alternative dispute resolution, as well as unique and innovative approaches addressing substance abuse, juvenile and status offenders, child abuse and family violence.

This announcement includes provisions for grant applications and consists of four parts. Part I provides information on the Special Tribal Court discretionary grant fund. Part II describes the programmatic priorities and eligibility criteria under which BIA is inviting applications to be considered for funding. Part III describes the application contents and provides guidance regarding what should be included in the application. Part IV describes the criteria to be used in evaluating applications and the appeal process.

All forms necessary to submit an application are published as a part of this announcement. No separate application kit is necessary.

Grants will be awarded in accordance with this announcement and are subject to the availability of FY 1994 Special Tribal Court funds. Based upon FY 1993 funds, it is estimated \$1.2 million will be available in FY 1994. Approximately \$1.1 million will be awarded for Project Grants and \$75,000 for Regional and National Special Initiatives.

DATES: An application will meet the deadline if it is received as described below before the close of business December 17, 1993. Hand-delivered applications will be accepted during normal working hours, 8 a.m. to 4:30 p.m., Monday through Friday. Once

applications are submitted they are considered final; no additional materials will be accepted.

ADDRESSES: All tribal, multi-tribal or consortia. Applications shall be submitted simultaneously as follows:

(1) The original and one photocopy of the application shall be received by the Area Director of the applicant's respective Bureau of Indian Affairs area office before the close of business December 17, 1993; in addition,

(2) Two photocopies of the application shall be submitted to the U.S. Department of the Interior, Bureau of Indian Affairs, Branch of Judicial Services, 1849 C Street, NW., MS-2611-MIB, Washington, DC 20240-4001.

Regional and National Special Initiatives. The original application and three (3) photocopies shall be received by the U.S. Department of the Interior, Bureau of Indian Affairs, Branch of Judicial Services, 1849 C Street, NW., MS 2611-MIB, Washington, DC 20240-4001, before the close of business December 17, 1993.

PUBLIC COMMENTS ON THIS ANNOUNCEMENT. The BIA's Branch of Judicial Services invites comments on this discretionary grants announcement; comments will be considered in the development of future announcements. Please direct your written comments to the Bureau of Indian Affairs, Branch of Judicial Services, 1849 C Street, NW., MS-2611-MIB, Washington, DC 20240-4001.

FOR FURTHER INFORMATION CONTACT: Bettie Rushing, (202) 208-4400, Department of the Interior, Bureau of Indian Affairs, Branch of Judicial Services, 1849 C Street, NW., MS-2611-MIB, Washington, DC 20240-4001.

SUPPLEMENTARY INFORMATION:**Part I—Background***Statutory Authority*

The authority for this discretionary grant program is the Snyder Act, 42 Stat. 208, 25 U.S.C. 13, and annual appropriations for the Bureau of Indian Affairs. Grants awarded under this announcement are made pursuant to 43 CFR part 12, Administrative and Audit Requirements and Cost Principles for Assistance Programs, which incorporates OMB Circulars A-102 and A-110. Project Grants, Part II—Priority Areas, applicants and awards are governed by OMB Circular A-102. Regional and National Initiatives, Part II—Priority Areas, applicants and awards are governed by OMB Circular A-110.

FY 1993 Awards

Special Tribal Court funds were awarded to 45 tribal projects to enhance the operation and management of trial and appellate courts; examine and develop codes, ordinances, rules, procedures and evidentiary standards; develop community based dispositional alternatives and support programs addressing substance abuse, juvenile and status offenders and family violence; as well as, court review and evaluation, community education, traditional dispute resolution, automation and technology acquisition, education and training for judges and court personnel. In addition, Special Tribal Court funds provided financial support to the national tribal court judges and court clerks associations, five intertribal courts of appeal, and purchased subscriptions for 170 Indian judiciaries to the Indian Law Reporter.

Purpose

Special Tribal Court funds are supplementary to the base funding for tribal judicial systems provided by the Bureau of Indian Affairs through Tribal Priorities Allocations. The purpose of the Special Tribal Court program is to enhance the capabilities of Indian tribes to manage and administer justice at a level which will insure the expeditious and impartial adjudication of violations of tribal law and resolution of civil disputes.

Technical Assistance for Prospective Applicants

Technical assistance may be requested from the prospective applicant's Area Director.

Part II—Priority Areas and Eligibility

Applications must be directly and explicitly responsive to the expressed concerns of the particular priority area under which they are submitted.

A. Project Grants

Approximately \$1 million will be awarded to:

(1) Assist tribes with the planning and development of new judicial systems, including:

- (a) Needs assessment, planning, community education;
- (b) Development of codes, ordinances, rules, procedures, and/or evidentiary standards which assure the fair and impartial administration of justice, expeditious adjudication, and implementation of the requirements of the Indian Civil Rights Act;
- (c) Equipment, automation and technology acquisition; and,
- (d) Education and training for judges and court personnel.

(2) Enhance the operation and management of existing tribal courts, including:

(a) Records management, court personnel management, processing time standards, caseload management, juror utilization, reporting;

(b) Court review and evaluation, community education, access to justice;

(c) Equipment, automation and technology acquisition;

(d) Education and training for judges and court personnel; and,

(e) Development of codes, ordinances, rules, procedures, evidentiary standards and appellate review to assure the fair and impartial administration of justice, expeditious adjudication, and implementation of the requirements of the Indian Civil Rights Act.

(3) Develop community-based dispositional alternatives, including:

(a) Traditional or alternative dispute resolution; and,

(b) Innovative, community-based responses to substance abuse, juvenile and status offenders, and family violence including spouse, elder and child abuse.

Awards

Funding awards for Project Grants will range in amounts from \$10,000 to \$35,000 for individual tribal judiciaries, and from \$20,000 to \$50,000 for multi-tribal projects or consortia.

Eligible Applicants

The governing body of a federally-recognized tribe, 25 U.S.C. 450b(e), with an established judicial system or newly created tribal judiciary, including those which intend to establish a judicial system, may apply for funding under this announcement.

Tribes with populations less than 400 are encouraged to apply for funding under a multi-tribal or consortium arrangement. Tribes currently served by Courts of Indian Offenses may apply for funding under this announcement; however, such funding shall be limited to the development of tribal law and order codes.

B. Regional and National Special Initiatives

Approximately \$75,000 will be awarded to assist regional and national tribal court professional organizations with professional training, professional certification programs, and projects which enhance the communications between tribal, state and federal court judges and personnel.

Awards

Funding awards will range in amounts from \$10,000 to \$25,000.

Eligible Applicants

Intertribal organizations applying as regional or national tribal court professional organizations, as well as regional and national Indian not-for-profit organizations may apply for funds as regional or national tribal court professional organizations.

Part III—Application Process

A. Preparing the Application

Applicants are required to address the following when preparing applications:

(1) *Background and Project Summary.*

On a separate page, applicants should provide the following information:

(a) Name of the applicant (consortia and multi-tribal organizations must list all member tribes);

(b) Whether the applicant is requesting assistance for an established judicial system, or newly created tribal judiciary, or yet to be developed tribal judiciary;

(c) A description of the jurisdiction exercised by the applicant;

(d) The number of criminal, civil, juvenile, family and children's court cases filed during the calendar or fiscal year 1992;

(e) Tribal court budget for fiscal year 1992 and fiscal year 1993;

(f) Title(s) and number of judicial personnel;

(g) Whether Special Tribal Court funds have been awarded to the applicant since 1990, indicating the year and the amount of the grant award, a short summary of the project, and the year the project was completed;

(h) A concise statement summarizing the proposed project, including objectives, approaches, and expected benefits/outcomes;

Regional and national tribal court professional organizations should provide the following information:

(i) name of applicant (consortia and multi-tribal organizations must list all member tribes);

(j) indicate anticipated participation in the proposed project;

(k) a concise summary of the organization's history, past and current projects which demonstrate a capability to provide professional training, professional certification, and/or develop and enhance tribal, state and federal court communications;

(l) a concise statement summarizing the proposed project, including objectives, approaches, and expected benefits/outcomes;

(2) *Program Narrative.* The program narrative must be clear, concise and responsive to one or more of the priority areas under which the application is submitted (see Part II, A and B).

(a) Applicants should respond to the evaluation criteria enumerated in Part IV of this announcement and thoroughly describe:

Statement of Need

- The problem to be addressed and how it affects the judiciary and the community;

Project Approach

- Why the approach identified is more appropriate than any other for the judiciary and community;

- What you plan to do (state the goals, objectives, and overall impact of the proposed project in measurable terms);

- How you will do it (what and when will tasks be accomplished and how do they relate to the goals of the proposed project);

Evaluation of Project

- How you will evaluate the impact and/or success of the proposed project (who, when and what standards or measurements will be used); and,

Evidence of Community Support

- Where appropriate, applicants are encouraged to seek the cooperation and support of tribal, state and federal agencies, institutions and programs (for example: training, research or technical writing provided by local college faculty and students).

(3) *Budget and Budget Justification.*

Applicants should demonstrate that project costs are fair and reasonable in view of the expected results and/or benefits.

