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DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 70

Poultry and Rabbit Products Grading; Office of Management and Budget Information Collection Control Numbers and One Miscellaneous Change

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Final rule.

SUMMARY: The list of information collection requirements approved by the Office of Management and Budget (OMB) is revised in the regulations for the voluntary grading of poultry and rabbit products (7 CFR Part 70). This action follows OMB's review and extension of approval of existing information collection requirements in the regulations.

The heading of one paragraph in the same regulations is also revised. It was inadvertently changed when the regulations underwent a recent revision and needs to be returned to its original wording.

EFFECTIVE DATE: July 22, 1986.

FOR FURTHER INFORMATION CONTACT: D.M. Holbrook, Chief, Standardization Branch, Poultry Division, Agricultural Marketing Service, U.S. Department of Agriculture, Room 3944, South Building, Washington, DC 20250 (202–447–3506).

SUPPLEMENTARY INFORMATION:

Executive Order 12291 and Department Regulation 1512–1

The Agency has determined that this amendment is merely administrative and is not subject to the requirements of Executive Order 12291 and Department Regulation 1512–1. It involves the identification and display of information collection requirements in the regulations approved by OMB pursuant to 5 CFR Part 1320, and corrects an editing mistake discovered in a final rule recently published in the **Federal Register.**

Administrative Procedure Act

Pursuant to the administrative procedure provisions in 5 U.S.C. 553, it is found upon good cause that notice and other public procedure with respect to this final rule are impracticable and contrary to the public interest because this amendment is nonsubstantive and imposes no new requirements. It merely updates the display listing section numbers of the regulations with information collection requirements and corrects the wording of a paragraph heading that was changed by mistake. Thus, good cause is found for making this final rule effective less than 30 days after publication of this document in the **Federal Register.**

Regulatory Flexibility Act

Since this rulemaking is exempt from the notice and comment provisions of the Administrative Procedure Act, a regulatory flexibility analysis under the Regulatory Flexibility Act is not required.

Paperwork Reduction Act

This rulemaking does not require an additional collection of information from the public under the Paperwork Reduction Act of 1980.

Background

The Paperwork Reduction Act of 1980 was designed both "to minimize the Federal paperwork burden for individuals, small businesses, State and local governments, and other persons" and "to maximize the usefulness of information collected by the Federal government." On March 31, 1983, OMB issued a final rule, 5 CFR Part 1320, implementing the provisions of the Paperwork Reduction Act of 1980. Among other provisions, the rule requires the display of OMB control numbers on collection of information requirements contained in agency rules adopted after public notice and comment. The control numbers provide a simple and effective way for the public to tell whether a paperwork burden an agency seeks to impose has been cleared as the Act requires. The Director of OMB, as the accountable individual in the Government, has assured that the information is needed, is not duplicative of information already collected, and is collected efficiently.

Each information collection requiremet in the regulations is reviewed and evaluated periodically. In addition, every three years the Agency submits a clearance docket to OMB, based on the criteria in 5 CFR Part 1320, for review and extension of approval of existing information collection and recordkeeping requirements.

OMB approval of collection of information under 7 CFR Part 70 would have expired in May 1986. Prior to that the Agency submitted to OMB a revised clearance docket requesting approval of the information collection requirements under 7 CFR Part 70. It also included existing sections of the regulations not previously listed and deleted one section inadvertently displayed as containing an information collection requirement. A notice of the OMB review was published April 2, 1986 (51 FR 11331), and subsequently the clearance docket for 7 CFR Part 70 was approved by OMB.

Therefore, § 70.6 of 7 CFR Part 70 is updated by adding section numbers not previously displayed to the list of sections with information collection requirements, and deleting one section number inadvertently displayed as containing an information collection requirement. The Agency has determined that this amendment is not substantive. It merely provides a convenient and current listing of the information collection requirements and the OMB control number in accordance with 5 CFR Part 1320.

Sections 70.220 and 70.221 of 7 CFR Part 70 list the standards for A quality and B quality, respectively, of ready-to-cook poultry. Paragraph headings in both sections are identical because the same quality factors are addressed by both standards. When numerous revisions were recently made in 7 CFR Part 70, the heading for paragraph (g) of § 70.221 was inadvertently changed and the mistake was not discovered until after the final rule had been published in the **Federal Register** May 9, 1986 (51 FR 17281). The heading for paragraph (g) of § 70.221 will be changed so it is the same as the heading for paragraph (g) of § 70.220.

List of Subjects in 7 CFR Part 70

Poultry, Poultry products, Rabbit products, Voluntary grading service.

PART 70—VOLUNTARY GRADING OF POULTRY PRODUCTS AND RABBIT PRODUCTS AND U.S. CLASSES, STANDARDS, AND GRADES

For reasons explained in the preamble, Part 70 of the Title 7 of the Code of Federal Regulations is amended as follows:

1. The authority citation for Part 70 continues to read as follows:

Authority: Secs. 202–208 of the Agricultural Marketing Act of 1946, as amended, (60 Stat. 1087–1091; 7 U.S.C. 1621–1627).

2. In § 70.6, paragraph (b) is revised to read as follows:

§ 70.6 OMB control numbers assigned pursuant to the Paperwork Reduction Act.

* * * * *

7 CFR section where identified and described	Current OMB control No.
70.3	0581–0127
70.10	0581–0127
70.17	0581–0127
70.18	0581–0127
70.20(a)	0581–0127
70.21	0581–0127
70.31(a)	0581–0127
70.31(b)	0581–0127
70.33	0581–0127
70.34	0581–0127
70.35	0581–0127
70.36	0581–0127
70.38(c)	0581–0127
70.38(d)	0581–0127
70.40	0581–0127
70.50	0581–0127
70.61	0581–0127
70.62	0581–0127
70.73	0581–0127
70.76(b)(1)	0581–0127
70.76(b)(3)(ii)	0581–0127
70.77(a)(1)	0581–0127
70.77(a)(4)	0581–0127
70.77(b)(1)	0581–0127
70.77(b)(3)(ii)	0581–0127
70.91(a)	0581–0127
70.91(c)	0581–0127
70.92	0581–0127
70.100	0581–0127
70.102	0581–0127
70.210(e)	0581–0127
70.310(e)	0581–0127

3. In § 70.221, the heading for paragraph (g) is revised to read as follows:

§ 70.221 B Quality.

* * * * *

(g) *Discolorations of the skin flesh.*

* * * * *

Done at Washington, DC, on July 17, 1986.

William T. Manley,

Deputy Administrator, Marketing Programs.

[FR Doc. 86–16435 Filed 7–21–86; 8:45 am]

BILLING CODE 3410–02–M

7 CFR Parts 1006, 1007, 1011, 1012, 1013, 1046, 1093, 1094, 1096, 1098 and 1099

[Docket Nos. AO-336-A27 et al.]

Milk in the Georgia and Certain Other Marketing Areas; Interim Amendment of Orders

7 CFR Parts	Marketing area	Docket Nos.
1007	Georgia	AO–366–A27
1006	Upper Florida	AO–356–A25
1011	Tennessee Valley	AO–251–A30
1012	Tampa Bay	AO–347–A28
1013	Southeastern Florida	AO–286–A35
1046	Louisville-Lexington-Evansville	AO–123–A56
1093	Alabama-West Florida	AO–386–A6
1094	New Orleans-Mississippi	AO–103–A48
1096	Greater Louisiana	AO–257–A35
1098	Nashville, Tennessee	AO–184–A50
1099	Paducah, Kentucky	AO–183–A42

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Interim amendment of rules.

SUMMARY: This action modifies on an interim basis the plant location adjustments to prices under 11 southeastern Federal milk marketing orders. The interim amendments would change the location adjustment provisions in the 11 orders to conform with the Class I differentials mandated by the Food Security Act of 1985, effective on May 1, 1986. The changes are based on evidence presented at a public hearing held in Atlanta, Georgia, on February 25–27, 1986. The hearing was requested by Dairymen, Inc. (DI). More than two-thirds of the producers in each of the 11 markets have approved the interim amendmens to the order for their market.

EFFECTIVE DATE: July 1, 1986.

FOR FURTHER INFORMATION CONTACT: Robert F. Groene, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447–2089.

SUPPLEMENTARY INFORMATION: This administrative action is governed by the provisions of sections 556 and 557 of Title 5 of the United States Code and, therefore, is excluded from the requirements of Executive Order 12291.

Prior documents in this proceeding:

Notice of Hearing: Issued February 7, 1986; published February 13, 1986 (51 FR 5363).

Extension of Time for Filing Briefs: Issued March 11, 1986.

Tentative Decision: Issued May 28, 1986; published June 5, 1986 (51 FR 20446).

Findings and Determinations

The findings and determinations hereinafter set forth supplement those that were made when the aforesaid orders were first issued and when they were amended. The previous findings and determinations are hereby ratified and confirmed, except where they may conflict with those set forth herein.

(a) *Findings upon the basis of the hearing record.* Pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674), and the applicable rules of practice and procedure governing the formulation of marketing agreements and marketing orders (7 CFR Part 900), a public hearing was held upon certain proposed amendments to the tentative marketing agreements and to the orders regulating the handling of milk in the respective marketing areas.

Upon the basis of the evidence introduced at such hearing and the record thereof, it is found that:

(1) The said orders as hereby amended on an interim basis, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the Act;

(2) The parity prices of milk, as determined pursuant to section 2 of the Act, are not reasonable in view of the price of feeds, available supplies of feeds, and other economic conditions which affect market supply and demand for milk in the said marketing areas; and the minimum prices specified in the orders as hereby amended on an interim basis, are such prices as will reflect the aforesaid factors, insure a sufficient quantity of pure and wholesome milk, and be in the public interest; and

(3) The said orders as hereby amended on an interim basis regulate the handling of milk in the same manner as, and are applicable only to persons in the respective classes of industrial or commercial activity specified in, marketing agreements upon which a hearing has been held.

(b) *Additional findings.* It is necessary in the public interest to make these interim amendments to each of the aforesaid orders effective July 1, 1986. Any delay beyond that date would tend to disrupt the orderly marketing of milk in the marketing areas.

The interim amendments to these orders are known to handlers. The Tentative decision of the Deputy Assistant Secretary containing proposed amendments to these orders was issued May 28, 1986 and published on June 5, 1986, in the **Federal Register** (51 FR 20446).

An order was issued by the Deputy Assistant Secretary on June 26, 1986, effective July 1, 1986, amendments that effective July 1, 1986, Amendments that were proposed in the tentative decision issued by the Deputy Assistant

Secretary on May 28, 1986 (51 FR 20446). Notice of the June 26, 1986, issuance of the order was made known prior to July 1, 1986, to all handlers subject to regulation under the 11 orders by the market administrators of the respective orders. The notice issued on June 26, 1986, incorporated by reference the proposed amendments set forth in the tentative decision issued on May 28, 1986. This document supplements the order issued on June 26, 1986, by setting forth in full the text of the proposed amendments.

The changes effected by these interim amendments will not require extensive preparation or substantial alteration in method of operation for handlers. In view of the foregoing, it is hereby found and determined that it would be contrary to the public interest to delay the effective date of these amendments for 30 days after publication in the **Federal Register.** (Sec. 553(d), Administrative Procedure Act, 5 U.S.C. 551–559).

(c) *Determinations.* It is hereby determined that:

(1) The refusal or failure of handlers (excluding cooperative associations specified in Sec. 8c (9) of the Act) of more than 50 percent of the milk, which is marketed within each of the respective marketing areas, to sign a proposed marketing agreement, tends to prevent the effectuation of the declared policy of the Act;

(2) The issuance of these interim amendments to each of the specified orders is the only practical means pursuant to the declared policy of the Act of advancing the interests of producers as defined in the respective orders; and

(3) The issuance of these interim amendments to each of the specified orders is approved by more than the necessary two-thirds of the producers who during the determined representative period were engaged in the production of milk for sale in the marketing area.

List of Subjects in 7 CFR Parts 1006, 1007, 1011, 1012, 1013, 1046, 1093, 1094, 1096, 1098 and 1099

Milk marketing order, Milk, Dairy products.

Order Relative to Handling

It is therefore ordered, That on and after the effective date hereof, the handling of milk in each of the specified marketing areas shall be in conformity to and in compliance with the terms and conditions of the aforesaid orders, as amended, and as hereby further amended, as follows:

The authority citation for Parts 1006, 1007, 1011, 1012, 1013, 1046, 1093, 1094, 1096, 1098 and 1099 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended (7 U.S.C. 601–674).

PART 1007—MILK IN THE GEORGIA MARKETING AREA

1. In § 1007.52, paragraphs (a) and (b) are revised to read as follows:

§ 1007.52 Plant location adjustments for handlers.

(a) The following zones are defined for the purpose of determining location adjustments:

(1) "Northern Zone" means all the territory in the following Georgia counties:

Bartow, Cherokee, Dawson, Floyd, Forsyth, Gilmer, Gordon, Habersham, Hall, Lumpkin, Pickens, Towns, Union, and White.

(2) "North Central Zone" means all the territory in the following Georgia counties:

Banks, Barrow, Butts, Carroll, Clarke, Clayton, Cobb, Coweta, De Kalb, Douglas, Elbert, Fayette, Franklin, Fulton, Greene, Gwinnett, Haralson, Hart, Heard, Henry, Jackson, Jasper, Lamar, Lincoln, Madison, Meriwether, Morgan, Newton, Oconee, Oglethorpe, Paulding, Pike, Polk, Putnam, Rockdale, Spalding, Stephens, Taliaferro, Troup, Walton, and Wilkes.

(3) "South Central Zone" means all the territory in the following Georgia counties:

Baldwin, Bibb, Bleckley, Burke, Chattahoochee, Columbia, Crawford, Crisp, Dodge, Dooly, Emanuel, Glascock, Hancock, Harris, Houston, Jefferson, Jenkins, Johnson, Jones, Laurens, Macon, Marion, McDuffie, Monroe, Muscogee, Peach, Pulaski, Richmond, Schley, Stewart, Sumter, Talbot, Taylor, Treutlen, Twiggs, Upson, Warren, Washington, Webster, Wilcox, and Wilkinson.

(4) "Southern Zone" means all the territory within the marketing area not specified in paragraphs (a)(1), (2), or (3) of this section.

(b) The Class I price for producer milk at a plant located outside the North Central Zone shall be adjusted as follows:

(1) For producer milk at a plant located in the "Northern Zone" the Class I price shall be reduced by 15 cents;

(2) For producer milk at a plant located in the "South Central Zone" the Class I price shall be increased by 10 cents;

(3) For producer milk at a plant located in the "Southern Zone" the Class I price shall be increased by 30 cents;

(4) For producer milk at a plant located in the State of North Carolina the Class I price shall be decreased by 11 cents;

(5) For producer milk at a plant located in the Tennessee Valley marketing area the Class I price shall be decreased by 31 cents;

(6) For producer milk at a plant located outside the marketing area and outside the Tennessee Valley marketing area and south of the southern boundary of the States of Tennessee and North Carolina the Class I price shall be the Class I price applicable at the nearer of the city halls in Augusta, Savannah, Lavonia, Waycross, Albany, Columbus, Atlanta, and Rome, Georgia; and

(7) For producer milk at a plant located outside the areas specified in paragraph (b)(1), (2), (3), (4), (5) or (6) of this section the Class I price shall be reduced 20 cents and an additional 2.5 cents for each 10 miles or fraction thereof in excess of 110 miles (by the shortest hard-surfaced highway distance as determined by the market administrator) that such plant is from the city hall in Atlanta, Georgia.

* * * * *

2. In § 1007.61, paragraph (a)(3) is revised to read as follows:

§ 1007.61 Computation of uniform price (including weighted average price and uniform prices for base and excess milk).

(a) * * *

(3) Add an amount equal to the total value of the minus adjustments and subtract an amount equal to the total value of the plus adjustments computed pursuant to § 1007.75;

* * * * *

3. In § 1007.75, paragraph (a) is revised to read as follows:

§ 1007.75 Plant location adjustments for producers and on nonpool milk.

(a) The uniform price and the uniform price for base milk shall be adjusted according to the location of the plant at which the milk is physically received at the rates set forth in § 1007.52(b); and

* * * * *

PART 1006—MILK IN THE UPPER FLORIDA MARKETING AREA

1. In § 1006.52, the table contained in paragraph (a) is revised to read as follows:

§ 1006.52 Plant location adjustments for handlers.

(a) * * *

Location of plant	Rate per cwt. (cents)
Outside the State of Florida:	
In excess of 70 but not more than 85 miles.	Subtract 15.
For each additional 10 miles or fraction thereof.	Subtract 2.0.
Inside the State of Florida:	
South of a line forming the southern boundary of the counties of Alachua, Dixie, Gilchrist, Putnam and St. Johns, but outside the defined marketing area of part 1013.	Add 30.
In the defined marketing area of part 1013.	Add 60.
The remaining area within the State of Florida.	No adjustment.

* * * * *

PART 1011—MILK IN THE TENNESSEE VALLEY MARKETING AREA

1. In § 1011.52, paragraph (a) is revised to read as follows:

§ 1011.52 Plant location adjustments for handlers.

(a) For milk received from producers or from a handler described in § 1011.9 (c) or (d) at a plant and which is classified as Class I milk subject to the limitations pursuant to paragraph (b) of this section, the Class I price shall be adjusted as follows:

(1) For such milk which is physically received at a plant located within the State of North Carolina, or a plant located outside the Georgia counties in the marketing area and south of the southern boundary of the States of North Carolina and Tennessee, the Class I price shall be increased by 20 cents;

(2) No adjustment shall be applicable on such milk which is physically received at a plant located within the marketing area except the Kentucky portion of the marketing area, or in the State of Virginia;

(3) For such milk which is physically received at a plant located within the Kentucky counties of Bell, Breathitt, Clay, Harlan, Knott, Knox, Laurel, Leslie, Letcher, McCreary, Perry, Pulaski, and Whitley, the Class I price shall be decreased by 32 cents; and

(4) For such milk which is physically received at a plant located more than 90 miles by the shortest hard-surfaced highway distance as determined by the market administrator from the nearest of the city halls of Bristol, Chattanooga, and Knoxville, Tennessee, and outside the areas specified in paragraphs (a)(1), (2), or (3) of this section, the Class I price applicable at the nearer of the city halls in Bristol, Chattanooga, or Knoxville, Tennessee shall be reduced by 2.5 cents for each 10 miles or fraction thereof that such plant is from the nearest of the city halls in Bristol, Chattanooga, and Knoxville, Tennessee.

PART 1012—MILK IN THE TAMPA BAY MARKETING AREA

1. In § 1012.52, the table contained in paragraph (a) is revised to read as follows:

§ 1012.52 Plant location adjustments for handlers.

(a) * * *

Location of plant	Rate per cwt. (cents)
Outside the State of Florida:	
For each 10 miles or fraction thereof from the city hall in Tampa, FL.	Subtract 2.0.
Inside the State of Florida:	
In the defined marketing area of part 1013.	Add 30.
South of a line forming the southern boundary of the counties of Alachua, Dixie, Gilchrist, Putnam and St. Johns, but outside the defined marketing area of part 1013.	No adjustment.
The remaining area within the State of Florida.	Minus 30.

* * * * *

PART 1013—MILK IN THE SOUTHEASTERN FLORIDA MARKETING AREA

1. In § 1013.52, the table contained in paragraph (a) is revised to read as follows:

§ 1013.52 Plant location adjustments for handlers.

(a) * * *

Location of plant	Rate per cwt. (cents)
Outside the State of Florida:	
For each 10 miles or fraction thereof from the U.S. Post Office in West Palm Beach, FL.	Subtract 2.0.
Inside the State of Florida:	
South of a line forming the southern boundary of the counties of Alachua, Dixie, Gilchrist, Putnam and St. Johns, but outside the defined marketing area of this order.	Subtract 30.
The remaining area within the State of Florida.	Subtract 60.

* * * * *

PART 1046—MILK IN THE LOUISVILLE-LEXINGTON-EVANSVILLE MARKETING AREA

1. In § 1046.52, paragraph (a) is revised to read as follows:

§ 1046.52 Plant location adjustments for handlers.

(a) For milk received from producers or from a handler described in § 1046.9(c) at a plant and which is classified as Class I milk subject to the limitations pursuant to paragraph (b) of this section, the Class I price shall be adjusted as follows:

(1) For such milk that is physically received at plants located in the Kentucky counties of Bell, Breathitt, Caldwell, Christian, Clay, Harlan, Hopkins, Knott, Knox, Laurel, Leslie, Letcher, Logan, Lyon, McCreary, Muhlenberg, Perry, Pulaski, Todd, Trigg and Whitley, the Class I price shall be increased by a location adjustment of 15 cents;

(2) For such milk that is physically received at plants located in the Kentucky counties of Ballard, Calloway, Carlisle, Fulton, Graves, Hickman, Livingstone, Marshall and McCracken and the Missouri counties of Mississippi, New Madrid, Pemiscot and Scot, the Class I price shall be increased by a location adjustment of 28 cents;

(3) For such milk that is physically received at plants located east of the Mississippi River and south of the northern boundary of Tennessee or the northern boundary of North Carolina, the Class I price shall be increased by a location adjustment of 41 cents;

(4) For such milk that is physically received at plants located in the marketing area or the state of Kentucky and outside the areas specified in paragraphs (a) (1), (2), or (3) of this section, no location adjustment shall apply; and

(5) For such milk that is physically received at plants located outside the areas specified in paragraphs (a) (1), (2), (3), or (4) of this section, and 85 miles or more from the City Halls in Louisville and Lexington, Kentucky, and Evansville, Indiana, by the shortest hard-surfaced highway distance as determined by the market administrator, the Class I price shall be reduced by a location adjustment of 2.5 cents for each 10 miles or fraction thereof that such plant is from the City Hall in Louisville, Lexington or Evansville, whichever is nearest.

* * * * *

PART 1093—MILK IN THE ALABAMA-WEST FLORIDA MARKETING AREA

1. In § 1093.52, the table contained in paragraph (a)(1) is revised to read as follows:

§ 1093.52 Plant location adjustments to handlers.

(a) * * *

(1) * * *

Zone	Adjustment per hundredweight (cents)
Zone 1	Minus 23.
Zone 2	No adjustment.
Zone 3	Plus 27.
Zone 4	Plus 57.
Zone 4a	Plus 30.

* * * * *

§ 1093.52 [Amended]

2. In § 1093.52(a)(2), the provision "20" is revised to read "31".

3. In § 1093.52(a)(3), the provision "45" is revised to read "56".

4. In § 1093.52(a)(4), the provision "20 cents. Such minus adjustment shall be increased 1.5" is revised to read "23 cents. Such minus adjustment shall be increased 2.5".

5. In § 1093.52(a)(6), the provision "55" is revised to read "50".

PART 1094—MILK IN THE NEW ORLEANS-MISSISSIPPI MARKETING AREA

1. In § 1094.2, Zone 3 and Zone 4 are revised and Zone 2A and Zone 3A are added to read as follows:

§ 1094.2 New Orleans-Mississippi marketing area.

* * * * *

Zone 2A

Mississippi Counties

Amite, Covington, Forrest, Franklin, Greene, Jefferson Davis, Jones, Lamar, Lawrence, Lincoln, Marion, Perry, Pike, Walthal, Wayne, and Wilkinson.

Zone 3

Mississippi Counties

Adams, Claiborne, Clarke, Copiah, Hinds, Issaquena, Jasper, Jefferson, Kemper, Lauderdale, Leake, Madison, Neshoba, Newton, Rankin, Scott, Sharkey, Simpson, Smith, Warren, and Yazoo.

Zone 3A

Mississippi Counties

Attala, Holmes, Humphreys, Noxubee, Washington, and Winston.

Zone 4

Mississippi Counties

Bolivar, Carroll, Choctaw, Leflore, Lowndes, Montgomery, Oktibbeha, Sunflower, and Webster.

2. In § 1094.52(a)(1), the table is revised to read as follows:

§ 1094.52 Plant location adjustments for handlers.

(a) * * *

(1) * * *

Zone	Adjustment per cwt. (cents)
Zone 1	No adjustment.
Zone 2	Minus 20.
Zone 2A	Minus 40.
Zone 3	Minus 50.
Zone 3A	Minus 65.
Zone 4	Minus 75.
Zone 5	Minus 80.
Zone 6	Minus 95.

* * * * *

§ 1094.52 [Amended]

3. In § 1094.52(a)(2)(i), the provision "No adjustment" is revised to read "Minus 7 cents";

4. In § 1094.52(a)(2)(ii), the provision "19" is revised to read "30";

5. In § 1094.52(a)(2)(iii) the provision "38" is revised to read "57";

6. In § 1094.52(a)(3) the provision "65" is revised to read "95".

7. In § 1094.(a)(5), the provision "1.5" is revised to read "2.5".

PART 1096—MILK IN THE GREATER LOUISIANA MARKETING AREA

1. In § 1096.52, paragraph (a) is revised to read as follows:

§ 1096.52 Plant location adjustments to handlers.

(a) For milk received at a plant from producers or a handler described in § 1096.9(c) and which is classified as Class I milk without movement in bulk form to a pool distributing plant at which a higher Class I price applies, the price computed pursuant to § 1096.50(a) shall be adjusted by an amount determined pursuant to paragraphs (a)(1) through (5) of this section for the location of such plant:

(1) For a plant located within one of the zones set forth in § 1096.2, the adjustment shall be as follows:

	Adjustment per hundredweight (cents)
Zone I	No adjustment.
Zone II	Plus 27.
Zone III	Plus 50.

(2) For a plant located in any of the following Louisiana parishes, the adjustment shall be as follows:

(i) *Plus 57 cents.* Jefferson, Lafourche, Orleans, Plaquemines, St. Bernard, St. Charles, Terrebonne.

(ii) *Plus 37 cents.* St. Tammany, Tangipahoa, Washington.

(3) For a plant located in any of the following Mississippi counties, the adjustment shall be as follows:

(i) *Plus 37 cents.* George, Hancock, Harrison, Jackson, Pearl River, Stone.

(ii) *Plus 17 cents.* Amite, Covington, Forrest, Franklin, Greene, Jefferson Davis, Jones, Lamar, Lawrence, Lincoln, Marion, Perry, Walthal, Wayne and Wilkinson.

(iii) *Plus 7 cents.* Adams, Claiborne, Clarke, Copiah, Hinds, Issaquena, Jasper, Jefferson, Kemper, Lauderdale, Leake, Madison, Neshoba, Newton, Rankin, Scott, Sharkey, Simpson, Smith, Warren and Yazoo.

(4) For a plant located in any of the following Texas counties, the adjustment shall be as follows:

(i) *Plus 54 cents.* Chambers, Hardin, Harris, Jefferson, Liberty, Orange.

(ii) *Plus 37 cents.* Jasper, Newton, Polk, Tyler.

(iii) *No adjustment.* Angelina, Cass, Harrison, Gregg, Marion, Nacogodoches, Panola, Rusk, Sabine, San Augustine, Shelby, Upshur.

(5) For a plant located outside of the areas described in paragraphs (a) (1) through (4) of this section and located more than 50 miles by the shortest hard-surfaced highway distance, as determined by the market administrator, from the nearer of the City Hall in Monroe or Shreveport, Louisiana, the adjustment shall be minus 2.2 cents per hundredweight for each 10 miles or fraction thereof.

* * * * *

PART 1098—MILK IN THE NASHVILLE, TENNESSEE, MARKETING AREA

1. In § 1098.52, paragraph (a) is revised to read as follows:

§ 1098.52 Plant location adjustments for handlers.

(a) For milk received from producers or from a handler described in § 1098.9(c) at a plant and which is classified as Class I milk subject to the limitations pursuant to paragraph (b) of this section, the Class I price shall be adjusted as follows:

(1) For such milk that is physically received at plants located in the Kentucky counties of Bell, Breathitt, Caldwell, Christian, Clay, Harlan, Hopkins, Knott, Knox, Laurel, Leslie, Letcher, Logan, Lyon, McCreary, Muhlenberg, Perry, Pulaski, Todd, Trigg, and Whitley, the Class I price shall be decreased by a location adjustment of 26 cents;

(2) For such milk that is physically received at plants located in the Kentucky counties of Ballard, Calloway, Carlisle, Fulton, Graves, Hickman, Livingstone, Marshall and McCracken and the Missouri counties of Mississippi, New Madrid, Pemiscot and Scot, the Class I price shall be decreased by a location adjustment of 13 cents;

(3) For such milk that is physically received at plants located outside the areas specified in paragraphs (a) (1) or (2) of this section and north of the northern boundary of Tennessee or the northern boundary of North Carolina and more than 50 miles from the State

Capitol in Nashville by the shortest hard-surfaced highway distance as determined by the market administrator, the Class I price shall be reduced by 17.5 cents plus 2.5 cents for each 10 miles or fraction thereof that such plant is more than 70 miles from the State Capitol; and

(4) For such milk that is physically received at plants located east of the Mississippi River and south of the northern boundary of Tennessee or the northern boundary of North Carolina, no adjustment shall be made under this paragraph.

* * * * *

PART 1099—MILK IN THE PADUCAH, KENTUCKY, MARKETING AREA

1. In § 1099.52 paragraph (a) is revised to read as follows:

§ 1099.52 Plant location adjustments for handlers.

(a) For milk received from producers at a plant located outside the State of Kentucky and north of an east-west line running through the southern boundary of the State of Kentucky and more than 40 miles by shortest highway distance as measured by the market administrator, from the nearest County Courthouse in any of the counties included in the marketing area and disposed of as Class I milk or assigned Class I location adjustment credit pursuant to paragraph (b) of this section, the price computed pursuant to § 1099.50(a) shall be reduced by 12.5 cents, plus 2.5 cents for each 10 miles or fraction thereof that such distance exceeds 50 miles.

* * * * *

Effective date: July 1, 1986.

Signed at Washington, DC, on: July 17, 1986.

Alan T. Tracy,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 86-16436 Filed 7-21-86; 8:45 am]

BILLING CODE 3410-02-M

FEDERAL HOME LOAN BANK BOARD

12 CFR Part 563

[No. 86-707]

Other Insurance or Guaranty; Correction

Dated: July 16, 1986.

AGENCY: Federal Home Loan Bank Board.

ACTION: Final rule; technical correction.

SUMMARY: Effective May 26, 1983, the Federal Home Loan Bank Board ("Board") recodified 12 CFR 545.24-2 as 12 CFR 545.16 and adopted 12 CFR 545.103, which together govern suretyship activities of Federal associations (48 FR 23032, May 23, 1983). When these regulations were adopted, cross references contained in 12 CFR 563.31(b) were not corrected. This action corrects that error. For the convenience of the public, the Board is republishing the entire text of § 563.31(b), as amended by its action today.

EFFECTIVE DATE: July 22, 1986.

FOR FURTHER INFORMATION CONTACT: Kathy Harris Jones, Paralegal Specialist, Regulations and Legislation Division, Office of General Counsel, (202) 377-7242, Federal Home Loan Bank Board, 1700 G Street, NW., Washington, DC 20552.

SUPPLEMENTARY INFORMATION: Pursuant to 12 CFR 508.11 and 508.14, the Board finds that, because of the minor, technical nature of this corrective amendment, notice and public procedure are unnecessary, as is the 30-day delay of the effective date.

List of Subjects in 12 CFR Part 563

Bank deposit insurance, Investments, Reporting and recordkeeping requirements, Savings and loan associations.

Accordingly, the Board hereby amends Part 563, Subchapter D, Chapter, V, Title 12, *Code of Federal Regulations*, as set forth below.

Subchapter D—Federal Savings and Loan Insurance Corporation

PART 563—OPERATIONS

1. The authority citation for Part 563 continues to read as follows:

Authority: Pub. L. 95-147 of Oct. 28, 1977, sec. 4, 82 Stat. 856, sec. 4, 80 stat. 824, sec. 17, 47 Stat. 736, as amended (12 U.S.C. 1425a, 1425b, and 1437); sec. 2, 48 Stat. 128, as amended (12 U.S.C. 1462); sec. 5, 48 Stat. 132, as amended (12 U.S.C. 1464); sec. 202, 96 Stat. 1469; sec. 409, 94 Stat. 160; secs. 401-407, 48 Stat. 1255-1260, as amended (12 U.S.C. 1724-1730); sec. 408, 82 Stat. 5, as amended (12 U.S.C. 1730a); Reorg. Plan No. 3 of 1947, 12 FR 4981, 3 CFR 1943-48 Comp., p. 1071, unless otherwise noted.

2. Amend § 563.31 by revising paragraph (b) to read as follows:

§ 563.31 Other insurance or guaranty.

* * * * *

(b) *Exceptions.* Paragraph (a) of this section notwithstanding:

(1) A Federal association may give bond or security pursuant to §§ 545.16 and 545.103 of this chapter;

(2) To the extent that it has legal power to do so, an insured institution that is not a Federal association may give bond or security in conformity with §§ 545.16 and 545.103 as if such institution were a Federal association as defined in § 541.8 of this chapter.

By the Federal Home Loan Bank Board.

Jeff Sconyers,

Secretary.

[FR Doc. 86-16350 Filed 7-21-86; 8:45 am]

BILLING CODE 6720-01-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 39

[Docket No. 86-NM-131-AD; Amdt. 30-5360]

Airworthiness Directives: Boeing Model 727 and 737 Series Airplanes

AGENCY: Federal Aviation Administration (FAA) DOT.

ACTION: Clarification of Final rule.

SUMMARY: This action clarifies Airworthiness Directive (AD) 83-01-05, applicable to all Boeing Models 727 and 737 series airplanes, which requires installation of engine start valve position indicator in the cockpit. By its terms, the existing AD applies to *all* Model 727 and 737 airplanes. However, the AD was issued prior to type certification of the Model 737-300, was not intended to apply to it, and cannot be applied appropriately to this model since it is equipped with a different starting system. This action is necessary to exclude the Model 737-300 from the applicability of the AD.

EFFECTIVE DATE: August 4, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. Stewart R. Miller, Propulsion Branch, ANM-140S, Seattle Aircraft Certification Office; telephone (206) 431-2969. Mailing address: FAA, Northwest Mountain Region, 17900 Pacific Highway South, C-68966, Seattle, Washington 98168.

SUPPLEMENTARY INFORMATION: On January 14, 1983, the FAA issued AD 83-01-05, Amendment 38-4542 (48 FR 2962; January 24, 1983), applicable to all Boeing Models 727 and 737 series airplanes, which requires that operators of Models 727 and 737 series airplanes install engine start valve position indicators in the cockpit prior to February 23, 1985. The compliance time was later extended to February 23, 1986, by Amendment 39-5000 (50 FR 6339; February 15, 1985).

The AD was intended to apply to the engine starting system on Models 727 and 737 series airplanes powered by Pratt and Whitney JT8D engines of all

variants. The Model 737-300 was subsequently certificated after the issuance of the AD. The Model 737-300 is powered by CFM56 engines equipped with a different starting system. Its starting system is not subject to the same failure conditions that the AD addresses, and should not be subject to the requirements of the AD. Therefore, action is taken herein to make this clarification.

Since this action only clarifies the applicability of a final rule, it has no adverse economic impact and imposes no additional burden on any person. Therefore, notice and procedures hereon are unnecessary and the amendment may be made effective in less than 30 days.

The FAA has determined that this regulation is not considered to be major under Executive Order 12291 or significant under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and it is further certified under the criteria of the Regulatory Flexibility Act that this rule will not have a significant economic effect on a substantial number of small entities, because there is no additional cost of compliance. A final evaluation has been prepared for this regulation and has been placed in the docket.

List of Subjects in 14 CFR Part 39

Aviation safety, Aircraft.