(a) The budget should include:

- All staff positions and project costs which relate to the tasks described in the program narrative;

- A detailed break-down for each budget category, such as personnel, fringe benefits, travel, supplies, equipment, and administrative costs;

(b) The budget justification should provide a clear rationale for all project related costs, including:

- Personnel cost estimates should indicate the amount of time each staff person or consultant will spend on the project and the hourly rate (if personnel are supported in part by other funds, identify the source, annual salary, and percentage of time which will be charged to the proposed project);

- Supplies and project expenses should indicate purpose and usage, for example: Telephone expenses should estimate the percentage of base and long distance telephone charges necessary to accomplish the goals and objectives of the project;

- Travel must be directly related to carrying out the activities of the proposed project;
- Transportation and per diem may be based on tribal rates, not to exceed Federal Travel Regulations, but applicants must indicate which personnel will be traveling, the purpose of the travel and how it supports the proposed project, the number of trips to be taken, lengths of stay, and cost estimates;
- Purchase of equipment must be related to the goals and objectives of the project;
- Reasonable administrative costs or the negotiated indirect cost rate; and,
- A description of the fiscal control and accounting procedures to be used to ensure prudent use, proper disbursement, and accurate accounting of funds.

(4) *Applicant's Capability Statement.* The capability statement should describe how the judicial system is organized, the nature and list of all personnel. An organization chart showing the relationship of the project to the current structure of the judicial system and other tribal programs should be included, as well as vitae for all key project personnel, including consultants and third-party technical assistance providers.

(5) *Program Sustainability.* A statement indicating how other available resources such as tribal income, other grants, or contracts will be committed to supplement and/or sustain the project.

B. Application Contents and Assembly.

Each applicant shall submit an original and three copies of the application as prescribed in the Summary-Addresses. The original and each copy of the application should be stapled securely in the upper left corner. Applicants should not use covers, binders or tabs. Applications must be assembled in the following order:

(1) Standard Form (SF) 424, Application for Federal Assistance; SF 424B, Assurances—Non-Construction Program; and DI-1955 (May 1990), Certification regarding a Drug-free Workplace; as well as, the Certification Regarding Lobbying. All required forms are found at the end of this announcement.

(2) A current tribal resolution or such other written expression as tribal laws or practice require which indicates the support or commitment of the council to the proposed project. Self-governance tribes shall include a current self-governance resolution and a letter from the chief executive officer of the tribe endorsing the proposed project.

Consortia and multi-tribal organizations shall include current resolutions from the tribal council of each participating tribe. Regional and national professional organizations shall include a current board of directors' resolution endorsing the proposed project.

Self-governance Tribes. For purposes of this announcement, a self-governance tribe is one which has a signed 1994 annual funding agreement at the time the application for Special Tribal Court funds is submitted. With the exception of the self-governance resolution and letter from the chief executive officer of the tribe, the application requirements for self-governance tribes are the same as those for all other tribes.

(3) A current written assurance of the procedures required in OMB Circular A-128 for fiscal management, accounting, and recordkeeping. Non-profit organizations must provide proof of not-for-profit status.

(4) Background and summary description.

(5) Program narrative.

(6) Budget and budget justification.

(7) Organization capability statement and vitae of current and prospective personnel, consultants, and third-party technical assistance providers.

(8) Letters of commitment and/or cooperation from institutions, organizations, or service providers who will participate in the proposed project.

C. Grant Amount

The amount of funds requested must not exceed the limits indicated in this announcement. Grant funds may be used for the costs of planning, training, and implementing activities to support attainment of project objectives. Funds shall not be used for the purchase of real property or construction. If renovation is proposed, the cost must be minimal and necessary to the success of the proposed project.

D. Duration of the Project

Grant awards will be for a one year (12 month) budget period. Applications proposing projects which cannot be completed within one year or intended to be on-going must include a plan for continuation which does not contemplate continued funding from Special Tribal Court funds.

Part IV—Review and Award Process

A. Notice of Receipt

The Branch of Judicial Services will notify applicants by mail of the receipt of applications. Prior to award decisions, BIA will not release information relative to an application other than it has been received and it is

being reviewed. Each applicant will be notified of the acceptance or rejection of the application.

B. Late Applications

Applications not received by the deadline will not be reviewed or considered for FY 1994 funding. The Branch of Judicial Services will notify each late applicant that its application will not be considered under the FY 1994 grant review competition.

C. Incomplete Applications

Incomplete applications will not be reviewed or rated. The Branch of Judicial Services will notify the applicant that its application will not be considered under the FY 1994 grant review competition. An incomplete application is an application which does not contain the information and documentation listed in Part IV-E, Application Requirements.

D. Multiple Applications

Only one (1) application per tribe, consortium or multi-tribal organization will be considered and reviewed. If multiple applications are received, one will be randomly selected and the remainder returned to the applicant, without review.

If applications are received from a consortium or multi-tribal organization, as well as a member tribe, only the tribal application will be reviewed. The consortium or multi-tribal organization will be notified that an application has been received from one of its members and its application will not be considered under the FY 1994 grant review competition.

E. Application Requirements

In order to be reviewed, each application must meet the following requirements:

(1) The original copy of the application must have an original signature in item 18d on the SF 424, Application for Federal Assistance.

(2) A current tribal resolution or such other written expression as tribal laws or practice require which indicates the support or commitment of the council to the proposed project. Applications from self-governance tribes shall include a current self-governance resolution and a letter from the chief executive officer of the tribe endorsing the proposed project. Applications from consortia and multi-tribal organizations shall include current resolutions from the tribal council of each participating tribe. Applications from regional and national professional organizations shall include a current board of directors' resolution

endorsing the proposed tribal judiciary project.

(3) Each application shall not exceed fifty (50) pages, space and one-half or double-spaced, exclusive of required forms and assurances which are listed below. Applications which are single-spaced will be considered only if it is determined the applicant has not thereby gained a competitive advantage.

(4) The following documents are excluded from the 50 page limitation: A tribal resolution or endorsement or such other written expression as tribal laws or practice require; written assurance of the procedures required in OMB Circular A-128; proof of non-profit status; Standard Forms (SF) 424 and 424B; Certification regarding a Drug-free Workplace, DI-1955 (May 1990); Assurance—Non-construction Programs; and, Certification Regarding Lobbying. All required forms are included at the end of this announcement.

(5) Within the 50 page limitation, the following guidelines are suggested:

(a) Background and summary description (one page);

(b) Program narrative (20-30 pages);

(c) Budget and budget justification (5-10 pages); and,

(d) Applicant's capability statement, including an organization chart and vitae for key project personnel, including consultants and third-party technical assistance providers (5-10 pages).

(6) In addition, applicants are encouraged to include letters endorsing or supporting the proposed project which are specific and/or verify tangible commitments to the project, e.g., staff, facilities, training.

F. BIA Certification

The Area Director, or his designee, will review each application received.

(1) The Area Director, or his designee, shall certify the date each application was received.

(2) If the application was received before the close of business December 17, 1993, the Area Director, or his designee, shall certify: a) the amount of Special Tribal Court funds awarded to the applicant in fiscal years 1991 and 1992;

(b) whether FY 1991 and/or FY 1992 funds were expended as provided in the grant award and final project reports detailing project accomplishments, along with all relevant deliverables and reports have been received by the area office;

(c) whether expenditures and financial reports were in compliance with applicable OMB requirements;

(d) the amount of Special Tribal Court funds awarded to the applicant in FY

1993, the date of the grant award, and whether the project has been completed and project reports submitted in a timely manner;

(e) whether the resources available to the applicant are adequate to carry out the proposed project; and,

(g) whether the impact and cost-benefits of the proposed project warrant a grant award.

(3) The Area Director's certification, along with one (1) photocopy of the application, shall be received by the Branch of Judicial Services, Bureau of Indian Affairs, 1849 C Street, NW., MS-2611-MIB, Washington, DC 20240-4001, before the close of business January 14, 1994.

G. Evaluation Criteria

Applications will be evaluated by a review panel of at least three individuals. Review panels may be composed of Federal personnel working with tribal judiciaries and tribal judges or judicial personnel selected by the area directors. Reviewers will comment on and score applications using the following criteria:

(a) Objectives and Activities of the Proposed Project (20 points).

• Does the application present relevant problem(s) requiring a solution?

• Are the principal and subordinate objectives and activities of the project stated in measurable terms and responsive to the problem(s) presented?

• Does the application include relevant data and a thorough discussion of the current state of knowledge or technology relevant to the proposed project?

(b) Expected Results and/or Benefits (15 points).

• Are the expected project benefits and/or results stated in measurable terms and consistent with the objectives of the project?

• Does the application specify how the expected results will directly and tangibly benefit the judiciary, the community, or a specific population?

(c) Approach (35 points).

• Does the application provide a sound and workable plan of action and specify how the proposed work will be accomplished?

• Are persuasive reasons offered for taking the proposed approach as opposed to other alternatives?

• Does the application explain the methodology for determining if the results and benefits identified are being achieved?

• Does the application include an evaluation component which identifies and discusses appropriate criteria for assessing performance and results of the project?

• Are the types of data, measurement, and indicators to be used for evaluation, as well as the methods and time frame for collecting and analyzing data indicated?

• Does the proposed work/task schedule offer a logical and realistic projection of accomplishments to be achieved?

• Is a time-line chart or its equivalent employed to list project activities in chronological order and show the target dates for the projected accomplishments?

• Has the applicant identified and secured the commitment of each of the key cooperating organizations, groups, and individuals who will work on the project and provided an adequate description of the nature of their effort or contribution?

(d) Resources and Staffing (15 points).

• Are project management, staff, resources and time-commitments adequate to carry out the proposed project effectively and efficiently?

• Is the staff chart consistent with the project plan/program narrative?