Adoption of the Correction

PART 71—[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 40 U.S.C. 106(g) (Revised Pub. L. 97-449; January 12, 1983); and 14 CFR 11.89.

2. By amending AD 83-01-05, Amendment 39-4542 (48 FR 2962; January 24, 1983), as amended by Amendment 39-5000 (50 FR 6339; February 15, 1985), to identify properly the affected airplanes by changing the applicability statement to read as follows:

Boeing: Applies to Models 727, 737-100, and 737-200 series airplanes certificated in any category.

This amendment becomes effective August 4, 1986.

Issued in Seattle, Washington, on July 9, 1986.

Wayne J. Barlow,

Director, Northwest Mountain Region.

[FR Doc. 86-16347 Filed 7-21-86; 8:45 am]

BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 86-CE-21-AD; Amdt. 39-5358]

Airworthiness Directives; Cessna Models 150, 150A, 150B, and 150C Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action adopts a new Airworthiness Directive (AD) applicable to Cessna Models 150, 150A, 150B, and 150C airplanes which have been modified by the installation of an engine larger in size and/or horsepower than the Continental 0-200-A. The AD requires weighing the airplane to determine the empty weight and center of gravity (cg) location and, if necessary, the installation of ballast. This action is necessary to prevent operation of the airplane outside the approved cg envelope wherein unknown flight characteristics could lead to loss of control of the airplane.

DATES: *Effective Date*: July 24, 1986.

Compliance: As prescribed in the body of the AD.

ADDRESSES: Background information pertinent to this AD is contained in the Rules Docket, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Mr. Douglas W. Haig, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Wichita, Kansas 67209; Telephone (316) 946-4409.

SUPPLEMENTARY INFORMATION: When a Cessna 150 airplane, modified by the installation of a 150 hp engine, was undergoing further modification to install a different propeller, it was found that the cg of the previously modified airplane was 2.01 inches in front of the forward limit. Further, the cg would be forward of the forward limit for most flight conditions. Installation of these larger engines requires relocation of the battery for balance purposes. Originally on the Cessna 150, 150A, 150B and 150C airplanes, the battery was located at fuselage station 73.57 (aft of the baggage compartment). On later models it was located on the firewall. The larger engines typically require the battery to be relocated from the firewall to fuselage station 130 to offset the increased engine weight. Many approvals failed to recognize that on the earlier airplanes the battery would be relocated only from fuselage station 73.57 to 130 (130 inches vs. 56.43 inches). Thus, the forward cg condition exists. This condition may exist on any Cessna 150, 150A, 150B or 150C airplane modified by the installation of an engine larger in size and/or horsepower than the Continental 0-200-A where actual weight and balance was not accomplished.

Operating outside of the cg limits places the airplane in a regime of unapproved and unknown handling qualities. In the case of excessive forward cg, the stall characteristics will change, elevator forces will increase, and the bahavior of the airplane during stall or near stall conditions will be unknown. This will occur during extremely critical portions of flight; i.e., take-off, landing, slow flight and stalls. Unknown flight qualities could lead to loss of control and subsequent loss of the airplane. In addition, this places heavier loads on the landing gear system and forward fuselage structure than those for which these airplanes were certificated. This could lead to failures in the landing gear system and/or fuselage structure.

Since the FAA has determined that the unsafe condition described herein is likely to exist or develop in other airplanes of the same type design, an AD is being issued requiring the airplane to be weighed, its cg calculated to determine ballast requirements, and the installation of ballast on Cessna Models 150, 150A, 150B and 150C airplanes modified by the installation of an engine larger in size and/or horsepower than the Continental 0-200-A. Because an emergency condition exists that requires the immediate adoption of this regulation, it is found that notice and public procedure herein are impractical and contrary to the public interest, and good cause exists for making this amendment effective in less than 30 days.

The FAA has determined that this regulation is an emergency regulation that is not major under section 8 of Executive Order 12291. It is impracticable for the agency to follow the procedures of Executive Order 12291 with respect to this rule since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this document involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a

significant regulation, a final regulatory evaluation or analysis as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the Rules Docket under the caption **"ADDRESSES"** at the location identified.

List of Subjects in 14 CFR Part 39

Air transportation, Aviation safety, Aircraft, Safety.

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends, § 39.13 of Part 39 of the FAR as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97-449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new AD:

Cessna: Applies to the following Models and Serial Numbers of airplanes certificated in any category which have been modified by the installation of an engine larger in size and/or horsepower than the Continental 0-200-A:

Models	Serial Numbers
150	17001 thru 17999 59001 thru 59018
150A	15059019 thru 15059350
150B	15059351 thru 15059700
150C	15059701 thru 15060087

Compliance: Required as indicated, unless already accomplished.

To assure operation of the airplane within the approved center of gravity (eg) limits, accomplish the following:

(a) Within the next 25 hours time-in-service (TIS) after the effective date of this AD, accomplish the following:

(1) Weigh the airplane to determine the empty weight (W_1) and calculate the cg (cg_1). The airplane, as weighed, must include full oil and unusable fuel (21 lbs at fuselage station 40.0 for standard fuel tanks).

(2) Add pilot weight (170 lbs at fuselage station 39.0) to the empty weight ($W_1+170=W_2$) and calculate the cg (cg_2) for this condition. If this cg is forward of fuselage station 32.2, add ballast between fuselage stations 70.69 and 76.44. (This was the location of the battery prior to the engine modification.)

(3) Determine the amount of ballast (B) required from the following equation:

$$B=\frac{(D)\times(W_2)}{X}\text{ ; where,}$$

B = weight in pounds of ballast required by this AD.

D = distance in inches the empty A/C (with pilot) cg must be moved aft in order to comply with this AD ($D=32.2-cg_2$). Obtain cg_2 from paragraph (2) above.

W_2 = empty weight in pounds of the airplane plus pilot determined in paragraph (2) above.

X = distance in inches from the point where the ballast is installed to the required location of the new cg (fuselage station 32.2 in the case). Using the battery box location, X = 41.36.

(4) Fabricate the channel detailed in Figure 1. Mount the channel between fuselage stations 70.69 and 76.44 using the existing 041328-3 brackets. Attach with MS20470-AD4 rivets through the existing holes in brackets. Installs the ballast in accordance with Figure 1. If ballast exceeds 60 pounds, contact the Wichita Aircraft Certification Office at the address given in paragraph (C) below for assistance.

(5) If the empty weight, as calculated in (1) above, plus the ballast exceeds 1142 lbs, prior to further flight, fabricate and install on the instrument panel a placard with a minimum letter size of 1/8 inch which states, "WARNING: THIS AIRPLANE LIMITED TO SINGLE OCCUPANT". If the empty weight exceeds 1195 lbs., equipment must be removed in order that this weight is not exceeded. The 1142 lbs and 1195 lbs are weight limitations established by Civil Air Regulations 3.74(b)(1) and 3.74(b)(2), respectively.

(b) Airplanes which were weighed at the time of installation of the larger engine and have an empty weight cg (including pilot, oil and unusable fuel) aft of fuselage station 32.2 are exempt from paragraphs (a)(1), (a)(2), (a)(3) and (a)(4) of this AD.

(c) Airplanes may be flown in accordance with FAR 91.197 to a location where this AD may be accomplished.

(d) An equivalent method of compliance with this AD may be used if approved by the Manager, Wichita Aircraft Certification Office, FAA, 1801 Airport Road, Room 100, Wichita, Kansas 67209; Telephone (316) 946-4400.

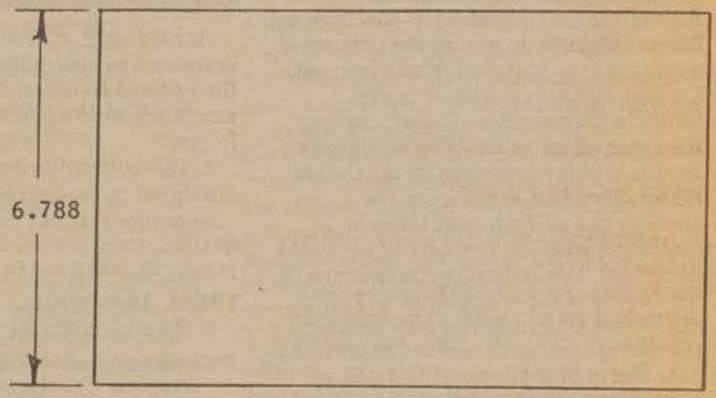
This amendment becomes effective July 24, 1986.

Issued in Kansas City, Missouri, on July 8, 1986.

Jerold M. Chavkin,

Acting Director, Central Region.

MATERIAL: 2024-T3
THICKNESS: .040
BEND RADII: .125
SCALE: 1/2
DIMENSIONS: Inches
NOTE: Lead ballast can be stacked sheet stock, ingot, or bar stock. Attach sheet stock with a minimum of 4-AN4 bolts or equivalent. Attach ingots or bar stock with a minimum of 2-AN4 bolts or equivalent per piece of lead, install a large diameter washer, such as an AN 970-4 under both the bolt head and nut. Use either a locknut or a castellated nut with cotter pin.



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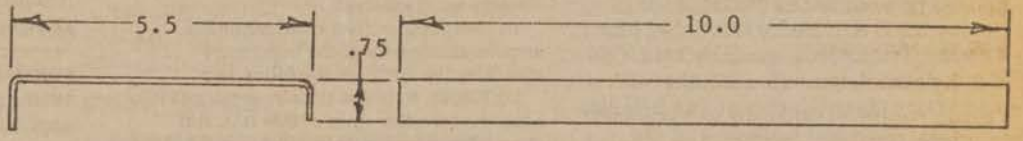

CHANNEL

FIGURE 1

[FR Doc. 86-16345 Filed 7-21-86; 8:45 am]
BILLING CODE 4910-13-M

14 CFR Part 39

[Docket No. 86-CE-17-AD; Amt. 39-5362]

Airworthiness Directives; DeHavilland DHC-6 Models 1, 100, 200 and 300 Airplanes

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment adopts a new Airworthiness Directive (AD), applicable to DeHavilland Models DHC-6 Models 1, 100, 200 and 300 airplanes which requires inspection of the four horizontal tail attachment brackets for loose rivets and subsequent replacement of the rivets. The manufacturer and the FAA have received reports that operators have found loose rivets in the tailplane front and rear spar attachment brackets, on airplanes which have been modified previously in accordance with DeHavilland Service Bulletin (S/B) No. 6/438, which could result in the loss of the stabilizer. The inspection will detect the loose rivets and preclude the possible loss of the stabilizer.

DATES: *Effective Date:* July 25, 1986.

Compliance: As prescribed in the body of the AD.

ADDRESSES: DeHavilland S/B No. 6/475, dated July 29, 1985, specified in this AD may be obtained from DeHavilland Aircraft of Canada, Limited, Downsview, Ontario, Canada M3K 1Y5. A copy of this information is also contained in the Rules Docket, FAA, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

FOR FURTHER INFORMATION CONTACT: Mr. Alfred A. Maila, FAA, New York Aircraft Certification Office, ANE-172, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581; Telephone (516) 791-6221.

SUPPLEMENTARY INFORMATION: DeHavilland, the manufacturer, has received reports from DHC-6 operators that there have been two instances of loose rivets which attach the tailplane attachment brackets to the adjacent spars structure on foreign registered DHC-6 airplanes. Attachment brackets Part Number (P/N) C6TPM1049-27 and C6TPM1050-27 were installed by incorporating modifications 6/1808 and 6/1809 to replace cracked parts found by inspection in compliance with DeHavilland S/B No. 6/438 on DHC-6 airplanes Serial Numbers (S/N) 3 through 820 inclusive. On U.S. registered DHC-6 airplanes this inspection and modification, if required, was made applicable by AD 83-26-05 (Amendment 39-4793) effective January 13, 1984. The modification kits, supplied by the manufacturer, contained the above replacement brackets and rivets with grip lengths sufficient only for airplane configuration with nominal skin thickness. Thus, in some cases, the rivet grip length may be inadequate due to

variations in material thickness. As a result, DeHavilland has issued S/B No. 6/475, which prescribes inspection and rivet replacement in the tailplane front and rear spar attachment brackets. Transport Canada who has responsibility and authority to maintain the continuing airworthiness of these airplanes in Canada has issued Airworthiness Directive CF–85–10, dated August 15, 1985, to assure the continued airworthiness of the affected airplanes. On the airplanes operated under Canadian registration, this action has the same effect as an AD on airplanes certificated for operation in the United States. The FAA relies upon the certification of Transport Canada combined with FAA review of pertinent documentation in finding compliance of the design of these airplanes with the applicable United States airworthiness requirements and the airworthiness and conformity of products of this design certificated for operation in the United States.

The FAA has examined the available information related to the issuance of DeHavilland S/B No. 6/475, dated July 29, 1985, Transport Canada AD No. CF–85–10, dated August 15, 1985, the mandatory classification of this S/B No. 6/475 by Transport Canada and the three U.S. Service Difficulty Reports (SDR). Based on the foregoing, the FAA has determined that the condition addressed by DeHavilland S/B No. 6/475, dated July 29, 1985, is an unsafe condition that may exist on other products of the same type design certificated for operation in the United States.

Therefore, an AD is being issued requiring inspection of the four horizontal tail attachment brackets for loose rivets on DeHavilland DHC–6 Models 1, 100, 200 and 300 airplanes.

Because an emergency condition exists that requires the immediate adoption of this regulation, it is found that notice and public procedure hereon are impractical and contrary to the public interest, and good cause exists for making this amendment effective in less than 30 days.

The FAA has determined that this regulation involves 194 DHC–6 U.S. registered airplanes and that the approximate inspection and modification cost is $3,500 for each airplane for a total cost of $679,000. Therefore, I certify that this action is not "major" under Executive Order 12291, and is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). A copy of the final evaluation prepared for this action is contained in the regulatory Docket. A copy of it may be obtained by contacting the person identified under the caption "**FOR FURTHER INFORMATION CONTACT**".

List of Subjects in 14 CFR Part 39

Air transportation, Aviation safety, Aircraft, Safety.

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends § 39.13 of Part 39 of the FARs as follows:

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

Authority: 49 U.S.C. 1354(a), 1421 and 1423; 49 U.S.C. 106(g) (Revised, Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By adding the following new AD:

DeHavilland: Applies to Model DHC–6 airplanes, Serial Numbers 3 through 820 inclusive with DeHavilland Modifications 6/1808 and 6/1809.

Compliance: Required as indicated, unless already accomplished.

To detect loose rivets and maintain structural integrity of the horizontal stabilizer, accomplish the following:

(a) Within 50 hours time-in-service (TIS) after the effective date of this AD, and thereafter at intervals not to exceed 150 hours TIS, inspect the four horizontal tail attachment brackets (P/N CTPM1049–27 and C6TPM1050–27) to the stabilizer front and rear spars in accordance with the "ACCOMPLISHMENT INSTRUCTIONS" of DeHavilland Service Bulletin (S/B) No. 6/475, dated July 29, 1985.

(b) If loose rivets are found during the inspection per Paragraph (a) of this AD, within 25 hours TIS thereafter accomplish DeHavilland modifications No. 6/1855 and No. 6/1856 in accordance with the "ACCOMPLISHMENT INSTRUCTIONS" of DeHavilland S/B No. 6/475, dated July 29, 1985.

(c) Within six months from the effective date of this Airworthiness Directive incorporate DeHavilland modifications 6/1855 and 6/1856 in accordance with the "ACCOMPLISHMENT INSTRUCTIONS" of DeHavilland S/B No. 6/475.

(d) The repetitive inspections specified in Paragraph (a) of this AD, may be discontinued upon the incorporation of DeHavilland modifications 6/1855 and 6/1856.

(e) Aircraft may be flown in accordance with FAR 21.197 to a location where this AD can be accomplished.

(f) Upon submission of substantiating data by an owner or operator, through an FAA Maintenance Inspector, the Manager, New York Aircraft Certification Office, FAA, New England Region, may adjust the inspection intervals specified in this AD.

(g) An equivalent method of compliance with this AD, if used, must be approved by the Manager, New York Aircraft Certification Office, FAA, New England Region.

All persons affected by this directive may obtain copies of the document(s) referred to herein upon request to DeHavilland Aircraft of Canada, Limited, Downsview, Ontario, Canada M3K 1Y5, or the FAA, Office of the Regional Counsel, Room 1558, 601 East 12th Street, Kansas City, Missouri 64106.

This amendment becomes effective on July 25, 1986.

Issued in Kansas City, Missouri, on July 10, 1986.

Jerold M. Chavkin,

Acting Director, Central Region.

[FR Doc. 86–16344 Filed 7–21–86; 8:45 am]

BILLING CODE 4910–13–M

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14 CFR Part 39

[Docket No. 84–ASW–21; Amdt. 39–5352]

Airworthiness Directives; Boeing Vertol Company Model 234 Series Helicopters

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment amends an existing airworthiness directive (AD), applicable to certain shafts on Boeing Vertol Model 234 series helicopters, which requires initial and repetitive inspections of the forward main rotor drive shaft and removal and replacement of cracked shafts prior to further flight. The present AD associates cracked shafts with the use of certain rotor hubs. Subsequent service history has shown corrosion pits occur on certain shafts even when mated with the hubs not listed in the AD. This amendment is needed to require inspections of shafts used with any hub and thereby detect cracks in the shaft.

DATES: *Effective Date:* July 24, 1986.

Compliance: As indicated in the body of the AD.

ADDRESSES: The applicable service information may be obtained from Boeing Vertol Company, Boeing Center, P.O. Box 16858, Philadelphia, Pennsylvania 19142. A copy of the inspection documents is contained in the Rules Docket, Office of the Regional Counsel, Federal Aviation Administration, Southwest Region, 4400 Blue Mound Road, Fort Worth, Texas 76106.

FOR FURTHER INFORMATION CONTACT: Murry Schoenberger, ANE–174, New York Aircraft Certification Office, Federal Aviation Administration, 181 South Franklin Avenue, Room 202, Valley Stream, New York 11581, telephone number (516) 791–7421.

SUPPLEMENTARY INFORMATION: This amendment amends Amendment 39–5024 (50 FR 15539; April 19, 1985), AD 84–10–51, which requires an initial and repetitive inspection at 35-hour intervals of the forward main rotor drive shaft that was mated with rotor hub P/N 114R2050–17 or –23 and replacement, if the shaft is cracked. The FAA determined that cracked shaft splines were associated with certain rotor hubs which placed a higher stress on the spline area where the cracks and corrosion pits were found. After issuing Amendment 39–5024, additional reports now indicate that corrosion pits, but no cracks, were found on shafts which had only operated with modified rotor hubs. This condition may result in cracks in a shaft and, if not detected, could result in a shaft failure. Therefore, the FAA is amending Amendment 39–5024 to require inspection for cracks in all P/N 114D1245–7 shafts, without regard to the rotor hub with which they have been mated, on Boeing Vertol Model 234 series helicopters. This amendment allows 70 hours' time in service after the effective date of the amendment for those shafts which have accumulated 1,600 or more hours' time in service before inspections must be commenced. Shafts mated with rotor hub P/N 114R2050–17 or –23 are still subject to inspection at 35-hour intervals as prescribed in the original Amendment 39–5024.

This amendment also incorporates by reference Service Bulletin No. 234–63–1009, Revision 1, May 1, 1986. The noted inspections shall be accomplished in accordance with the revised or original bulletin.

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

Thirteen aircraft may be affected by this amendment. None of these are owned by a small entity. The FAA has determined that this regulation is an emergency regulation that 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 further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption **"FOR FURTHER INFORMATION CONTACT."**

List of Subjects in 14 CFR Part 39

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

Adoption of the Amendment

PART 39—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration amends § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) as follows:

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

Authority: 49 U.S.C. 1354(a), 1421, and 1423; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); and 14 CFR 11.89.

§ 39.13 [Amended]

2. By amending Amendment 39–5024 (50 FR 15539; April 19, 1985), AD 84–10–51, by revising the applicability statement and paragraph (a) to read as follows:

Boeing Vertol Company: Applies to Model 234 series helicopters, certificated in any category, equipped with forward main rotor drive shaft P/N 114D1245–7.

* * * * *

(a) Within 70 hours' time in service after the effective date of this amendment or upon accumulation of 1,600 total hours' time in service on the rotor shaft, whichever occurs later, and thereafter at intervals not to exceed 35 hours' time in service from the last inspection, inspect the rotor drive shaft in accordance with paragraph 3, "Accomplishment Instructions," Boeing Vertol Service Bulletin No. 234–63–1009, dated June 29, 1984, or Revision 1 dated May 1, 1986, or an FAA-approved equivalent.

* * * * *

This amendment becomes effective July 24, 1986.

This amendment amends Amendment 39–5024 (50 FR 15539), AD 84–10–51.

Issued in Fort Worth, Texas, on June 25, 1986.

C.R. Melugin, Jr.,

Director, Southwest Region.

[FR Doc. 86–16339 Filed 7–21–86; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 71

[Airspace Docket No. 86–ASO–17]

Alteration of Transition Area, Erwins, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment increases the size of the Erwin, North Carolina, transition area to accommodate a new instrument approach procedure which has been developed to serve Harnett County Airport. This action lowers the base of controlled airspace, northeast of the airport, from 1,200 to 700 feet above the surface. This additional controlled airspace is required for protection of Instrument Flight Rules (IFR) aeronautical activities.

EFFECTIVE DATE: 0901 UTC, October 23, 1986.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Supervisor, Airspace Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763–7646.

SUPPLEMENTARY INFORMATION:

History

On Wednesday, May 21, 1986, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) by altering the Erwin, North Carolina, transition area to designate additional controlled airspace northeast of Harnett County Airport (51 FR 18604). This airspace is required to support IFR aeronautical activities in the Erwin area. 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. This amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in FAA Handbook 7400.6B dated January 2, 1986.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations increases the size of the Erwin, North Carolina, transition area to accommodate a new instrument approach procedure which has been developed to serve Harnett County Airport.

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 "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

Aviation safety, Transition area.

Adoption of the Amendment

PART 71—[AMENDED]

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. By amending § 71.181 as follows:

Erwin, NC—[Revised]

Following ". . . longitude 78°44'04"W.); . . ." insert the following words: "within three miles each side of the 042° bearing from the Harnett RBN (lat. 35°25'59"N., long. 78°40'31"W.), extending from the 7.5 mile radius area to 8.5 miles northeast of the RBN; . . .".

Issued in East Point, Georgia, on July 14, 1986.

James L. Wright,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 86-16338 Filed 7-21-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 71

[Airspace Docket No. 86-ASO-18]

Alteration of Transition Area, Smithfield, NC

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment increases the size of the Smithfield, North Carolina, transition area to accommodate changes in an instrument approach procedure which serves Johnston County Airport. This action lowers the floor of controlled airspace in an area northeast of the airport from 1,200 to 700 feet above the surface. This additional controlled airspace is required for protection of Instrument Flight Rules (IFR) aeronautical activities.

EFFECTIVE DATE: 0901 UTC, October 23, 1986.

FOR FURTHER INFORMATION CONTACT: Donald Ross, Supervisor, Airspace Section, Airspace and Procedures Branch, Air Traffic Division, Federal Aviation Administration, P.O. Box 20636, Atlanta, Georgia 30320; telephone: (404) 763-7646.

SUPPLEMENTARY INFORMATION:

History

On Wednesday, May 21, 1986, the FAA proposed to amend Part 71 of the Federal Aviation Regulations (14 CFR Part 71) to alter the Smithfield, North Carolina, transition area by designating additional controlled airspace northeast of Johnston County Airport. This airspace is required to support Instrument Flight Rule aeronautical activities in the Smithfield area. (51 FR 18604). 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. This amendment is the same as that proposed in the notice. Section 71.181 of Part 71 of the Federal Aviation Regulations was republished in FAA Handbook 7400.6B dated January 2, 1986.

The Rule

This amendment to Part 71 of the Federal Aviation Regulations increases the size of the Smithfield, North Carolina, transition area to accommodate changes in instrument approach procedures which serve Johnston County Airport.

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

Aviation safety, Transition area.

Adoption of the Amendment

PART 71—[AMENDED]

Accordingly, pursuant to the authority delegated to me, Part 71 of the Federal Aviation Regulations (14 CFR Part 71) is amended, as follows:

1. The authority citation for Part 71 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Public Law 97-449, January 12, 1983); 14 CFR 11.69.

§ 71.181 [Amended]

2. By amending § 71.181 as follows:

Smithfield, NC—[Revised]

That airspace extending upward from 700 feet above the surface within a seven-mile radius of Johnston County Airport (lat.35°32'36"N., long. 78°23'21"W.); within 3.5 miles each side of the 024° bearing from the Neuse RBN (lat. 35°36'24"N., long. 78°21'17"W.), extending from the seven-mile radius area to 9.5 miles northeast of the RBN.

Issued in East Point, Georgia, on July 10, 1986.

James L. Wright,

Acting Manager, Air Traffic Division, Southern Region.

[FR Doc. 85-16348 Filed 7-21-85; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 97

[Docket No. 25039; Amdt. No. 1325]

Standard Instrument Approach Procedures; Miscellaneous Amendments

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This amendment establishes, amends, suspends, or revokes Standard Instrument Approach Procedures (SIAPs) for operations at certain airports. These regulatory actions are needed because of the adoption of new or revised criteria, or because of changes occurring in the National Airspace System, such as the commissioning of new navigational facilities, addition, of new obstacles, or changes in air traffic requirements. These changes are designed to provide safe and efficient use of the navigable airspace and to promote safe flight operations under instrument flight rules at the affected airports.

DATES: Effective: An effective date for each SIAP is specified in the amendatory provisions.

Incorporation by reference—approved by the Director of the **Federal Register** on December 31, 1980, and reapproved as of January 1, 1982.

ADDRESSES: Availability of matters incorporated by reference in the amendment is as follows:

For Examination—

1. FAA Rules Docket, FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591;
2. The FAA Regional Office of the region in which the affected airport is located; or
3. The Flight Inspection Field Office which originated the SIAP.

For Purchase—

Individual SIAP copies may be obtained from:

1. FAA Public Inquiry Center (APA—430), FAA Headquarters Building, 800 Independence Avenue SW., Washington, DC 20591; or
2. The FAA Regional Office of the region in which the affected airport is located.

By Subscription—

Copies of all SIAPs, mailed once every 2 weeks, are for sale by the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402.

FOR FURTHER INFORMATION CONTACT: Donald K. Funai, Flight Procedures Standards Branch (AFS–230), Air Transportation Division, Office of Flight Standards, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 426–8277.

SUPPLEMENTARY INFORMATION: This amendment to Part 97 of the Federal Aviation Regulations (14 CFR Part 97) prescribes new, amended, suspended, or revoked Standard Instrument Approach Procedures (SIAPs). The complete regulatory description of each SIAP is contained in official FAA form documents which are incorporated by reference in this amendment under 5 U.S.C. 552(a), 1 CFR Part 51 and § 97.20 of the Federal Aviation Regulations (FARs). The applicable FAA Forms are identified as FAA Forms 8260–3, 8260–4, and 8260–5. Materials incorporated by reference are available for examination or purchase as stated above.

The large number of SIAPs, their complex nature, and the need for a special format make their verbatim publication in the **Federal Register** expensive and impractical. Further, airmen do not use the regulatory text of the SIAPs, but refer to their graphic depiction on charts printed by publishers of aeronautical materials. Thus, the advantages of incorporation by reference are realized and publication of the complete description of each SIAP contained in FAA form document is unnecessary. The provisions of this amendment state the affected CFR (and FAR) sections, with the types and effective dates of the SIAPs. This amendment also identifies the airport, its location, the procedure identification and the amendment number.

This amendment to Part 97 is effective on the date of publication and contains separate SIAPs which have compliance dates stated as effective dates based on related changes in the National Airspace System or the application of new or revised criteria. Some SIAP amendments may have been previously issued by the FAA in a National Flight Data Center (FDC) Notice to Airmen (NOTAM) as an emergency action of immediate flight safety relating directly to published aeronautical charts. The circumstances which created the need for some SIAP amendments may require making them effective in less than 30 days. For the remaining SIAPs, an effective date at least 30 days after publication is provided.

Further, the SIAPs contained in this amendment are based on the criteria contained in the U.S. Standard for Terminal Instrument Approach Procedures (TERPs). In developing these SIAPs, the TERPS criteria were applied to the conditions existing or anticipated at the affected airports. Because of the close and immediate relationship between these SIAPs and safety in air commerce, I find that notice and public procedure before adopting these SIAPs is unnecessary, impracticable, and contrary to the public interest and, where applicable, that good cause exists for making some SIAPs effective in less than 30 days.

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 "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. For the same reason, the FAA certifies that this amendment 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 97

Approaches, Standard instrument, Incorporation by reference.

Issued in Washington, DC on July 11, 1986.

John S. Kern,

Director of Flight Standards.

Adoption of the Amendment

PART 97—[AMENDED]

Accordingly, pursuant to the authority delegated to me, Part 97 of the Federal Aviation Regulations (14 CFR Part 97) is amended by establishing, amending, suspending, or revoking Standard Instrument Approach Procedures, effective at 0901 G.M.T. on the dates specified, as follows:

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

Authority: 49 U.S.C. 1348, 1354(a), 1421, and 1510; 49 U.S.C. 106(g) (revised, Pub. L. 97–449, January 12, 1983; and 14 CFR 11.49(b)(2)).

§§ 97.23, 97.25, 97.27, 97.29, 97.31, 97.33 and 97.35 [Amended]

By amending: Section 97.23 VOR, VOR/DME, VOR or TACAN, and VOR/DME or TACAN; § 97.25 LOC, LOC/DME, LDA, LDA/DME, SDF, SDF/DME; § 97.27 NDB, NDB/DME; § 97.29 ILS, ILS/DME, ISMLS, MLS, MLD/DME, MLS/RNAV; § 97.31 RADAR SIAPs; § 97.33 RNAV SIAPs; and § 97.35 COPTER SIAPs, identified as follows:

** * * Effective September 25, 1986*

South Bend, IN—Michiana Regional, VOR RWY 18, Amdt. 4
South Bend, IN—Michiana Regional, NDB RWY 27, Amdt. 25
South Bend, IN—Michiana Regional, ILS RWY 9, Amdt. 3
South Bend, IN—Michiana Regional, ILS RWY 27, Amdt. 31

** * * Effective August 28, 1986*

Fresno, CA—Fresno-Chandler Downtown, NDB–B, Amdt. 5
Lodi, CA—Lodi, VOR–A, Amdt. 2
Santa Barbara, CA—Santa Barbara Muni, ILS RWY 7, Amdt. 1
Daytona Beach, FL—Daytona Beach Regional, LOC BC RWY 25R, Amdt. 12
Daytona Beach, FL—Daytona Beach Regional, NDB RWY 7L, Amdt. 22
Daytona Beach, FL—Daytona Beach Regional, ILS RWY 7L, Amdt. 26
Daytona Beach, FL—Daytona Beach Regional, RADAR–1, Amdt. 6
Fort Lauderdale, FL—Ft Lauderdale Executive, NDB RWY 8, Amdt. 7
Fort Lauderdale, FL—Ft Lauderdale Executive, ILS RWY 8, Amdt. 3
Albany, GA—Albany-Dougherty County, RNAV RWY 34, Amdt. 3
Camilla, GA—Camilla-Mitchell County, NDB RWY 8, Amdt. 1

Columbus, GA—Columbus Metropolitan, RNAV RWY 23, Orig.
Moultrie, GA—Moultrie Muni, VOR RWY 4, Amdt. 12
Moultrie, GA—Moultrie Muni, VOR RWY 22, Amdt. 9
Thomasville, GA—Thomasville Muni, VOR RWY 22, Amdt. 11
Thomasville, GA—Thomasville Muni, VOR/DME RWY 22, Amdt. 5
Thomasville, GA—Thomasville Muni, LOC RWY 22, Amdt. 3
Thomasville, GA—Thomasville Muni, NDB RWY 22, Amdt. 3
Tifton, GA—Henry Tift Myers, VOR RWY 27, Amdt. 9
Tifton, GA—Henry Tift Myers, VOR RWY 33, Amdt. 11
Tifton, GA—Henry Tift Myers, NDB RWY 33, Amdt. 12
Lihue, HI—Lihue, VOR or TACAN RWY 35, Amdt. 4
Lihue, HI—Lihue, ILS RWY 35, Amdt. 5
Danville, IL—Vermilion County, VOR RWY 21, Amdt. 12
Danville, IL—Vermilion County, VOR/DME RWY 3, Amdt. 10
Danville, IL—Vermilion County, ILS RWY 21, Amdt. 4
Danville, IL—Vermilion County, RNAV RWY 34, Amdt. 3
Galesburg, IL—Galesburg Muni, VOR RWY 2, Amdt. 4
Galesburg, IL—Galesburg Muni, VOR RWY 20, Amdt. 4
Galesburg, IL—Galesburg Muni, ILS RWY 2, Amdt. 7
Detroit, MI—Detroit City, VOR RWY 33, Amdt. 26
Detroit, MI—Detroit City, NDB RWY 15, Amdt. 21
Detroit, MI—Detroit City, ILS RWY 15, Amdt. 8
Detroit, MI—Detroit City, ILS RWY 33, Amdt. 12
Detroit, MI—Detroit Metropolitan Wayne County, NDB RWY 27, Amdt. 8
Detroit, MI—Detroit Metropolitan Wayne County, ILS RWY 27, Amdt. 7
Detroit, MI—Detroit Metropolitan Wayne County, RADAR-1, Amdt. 16
Brookhaven, MS—Brookhaven-Lincoln County, VOR/DME-A, Amdt. 7
Brookhaven, MS—Brookhaven-Lincoln County, NDB RWY 22, Amdt. 2
McComb, MS—McComb-Pike County—John E. Lewis Field, VOR/DME-A, Amdt. 7
McComb, MS—McComb-Pike County—John E. Lewis Field, LOC RWY 15, Amdt. 5
McComb, MS—McComb-Pike County—John E. Lewis Field, NDB RWY 15, Amdt. 4
McComb, MS—McComb-Pike County—John E. Lewis Field, RNAV RWY 33, Amdt. 6
St. Louis, MO—Lambert-St Louis Intl, LOC RWY 12L, Orig.
St. Louis, MO—Lambert-St Louis Intl, LDA/DME RWY 12L, Amdt. 1
St. Louis, MO—Lambert-St Louis Intl, ILS RWY 12R, Amdt. 17
Reno, NV—Reno Cannon Intl, VOR/DME RWY 34L, Amdt. 1
Kileen, TX—Kileen Muni, VOR-A, Amdt. 2
Kileen, TX—Kileen Muni, NDB RWY 1, Amdt. 3
Rice Lake, WI—Rice Lake Muni, VOR RWY 36, Orig.

** * * Effective July 31, 1986*

Miami, FL—Miami Intl, NDB RWY 9R, Orig.

** * * Effective July 3, 1986*

Boise, ID—Boise Air Terminal (Gowen Field), NDB RWY 10R, Amdt. 27
Boise, ID—Boise Air Terminal (Gowen Field), ILS RWY 10R, Amdt. 7
Lakeville, MN—Airlake, ILS RWY 29, Amdt. 1
Ontario, OR—Ontario Municipal Airport, NDB RWY 32, Amdt. 3

** * * Effective July 2, 1986*

Richmond, VA—Richmond Intl. (Byrd Field), MLS RWY 2, Amdt. 1

** * * Effective July 1, 1986*

Cadillac, MI—Wexford County, MLS RWY 25, Amdt. 2

[FR Doc. 86-16346 Filed 7-21-86; 8:45 am]
BILLING CODE 4910-13-M

COMMODITY FUTURES TRADING COMMISSION

17 CFR Parts 1 and 16

Domestic Exchange-traded Commodity Options

AGENCY: Commodity Futures Trading Commission.