• Has the applicant indicated how other available resources such as tribal income, self-determination grants or contracts will be committed to supplement and/or sustain the project?

• Are key staff well qualified for this project? Are consultants and advisers used appropriately? Is the project actually within the control of the applicant or are all activities conducted consultants or third-party technical assistance providers?

• If volunteers will be used, is there adequate supervision and support from project staff?

• Are the authors of the proposal, their relationship with the applicant, and their intended role in the project, if any, identified?

(e) Budget and Budget Justification (15 points).

• Does the budget justification adequately describe the resources necessary to conduct the project?

• Is the budget reasonable in terms of the intended results?

H. Review Panel Volunteers

Tribal judges or judicial personnel wishing to volunteer, on a non-reimbursable basis, to serve as reviewers should submit a letter of interest and vitae to their respective Bureau of Indian Affairs Area Director.

I. Awards

The Assistant Secretary—Indian Affairs or her designee shall select for grant awards those applicants which will in her judgment best promote the purposes for which Special Tribal Court

funds are appropriated. Such selection will be made through a competitive review process in which each application will be scored individually using the review criteria listed above. Reviewers' recommendations will be used by the Assistant Secretary—Indian Affairs or her designee to approve or disapprove all grant applications and make funding recommendations. The funding approved shall be in accordance with the funding levels published under this announcement and shall be based on demonstrated need and the availability of funds.

J. Appeals

Appeals will be governed by 25 C.F.R. Part 2, Appeals from Administrative Actions. Notices of appeal must be submitted within 30 days of receipt of

the decision being appealed. It must be signed by the appellant and mailed to the Interior Board of Indian Appeals, 4015 Wilson Boulevard, Arlington, Virginia 22203. The notice of appeal should identify clearly the decision being appealed, as well as the name, address and telephone number of the appellant.

No extension of time will be granted for filing a notice of appeal. The date of filing is the date the notice of appeal is postmarked or the date it is personally delivered to the Interior Board of Indian Appeals.

A photocopy of the notice of appeal must be mailed to the Assistant Secretary—Indian Affairs, Department of the Interior, 18th and C Streets, NW., MS-4140-MIB, Washington, DC 20240,

and to the Department of the Interior Bureau of Indian Affairs, Branch of Judicial Services, 1849 C Street, NW., MS-2611-MIB, Washington, DC 20240-4001, as well as each interested party known to the appellant. Notices of appeal submitted to the Interior Board of Indian Appeals must certify that the appellant has mailed copies to the foregoing parties.

Ten percent (10%) of the funds available under this announcement shall be retained to assure funding for any appellant who may successfully appeal a denial. If these funds are not expended for appeals, they will be used to fund approved applicants.

Ada E. Deer,

Assistant Secretary—Indian Affairs.

BILLING CODE 4310-02-P

APPLICATION FOR
FEDERAL ASSISTANCE

OMB Approval No. 0348-0043

1 TYPE OF SUBMISSION: Application <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		2 DATE SUBMITTED		Applicant Identifier	
Preapplication <input type="checkbox"/> Construction <input type="checkbox"/> Non-Construction		3 DATE RECEIVED BY STATE		State Application Identifier	
		4 DATE RECEIVED BY FEDERAL AGENCY		Federal Identifier	
3. APPLICANT INFORMATION					
Legal Name			Organizational Unit		
Address (give city, county, state, and zip code):			Name and telephone number of the person to be contacted on matters involving this application (give area code)		
6. EMPLOYER IDENTIFICATION NUMBER (EIN): [][] - [][][][][][][][][]			7. TYPE OF APPLICANT: (enter appropriate letter in box) <input type="checkbox"/>		
8. TYPE OF APPLICATION: <input type="checkbox"/> New <input type="checkbox"/> Continuation <input type="checkbox"/> Revision If Revision, enter appropriate letter(s) in box(es) <input type="checkbox"/> <input type="checkbox"/> A Increase Award B Decrease Award C Increase Duration D Decrease Duration Other (specify): _____			A State H Independent School Dist B County I State Controlled Institution of Higher Learning C Municipal J Private University D Township K Indian Tribe E Interstate L Individual F Intermunicipal M Profit Organization G Special District N Other (Specify) _____		
10. CATALOG OF FEDERAL DOMESTIC ASSISTANCE NUMBER: [][][] - [][][][][][][][][]			9. NAME OF FEDERAL AGENCY:		
12. AREAS AFFECTED BY PROJECT (cities, counties, states, etc.):			11. DESCRIPTIVE TITLE OF APPLICANT'S PROJECT:		
13. PROPOSED PROJECT: Start Date Ending Date			14. CONGRESSIONAL DISTRICTS OF: a Applicant b Project		
15. ESTIMATED FUNDING:			16. IS APPLICATION SUBJECT TO REVIEW BY STATE EXECUTIVE ORDER 12372 PROCESS?		
a Federal	\$.00	a YES THIS PREAPPLICATION/APPLICATION WAS MADE AVAILABLE TO THE STATE EXECUTIVE ORDER 12372 PROCESS FOR REVIEW ON DATE _____		
b Applicant	\$.00	b NO <input type="checkbox"/> PROGRAM IS NOT COVERED BY E.O. 12372		
c State	\$.00	<input type="checkbox"/> OR PROGRAM HAS NOT BEEN SELECTED BY STATE FOR REVIEW		
d Local	\$.00	17. IS THE APPLICANT DELINQUENT ON ANY FEDERAL DEBT?		
e Other	\$.00	<input type="checkbox"/> Yes # "Yes." attach an explanation. <input type="checkbox"/> No		
f Program Income	\$.00			
g TOTAL	\$.00			
18. TO THE BEST OF MY KNOWLEDGE AND BELIEF, ALL DATA IN THIS APPLICATION/PREAPPLICATION ARE TRUE AND CORRECT, THE DOCUMENT HAS BEEN DULY AUTHORIZED BY THE GOVERNING BODY OF THE APPLICANT AND THE APPLICANT WILL COMPLY WITH THE ATTACHED ASSURANCES IF THE ASSISTANCE IS AWARDED					
a. Typed Name of Authorized Representative		b. Title		c. Telephone number	
d. Signature of Authorized Representative				e. Date Signed	

Previous Editions Not Usable

Standard Form 424 (REV 4-88)
Prescribed by OMB Circular A-102

Authorized for Local Reproduction

INSTRUCTIONS FOR THE SF 424

This is a standard form used by applicants as a required facesheet for preapplications and applications submitted for Federal assistance. It will be used by Federal agencies to obtain applicant certification that States which have established a review and comment procedure in response to Executive Order 12372 and have selected the program to be included in their process, have been given an opportunity to review the applicant's submission.

- | Item: | Entry: | Item: | Entry: |
|-------|--|-------|--|
| 1. | Self-explanatory. | 12. | List only the largest political entities affected (e.g., State, counties, cities). |
| 2. | Date application submitted to Federal agency (or State if applicable) & applicant's control number (if applicable). | 13. | Self-explanatory. |
| 3. | State use only (if applicable). | 14. | List the applicant's Congressional District and any District(s) affected by the program or project. |
| 4. | If this application is to continue or revise an existing award, enter present Federal identifier number. If for a new project, leave blank. | 15. | Amount requested or to be contributed during the first funding/budget period by each contributor. Value of in-kind contributions should be included on appropriate lines as applicable. If the action will result in a dollar change to an existing award, indicate <i>only</i> the amount of the change. For decreases, enclose the amounts in parentheses. If both basic and supplemental amounts are included, show breakdown on an attached sheet. For multiple program funding, use totals and show breakdown using same categories as item 15. |
| 5. | Legal name of applicant, name of primary organizational unit which will undertake the assistance activity, complete address of the applicant, and name and telephone number of the person to contact on matters related to this application. | 16. | Applicants should contact the State Single Point of Contact (SPOC) for Federal Executive Order 12372 to determine whether the application is subject to the State intergovernmental review process. |
| 6. | Enter Employer Identification Number (EIN) as assigned by the Internal Revenue Service. | 17. | This question applies to the applicant organization, not the person who signs as the authorized representative. Categories of debt include delinquent audit disallowances, loans and taxes. |
| 7. | Enter the appropriate letter in the space provided. | 18. | To be signed by the authorized representative of the applicant. A copy of the governing body's authorization for you to sign this application as official representative must be on file in the applicant's office. (Certain Federal agencies may require that this authorization be submitted as part of the application.) |
| 8. | Check appropriate box and enter appropriate letter(s) in the space(s) provided:
— "New" means a new assistance award.
— "Continuation" means an extension for an additional funding/budget period for a project with a projected completion date.
— "Revision" means any change in the Federal Government's financial obligation or contingent liability from an existing obligation. | | |
| 9. | Name of Federal agency from which assistance is being requested with this application. | | |
| 10. | Use the Catalog of Federal Domestic Assistance number and title of the program under which assistance is requested. | | |
| 11. | Enter a brief descriptive title of the project. If more than one program is involved, you should append an explanation on a separate sheet. If appropriate (e.g., construction or real property projects), attach a map showing project location. For preapplications, use a separate sheet to provide a summary description of this project. | | |

ASSURANCES — NON-CONSTRUCTION PROGRAMS

Note: Certain of these assurances may not be applicable to your project or program. If you have questions, please contact the awarding agency. Further, certain Federal awarding agencies may require applicants to certify to additional assurances. If such is the case, you will be notified.