ACTION: Rule related notice.

SUMMARY: On August 27, 1982, the Commission published in the **Federal Register** notification of its list of occupation categories for option contracts (47 FR 37880). This list, as amended on January 10, 1983 (48 FR 1047), February 3, 1984 (49 FR 4200), October 15, 1984 (49 FR 40159), October 26, 1984 (49 FR 43048), and December 17, 1985 (50 FR 51385) forms the basis from which the Commission measures commercial participation in domestic exchange-traded commodity options. Futures commission merchants and members of contract markets are required under Commission Rule § 1.37(a), 17 CFR 1.37(a)(1982), to record for each option customer account they carry an appropriate occupation category from a list of such categories set forth by the Commission and a symbol indicating whether the option customer is commercial or non-commercial. In order to accommodate proposed options on coffee "C", frozen pork belly, soybean oil and soybean meal futures, the Commission has determined to revise its current list of occupation categories.

FOR FURTHER INFORMATION CONTACT: Fred Linse, Chief, Agricultural Commodities Unit, Division of Economic Analysis, (202) 254-7303, Commodity Futures Trading Commission, 2033 K Street NW., Washington DC 20581.

SUPPLEMENTARY INFORMATION: The Commission has revised the list of occupation categories for option contracts as follows:

Commodity	Occupation categories
Sugar, cocoa, and coffee "C".	1. Producer. 2. Merchant or dealer. 3. Refiner/processor of raw commodities. 4. Manufacturer of intermediate or final products. 5. Other commercial.
Metals/precious metals	6. Mineral/producer. 7. Primary or secondary refiner. 8. Dealer (metal merchant). 9. Commercial end user. 46. Fabricator or alloyer. [1] 11. Other commercial.
Petroleum	39. Crude oil producer. 40. Crude oil reseller. 12. Refiner. 13. Product marketer and/or distributor. 14. End user. 15. Other commercial.
Financial instruments/foreign exchange.	16. Savings and loan, mortgage bank or thrift institution. 17. Commercial bank. 18. Insurance company. 19. Pension and retirement fund. 20. Mutual fund. 21. Broker/dealer. 22. Foundation or endowment. 23. Other commercial. 24. Importer exporter of goods and services. 25. Investor/issuer of foreign currency denominated securities.
Grains, soybeans, and soybean products.	26. Grain or soybean producer. 27. Producer cooperative. 28. Elevator operator or merchant other than a producer cooperative. 29. Processor, including feed manufacturing and soybean crushing. 30. Livestock feeder or producer. 47. Soybean oil refiner. 31. Other commercial.
Livestock and frozen pork bellies.	32. Farmer or rancher. 33. Commercial feedlot operator. 34. Other livestock feeder. 35. Marketing agency and/or commission merchant. 36. Packer or other meat processor. 37. Meat wholesaler, retailer, or buyer. 38. Other commercial.
Cotton and frozen concentrated orange juice.	41. Producer/grower. 42. Producer/grower cooperative. 43. Merchant wholesaler. 44. Mill operator/processor. 45. Other commercial.

[1] Category 10 intentionally blank.

Under the revisions, Categories 1 through 5, which are currently applicable to cocoa and sugar options also will be applicable to coffee "C" options. In order to accommodate options on frozen pork bellies, current Categories 32 through 38 which are now applicable to livestock options, including a proposed feeder cattle

option, also will be applicable to options on frozen pork bellies. In order to accommodate options on soybean meal and soybean oil, existing Categories 26 through 31, which are currently applicable to grain and soybeans, also will be applicable to options on soybean products and Category 47, Soybean Oil Refiner, has been added.

As is the case with the existing categories, the appropriate classification for a customer is baded on the primary activity of the customer in using the option market in conjunction with its cash market activities.

Issued in Washington, DC on July 17, 1986.

Lynn K. Gilbert,

Deputy Secretary of the Commission.

[FR DOC 86-16423 Filed 7-21-86; 8:45 am]

BILLING CODE 6351-01-M

DEPARTMENT OF ENERGY

Federal Energy Regulatory Commission

18 CFR Part 37

[Docket No. RM85-19-000]

Generic Determination of Rate of Return on Common Equity For Public Utilities

July 16, 1986.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Notice of update to benchmark rate of return on common equity for public utilities.

SUMMARY: In accordance with § 37.5, the Commission issues the update to the "advisory" benchmark rate of return on common equity applicable to rate filings made by electric utilities during the period August through October 1986. This rate is set at 12.75 percent.

EFFECTIVE DATE: August 1, 1986.

FOR FURTHER INFORMATION CONTACT: Ronald L. Rattey, Office of Regulatory Analysis, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 357-8293.

SUPPLEMENTARY INFORMATION:

In accordance with § 37.9 of its regulations, the Commission has determined that the benchmark rate of return on common equity applicable to electric utility rate filings made during the period August 1 through October 31, 1986 is 12.75 percent.[1] This rate represents a decrease of 50 basis points from the benchmark for the prior three month period, May through July.

As provided in § 37.9, the quarterly benchmark rates of return are set equal to estimates of the industry average cost of common equity subject to a 50 basis point limitation on the quarter-to-quarter changes. Between annual proceedings, changes in the estimates of the cost of common equity from one quarter to another are based on changes in the median dividend yield for a sample of electric utilities.[2] The median dividend yield is applied to a formula with fixed adjustment factors determined in the annual proceeding.

The median dividend yields for the sample of utilities for the first and second quarters of 1986 are 7.82 and 7.16 percent, respectively, for an average of 7.49 percent. Using the latter yield produces an industry average cost of common equity estimate of 12.18 percent based on the following formula:[3]

$k_t = 1.02\ (y_t) + 4.54$

where

k_t = average cost of common equity for the jurisdictional operations of public utilities for period t;

y_t = dividend yield applicable to period t;

$_t$ = three month time period August 1 through October 31. Since this cost estimate is greater than 50 basis points below the benchmark for the prior quarter, the new benchmark is determined by the rule's 50 basis point limit on the quarter-to-quarter changes.

The attached appendix provides the underlying data on dividends and market prices for the second quarter of 1986 to support this update. Supporting data for the first quarter of 1986 was published previously. (*See* 51 FR 14982.) Exhibit 1 lists the 99 companies in the initial sample. Exhibit 2 indicates that 14 utilities are excluded in this second quarter because of zero or reduced dividends. Exhibit 3 provides the basic data on dividends and market prices.

Generally, a rule becomes effective not less than 30 days after it is published in the **Federal Register.** A rule may become effective sooner if the agency finds that there is good cause to do so. 5 U.S.C. 553(d) (1982). The Commission finds good cause to make this rule effective August 1, 1986. Specifically, this notice is intended to supplement the generic rate of return rule announced in Order No. 442 (issued December 26, 1985 and effective on February 1, 1986) and the rehearing order on that rule (issued June 11, 1986 and effective July 21, 1986) by applying the method adopted in that rule, as amended on rehearing, to data which was not available. In addition, the benchmark rate of return established by this rule is effective on an advisory basis only.

List of Subjects contained in 18 CFR Part 37

Electric Power Rates, Electric utilities, Rate of return.

PART 37—[AMENDED]

In consideration of the foregoing, the Commission revises Chapter I, Title 18 of the *Code of Federal Regulations,* as set forth below, effective August 1, 1986.

By direction of the Commission.

Kenneth F. Plumb,

Secretary.

1. The authority citation for Part 37 continues to read as follows:

Authority: Federal Power Act, 16, U.S.C. 791a-825r (1982); Department of Energy Organization Act 42 U.S.C. 7101-7352 (1982).

2. In paragraph (d) of § 37.9, the table is revised to read as follows:

§ 37.9 Quarterly Indexing Procedure.

* * * * *

(d) * * *

Benchmark applicability period (t)	Dividend increase adjustment factor (a)	Expected growth adjustment factor (b)	Current dividend yield (y_t)	Cost of common equity (r_t)	Benchmark rate of return
2/1/86 to 4/30/86	1.02	4.54	9.03	13.75	13.75
5/1/86 to 7/31/86	1.02	4.54	8.37	13.08	13.25
8/1/86 to 10/31/86	1.02	4.54	7.49	12.18	12.75
11/1/86 to 1/31/87	1.02	4.54			

APPENDIX

Exhibit No. and title:

1 Initial sample of utilities

2 Utilities excluded from the sample for the indicated quarter due to either zero dividends or a cut in dividends for that quarter or the prior three quarters

3 Quarterly dividend yields for the indicated quarter or the prior three quarters. sample.

Source of data: Standard and Poor's Compustat Services Inc., Utility COMPUSTAT® II Quarterly Data Base.

BILLING CODE 6717-01-M

[1] On December 26, 1985, the Commission issued a final rule amending § 37.9, the quarterly indexing procedure for determining benchmark rates of return on common equity applicable to electric utility rate filings. Generic Determination of Rate of Return on Common Equity for Public Utilities, 51 FR 343 (January 6, 1986) (Docket No. RM85-19-000) (Final Rule) (Order No. 442). Using this procedure, the Commission determined and published benchmark rates of return for the periods February 1 through April 30, 1986 and May 1 through July 31, 1986. 51 FR 3328 (January 27, 1986) and 51 FR 14982 (April 22, 1986). However, on rehearing of the December 26 order, the Commission revised the quarterly indexing procedure (§ 37.9) and the benchmark rates of return for the two aforementioned periods. 51 FR 22505 (June 20, 1986).

[2] The appropriate median dividend yield is defined as the simple average of the median dividend yields for the most recent two calendar quarters for a 100 company sample of electric utilities. As a result of a recent merger between Cleveland Electric Illuminating Co. and Toledo Edison Co. to form Centerior Energy Corp., the number of companies in the sample was reduced to 99 companies during the most recent calendar quarter.

[3] *See* 51 FR 22505 at 22509 (June 20, 1986).

UTILITY	TICKER SYMBOL
ALLEGHENY POWER SYSTEM	AYP
AMERICAN ELECTRIC POWER	AEP
ATLANTIC CITY ELECTRIC	ATE
AZP GROUP INC	AZP
BALTIMORE GAS & ELECTRIC	BGE
BLACK HILLS CORP	BKH
BOSTON EDISON CO	BSE
CAROLINA POWER & LIGHT	CPL
CENTERIOR ENERGY CORP	CX
CENTRAL & SOUTH WEST CORP	CSR
CENTRAL HUDSON GAS & ELEC	CNH
CENTRAL ILL PUBLIC SERVICE	CIP
CENTRAL LOUISIANA ELECTRIC	CNL
CENTRAL MAINE POWER CO	CTP
CENTRAL VERMONT PUB SERV	CV
CILCORP INC	CER
CINCINNATI GAS & ELECTRIC	CIN
COMMONWEALTH EDISON	CWE
COMMONWEALTH ENERGY SYSTEM	CES
CONSOLIDATED EDISON OF NY	ED
CONSUMERS POWER CO	CMS
DELMARVA POWER & LIGHT	DEW
DETROIT EDISON CO	DTE
DOMINION RESOURCES INC-VA	D
DPL INC	DPL
DUKE POWER CO	DUK
DUQUESNE LIGHT CO	DQU
EASTERN UTILITIES ASSOC	EUA
EMPIRE DISTRICT ELECTRIC CO	EDE
FITCHBURG GAS & ELEC LIGHT	FGE
FLORIDA PROGRESS CORP	FPC
FPL GROUP INC	FPL
GENERAL PUBLIC UTILITIES	GPU
GREEN MOUNTAIN POWER CORP	GMP
GULF STATES UTILITIES CO	GSU
HAWAIIAN ELECTRIC INDS	HE
HOUSTON INDUSTRIES INC	HOU
IDAHO POWER CO	IDA
ILLINOIS POWER CO	IPC
INTERSTATE POWER CO	IPW
IOWA ELECTRIC LIGHT & PWR	IEL
IOWA RESOURCES INC	IOR
IOWA-ILLINOIS GAS & ELEC	IWG
IPALCO ENTERPRISES INC	IPL
KANSAS CITY POWER & LIGHT	KLT
KANSAS GAS & ELECTRIC	KGE
KANSAS POWER & LIGHT	KAN
KENTUCKY UTILITIES CO	KU
LONG ISLAND LIGHTING	LIL
LOUISVILLE GAS & ELECTRIC	LOU
MAINE PUBLIC SERVICE	MAP
MIDDLE SOUTH UTILITIES	MSU
MIDWEST ENERGY CO	MWE
MINNESOTA POWER & LIGHT	MPL
MONTANA POWER CO	MTP
NEVADA POWER CO	NVP
NEW ENGLAND ELECTRIC SYSTEM	NES
NEW YORK STATE ELEC & GAS	NGE
NEWPORT ELECTRIC CORP	NPT
NIAGARA MOHAWK POWER	NMK
NORTHEAST UTILITIES	NU
NORTHERN INDIANA PUBLIC SERV	NI
NORTHERN STATES POWER-MN	NSP
OHIO EDISON CO	OEC
OKLAHOMA GAS & ELECTRIC	OGE
ORANGE & ROCKLAND UTILITIES	ORU
PACIFIC GAS & ELECTRIC	PCG
PACIFICORP	PPW
PENNSYLVANIA POWER & LIGHT	PPL
PHILADELPHIA ELECTRIC CO	PE
PORTLAND GENERAL CO	PGN
POTOMAC ELECTRIC POWER	POM
PUBLIC SERVICE CO OF COLO	PSR
PUBLIC SERVICE CO OF IND	PIN
PUBLIC SERVICE CO OF N H	PNH
PUBLIC SERVICE CO OF N MEX	PNM
PUBLIC SERVICE ENTERPRISES	PEG
PUGET SOUND POWER & LIGHT	PSD
ROCHESTER GAS & ELECTRIC	RGS
SAN DIEGO GAS & ELECTRIC	SDO
SAVANNAH ELEC & POWER	SAV
SCANA CORP	SCG
SIERRA PACIFIC RESOURCES	SRP
SOUTHERN CALIF EDISON CO	SCE
SOUTHERN CO	SO
SOUTHERN INDIANA GAS & ELEC	SIG
ST JOSEPH LIGHT & POWER	SAJ
TECO ENERGY INC	TE
TEXAS UTILITIES CO	TXU
TNP ENTERPRISES INC	TNP
TUCSON ELECTRIC POWER CO	TEP
UNION ELECTRIC CO	UEP
UNITED ILLUMINATING CO	UIL
UTAH POWER & LIGHT	UTP
UTILICORP UNITED INC	UCU
WASHINGTON WATER POWER	WWP
WISCONSIN ELECTRIC POWER	WPC
WISCONSIN POWER & LIGHT	WPL
WISCONSIN PUBLIC SERVICE	WPS

EXHIBIT 1

UTILITIES EXCLUDED FROM THE SAMPLE FOR THE INDICATED QUARTER
DUE TO EITHER ZERO DIVIDENDS OR A CUT IN DIVIDENDS FOR
THIS QUARTER OR THE PRIOR THREE QUARTERS

YEAR=86 QUARTER=2

TICKER SYMBOL	UTILITY	REASON FOR EXCLUSION
CMS	CONSUMERS POWER CO	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86
DQU	DUQUESNE LIGHT CO	DIVIDEND RATE REDUCED IN THE QUARTER ENDING 06/30/86
FGE	FITCHBURG GAS & ELEC LIGHT	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86
GPU	GENERAL PUBLIC UTILITIES	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86
GSU	GULF STATES UTILITIES CO	DIVIDEND RATE REDUCED IN THE QUARTER ENDING 06/30/86
KGE	KANSAS GAS & ELECTRIC	DIVIDEND RATE REDUCED IN THE QUARTER ENDING 12/31/85
KLT	KANSAS CITY POWER & LIGHT	DIVIDEND RATE REDUCED IN THE QUARTER ENDING 06/30/86
LIL	LONG ISLAND LIGHTING	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86
MAP	MAINE PUBLIC SERVICE	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 03/31/86
MSU	MIDDLE SOUTH UTILITIES	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86
NI	NORTHERN INDIANA PUBLIC SERV	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86
PIN	PUBLIC SERVICE CO OF IND	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86
PNH	PUBLIC SERVICE CO OF N H	DIVIDEND RATE WAS ZERO FOR THE QUARTER ENDING 06/30/86