As the duly authorized representative of the applicant I certify that the applicant:

1. Has the legal authority to apply for Federal assistance, and the institutional, managerial and financial capability (including funds sufficient to pay the non-Federal share of project costs) to ensure proper planning, management and completion of the project described in this application.
2. Will give the awarding agency, the Comptroller General of the United States, and if appropriate, the State, through any authorized representative, access to and the right to examine all records, books, papers, or documents related to the award; and will establish a proper accounting system in accordance with generally accepted accounting standards or agency directives.
3. Will establish safeguards to prohibit employees from using their positions for a purpose that constitutes or presents the appearance of personal or organizational conflict of interest, or personal gain.
4. Will initiate and complete the work within the applicable time frame after receipt of approval of the awarding agency.
5. Will comply with the Intergovernmental Personnel Act of 1970 (42 U.S.C. §§ 4728-4763) relating to prescribed standards for merit systems for programs funded under one of the nineteen statutes or regulations specified in Appendix A of OPM's Standards for a Merit System of Personnel Administration (5 C.F.R. 900, Subpart F).
6. Will comply with all Federal statutes relating to nondiscrimination. These include but are not limited to: (a) Title VI of the Civil Rights Act of 1964 (P.L. 88-352) which prohibits discrimination on the basis of race, color or national origin; (b) Title IX of the Education Amendments of 1972, as amended (20 U.S.C. §§ 1681-1683, and 1685-1686), which prohibits discrimination on the basis of sex; (c) Section 504 of the Rehabilitation Act of 1973, as amended (29 U.S.C. § 794), which prohibits discrimination on the basis of handicaps; (d) the Age Discrimination Act of 1975, as amended (42 U.S.C. §§ 6101-6107), which prohibits discrimination on the basis of age; (e) the Drug Abuse Office and Treatment Act of 1972 (P.L. 92-255), as amended, relating to nondiscrimination on the basis of drug abuse; (f) the Comprehensive Alcohol Abuse and Alcoholism Prevention, Treatment and Rehabilitation Act of 1970 (P.L. 91-616), as amended, relating to nondiscrimination on the basis of alcohol abuse or alcoholism; (g) §§ 523 and 527 of the Public Health Service Act of 1912 (42 U.S.C. 290 dd-3 and 290 ee-3), as amended, relating to confidentiality of alcohol and drug abuse patient records; (h) Title VIII of the Civil Rights Act of 1968 (42 U.S.C. § 3601 et seq.), as amended, relating to nondiscrimination in the sale, rental or financing of housing; (i) any other nondiscrimination provisions in the specific statute(s) under which application for Federal assistance is being made; and (j) the requirements of any other nondiscrimination statute(s) which may apply to the application.
7. Will comply, or has already complied, with the requirements of Titles II and III of the Uniform Relocation Assistance and Real Property Acquisition Policies Act of 1970 (P.L. 91-646) which provide for fair and equitable treatment of persons displaced or whose property is acquired as a result of Federal or federally assisted programs. These requirements apply to all interests in real property acquired for project purposes regardless of Federal participation in purchases.
8. Will comply with the provisions of the Hatch Act (5 U.S.C. §§ 1501-1508 and 7324-7328) which limit the political activities of employees whose principal employment activities are funded in whole or in part with Federal funds.
9. Will comply, as applicable, with the provisions of the Davis-Bacon Act (40 U.S.C. §§ 276a to 276a-7), the Copeland Act (40 U.S.C. § 276c and 18 U.S.C. §§ 874), and the Contract Work Hours and Safety Standards Act (40 U.S.C. §§ 327-333), regarding labor standards for federally assisted construction subagreements.

10. Will comply, if applicable, with flood insurance purchase requirements of Section 102(a) of the Flood Disaster Protection Act of 1973 (P.L. 93-234) which requires recipients in a special flood hazard area to participate in the program and to purchase flood insurance if the total cost of insurable construction and acquisition is \$10,000 or more.
11. Will comply with environmental standards which may be prescribed pursuant to the following: (a) institution of environmental quality control measures under the National Environmental Policy Act of 1969 (P.L. 91-190) and Executive Order (EO) 11514; (b) notification of violating facilities pursuant to EO 11738; (c) protection of wetlands pursuant to EO 11990; (d) evaluation of flood hazards in floodplains in accordance with EO 11988; (e) assurance of project consistency with the approved State management program developed under the Coastal Zone Management Act of 1972 (16 U.S.C. §§ 1451 et seq.); (f) conformity of Federal actions to State (Clear Air) Implementation Plans under Section 176(c) of the Clear Air Act of 1955, as amended (42 U.S.C. § 7401 et seq.); (g) protection of underground sources of drinking water under the Safe Drinking Water Act of 1974, as amended, (P.L. 93-523); and (h) protection of endangered species under the Endangered Species Act of 1973, as amended, (P.L. 93-205).
12. Will comply with the Wild and Scenic Rivers Act of 1968 (16 U.S.C. §§ 1271 et seq.) related to protecting components or potential components of the national wild and scenic rivers system.
13. Will assist the awarding agency in assuring compliance with Section 106 of the National Historic Preservation Act of 1966, as amended (16 U.S.C. 470), EO 11593 (identification and protection of historic properties), and the Archaeological and Historic Preservation Act of 1974 (16 U.S.C. 469a-1 et seq.).
14. Will comply with P.L. 93-348 regarding the protection of human subjects involved in research, development, and related activities supported by this award of assistance.
15. Will comply with the Laboratory Animal Welfare Act of 1966 (P.L. 89-544, as amended, 7 U.S.C. 2131 et seq.) pertaining to the care, handling, and treatment of warm blooded animals held for research, teaching, or other activities supported by this award of assistance.
16. Will comply with the Lead-Based Paint Poisoning Prevention Act (42 U.S.C. §§ 4801 et seq.) which prohibits the use of lead based paint in construction or rehabilitation of residence structures.
17. Will cause to be performed the required financial and compliance audits in accordance with the Single Audit Act of 1984.
18. Will comply with all applicable requirements of all other Federal laws, executive orders, regulations and policies governing this program.

SIGNATURE OF AUTHORIZED CERTIFYING OFFICIAL	TITLE
APPLICANT ORGANIZATION	DATE SUBMITTED

U.S. Department of the Interior Certification Regarding Lobbying

This certification is required by Section 1352, title 31, U.S. Code, entitled "Limitation on use of appropriated funds to influence certain Federal contracting and financial transactions."

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

Certification for Contracts, Grants, Loans, and Cooperative Agreements

The undersigned certifies, to the best of his or her knowledge and belief, that:

- (1) No Federal appropriated funds have been paid or will be paid, by or on behalf of the undersigned, to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, and officer or employee of Congress, or an employee of a Member of Congress in connection with the awarding of any Federal contract, the making of any Federal grant, the making of any Federal loan, the entering into of any cooperative agreement, and the extension, continuation, renewal, amendment, or modification of any Federal contract, grant, loan, or cooperative agreement.
- (2) If any funds other than Federal appropriated funds have been paid or will be paid to any person for influencing or attempting to influence an officer or employee of any agency, a Member of Congress, an officer or employee of Congress, or an employee of a Member of Congress in connection with this Federal contract, grant, loan, or cooperative agreement, the undersigned shall complete and submit Standard Form-LLL, "Disclosure Form to Report Lobbying," in accordance with its instructions.
- (3) The undersigned shall require that the language of this certification be included in the award documents for all subawards at all tiers (including subcontracts, subgrants, and contracts under grants, loans, and cooperative agreements) and that all subrecipients shall certify accordingly.

This certification is a material representation of fact upon which reliance was placed when this transaction was made or entered into. Submission of this certification is a prerequisite for making or entering into this transaction imposed by Section 1352, title 31, U.S. Code. Any person who fails to file the required certification shall be subject to a civil penalty of not less than \$10,000 and not more than \$100,000 for each such failure.

Signature _____

Date _____

Instructions for Certification

1. This certification and a disclosure form should be filed by each person as required, with each submission that initiates agency consideration of such person for: (1) award of a Federal contract, grant, or cooperative agreement exceeding \$100,000 or (2) an award of a Federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding \$150,000.
2. This certification and a disclosure form should be filed by each person as required, upon receipt by such person of (1) a Federal contract, grant, or cooperative agreement exceeding \$100,000; or (2) a Federal loan or a commitment providing for the United States to insure or guarantee a loan exceeding \$150,000, unless such person previously filed a certification, and a disclosure form, if required, at the time agency consideration was initiated.
3. Any person who requests or receives from a person referred to in paragraphs (1) and (2) above: (1) a subcontract exceeding \$100,000 at any tier under a Federal contract; (2) a subgrant, contract, or subcontract exceeding \$100,000 at any tier under a Federal grant; (3) a contract or subcontract exceeding \$100,000 at any tier under a Federal loan exceeding \$150,000; or, (4) a contract or subcontract exceeding \$100,000 at any tier under a Federal cooperative agreement, shall file a certification, and a disclosure form, as required, to the next tier above.
4. All disclosure forms, but not certifications, shall be forwarded from tier to tier until received by the person referred to in paragraphs (1) or (2) above. That person shall forward all disclosure forms to the appropriate Bureau/Office within the Department of the Interior.
5. Any certification or disclosure form filed under paragraph (4) above shall be treated as a material representation of fact upon which all receiving tiers shall rely. All liability arising from an erroneous representation shall be borne solely by the tier filing that representation and shall not be shared by any tier to which the erroneous representation is forwarded. Submitting an erroneous certification or disclosure constitutes a failure to file the required certification or disclosure, respectively. If a person fails to file a required certification or disclosure, the United States may pursue all available remedies, including those authorized by Section 1352, title 31, U.S. Code.