N= 13

EXHIBIT 2

ANNUALIZED DIVIDEND YIELDS FOR THE INDICATED QUARTER FOR UTILITIES RETAINED IN THE SAMPLE

10:08 MONDAY, JULY 7, 1986 4

YEAR=86 QUARTER=2

TICKER SYMBOL	PRICE, 1ST MONTH OF QRTR-HIGH	PRICE, 1ST MONTH OF QRTR-LOW	PRICE, 2ND MONTH OF QRTR-HIGH	PRICE, 2ND MONTH OF QRTR-LOW	PRICE, 3RD MONTH OF QRTR-HIGH	PRICE, 3RD MONTH OF QRTR-LOW	DIVIDENDS: ANNUAL RATE	ANNUALIZED DIVIDEND YIELD
AEP	28.375	25.375	26.625	24.250	26.875	25.000	2.260	8.665
ATE	37.500	32.625	36.750	32.500	38.875	36.250	2.620	7.329
AYP	41.500	36.750	41.000	38.375	44.875	40.250	2.800	6.921
AZP	32.000	28.000	29.625	27.000	29.750	26.500	2.720	9.440
BGE	30.375	25.750	30.625	27.750	33.125	27.875	1.800	6.154
BKH	24.750	20.750	24.000	22.375	25.250	22.750	1.140	4.890
BSE	52.625	48.000	51.000	49.000	52.875	49.625	3.440	6.809
CER	32.875	30.750	33.125	31.125	36.250	32.875	2.280	6.944
CES	37.500	34.875	36.500	34.375	40.000	35.000	2.520	6.928
CIN	26.625	23.125	25.000	23.250	25.750	21.875	2.160	8.900
CIP	24.875	22.750	25.125	22.375	27.125	24.500	1.680	6.869
CNH	35.125	30.875	33.750	31.000	34.125	32.625	2.960	8.992
CNL	34.875	31.500	33.000	30.625	33.750	31.500	2.080	6.392
CPL	35.875	32.375	33.875	31.625	34.375	30.250	2.680	8.106
CSR	33.750	30.125	30.875	28.625	31.375	28.625	2.140	7.002
CTP	18.125	16.250	17.375	15.375	18.000	16.250	1.400	8.286
CV	25.625	23.875	24.000	22.750	25.625	23.625	1.900	7.835
CWE	35.625	30.375	32.000	30.000	32.750	29.375	3.000	9.467
CX	29.875	25.625	25.000	22.125	25.500	22.250	2.640	10.534
D	41.875	37.500	39.875	37.750	42.500	38.750	2.840	7.152
DEW	31.750	29.750	31.000	29.250	34.750	30.250	2.020	6.490
DPL	25.000	21.000	23.500	21.500	23.750	21.625	2.000	8.799
DTE	19.250	16.500	17.750	16.375	17.125	15.875	1.680	9.798
DUK	43.000	39.125	42.875	39.500	45.125	41.250	2.600	6.218
ED	45.250	41.000	43.750	42.000	44.250	40.000	2.680	6.275
EDE	28.375	25.875	29.000	27.625	30.250	28.500	1.880	6.650
EUA	37.000	29.875	32.125	26.750	35.750	30.125	2.180	6.826
FPC	39.875	35.375	37.875	35.250	39.375	35.750	2.280	6.121
FPL	34.375	30.000	32.375	30.125	32.000	29.125	2.040	6.511
GMP	24.000	22.500	24.500	23.000	27.625	24.500	1.760	7.227
HE	31.250	28.000	30.250	28.500	31.625	28.500	1.720	5.794
HOU	33.375	30.000	32.000	29.250	31.625	29.125	2.800	9.063
IDA	27.750	24.750	26.000	24.250	28.000	26.000	1.720	6.584
IEL	24.875	21.500	24.625	22.250	24.625	22.625	1.940	8.285
IOR	21.000	19.375	21.938	20.125	23.625	21.375	1.580	7.439
IPC	29.250	25.000	26.625	24.125	27.125	23.875	2.640	10.154
IPL	47.250	42.750	46.875	43.250	50.000	45.000	3.040	6.630
IPW	25.625	23.250	25.625	23.875	26.875	24.375	1.960	7.860
IWG	41.125	37.500	40.500	36.875	42.250	39.625	2.900	7.315
KAN	50.125	46.500	50.125	48.125	52.500	49.250	3.160	6.392
KU	38.000	34.625	38.500	34.625	40.000	36.375	2.520	6.807
LOU	35.875	32.875	35.750	33.750	39.125	34.875	2.520	7.124
MPL	49.750	46.500	53.250	48.000	59.000	51.500	3.040	5.922
MTP	37.125	33.250	38.000	34.125	39.000	35.625	2.480	6.853
MWE	21.688	18.000	22.250	19.750	24.375	20.875	1.480	6.996
NES	28.125	25.125	27.250	25.250	28.000	25.875	1.920	7.217
NGE	33.125	28.375	31.500	28.875	33.000	30.125	2.560	8.303
NMK	25.500	21.250	23.250	20.875	22.375	19.750	2.080	9.383
NPT	20.125	19.000	21.375	19.875	22.375	20.750	1.500	7.287
NSP	32.750	29.563	32.063	30.500	35.375	30.000	1.900	5.992
NU	22.875	19.625	21.125	19.500	22.500	17.750	1.680	8.170

EXHIBIT 3
page 1 of 2

YEAR=86 QUARTER=2

TICKER SYMBOL	PRICE, 1ST MONTH OF QRTR-HIGH	PRICE, 1ST MONTH OF QRTR-LOW	PRICE, 2ND MONTH OF QRTR-HIGH	PRICE, 2ND MONTH OF QRTR-LOW	PRICE, 3RD MONTH OF QRTR-HIGH	PRICE, 3RD MONTH OF QRTR-LOW	DIVIDENDS: ANNUAL RATE	ANNUALIZED DIVIDEND YIELD
NVP	39.875	35.500	39.875	35.625	42.875	39.000	2.840	7.321
OEC	20.750	17.000	19.875	18.000	19.875	18.125	1.920	10.139
OGE	30.875	27.750	30.375	28.500	33.750	30.000	2.080	6.886
ORU	32.000	30.250	32.375	30.125	35.375	31.875	2.140	6.687
PCG	23.375	21.000	23.250	21.000	23.250	21.250	1.920	8.654
PE	20.250	17.250	18.875	17.250	20.375	17.125	2.200	11.879
PEG	38.750	34.625	38.125	34.625	37.500	35.000	2.960	8.123
PGN	27.500	25.375	28.250	24.250	31.000	27.750	1.960	7.165
PNM	37.125	31.500	34.000	31.250	33.750	30.500	2.920	8.843
POM	42.750	39.625	43.250	40.000	47.875	43.000	2.360	5.520
PPL	33.250	31.250	33.625	31.125	34.000	31.875	2.560	7.872
PPW	36.375	32.375	33.750	31.375	36.875	31.750	2.400	7.111
PSD	22.750	19.875	21.000	19.625	22.375	19.875	1.760	8.414
PSR	22.375	18.875	19.750	17.500	20.125	18.250	2.000	10.267
RGS	27.875	24.125	25.750	24.250	28.250	25.500	2.200	8.475
SAJ	30.750	27.875	30.375	28.000	32.500	28.500	1.820	6.135
SAV	29.625	27.000	33.750	28.875	35.000	32.625	1.760	5.651
SCE	31.625	28.375	31.375	28.500	32.125	29.000	2.280	7.558
SCG	34.000	31.375	34.375	31.250	36.750	33.000	2.240	6.695
SDO	34.250	31.375	34.125	31.500	36.750	33.250	2.380	7.096
SIG	35.000	32.625	33.750	31.750	35.375	31.500	1.960	5.880
SO	25.000	21.875	23.375	20.375	23.875	20.750	2.040	9.050
SRP	23.875	21.500	22.750	21.750	24.375	22.250	1.660	7.297
TE	43.250	39.875	41.750	40.125	46.750	41.250	2.520	5.976
TEP	54.750	49.125	53.750	51.000	59.500	52.000	3.300	6.185
TNP	20.875	19.750	21.500	20.000	20.875	20.375	1.320	6.419
TXU	35.250	31.500	32.875	30.750	31.875	29.750	2.680	8.375
UCU	34.069	31.127	33.701	30.375	32.750	30.375	1.451	4.525
UEP	25.625	22.750	25.250	21.250	27.875	22.750	1.840	7.588
UIL	35.750	29.000	32.375	27.250	30.875	27.750	2.320	7.607
UTP	30.000	27.875	30.500	28.125	29.875	27.875	2.320	7.989
WPC	51.125	46.125	50.000	46.750	55.375	49.375	2.680	5.382
WPL	49.750	46.000	48.125	44.750	49.875	47.500	2.840	5.958
WPS	49.500	45.625	49.250	46.375	50.375	47.750	2.860	5.940
WWP	31.500	28.000	29.750	27.625	29.875	27.250	2.480	8.552

N= 86

EXHIBIT 3
page 2 of 2

18 CFR Part 270

[Docket No. RM 86-3-002]

Ceiling Prices; Old Gas Pricing Structure

Issued July 17, 1986.

AGENCY: Federal Energy Regulatory Commission.

ACTION: Interim order on rehearing.

SUMMARY: The Commission is amending its regulations at 18 CFR 270.201(a)(3)(i) (1986) to permit parties to mutually agree to preserve their rights under the good faith negotiation procedures established in Order No. 451, even though they execute an amendment to an existing contract after July 18, 1986. This will permit parties to make necessary contract amendments and yet not constitute a disincentive to voluntary renegotiations.

EFFECTIVE DATE: July 18, 1986.

FOR FURTHER INFORMATION CONTACT: Richard Howe, Jr., Office of the General Counsel, Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, (202) 357-8308.

SUPPLEMENTARY INFORMATION:

Interim Order on Rehearing

Before Commissioners: Anthony G. Sousa, Acting Chairman; Charles G. Stalon, Charles A. Trabandt and C. M. Naeve.

On June 6, 1986, the Commission issued Order No. 451[1] establishing an alternative maximum lawful ceiling price for old gas. Order No. 451 also established a "good faith negotiation rule" which the producer must comply with before collecting a higher price under an existing contract.[2] On July 1, 1986, the Indicated Producers filed a motion to clarify § 270.201(a)(3)(i) of the Commission's regulations as promulgated by Order No. 451. That section provides that an existing contract may not be renegotiated under the good faith negotiation rule if the parties "have renegotiated the price or any other terms for the sale of any old gas under the contract after July 18, 1986, with or without using the good faith negotiation procedures of this section."

Indicated Producers observe that parties often must make routine amendments to their contracts for operational and other reasons; these amendments include changes in delivery points, quality specifications, and billing procedures. Also, Indicated Producers state that parties are currently negotiating limited-term price reductions and take-or-pay settlements. Indicated Producers assert that if such amendments are make after July 18, 1986, the operation of § 270.201(a)(3)(i) would cause producers to lose their rights under the good faith negotiation rule with respect to the amended contract and that as a result producers would be reluctant to enter into any contract amendments subsequent to July 18, 1986, however minor, until each producer has reviewed its contracts with a purchaser to determine the consequences of the loss of its rights under the good faith negotiation rule. This allegedly could result in the unnecessary deferral of necessary and beneficial amendments to contract and even result in the shutting in of some gas supplies.

Five other petitioners, including the American Gas Association (AGA) and the Interstate Natural Gas Association of America (INGAA), raise the same issue in their requests for rehearing [3] and seek amendment of §270.201(a)(3)(i) in order to permit parties to amend contracts without loss of their rights under the good faith negotiation rule. On July 10 and 11, 1986, El Paso Natural Gas Company and Northwest Central Pipeline Corporation filed answers to the motion of Indicated Producers, supporting Indicated Producers' proposal to permit parties to mutually agree to amend their contracts but preserve their rights under the good faith negotiation rule.

The purpose of § 270.201(a)(3)(i) was to provide encouragement for voluntary renegotiation of contracts in light of the higher ceiling price adopted by Order No. 451 while at the same time adhering to DOE's proposal that a party's right to renegotiate a contract would be available on a one-time only basis. Without the subject regulation, purchasers who voluntarily renegotiated contracts with their producers could be subject to requests for further renegotiation under the good faith negotiation rule at a later date. In such circumstances purchasers might well be reluctant to voluntarily renegotiate their contracts outside the parameters of the good faith negotiation rule. The regulation at issue was promulgated so as to encourage comprehensive voluntary renegotiation of old gas contracts without the need to resort to the mandatory renegotiation procedures of the good faith negotiation rule. However, the Commission did not intend to cause parties to lose their rights under the good faith negotiation rule as a result of making routine amendments to their contracts in an ordinary or customary manner necessary to facilitate the normal working of their contractual relationship. The producers are correct, however, that under the rule as drafted any amendment executed after July 18, no matter how minor, would deprive the parties of their rights under the good faith negotiation rule with regard to the contract. The Commission will accordingly amend the rule on an interim basis, subject to further consideration and prospective modification in the order on rehearing, so as to eliminate this unintended effect.

Indicated Producers suggest four different methods for amending or clarifying the regulation to avoid the problem they have described. These suggestions are as follows:

1. Delete § 270.201(a)(3)(i), thereby allowing producers to invoke their rights under the good faith negotiation procedures commencing on November 1, 1986, regardless of whether they have previously renegotiated existing contracts for the sale of old gas informally after July 18, 1986.

2. Delete the phrase "or any other terms" from the clause in question, so that only informal renegotiations of the *price* of old gas after July 18, 1986, would bar subsequent resort to the good faith negotiation procedures.

3. Establish November 1, 1986, rather than July 18, as the date after which informal amendments to existing contracts would preclude subsequent resort to the good faith negotiation procedures.

4. Amend the clause in question to permit parties to mutually consent to preserve their rights under the good faith negotiation procedures, even though they execute an amendment to an existing contract for old gas after July 18, 1986. AGA, INGAA, El Paso and Northwest Central all support this proposal. Florida Gas Transmission Company and Transwestern Pipeline Company suggest a similar proposal of amending the clause in question so that parties may amend their contracts without losing their rights under the

[1] 51 FR 22,168 (June 18, 1986).

[2] Order No. 451 becomes effective on July 18, 1986. However, no producer may make a nomination request under the good faith negotiation rule before November 1, 1986.

[3] Panhandle Eastern Pipe Line Company at 17, Transwestern Pipeline Company at 22, INGAA at 17, Florida Gas Transmission Company at 28, and AGA at 34.

good faith negotiation rule unless they mutually agree to waive those rights.[4]

Indicated Producers' fourth proposal appears reasonable as a means of accomplishing the goals suggested by Indicated Producers and others of permitting parties, if they desire, to make routine, or for that matter substantial, amendments without loss of their rights under the good faith negotiation rule. However, this suggestion does not deter voluntary renegotiation since the producer would retain its rights under the good faith negotiation rule only if the purchaser so agreed. Accordingly, the Commission adopts this suggestion subject to further consideration and prospective modification on rehearing.

The Administrative Procedure Act generally requires that a substantive rule be published "not less than 30 days before its effective date." 5 U.S.C. 553(d). The primary purpose of the delayed effective date requirement is to give those affected a reasonable time to prepare to comply with the proposed rule. There is an exception to the advance notice requirement for "a substantive rule which grants or recognizes an exemption or relieves a restriction" 5 U.S.C. 553(d)(1). Since the amendment adopted by this order relieves a restriction on the parties' freedom to bargain for retention of the good faith negotiation procedures, it may be made effective upon less than 30 days notice on July 18, 1986, concurrently with the effective date of Order No. 451. This order so provides.

The Commission's action herein only grants rehearing on an interim basis, and is not to be construed as a final action on the merits of any rehearing application of Order No. 451 now pending before the Commission.

List of subjects in 18 CFR Part 270

Natural gas, Price controls, Reporting and recordkeeping requirements.

PART 270—(AMENDED)

In consideration of the foregoing, the Commission is amending Part 270, Title 18, *Code of Federal Regulations*, as set forth below.

By the Commission.

Kenneth F. Plumb,

Secretary.

1. The authority citation for Part 270 continues to read as follows:

Authority: Natural Gas Act, 15 U.S.C. 717–717w (1982); Department of Energy Organization Act, 42 U.S.C. 7101–7352 (1982); Executive Order No. 12,009, 3 CFR 142 (1978); Natural Gas Policy Act of 1978, 15 U.S.C. 3301–3432 (1982).

2. Section 270.201 is amended by revising paragraph (a)(3)(i) as follows:

§ 270.201 Good faith negotiation procedures.

(a) *Applicability and general rule.*

* * *

(3) * * *

(i) the parties to the contract have renegotiated the price or any other terms for the sale of any old gas under the contract after July 18, 1986, without agreeing in writing to preserve their rights under this section, whether or not the parties have utilized the good faith negotiation procedures of this section; or

* * * * *

[FR Doc. 86–16416 Filed 7–21–86; 8:45 am]

BILLING CODE 6717-01-M

[4] Panhandle Eastern Pipe Line Company would permit amendments to any contract provisions other than those concerning price and delivery terms without loss of good faith negotiation rights.

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 143

[T.D. 86–143]

Special Procedures for Clearance of Cargo Carried by Courier or Express Air Services

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: Customs is amending its regulations relating to the informal entry and clearance of merchandise transported by courier and express air services. The amendments will, for the first time, specifically make the informal entry procedures available to courier and express air services, and, with the exception of restricted and prohibited merchandise, and merchandise subject to quota or quantitative restraints, will apply to merchandise not exceeding $1,000 in value. Customs will provide expedited clearance procedures in recognition of the special needs of the growing courier and express air industry. The amendments will promote uniform, fair, and consistent treatment of the various courier and express air services, while at the same time assuring the protection of the revenue in accord with all applicable laws and regulations.

EFFECTIVE DATE: August 21, 1986.

FOR FURTHER INFORMATION CONTACT: Jerrold O. Worley, Office of Inspection and Control, U.S. Customs Service, 1301 Constitution Avenue NW., Washington, DC 20229 (202–566–8151).

SUPPLEMENTARY INFORMATION: .

Background

All imported merchandise entering the customs territory of the U.S. is subject to procedures relating to entry and clearance. The procedures ensure the proper appraisement, valuation, and tariff classification of the merchandise for the purpose of collecting the lawful amount of duties, as well as compliance with all other laws and regulations administered and enforced by Customs. Different procedures are provided for the entry and clearance of merchandise depending upon its value. There are formal entry procedures set forth in Part 141, Customs Regulations (19 CFR Part 141), with certain exceptions, applicable to shipments valued in excess of $1,000, and informal entry procedures set forth in Part 143, Customs Regulations (19 CFR Part 143), for the most part limited to shipments valued at $1,000 or less.

Although the procedures for the informal entry of merchandise are less cumbersome and comprehensive than those for formal entry, they may still present an impediment to courier and express air services seeking to fulfill their obligations.

The most recent development in the express air industry is the planned rapid expansion of services from foreign locations to the U.S. These express air services fly into various hub cities in the midwest U.S. at which Customs has limited manpower, and at non-traditional business hours (generally between 10:00 p.m. and 3:00 a.m.). The interplay of these factors (the necessity for expeditious clearance of merchandise, and the limited Customs service available at the hub locales at off-peak time periods) necessitates the institution of special procedures applicable only to this industry.

The companies concerned are able to provide Customs with certain useful advance information on incoming international shipments. However, other information necessary for the normal entry process is not always available in advance of arrival, such as the importer number and tariff classification item number from the Tariff Schedules of the United States (TSUS; 19 U.S.C. 1202).