U.S. Department of the Interior
Certification Regarding
Drug-Free Workplace Requirements

This certification is required by the regulations implementing the drug-free workplace requirements for Federal grant recipients under the Drug-Free Workplace Act of 1988 (43 CFR Part 12, Subpart D). A copy of the regulation is available from the issuing office.

(BEFORE COMPLETING CERTIFICATION, READ INSTRUCTIONS ON REVERSE)

Alternate I. (Grantees Other Than Individuals)

A. The grantee certifies that it will or continues to provide a drug-free workplace by:

- (a) Publishing a statement notifying employees that the unlawful manufacture, distribution, dispensing, possession, or use of a controlled substance is prohibited in the grantee's workplace and specifying the actions that will be taken against employees for violation of such prohibition;
- (b) Establishing an ongoing drug-free awareness program to inform employees about --
 - (1) The dangers of drug abuse in the workplace;
 - (2) The grantee's policy of maintaining a drug-free workplace;
 - (3) Any available drug counseling, rehabilitation, and employee assistance programs; and
 - (4) The penalties that may be imposed upon employees for drug abuse violations occurring in the workplace;
- (c) Making it a requirement that each employee to be engaged in the performance of the grant be given a copy of the statement required by paragraph (a);
- (d) Notifying the employee in the statement required by paragraph (a) that, as a condition of employment under the grant, the employee will --
 - (1) Abide by the terms of the statement; and
 - (2) Notify the employer in writing of his or her conviction for a violation of a criminal drug statute occurring in the workplace no later than five calendar days after such conviction;
- (e) Notifying the agency in writing, within ten calendar days after receiving notice under subparagraph (d) (2) from an employee or otherwise receiving actual notice of such conviction. Employers of convicted employees must provide notice, including position title, to every grant officer on whose grant activity the convicted employee was working, unless the Federal agency has designated a central point for the receipt of such notices. Notice shall include the identification number(s) of each affected grant;
- (f) Taking one of the following actions, within 30 calendar days of receiving notice under subparagraph (d)(2), with respect to any employee who is so convicted --
 - (1) Taking appropriate personnel action against such an employee, up to and including termination, consistent with the requirements of the Rehabilitation Act of 1973, as amended; or
 - (2) Requiring such employee to participate satisfactorily in a drug abuse assistance or rehabilitation program approved for such purposes by a Federal, State, or local health, law enforcement, or other appropriate agency;
- (g) Making a good faith effort to continue to maintain a drug-free workplace through implementation of paragraphs (a), (b), (c), (d), (e) and (f).

B. The grantee may insert in the space provided below the site(s) for the performance of work done in connection with the specific grant:

Place of Performance (Street address, city, county, state, zip code)

Check if there are workplaces on file that are not identified here.

Name and Title of Authorized Representative

Signature _____

Date _____

Instructions for Certification

1. By signing and/or submitting this application or grant agreement, the grantee is providing the Certification Regarding Drug-Free Workplace Requirements.
2. This certification is a material representation of fact upon which reliance is placed when the agency awards the grant. If it is later determined that the grantee knowingly rendered a false certification, or otherwise violates the requirements of the Drug-Free Workplace Act, the agency, in addition to any other remedies available to the Federal Government, may take action authorized under the Drug-Free Workplace Act.
3. For grantees other than individuals, Alternate I applies.
4. For grantees who are individuals, Alternate II applies.
5. Workplaces under grants, for grantees other than individuals, need not be identified on the certification. If known, they may be identified in the grant application. If the grantee does not identify the workplaces at the time of application, or upon award, if there is no application, the grantee must keep the identity of the workplace(s) on file in its office and make the information available for Federal inspection. Failure to identify all known workplaces constitutes a violation of the grantee's drug-free workplace requirements.
6. Workplace identifications must include the actual address of buildings (or parts of buildings) or other sites where work under the grant takes place. Categorical descriptions may be used (e.g., all vehicles of a mass transit authority or State highway department while in operation, State employees in each local unemployment office, performers in concert halls or radio studios).
7. If the workplace identified to the agency changes during the performance of the grant, the grantee shall inform the agency of the change(s), if it previously identified the workplaces in question (see paragraph five).
8. Definitions of terms in the Nonprocurement Suspension and Debarment common rule and Drug-Free Workplace common rule apply to this certification. Grantees' attention is called, in particular, to the following definitions from these rules:

"Controlled substance" means a controlled substance in Schedules I through V of the Controlled Substances Act (21 U.S.C. 812) and as further defined by regulation (21 CFR 1308.11 through 1308.15);

"Conviction" means a finding of guilt (including a plea of nolo contendere) or imposition of sentence, or both, by any judicial body charged with the responsibility to determine violations of the Federal or State criminal drug statutes;

"Criminal drug statute" means a Federal or non-Federal criminal statute involving the manufacture, distribution, dispensing, use, or possession of any controlled substance;

"Employee" means the employee of a grantee directly engaged in the performance of work under a grant, including (i) all "direct charge" employees; (ii) all "indirect charge" employees unless their impact or involvement is insignificant to the performance of the grant; and (iii) temporary personnel and consultants who are directly engaged in the performance of work under the grant and who are on the grantee's payroll. This definition does not include workers not on the payroll of the grantee (e.g., volunteers, even if used to meet a matching requirement; consultants or independent contractors not on the grantee's payroll; or employees of subrecipients or subcontractors in covered workplaces).

Federal Register

**Thursday
October 14, 1993**

Part VIII

**Department of Education
Department of Labor**

**Cooperative Demonstration—School-to-
Work Opportunities Implementation Grant;
Notice**

DEPARTMENT OF EDUCATION

DEPARTMENT OF LABOR

Cooperative Demonstration—School-to-Work Opportunities Implementation Grants

AGENCIES: Department of Education and Department of Labor.

ACTION: Notice of proposed priority and proposed selection criteria for fiscal year 1994.

SUMMARY: The Secretaries of Education and Labor propose an absolute priority for awards to be made in fiscal year 1994 to enable States to implement plans for statewide School-to-Work Opportunities systems. These systems would offer young Americans access to education and training programs designed to prepare them for a first job in high-skill, high-wage careers, and to increase their opportunities for further education. The Secretaries also propose selection criteria that will be applied in evaluating applications submitted for this competition.

DATES: Comments must be received on or before November 15, 1993.

ADDRESSES: Comments should be addressed to Marian Banfield, U.S. Department of Education, 400 Maryland Avenue, SW., room 4512, Switzer Building, Washington, DC 20202-7327.

FOR FURTHER INFORMATION CONTACT: Marian Banfield, U.S. Department of Education. Telephone: (202) 205-8838. Or Janet Moore, U.S. Department of Labor. Telephone (202) 219-5281. Individuals who use a telecommunications device for the deaf (TDD) may call the Federal Information Relay Service (FIRS) at 1-800-877-8339 between 8 a.m. and 8 p.m., Eastern time, Monday through Friday.

SUPPLEMENTARY INFORMATION:**Background**

The Departments of Education and Labor have entered into a partnership to establish a national framework within which all States can create statewide School-to-Work Opportunities systems. These systems will help our youth acquire the knowledge, skills, abilities, and labor market information they need to make a smooth and effective transition from school to career-oriented work or to further education or training.

Currently, three-fourths of America's high school students enter the workforce without baccalaureate degrees. Many of them do not possess the basic academic and entry-level occupational skills necessary to succeed in the changing workplace.

Unemployment among American youth is intolerably high, and earnings of high school graduates have been falling relative to those with mere education. In addition, the American workplace is changing in response to heightened international competition and new technologies, and these forces, which are ultimately beneficial to the Nation, are shrinking the demand for and undermining the earning power of unskilled labor. The School-to-Work Opportunities initiative is the result of a broad-based and growing interest in creating a school-to-work transition system in which young Americans choose and navigate a path to productive and progressively more rewarding roles in the workplace.

Under the School-to-Work Opportunities initiative and the fiscal year 1994 Cooperative Demonstration Program competition, Federal funds will be used as "venture capital" to stimulate State and local creativity in establishing statewide School-to-Work Opportunities systems. To achieve this systemic reform, States may choose to build on and enrich current promising programs such as tech-prep education, career academies, school-to-apprenticeship, cooperative education, youth apprenticeship, and business-education compacts, that can be developed into programs under a School-to-Work Opportunities system. Through the formation of local education and training systems among secondary and postsecondary educational institutions, private and public employers, labor organizations, government, community groups, parents, and other key groups, communities will take ownership and responsibility for giving American youth access to skills and employment opportunities that will launch them on paths leading to high-skill, high-wage careers. Together, States and localities will take the lead in determining goals and priorities, developing new strategies, and measuring progress.

The Federal role in the School-to-Work Opportunities initiative is important, but limited to the establishment of broad national criteria and a framework within which States create School-to-Work Opportunities systems. The Federal role is to (a) invest in State and local initiatives by providing seed capital; (b) help States and localities learn from each other and from the experience of our international competitors; and (c) build a knowledge base of effective school-to-work models.