In view of the special needs of the courier and express air industry and the inability to have access to complete advance information, by notice published in the **Federal Register** on October 21, 1985 (50 FR 42569), Customs proposed to amend Part 143, Customs Regulations (19 CFR Part 143), by setting forth new procedures to apply to courier and express air services. Specifically, § 143.21 would be amended to state that

cargo transported by courier and express air services may use the informal entry procedures. Additionally, a new § 143.29 set forth the exact procedures applicable to these courier and express air services. The amendment provides that for shipments valued at $250 or less, an invoice or advance manifest must be presented to Customs which contains necessary information such as the shipper's address, name and address of the consignee, value and country of origin of the merchandise, and a description of the merchandise, prior to arrival of a shipment. Submission of this information is permitted as an accommodation to the courier and express air services, and will be submitted in lieu of the normal entry documents (Customs Form 3461, Application for Special Permit for Immediate Delivery; Customs Form 5119, Informal Entry). The amendment requires that for shipments valued over $250 but not more than $1,000, the previous information must be supplemented by the addition of the appropriate TSUS item number for tariff classification purposes.

Section 321, Tariff Act of 1930, as amended (19 U.S.C. 1321), provides that in order to avoid expense and inconvenience to the Government which is disproportionate to the amount of revenue that would be collected, the Secretary of the Treasury is authorized to promulgate regulations to waive import duties on shipments valued at $5.00 or less in the country of shipment.

Accordingly, § 10.151, Customs Regulations (19 CFR 10.151), provides for the waiver of duty on such shipments, unless the district director has reason to believe that the shipment is one of several lots covered by a single order or contract and that it was sent separately for the express purpose of securing free entry, or of avoiding compliance with any pertinent law or regulation. To expedite the entry and clearance of shipments valued at $5.00 or less, under the amendment the courier and express air services will be required to segregate those shipments from others on the advance manifest, if the manifest is to be used as the entry document. The courier and express air services also will be required to present a properly executed Entry Summary (Customs Form 7501) within 10 days of filing an entry, with estimated duties attached. Finally, the amendment provides that Customs will accept an annual blanket Customs Form 3461, in which the importer of record assumes all liability for shipments released under the new expedited procedures. The blanket form will be required each year before a courier or express air service commences operations using the new procedures.

Analysis of Comments

The numerous comments received in response to the notice were submitted by Customs brokers, air express services, government offices, and members of Congress. A discussion of the issues raised and our response follows:

Many commenters stated that the proposal does not comply with the statutory requirements concerning parties legally authorized to submit written documentation for the entry of merchandise into the U.S. Section 484, Tariff Act of 1930, as amended (19 U.S.C. 1484), provides that only the owner, purchaser, or licensed broker may submit entry documentation. The commenters incorrectly perceived the proposal as allowing couriers or express air services to perform this function. The courier and express air services are merely nominal consignees who must designate licensed brokers to make entry of merchandise. The broker becomes the importer of record and the bond of the broker is liable for any deficiencies. Appropriate changes have been made to accurately reflect this point.

Many commenters expressed concern about the ability of Customs to maintain enforcement capabilities under the new procedures. Customs is aware of the potential for smuggling and other abuses. Customs currently conducts random intensive examinations of merchandise from courier and air express shipments with the use of specially trained personnel and detector dogs, and will continue that practice. Further, audits will be conducted on the operations of the express companies and brokers to ensure that proper duty has been collected. Cooperative agreements are being negotiated with the companies which set forth specific preventative steps that can be taken to ensure that smuggling and other abuses are detected and reported to Customs.

Some parties questioned whether the new procedures might be used to circumvent quota or visa requirements on merchandise. The new procedures are not available for merchandise subject to any prohibition or restriction, or to quota or quantitative restraints, and individual entries must be filed for such articles. Full tariff data is required to be filed on the entry summary documentation so no statistical information will be lost.

Some commenters claim that the new procedure illegally creates different classes of merchandise based upon value and promotes unequal treatment of entries. Under section 498, Tariff Act of 1930, as amended (19 U.S.C. 1498), as amended by section 206 of Pub. L. 98–573, the Trade and Tariff Act of 1984, clear authority is established to prescribe regulations for the entry of merchandise valued at $1250, or less. In fact, different treatment already exists for different classes of informal entries. Passengers are allowed to list accompanied shipments on their baggage declaration, and mail shipments are examined and released on the basis of a simple declaration form on the package. This new procedure is designed to treat small express parcels in a fashion similar to that used for U.S. Postal Service parcels. The information on the commercial invoice is sufficient for examination and release purposes. The broker who files the entry must furnish the full entry summary within 10 days. We will audit brokers employed by the courier and air express industry to ensure that accurate information is supplied. The new procedures simply eliminate the need to prepare Customs documentation on numerous small shipments when the information required is already present on the existing commercial documentation.

Some parties have requested that Customs define courier or express air services. We are aware of no accepted international definition. However, generally, a courier company uses air passengers to carry shipments as baggage on an arriving international air carrier. An express air service ships the freight as air cargo. In both cases, the shipments are limited in size and weight, and the company is responsible for the door to door service to the ultimate consignee. The companies provide a complete "closed loop" transaction including Customs clearance through their brokers. Many of the air express companies use central facilities located in interior U.S. cities to clear the cargo through Customs, and route it to its ultimate destination. Airlines may establish small parcel express services and use these procedures, provided they provide door to door service, including Customs clearance.

Comments were received concerning the impact the new rules will have on Customs inspectional manpower and overtime. Generally, service is provided equally to all parties based upon the volume of work and the availability of manpower. However, since service is provided at some express air companies at small inland ports outside of normal port hours and for the sole benefit of the party in interest, Customs is able to

obtain complete reimbursement for the costs of personnel assigned, including salary, benefits, and administrative costs. These reimbursable positions are established in addition to the normal complement of Customs personnel assigned to these ports and will not result in a reduction of the level of service to other parties during normal business hours.

Some concern was expressed that the new procedure will give unfair benefits to private companies competing with the express service offered by the U.S. Postal Service. Customs provides officers for the clearance of postal shipments without reimbursement from the Postal Service. There have been complaints from the Postal Service because Customs officers are not usually assigned on weekends or at night. While this is true, it is noted that the private courier and express air services pay overtime or complete reimbursement for services provided outside of normal working hours. The Postal Service can obtain the services of a broker and pay the same charge as private companies.

In this time of Federal deficits and the need to reduce the operating costs of Federal agencies, Customs is not able to provide additional personnel for clearance without reimbursement. Private companies and the Postal Service are treated the same in so far as documentation is concerned. Postal shipments arrive with a postage declaration form affixed which contains less information than the commercial invoice, although the invoice is usually inside the package. The Customs officer at the mail facility makes a decision to examine a parcel based upon information on the declaration form. As in the case of mail shipments, the Customs officer at a private facility examines as many parcels as are necessary. A broker provides the necessary entry paperwork for shipments examined at private facilities, and is liable under his bond for any irregularities. In many ways, the procedure for the clearance of parcels for courier and express air services is more stringent than the procedure for postal parcels.

Several commenters suggested that Customs waive the collection of small amounts of duty on shipments under $25 in value or when $10 or less in duty is involved. As previously discussed in this document, 19 U.S.C. 1321 provides authority to waive duties on shipments valued at $5.00 or less. Congress would have to enact new legislation to enable Customs to waive entry on shipments over $5.00 in value. It is noted that the costs of collection are minimized to Customs if all the appraisement work is done by a broker.

Several parties have asked Customs to revise the distinction made between shipments $250 and under and those over $250 but not more than $1,000. This distinction was made in the notice due to the special requirements for formal entries concerning sensitive commodities such as textiles. Customs still believes that there is a need to be provided with tariff item numbers for shipments valued over $250. However, we will review our experience in processing shipments under this procedure at a later date to determine if it is feasible to change this requirement.

It was suggested that brokers making entries under the new procedure be specifically required to maintain records on their transactions. Customs brokers are already required to maintain records of all transactions pursuant to § 111.21, Customs Regulations (19 CFR 111.21), and to make these records accessible to Customs for audit. It is not necessary to create additional requirements.

It was also suggested that the new procedure be extended to formal as well as informal entries. The requirements for formal shipments are much more rigid than informal shipments. Customs needs additional information, such as tariff item numbers, in order to process a formal shipment through the new computerized Automated Commercial System (ACS) cargo selectivity program. The additional information requirements make Customs aware of other agencies' requirements and examination instructions. Brokers and importers may use the new Automated Brokers Interface (ABI) System in order to transmit entry data and receive timely notice of merchandise release status. Therefore, on both operational and legal grounds, the simplified procedures should not be extended to formal entries.

One commenter requested that the final rule on this matter be delayed until a decision is made on another proposal concerning consoldiated shipments. That project, which was published in the **Federal Register** on December 24, 1985 (50 FR 53532), concerns the right of a nominal consignee to designate a broker if the shipper or owner specifies a different broker, or the consignee wishes to make entry on his own behalf. This is a particular problem when a freight forwarder handles a consolidated shipment consisting of many house bills traveling under one master bill.

While the consoldiated shipment proposal is a related matter, it does not directly impact upon this new procedure. The nominal consignee, in this case the courier or air express service, is assumed to have the right to designate a broker. If he does not have that right, the procedure cannot be used by the broker of the courier or air express service. A decision on the consoldiated shipment project will be the subject of another **Federal Register** document.

One commenter asked that the air waybill document of a particular courier service be accepted as the entry/release document in lieu of the commercial invoice, since it contains an invoice section. This proposal cannot be accepted because the person who completes the air waybill may not be the actual shipper or manufacturer who prepares the commercial invoice. Customs needs the precise data contained on the commercial invoice. However, Customs is willing to accept facsimile invoices or an advance manifest prepared by the automated system of the courier or air express company.

Some commenters questioned the statement in the proposal that the amendment would not have a significant economic impact on a substantial number of small entities under the terms of the Regulatory Flexibility Act. They are apparently concerned about the competitive effect of the proposal on brokers, freight forwarders and other similar organizations, although no specifics are provided.

The purpose of the amendment is clearly explained in the document. Customs does not believe that the amendment will have a significant effect on the business of these groups. Courier and express air service companies must still use a licensed broker to transact Customs business. Some brokers may obtain more business, others less, regardless of this change. We are not aware of any significant impact on freight forwarders or other "similar organizations".

A final issue for consideration is the problem of the proper control of entries at central courier facilities, such as those which are being established at JFK Airport in New York, and at Miami International Airport. Numerous courier services and their brokers will use these facilities, and it will be difficult to ensure that the necessary Entry Summary (CF 7501) is filed within 10 days for the cargo released under the new informal entry procedures. Customs uses the entry number on the Application for Special Permit for Immediate Delivery (CF 3461) as the control mechanism to ensure that entry summaries are presented in a timely

manner. This is done through the Customs computerized cargo selectivity system. It would be too labor intensive to maintain a paper control system for the many informal shipments released by brokers at a centralized courier facility. Therefore, at such locations, the district or area director may require a CF 3461 for each day's or each flight's informal entries released under this procedure. The CF 3461 will be completed except for the description of the merchandise. The commercial invoices or advance manifest will be attached to the CF 3461. The CF 3461 will contain a notation that it covers various informal entries released under § 143.29, Customs Regulations (19 CFR 143.29). The CF 3461 should also indicate the total number of invoices attached. This will meet the control objectives of Customs without sacrificing the benefits of reduced documentation.

After consideration of the numerous comments received in response to the notice, and following further review of the matter, it has been determined advisable to adopt the proposal with minor modifications.

Executive Order 12291

This is not a "major rule" as defined in § 1(b) of E.O. 12291. Accordingly, a regulatory impact analysis is not required.

Regulatory Flexibility Act

Under the provisions of the Regulatory Flexibility Act (5 U.S.C. 301 *et. seq.*), it is certified that these amendments will not have a significant economic impact on a substantial number of small entities.

Drafting Information

The principal author of this document was Larry L. Burton, Regulations Control Branch, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 143

Customs duties and inspection, Imports.

Amendments to the Regulations

Part 143, Customs Regulations (19 CFR Part 143), is amended as set forth below:

PART 143—CONSUMPTION, APPRAISEMENT, AND INFORMAL ENTRIES

1. The authority citation for Part 143 continues to read as follows:

Authority: 19 U.S.C. 66, 1481, 1484, 1498, 1624.

2. Section 143.21 is amended by adding, at the end thereof, a new paragraph (l) to read as follows:

§ 143.21 Merchandise eligible for informal entry.

* * * * *

(l) Cargo transported by courier and air express services not exceeding $1,000 in value, with the exception of prohibited and restricted merchandise, merchandise subject to quota or quantitative restraints, or in any instance in which the district director may require formal entry under § 143.22 of this Part. (See § 143.29 of this part).

3. Part 143 is amended by adding a new § 143.29, to read as follows:

§ 143.29 Special informal entry procedures for cargo transported by courier and express air services.

This procedure is available for accompanied or air shipments not exceeding $1,000 in value imported by courier and express air services, with the exception of prohibited and restricted merchandise, merchandise subject to quota or quantitative restraints, or in any instance in which the district director may require formal entry under § 143.22 of this part.

(a) *Shipments valued at $250 or less.* To obtain expedited clearance under this section, the party with the right to file entry shall submit a copy of the invoice or advance manifest containing necessary information including name and address of the shipper, name and address of the consignee, value of the merchandise, country of origin of the merchandise, and description of the merchandise. The completed invoice or advance manifest will be accepted by Customs in lieu of a Customs Form 3461 (Application for Special Permit for Immediate Delivery), or Customs Forms 7501 or 5119 (Informal Entry), as the entry control document.

(b) *Shipments valued in excess of $250 and not exceeding $1,000.* In addition to the information required on the documentation specified in paragraph (a) of this section, the appropriate item number from the Tariff Schedules of the United States (TSUS; 19 U.S.C. 1202), must be furnished for classification purposes.

(c) If an adverse manifest is used as the entry document, shipments valued in excess of $5.00 must be segregated from those valued at $5.00 or less.

(d) Within 10 days of the filing of the entry, the Entry Summary (Customs Form 7501) must be presented, in proper form, with estimated duties attached.

(e) An Application for Special Permit for Immediate Delivery (Customs Form 3461), appropriately modified to cover all importations under the special procedures provided in this section for a period of 1-year, shall be submitted to the district director before the procedure permitted by this section shall be commenced by the courier or air express service.

(f) *Centralized courier facilities.* At airports with high volumes of accompanied courier traffic at a central facility with numerous couriers and their brokers, the district director may require an individual Application for Special Permit for Immediate Delivery (Customs Form 3461), from the brokers representing each courier and covering the various eligible shipments per day or per flight. The commercial invoices or advance manifests will be attached to the Customs Form 3461 which will contain the entry number and other necessary information. In lieu of a description of the merchandise, a notation will be inserted indicating that the entry covers multiple shipments in accordance with this section.

William von Raab,

Commissioner of Customs.

Approved: July 2, 1986.

Francis A. Keating II,

Assistant Secretary of the Treasury.

[FR Doc. 86-16413 Filed 7-21-86; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF STATE

22 CFR Parts 22, 52, and 53

[Department Regulation 108.852]

Schedule of Fees for Consular Services

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State amends 22 CFR Part 22, Schedule of Fees for Consular Services. Since no public comments on the proposed rule have been received, § 22.1 is amended as proposed. These amendments increase the immigrant visa application fee, decrease the immigrant visa issuance fee, and increase crew list visa fees. In addition, the fees for authentication of original documents of marriage, for document searches, and for granting an exception to travel control regulations (passport waiver) are also increased. The Schedule is being changed in accordance with a recent study of policies, costs and fees for consular services and with the user charge principle, as prescribed by the Congress and applied by the Department in keeping with Office of

Management and Budget guidelines. The Witness to Marriage item is eliminated from the Schedule since the service is rarely used and now redundant. Parts 52 and 53 of 22 CFR are also amended to conform with the amendments to § 22.1.

EFFECTIVE DATE: October 1, 1986.

FOR FURTHER INFORMATION CONTACT: Sylvia J. Bazala, (202) 647–3118.

SUPPLEMENTARY INFORMATION: The amendments to 22 CFR, Part 22, Schedule of Fees for Consular Services, were published as a proposed rule on May 14, 1986, (51 FR 17651)

List of Subjects

22 CFR Part 22

Passports and Visas.

22 CFR Part 52

Foreign Service.

22 CFR Part 53

Emergency powers, Travel restrictions.

Parts 22, 52, and 53 of Title 22 CFR are amended as follows:

PART 22—SCHEDULE OF FEES FOR CONSULAR SERVICES—DEPARTMENT OF STATE AND FOREIGN SERVICES

1. The authority citation for 22 CFR Part 22 continues to read as follows:

Authority: Secs. 3, 4, 63 Stat. 111, as amended (22 U.S.C. 811a; 2658; 22 U.S.C. 2651; 5 U.S.C. 583a; 22 U.S.C. 1201); E.O. 10718, 22 FR 4632; 3 CFR 1954–1958 Comp. page 382.

§ 22.1 [Amended]

2. Section 22.1 is amended as follows:

A. Item No. 13(b) is removed.

B. Item No. 13(c) revised.

C. Item No. 16 is revised.

D. Item No. 20 is revised.

E. Item No. 21 is revised.

F. Item No. 24 is revised.

G. Item No. 88 is revised.

As amended, the revised portions of § 22.1 reads as follows:

§ 22.1 Schedule of fees [Amended]

Item number	Fee
Passport and Citizenship Services	
* * * * *	
13 * * *	
(c) Authentication of original documents of marriage per copy	$36.00
* * * * *	
16. Granting an exception under 22 CFR 53.2(h) of Travel Control Regulations	$80.00
* * * * *	
Visa Services for Aliens	
* * * * *	
20. Furnishing and verification of application for immigrant visa, including duplicate copy [112-IV-APPL]	$125.00
* * * * *	
21. Issuance of each immigrant visa [113-IV ISSUANCE], [114-R IV ISS], [115-211 WAIV/ISS]	$25.00
* * * * *	
24. Visa or supplemental visa of alien crew list: (If item 93 is applicable, only one Surcharge shall be applied per group served on the same visit):	
(a) Up to 40 crew members	$37.00
(b) 41 to 100 crew members	$86.00
(c) 101 to 200 crew members	$185.00
(d) Over 200 crew members	$246.00
* * * * *	
Other Consular Services	
* * * * *	
88. Searching for and forwarding a document requested from a Foreign Service post by a non-government individual organization or group (for each document)	$13.00
* * * * *	

PART 52—MARRIAGES

1. The authority citation for Part 52 continues to read as follows:

Authority: Sec. 4, 63 Stat. 111, as amended; 22 U.S.C. 2658.