Grant Program Schedule

The School-to-Work Opportunities initiative will proceed on two funding

tracks—(1) during fiscal year 1994, the initiative will be funded under current legislative authority in the Job Training Partnership Act and the Carl D. Perkins Vocational and Applied Technology Education Act (Perkins Act); and (2) for fiscal years 1995 through 2002, the Departments plan to fund the initiative under the proposed "School-to-Work Opportunities Act of 1993," which was introduced in Congress August 5, 1993 as H.R. 2884 and S.1361. The funds will be made available through a grants program. The Department of Education and the Department of Labor will jointly design and provide for the administration of the grants program, that consists in a large part of—

(a) Development Grants, awarded to each State for developing a statewide School-to-Work Opportunities plan; and

(b) Implementation Grants, as proposed in this notice, awarded competitively to States that can demonstrate substantial ability to begin full-scale operations and implement the statewide plan.

The efforts that take place under both current authority and the proposed legislation are built on a phased-in approach that allows States to "come on line" at different points in time, depending on each State's readiness to undertake broad-scale change and on the availability of funds. Development Grants financed from funds requested by the Department of Labor under the Job Training Partnership Act will be awarded to States from October to December 1993 to permit them to begin or enhance planning and developmental efforts to create comprehensive statewide School-to-Work Opportunities systems.

Each Development Grant discussed above will be awarded for a nine-month period. The Secretaries may make additional Development Grants available subsequent to that period to States that do not receive an Implementation Grant, if those States can demonstrate substantial progress towards developing a comprehensive statewide School-to-Work Opportunities plan and if those States can demonstrate that Federal funds will be used effectively.

Implementation Grants Competition

In this notice, the Secretaries propose to reserve funds appropriated under the Perkins Act only for grants to States to implement statewide School-to-Work Opportunities systems based on State plans. The Secretaries propose selection criteria to be applied in evaluating applications submitted under the fiscal year 1994 Cooperative Demonstration Program. The Secretaries propose to

limit eligibility for implementation grants to States because the Secretaries have concluded that the purposes of 34 CFR 426.4(b)(2) for this competition can best be achieved by awarding grants only to State level applicants. Implementation Grants will be funded for up to a five-year period.

Under this proposed priority, grantees would be required to fund local partnerships in carrying out activities under the School-to-Work Opportunities program. The Secretaries intend grantees to fund local partnerships by any means authorized by applicable Federal law, as appropriate. Although under currently applicable Federal law grantees are not authorized to support partnerships by means of subgrants of Federal funds awarded under this competition, the Secretaries anticipate that with the enactment of the fiscal year 1994 appropriation for the Cooperative Demonstration Program, grantees will be authorized to award subgrants to partnerships.

The Secretaries will announce the final absolute priority and the final selection criteria for this competition, as well as whether or not grantees will be authorized to fund local partnerships by means of subgrants, in a notice in the Federal Register. The final priority and the final selection criteria will be determined by responses to this notice and other considerations of the Departments. The publication of this proposed priority does not preclude the Secretaries from proposing additional priorities, nor does it limit the Secretary of Education to funding only under this priority, subject to applicable rulemaking requirements.

Note: This notice of proposed priority and proposed selection criteria does not solicit applications. A notice inviting applications under this competition will be published in the Federal Register concurrent with, or following, publication of the notice of final priority and final selection criteria.

Definitions

As used in this notice—

"Elements of an industry" means, with respect to a particular industry that a student is preparing to enter, such elements as planning, management, finances, technical and production skills, underlying principles of technology, labor and community issues, health and safety, and environmental issues related to that industry;

"All students" means students from the broad range of backgrounds and circumstances, including disadvantaged students, students of diverse racial, ethnic, and cultural backgrounds, students with disabilities, students with

limited English proficiency, and academically talented students;

"Career major" means a coherent sequence of courses or field of study that prepares a student for a first job and that—

(a) Integrates occupational and academic learning, integrates work-based and school-based learning, and establishes linkages between secondary and postsecondary education;

(b) Prepares the student for employment in broad occupational clusters or industry sectors;

(c) Typically includes at least two years of secondary school and one or two years of postsecondary education;

(d) Results in the award of a high school diploma, a certificate or diploma recognizing successful completion of one or two years of postsecondary education (if appropriate), and a skill certificate; and

(e) May lead to further training, such as entry into a registered apprenticeship program;

"Partnership" means a local entity that is responsible for local School-to-Work Opportunities programs and that consists of employers, public secondary and postsecondary educational institutions or agencies, and labor organizations or employee representatives as defined in section 403(c)(1)(B) of the Goals 2000: Educate America Act, and may include other entities, such as non-profit or community-based organizations, rehabilitation agencies and organizations, registered apprenticeship agencies, local vocational education entities, local government agencies, parent organizations and teacher organizations, private industry councils established under the Job Training Partnership Act, and Federally recognized Indian tribes and Alaska Native villages;

"Skill certificate" means a portable, industry-recognized credential issued by a School-to-Work Opportunities program under an approved plan, that certifies that a student has mastered skills at levels that are at least as challenging as skill standards envisioned in the proposed Goals 2000: Educate America Act, except that until such skill standards are developed under the Act, the term "skill certificate" means a credential issued under a process described in a State's approved plan; and

"Workplace mentor" means an employee at the workplace who possesses the skills to be mastered by a student, and who instructs the student, critiques the student's performance, challenges the student to perform well,

and works in consultation with classroom teachers and the employer.

Priority

Implementation of Comprehensive Statewide School-to-Work Opportunities Plans

Under 34 CFR 75.105(c)(3), the Secretaries of the Departments of Education and Labor propose to give an absolute preference to applications that—

(a) Are submitted by States; and
(b) Propose to implement statewide School-to-Work Opportunities plans that are included in the applications and that—

(1) Designate the geographical areas to be served by partnerships, which shall, to the extent feasible, reflect local labor market areas;

(2) Describe the procedure by which the Governor; the chief State school officer; the State agency officials responsible for job training and employment, economic development and postsecondary education; and other appropriate officials, will collaborate in the implementation of the State School-to-Work Opportunities system;

(3) Describe the procedure for obtaining the active and continued involvement in the statewide School-to-Work Opportunities system of employers and other interested parties such as locally elected officials, secondary and postsecondary educational institutions or agencies, business associations, employees, labor organizations or associations thereof, teachers, students, parents, community-based organizations, rehabilitation agencies and organizations, registered apprenticeship agencies, and local vocational educational agencies;

(4) Describe how the State's School-to-Work Opportunities system will coordinate the use of education and training funds from State and private sources with funds available from such related Federal programs as the Adult Education Act (20 U.S.C. 1201 *et seq.*), the Carl D. Perkins Vocational and Applied Technology Education Act (20 U.S.C. 2301 *et seq.*), the Elementary and Secondary Education Act of 1965 (20 U.S.C. 2701 *et seq.*), the Family Support Act of 1988 (42 U.S.C. 602 note, 606 note), the proposed Goals 2000: Educate America Act, the Individuals with Disabilities Education Act (20 U.S.C. 1400 *et seq.*), the Job Training Partnership Act (29 U.S.C. 1501 *et seq.*), the National Apprenticeship Act (29 U.S.C. 50 *et seq.*), and the Rehabilitation Act of 1973 (29 U.S.C. 701 *et seq.*);

(5) Describe the resources, including private sector resources, the State

intends to employ in maintaining the State's School-to-Work Opportunities system when Federal School-to-Work Opportunities funds are no longer available;

(6) Describe how the State will ensure opportunities for all students to participate in School-to-Work Opportunities programs;

(7) Describe how the State will ensure opportunities for young women to participate in School-to-Work Opportunities programs in a manner that leads to employment in high-performance, high-paying jobs, including jobs in which women traditionally have been under-represented;

(8) Describe how the State will ensure opportunities for low achieving students, students with disabilities, and former students who have dropped out of school to participate in School-to-Work Opportunities programs;

(9) Describe the State's process for assessing the skills and knowledge required in career majors, and awarding skill certificates that take into account the work of the proposed National Skill Standards Board and the criteria established under the proposed Goals 2000: Educate America Act;

(10) Describe the performance standards that the State intends to meet;

(11) Designate a fiscal agent to receive and be accountable for School-to-Work Opportunities funds awarded under the program; and

(12) Describe how the State will stimulate and support local School-to-Work Opportunities programs that meet the requirements of this notice and how the State's system will be expanded over time to cover all geographic areas in the State.

General Program Requirements

A School-to-Work Opportunities program under this proposed priority must include the following common features and basic program components:

(a) The basis of the School-to-Work Opportunities system is—

(1) The integration of work-based learning and school-based learning;

(2) The integration of occupational and academic learning; and

(3) The linking of secondary and postsecondary education.

(b) School-to-Work Opportunities programs will result in students attaining—

(1) A high school diploma;

(2) A certificate or diploma recognizing successful completion of one or two years of postsecondary education, if appropriate; and

(3) A skill certificate.

(c) School-to-Work Opportunities programs must incorporate three basic program components:

(1) *Work-Based Learning*, that includes—

- A planned program of job training and experiences, including skills to be mastered at progressively higher levels, that are relevant to a student's career major and lead to the award of a skill certificate;

- Paid work experience;
- Workplace mentoring;
- Instruction in general workplace competencies; and

- Broad instruction in a variety of elements of an industry.

(2) *School-Based Learning*, that includes—

- Career exploration and counseling in order to help students who may be interested to identify, and select or reconsider, their interests, goals, and career majors;

- Initial selection by interested students of a career major not later than the beginning of the 11th grade;

- A program of study designed to meet the same challenging academic standards developed by States for all students such as those envisioned in the proposed Goals 2000: Educate America Act, and to meet the requirements necessary for a student to earn a skill certificate; and

- Regularly scheduled evaluations to identify academic strengths and weaknesses of students and the need for additional learning opportunities to master core academic skills.

(3) *Connecting Activities*, that include:

- Matching students with employers' work-based learning opportunities;

- Serving as a liaison among the employer, school, teacher, parent, and student;

- Providing technical assistance and services to employers and others in designing work-based learning components and counseling and case management services, and in training teachers, workplace mentors, and counselors;

- Providing assistance to students who have completed the program in finding an appropriate job, continuing their education, or entering into an additional training program;

- Collecting and analyzing information regarding post-program outcomes of students who participate in the School-to-Work Opportunities program; and

- Linking youth development activities under the School-to-Work Opportunities program with employer strategies for upgrading the skills of their workers.

Examples of Statewide Activities

Funds awarded under this program shall be expended by the grantee only for activities undertaken to implement the State's School-to-Work Opportunities system, which may include—

(a) Recruiting and providing assistance to employers to provide work-based learning for students;

(b) Conducting outreach activities to promote and support collaboration in School-to-Work Opportunities programs by businesses, labor organizations, and other organizations;

(c) Providing training for teachers, employers, workplace mentors, counselors, and others;

(d) Providing labor market information to local partnerships that is useful in determining which high-skill, high-wage occupations are in demand;

(e) Designing or adapting model curricula that can be used to integrate academic and vocational learning, school-based and work-based learning, and secondary and postsecondary education;

(f) Designing or adapting model work-based learning programs and identifying best practices; and

(g) Conducting outreach activities and providing technical assistance to other States that are developing or implementing School-to-Work Opportunities systems.

Allocation of Funds to Local Partnerships

A grantee under this proposed priority must fund local partnerships in carrying out activities under the School-to-Work Opportunities program, according to criteria established by the grantee. The grantee's funding shall total no less than 65 percent of the sums awarded to it in the first year, 75 percent of such sums in the second year, and 85 percent of such sums in each year thereafter.

A partnership that seeks support in carrying out a local School-to-Work Opportunities program shall submit an application to the recipient of the School-to-Work Implementation grant that—

(a) Describes how the local program would include the basic School-to-Work Opportunities program components and otherwise meet the requirements of this notice;

(b) Sets forth measurable program goals and outcomes;

(c) Describes the local strategies and timetables to provide School-to-Work Opportunities program opportunities for all students; and

(d) Provides such other information as the statewide grantee may require.

Examples of Activities for Local Partnerships

Funds under this program that are used to support partnerships shall be expended only for activities undertaken to carry out School-to-Work programs as defined in this notice, and such activities may include—

(a) Recruiting and providing assistance to employers to provide the work-based learning components in the School-to-Work Opportunities program;

(b) Establishing consortia of employers to support the School-to-Work Opportunities program and provide access to jobs related to students' career majors;

(c) Supporting or establishing intermediaries to perform the connecting activities described above in paragraph (c)(3) under General Program Requirements and to provide assistance to students in obtaining jobs and further education and training;

(d) Designing or adapting school curricula that can be used to integrate academic and vocational learning, school-based and work-based learning, and secondary and postsecondary education;

(e) Providing training to work-based and school-based staff on new curricula, student assessments, student guidance, and feedback to the school regarding student performance;

(f) Establishing in schools participating in a School-to-Work Opportunities program a graduation assistance program to assist at-risk and low-achieving students in graduating from high school, enrolling in postsecondary education or training, and finding or advancing in jobs;

(g) Conducting or obtaining an in-depth analysis of the local labor market and the generic and specific skill needs of employers to identify high-demand, high-wage careers to target;

(h) Integrating work-based and school-based learning into existing job training programs for youth who have dropped out of school;

(i) Establishing or expanding school-to-apprenticeship programs in cooperation with registered apprenticeship agencies and apprenticeship sponsors; and

(j) Assisting participating employers, including small- and medium-size businesses, to identify and train workplace mentors and to develop work-based learning components.

Safeguards

The Secretaries propose to apply the following safeguards to School-to-Work Opportunities programs funded under this proposed priority:

(a) No student shall displace any currently employed worker (including a partial displacement, such as a reduction in the hours of non-overtime work, wages, or employment benefits).

(b) No School-to-Work Opportunities program shall impair existing contracts for services or collective bargaining agreements, except that no program under this proposed priority that would be inconsistent with the terms of a collective bargaining agreement shall be undertaken without the written concurrence of the labor organization and employer concerned.

(c) No student shall be employed or job opening filled—

(1) When any other individual is on temporary layoff from the participating employer, with the clear possibility of recall, from the same or any substantially equivalent job; or

(2) When the employer has terminated the employment of any regular employee or otherwise reduced its workforce with the intention of filling the vacancy so created with a student.

(d) Students shall be provided with adequate and safe equipment and a safe and healthful workplace in conformity with all health and safety standards of Federal, State, and local law.

(e) Nothing in this proposed priority shall be construed so as to modify or affect any Federal or State law prohibiting discrimination on the basis of race, religion, color, ethnicity, national origin, gender, age, or disability.

(f) Funds awarded under this proposed priority shall not be expended for wages of students.

(g) The grantee shall implement and maintain such other safeguards as the Secretaries may deem appropriate in order to ensure that School-to-Work Opportunities participants are afforded adequate supervision by skilled adult workers, or, otherwise, to further the purposes of this program.

Applicants must provide assurances, in the application, that the foregoing safeguards will be implemented and maintained throughout all program activities.

Selection Criteria for Evaluating Applications

Under the School-to-Work Opportunities Implementation Grant competition, the Secretaries propose to use the following selection criteria in evaluating applications. The Secretaries will evaluate applications using a two phase review process. In the first phase of the review process, the Secretaries will use peer reviewers to evaluate applications using the proposed selection criteria and the associated

point values. In the second phase, review teams will visit high ranking States to gain further information and further assess State plans. The second phase review teams will use the criteria, but not necessarily the associated point values, in their information gathering and assessment activities. Final funding decisions made by the Secretaries will be based on information gained during the site visits, the ranking of applications during the first phase review, and such other factors as geographic balance and diversity of program approaches.

(a) *Comprehensive Statewide System.* (25 points) Is the School-to-Work Opportunities plan described in the application likely to produce systemic statewide change that will have substantial impact on the preparation of youth for a first job in a high-skill, high-wage career and in increasing their opportunities for further education? Does the plan provide information reflecting the needs of each local labor market area in the designated geographic areas of the State? Does the State propose a feasible plan for expanding the system so that students in all parts of the State will have an opportunity to participate in School-to-Work Opportunities programs within a reasonable period of time? Is the process for assessing skills and issuing skill certificates likely to lead to portable credentials for students and is the process adequately benchmarked to high standards such as those envisioned in the proposed Goals 2000: Educate America Act? Has the State described State and local performance standards that should lead to statewide systemic reform of secondary education?

(b) *Collaboration and Involvement of Key Partners.* (25 points)

(1) *State collaboration:* Is there a vision for implementing a statewide School-to-Work Opportunities system that is shared by the Governor; the chief State school officer; the State agency officials responsible for job training and employment, economic development, and postsecondary education; and other appropriate officials? Does the plan substantially demonstrate sufficient commitment and specific involvement of these partners in the statewide implementation? Are the proposed activities appropriate to the partners and likely to produce the desired changes in the way students are prepared for the future? Is there evidence that the State partners have the capacity to support the statewide implementation?

(2) *Involvement by key parties:* Does the State plan include an effective and convincing strategy for obtaining the

active and continued involvement of employers and other interested parties such as locally elected officials, secondary and postsecondary educational institutions or agencies, business associations, employees, labor organizations or associations thereof, teachers, students, parents, community-based organizations, rehabilitation agencies and organizations, registered apprenticeship agencies, and local vocational educational agencies in the implementation of statewide systems? Does the strategy recognize the interests of the key parties and utilize their strengths appropriately?

(c) *Resources.* (10 points) Is the plan for a comprehensive statewide School-to-Work Opportunities system supported by resources adequate to implement the plan? Does the plan effectively integrate State and private education and training resources with other Federal education and training resources? Is there an effective long-term plan for maintaining the School-to-Work Opportunities system with resources other than Federal School-to-Work Opportunities funds?

(d) *Student Participation.* (15 points) Does the plan propose realistic strategies and programs to ensure that "all students," including young women, minorities, low-achieving students, students with disabilities, and former students who have dropped out have the opportunity to participate in School-to-Work Opportunities programs? Does the strategy recognize barriers to their participation and propose effective ways of overcoming them so that these students are prepared for high-skill, high-wage jobs—including, for young women and minorities, jobs in which they have traditionally been under-represented?

(e) *Local Programs.* (15 points) Does the plan include an effective strategy for supporting local School-to-Work Opportunities programs that integrate occupational and academic learning, integrate work-based and school-based learning, establish linkages between secondary and postsecondary education, include components for work-based learning, school-based learning and connecting activities, and result in the award of a high school diploma, a certificate or diploma recognizing successful completion of one or two years of postsecondary education (if appropriate), and a skill certificate? Have promising existing programs been considered for adaptation? What new directions and approaches are planned to ensure that these programs meet the proposed priority? Does the plan show evidence that local School-to-Work

Opportunities programs throughout the State, including those that have been funded by the Department of Education or the Department of Labor, are an effective part of a statewide School-to-Work Opportunities system?

(f) *Management Plan.* (10 points) Does the entity submitting the application on behalf of the State have the capacity to manage the implementation of a comprehensive statewide School-to-Work Opportunities system? Does the State's management plan anticipate barriers to statewide implementation and include a system for addressing them as they arise? Does the management plan include methods to improve or redesign the implementation system based on program outcomes, for example, through an evaluation plan? How will the State's performance standards apply to local partnerships and how will the standards be used to evaluate and improve their outcomes? Are key personnel under the plan qualified to perform the required activities, particularly to maintain the essential partnerships at the State level in a manner sufficient to implement the plan? Will Federal funds under the School-to-Work Opportunities Program grant be used to support partnerships that seek to carry out local School-to-Work Opportunities programs?

Other Factors

In addition to considering the factor of geographic distribution authorized under 34 CFR 426.25, prior to making final funding decisions, the Secretaries also propose to consider as a factor the diversity of approaches to school-to-work opportunities proposed by each applicant.

Paperwork Reduction Act of 1980

This proposed priority contains information collection requirements. As required by the Paperwork Reduction Act of 1980, the Departments of Education and Labor will submit a copy of the proposed priority and proposed selection criteria to the Office of Management and Budget (OMB) for its review. (44 U.S.C. 3504(h))

This proposed priority and proposed selection criteria would primarily affect the following types of entities eligible to apply for a grant under this program: State and local educational agencies. The Departments of Education and Labor need and will use the information solicited under the proposed priority and proposed selection criteria to enable the Secretaries to determine which applicants would most likely implement successful comprehensive School-to-Work Opportunities systems.

Annual public reporting and recordkeeping burden for this collection of information is estimated to average 100 hours per response for 52 State respondents and 100 hours per response for 468 local respondents, including the time for reviewing instructions, searching existing data sources, gathering and maintaining the data needed, and completing and reviewing the collection of information.

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 3002, New Executive Office Building, Washington, DC 20503; Attention: Daniel J. Chenok.

Intergovernmental Review

This program is subject to the requirements of Executive Order 12372 and the regulations in 34 CFR part 79. The objective of the Executive order is to foster an intergovernmental partnership and a strengthened federalism by relying on processes developed by State and local governments for coordination and review of proposed Federal financial assistance.

In accordance with the order, this document is intended to provide early notification of the Departments' specific plans and actions for this competition.

Invitation To Comment

Interested persons are invited to submit comments and recommendations regarding this proposed absolute priority and these proposed selection criteria.

All comments submitted in response to this notice will be available for public inspection, during and after the comment period, in room 4050, Switzer Building, 330 C Street, SW, Washington, DC, between the hours of 8:30 a.m. and 4 p.m., Monday through Friday of each week, except Federal holidays.

Applicable Program Regulations: 34 CFR part 426, and the Education Department General Administrative Regulations in 34 CFR parts 74, 75, 77, 79, 80, 81, 82, 85, and 86.

Program Authority: 20 U.S.C. 2420a. (Catalog of Federal Domestic Assistance Number 84.199-H Cooperative Demonstration Program)

Dated: October 5, 1993.

Richard W. Riley,
Secretary of Education.

Robert B. Reich,
Secretary of Labor.

[FR Doc. 93-25147 Filed 10-13-93; 8:45 am]

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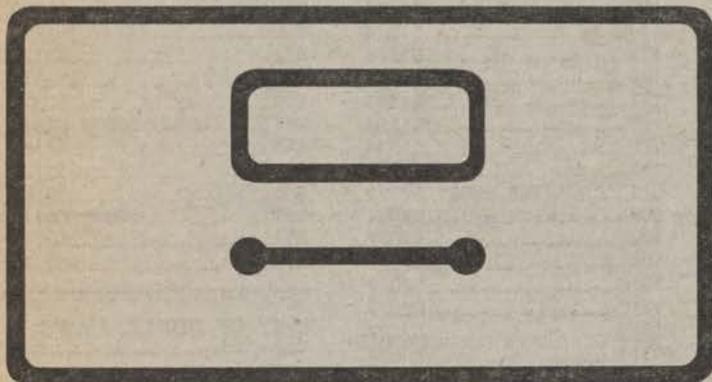
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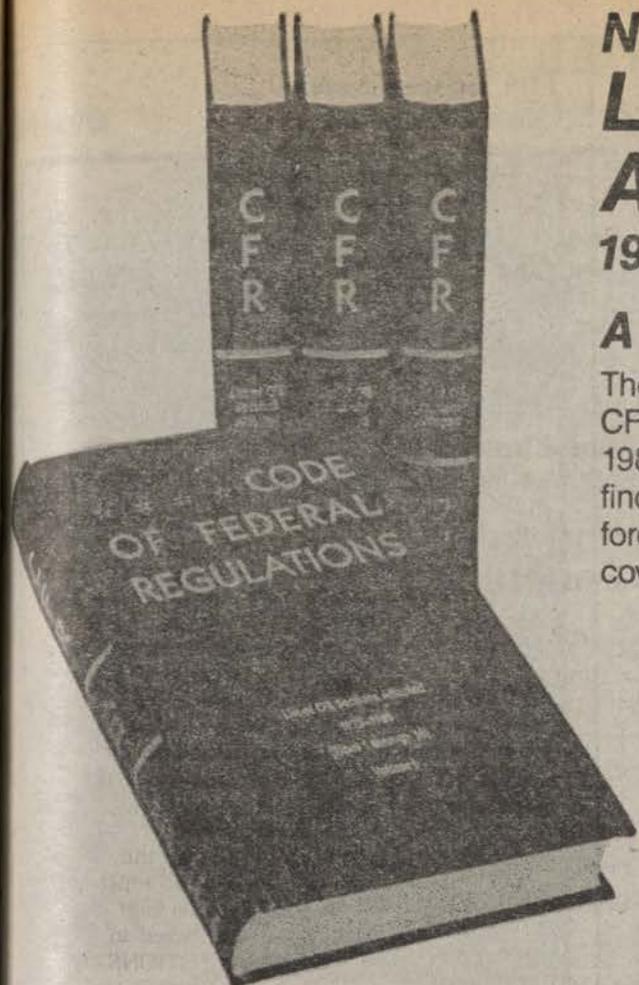
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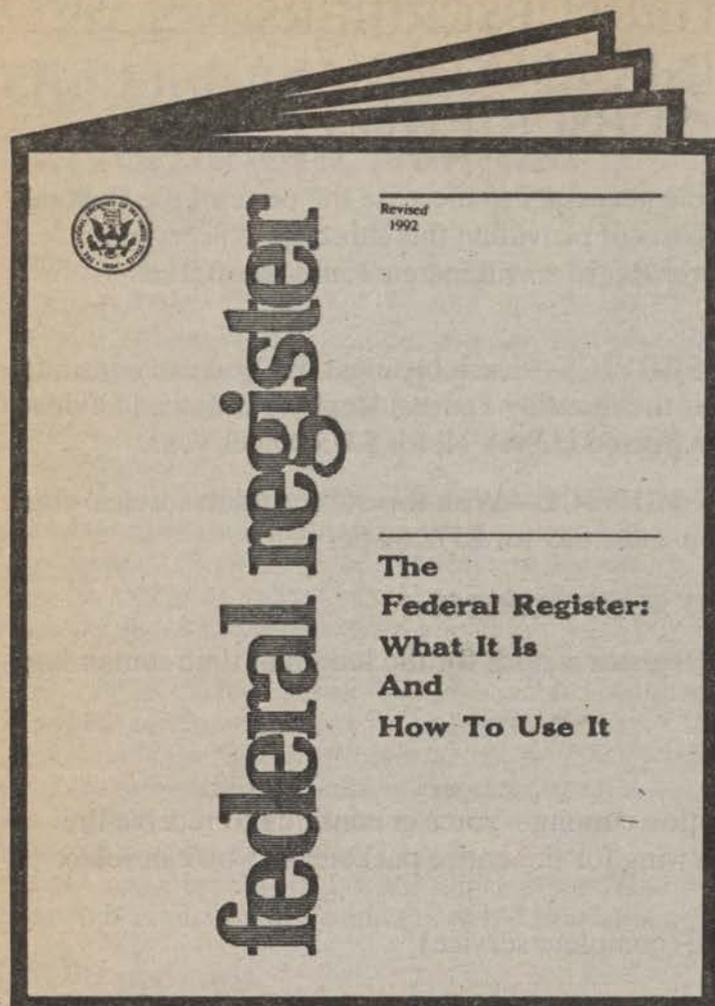
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Accounting

Principles

Volume I

Accounting



Accounting is the systematic recording, classifying, summarizing in terms of money transactions and events which are in part at least financial, and interpreting the results thereof for the purpose of providing information about the transactions, events, and business conditions which in part at least are financial in nature, and in terms of which the financial position, results of operations, and cash flows may be determined and explained.

Accounting is the language of business. It provides a common language for business transactions and events. The primary purpose of accounting is to provide information about the financial position, results of operations, and cash flows of an organization. This information is used by management, investors, and other stakeholders to make informed decisions. Accounting also helps in the identification of trends and the detection of errors or fraud. The accounting process involves recording transactions, classifying them into accounts, summarizing them into financial statements, and interpreting the results. The financial statements include the balance sheet, income statement, and cash flow statement. The accounting process is essential for the success of any business organization.



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