2. Sections 52.2 and 52.3 are removed. Sections 52.4 and 52.5 are redesignated as § 52.2 and § 52.3, respectively.

PART 53—TRAVEL CONTROL OF CITIZENS OF UNITED STATES IN TIME OF WAR OR NATIONAL EMERGENCY

1. The authority citation for Part 53 continues to read as follows:

Authority: Sec. 215, 66 Stat. 190; 8 U.S.C. 1185. Proc. 3004, 18 FR CFR, 1949–1953 Comp.

Section 53.2 Exceptions is amended by revising paragraph (h) to read as follows:

§ 53.2 Exceptions.

* * * * *

(h) When specifically authorized by the Secretary of State through appropriate official channels to depart from or enter the United States, as defined in § 50.1 of this chapter. The fee for a waiver of the passport requirement under this section shall be collected in the amount prescribed in the Schedule of Fees for Consular Services [22 CFR 22.1].

Dated: July 7, 1986.

Ronald I. Spiers,

Under Secretary for Management.

[FR Doc. 86–15825 Filed 7–21–86; 8:45 am]

BILLING CODE 4710–06–M

VETERANS ADMINISTRATION

38 CFR Part 19

Appeals—General; Rules of Practice

AGENCY: Veterans Administration.

ACTION: Final regulations.

SUMMARY: The Veterans Administration is amending 38 CFR 19.129(b) to clarify that a response is not required to the Supplemental Statement of the Case for the perfection of an appeal, unless the Supplemental Statement of the Case pertains to issues that were not included in the original Statement of the Case; and provided that a timely response has been made to the Statement of the Case. The Board of Veterans Appeals is also amending 38 CFR 19.132 to include an additional holiday as a result of recently passed legislation. The birthday of Martin Luther King, Jr., will be observed on the third Monday in January.

EFFECTIVE DATE: July 18, 1986.

FOR FURTHER INFORMATION CONTACT: Mr. Jan Donsbach, Special (Legal) Assistant to the Chairman, Board of Veterans Appeals, Veterans Administration, 810 Vermont Avenue NW., Washington, DC 20420 (202–389–2978).

SUPPLEMENTARY INFORMATION: Proposed amendments to 38 CFR Part 19 were published in the **Federal Register** of December 11, 1985, at page 50632. Interested persons were given 30 days in which to submit comments, suggestions or objections. The Veterans Administration received one comment. It was suggested that Rule 29 should not apply where the Supplement Statement of the Case pertains solely to issues that were not included in the original Statement of the Case, i.e., entirely new issues. This suggestion which assisted in clarifying this rule was adopted.

The Administrator hereby certifies that these final rules will not, if promulgated, have a significant economic impact on a substantial number of small entities as they are defined in the Regulatory Flexibility Act (RFA), 5 U.S.C. 601–612. Pursuant to 5 U.S.C. 605(b), these final rules therefore are exempt from the initial and final regulatory flexibility analyses requirements of sections 603 and 604. They will have no significant direct impact on small entities (i.e., small businesses, small private and nonprofit organizations, and small governmental jurisdictions).

The Agency has also determined that these rules are nonmajor in accordance with Executive Order 12291, Federal Regulation. They will not result in any significant effect on the economy, they will not have any significant impact upon private or governmental costs, and they will not affect business enterprises or otherwise have any adverse effect on the economy.

There is no Catalog of Federal Domestic Assistance number involved.

The proposed rules, as amended, are hereby adopted and are set forth below.

List of Subjects in 38 CFR Part 19

Administrative practice and procedure, Claims, Veterans.

Approved: June 18, 1986.

Thomas K. Turnage,

Administrator.

PART 19—[AMENDED]

38 CFR Part 19, Board of Veterans Appeals, is amended as follows:

1. Section 19.129 is amended by removing the last sentence in paragraph (b) and by adding a new paragraph (c) to read as follows:

§ 19.129 Rule 29; time limit for filing.

* * * * *

(c) *Response to supplemental statement of the case.* Where a supplemental statement of the case is furnished in accordance with Rule 22 (§ 19.122), a period of 30 days will be allowed for response. Provided a substantive appeal has been timely filed in accordance with paragraph (b) of this section, the response to a supplemental statement of the case is optional and is not required for the perfection of an appeal unless the supplemental statement of the case covers issues that were not included in the original statement of the case. (38 U.S.C. 4005(d)(3))

2. Section 19.132 is amended by adding another holiday. The section is revised to read as follows:

§ 19.132 Rule 32, legal holidays.

For the purpose of Rule 31 § 19.131), the legal holidays, in addition to any other day appointed as a holiday by the President or the Congress of the United States, are as follows: New Year's Day—January 1; Inauguration Day—January 20, of every fourth year or, if the 20th falls on a Sunday, the next succeeding day selected for public observance of the inauguration; Martin Luther King, Jr.'s Birthday-third Monday in January; Washington's Birthday—third Monday in February; Memorial Day—last Monday in May; Independence Day—July 4; Labor Day—first Monday in September; Columbus Day—second Monday in October; Veterans' Day—November 11; Thankgiving Day—fourth Thursday in November, and Christmas Day—December 25, (5 U.S.C. 6103)

[FR Doc. 86-16411 Filed 7-21-86; 8:45 am]

BILLING CODE 8320-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[Circular No. 2584]

43 CFR Part 1820

Application Procedures; Changes of Addresses of State Offices; Correction Notice

AGENCY: Bureau of Land Management, Interior.

ACTION: Correction notice to final rulemaking.

SUMMARY: This notice corrects an error in the "area of jurisdiction" for the Colorado State Office previously published in a final rulemaking on June 30, 1986 (51 FR 23547). In § 1821.2-1(d), the words "and Kansas" are removed, so that the area of jurisdiction for the Colorado State Office is "Colorado."

FOR FURTHER INFORMATION CONTACT: Eleanor R. Schwartz (202) 343-8735.

July 17, 1986.

J. Steven Griles,

Assistant Secretary of the Interior.

[FR Doc. 86-16433 Filed 7-21-86; 8:45 am]

BILLING CODE 4310-84-M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Parts 73, 74 and 76

Oversight of the Radio and TV Broadcast Rules

AGENCY: Federal Communications Commission.

ACTION: Final rule.

SUMMARY: This Order amends broadcast and Cable TV regulations in Parts 73, 74 and 76 of the rules of the FCC. Amendments are made to delete regulations that are no longer necessary, correct inaccurate rule texts, contemporize certain requirements and to execute editorial revisions as needed for purposes of clarity and ease of understanding.

EFFECTIVE DATE: July 22, 1986.

FOR FURTHER INFORMATION CONTACT: Steve Crane, Policy and Rules Division, Mass Media Bureau, (202) 632-5414.

SUPPLEMENTARY INFORMATION:

Order

Adopted: July 11, 1986.
Released: July 15, 1986.

By the Chief, Mass Media Bureau.

1. In this *Order*, the Commission focuses its attention on the oversight of its radio and TV broadcast rules. Modifications are made herein to update, delete, clarify or correct broadcast regulations as described in the following amendment summaries:

(a) Amendments are made in paragraph (c)(1) of § 73.45, AM antenna systems, clarifying the requirement to file a Form 302 when measurements show antenna resistance varies by 2% or more from that shown on the station authorization. Present text states the Form 302 must be filed "in accordance with § 73.54." It should state that the Form 302 must be *filed with the information and measurement data specified in § 73.54.*

Also in this section, a new subparagraph (2) will be added to paragraph (c). Subparagraph (c)(1) will continue to state what measurement results trigger the requirement to file a Form 302. The new subparagraph (c)(2) will direct that certain information may be sent via informal notification to the FCC in Washington when direct reading power meters are used at the station. (See Appendix item 2.)

(b) Two modifications are made in § 73.54, Antenna resistance and reactance measurements, for ease of understanding. In paragraph (d) reference is made to "notification" being given without stating to whom. It is to the FCC in Washington, DC and is amended to so state.

In paragraph (e), the rule's final paragraph, the requirement is made to "submit the above information" without clearly stating "the above information" is that found in paragraph (d). Revision is made herein. (See Appendix item 3.)

(c) Subparagraph (b)(2) and paragraph (c) of § 73.128, AM stereophonic broadcasting, were removed and marked [Reserved] in the Report and Order in Mass Media Docket 85-125 adopted December 20, 1985.

Paragraphs (b)(2) and (c) happen to be at the end of § 73.128. Marking them [Reserved] retains two useless appendages at the rule's end. They are excised herein, ending the rule with the text of paragraph (b)(1)(iii). (See Appendix item 4.)

(d) Table B in § 73.207, Minimum distance separation between stations, was revised by Commission *Order* on December 13, 1984, to conform to the agreements reached in the new Working Arrangement between the United States and Canada dated September 7, 1984. *Order* 49 FR 50045, December 26, 1984.

The revised Table B was correctly printed in Title 47 of the Code of Federal Regulations in the publication revised as of October 1, 1985. However, the *old* Table B also was inadvertently printed. So, § 73.207 presently shows two Table

B's. The old Table B titled "Table B—Minimum Distance Separation Requirements in Kilometers (miles)" is removed via this *Order*. The correct Table B title "Table B—Minimum Distance Separation Requirements in Kilometers" is retained.

In the *Order* cited above, paragraph (b)(2)(ii) was removed, leaving only paragraph (2)(i) of paragraph (b) surviving. There is no introductory text to (b)(2), so that subdivision designation (i) is removed.

Finally, the text of paragraph (b)(2) is amended here to remove the statement that "Class B1 allotments and assignments must be considered Class B . . . where using this table." Class B1 is now included in the new table; only the statement that Class C2 allotments and assignments be considered Class B will remain. (See Appendix item 5.)

(e) Section 73.525, TV Channel 6 Protection, was added to Part 73 via the *Memorandum Opinion and Order* in Docket No. 20735 adopted June 20, 1985: In the Matter of Changes in the Rules Relating to NCE–FM Broadcast Stations. 50 FR 27954, July 9, 1985. Paragraph (b)(1) reads:

> An NCE–FM station operating on Channels 201–220 with facilities authorized as of December 31, 1984, is not subject to this section unless it proposes either:

Questions have been raised as to paragraph (b)(1) applying to permittees who have been granted construction permits as of December 31, 1984, as well as to stations licensed and operating prior to that date. Such rights do apply to permittees with construction permits granted prior to the December 1984 date. The *Memorandum Opinion and Order* clearly describes the Commission's intent in paragraph 53 of the document where is states:

> These stations for which a construction permit has been issued, as of December 31, 1984, need not conform to the new station rules and will be considered as existing stations for the purpose of further modifications.

Section 73.525(b)(1) is amended herein to clearly state that licensed stations *and* stations for which a construction permit has been granted are entitled to grandfathered rights if authorized as of December 31, 1984. (See Appendix item 6.)

(f) The *Report and Order* in Gen. Docket 84–705 amended rules to standardize the use of digitized terrain data for determining antenna height above average terrain. 49 FR 48935, December 17, 1984. One of the rule changes was the adding of new text at the end of paragraph (g) of § 73.684.

Subsequent to this amendment the Commission adopted an *Order* in which measurement units in the radio and television rules were converted to the metric system. 50 FR 23697, June 5, 1985. In making the conversions in § 73.684, the text which had been added to paragraph (g) in Gen. Docket 84–705 was inadvertently omitted in the *Order*. It is replaced herein. (See Appendix item 7.)

(g) As a result of ongoing discussions with Mexico, it became clear that it was no longer necessary to retain the modulation restriction on Subsidiary Communications Authorization (SCA) operations contained in the Note § 73.1570(b)(2)(ii), Modulation levels: AM, FM and TV aural. Accordingly, this note can be deleted so that SCA operations in the Mexican border area can be conducted on the same basis as elsewhere in the U.S. (See Appendix item 8.)

(h) In an *Order* adopted on June 11, 1985 and printed in the Federal Register on June 27, 1985 at 50 FR 26567, amendments were made to 47 CFR Part 73 to relax requirements for determining TV aural power. One of the rule changes removed subparagraph (c)(4) of § 73.1690, Modification of transmission systems. However, the rule drafter left behind a cross reference in § 73.1690(b)(4) to the excised subparagraph (c)(4). The reference is removed herein.

Another error in § 73.1690 is corrected via this *Order*. Paragraph (c) contains a requirement to file a Form 341 for noncommercial educational stations after completing certain modifications of the transmission systems. Effective April 24, 1985 the new Form 302 has been used to service both commercial and noncommercial licensees; use of the Form 341 was discontinued at that time. Reference to it is deleted from the rule. (See Appendix item 9.)

(i) Mass Media Docket 84–231, deals with the implementation of BC Docket 80–90, Modification of FM Broadcast Station Rules to Increase the Availability of Commercial FM Broadcast Assignments. *See Notice of Proposed Rule Making*, in MM Docket 84–231. 49 FR 11214, March 26, 1984; *First Report and Order*, 50 FR 3514, January 25, 1985; *Second Report and Order*, 50 FR 15558, April 19, 1985; and *Memorandum Opinion and Order*, 51 FR 9210, March 18, 1986.

The decisions that the Commission reached and adopted in the successive stages of MM Docket 84–231 set the procedures and established the criteria in the licensing of the hundreds of FM stations added to the table of allotments by BC Docket 80–90. The listing of these policies is effected herein by adding a new policy section, with its multiple citations, as § 73.4107, FM Broadcast Assignment Increasing availability. (See Appendix item 10.)

(j) Section 73.4135, Interference to TV reception by FM stations, is one of the FCC policies listed in 47 CFR Part 73. It has an informational note appended to it by the CFR office which reads:

> Note: At 49 FR 45154, November 15, 1984, §73.4135 was removed, effective January 1, 1985. Subsequently, at 50 FR 5073, February 6, 1985, this amendment was suspended and stayed until after disposition of reconsideration petitions.

This type note is used by the CFR to provide its users with the knowledge that action was still pending on a certain rule or policy when they "closed the book" on October 1 to begin finalization of the new, upcoming edition of 47 CFR.

This Note should have been removed from the 1985 edition of Title 47. The proceeding to which it referred was terminated with the adoption of the *Memorandum Opinion and Order* in Docket 20735. 50 FR 27954, July 9, 1985. The *Memorandum Opinion and Order* retained the policy and the listing.

To review: Section 73.4135 was removed in the *Third Report and Order* in Docket 20735, the effective date of which, as the note states, "was suspended and stayed until after disposition of the reconsideration petitions" filed subsequent to the adoption of the *Third Report and Order*.

The *Memorandum Opinion and Order*, which finalized the proceeding, amended our rules as set forth in the Appendix of that document. The stay on the *Third Report and Order* was "dissolved." In do doing the removal of the § 73.4135 policy listing was no longer applicable. Therefore, the Note regarding the stay is herein removed and § 73.4135 will remain in 47 CFR as part of FCC's listing of policies. (See Appendix item 11).

(k) On April 10, 1986, the Commission adopted a Public Notice pertaining to the non-commercial nature of educational broadcasting stations. *Public Notice*, FCC 86–161, released April 11, 1986. This Notice is added to the citations of previous pertinent guidelines, articulated in the past by the Commission regarding this matter, which may be found in § 73.4163, Noncommercial nature of educational broadcast stations. The newly added citation will be designated paragraph (d). Also, correction will be made to references in paragraph (b) and (c) of the Section. In paragraph (b), by changing the citation FCC 82–237 to correctly read FCC 82–327; and the

citation of 90 FCC 2d 114 to correctly read 90 FCC 2d 895. Paragraph (c) is modified by adding the FCC Report citation, 97 FCC 2d 255. (See Appendix item 12).

(l) On January 30, 1986 the Commission adopted a *Policy Statement* on the procedures governing tender offers and proxy contests involving Commission licensees and corporations that control Commission licensees. *Policy Statement,* MM Docket 85–218. 51 FR 9794, March 21, 1986. The Statement is, via this Order, added to the FCC's listing of policies as § 73.4266, Tender offers and proxy statements. (See Appendix item 13).

(m) Paragraph (e) of § 74.655, Authorization of equipment, cross references paragraph (g) of that same section. Paragraph (g) was redesignated paragraph (f) in the *Order* adopted July 22, 1985. 50 FR 32414, August 12, 1985. The reference is corrected herein. (See Appendix item 14).

(n) Section 74.966, Operator requirements [for Instructional TV Fixed Service], was removed from the rules in the *Report and Order* in General Docket 83–322. 49 FR 20658, May 16, 1984. At the time § 74.18 in Subpart—General of Part 74 (Rules applicable to all Part 74 Services) was expanded to include operator requirements for all Part 74 services. There is a reference in § 74.933(a)(2) to the deleted § 74.966. It is corrected to cross reference § 74.18. (See Appendix item 15).

(o) The FCC rules were revised in September, 1985 to conform to the new cable television EEO policies mandated by public law. *Report and Order.* MM Docket 85–61. 50 FR 40836, October 7, 1985.

These amendments conformed 47 CFR to the policies enacted as a result of Congressional passage of the Cable Communications Policy Act of 1984. *Cable Communications Policy Act of 1984.* Pub. L. 98–549, 98 Stat. 2779 (1984). Added to 47 CFR Part 76 was new subpart E—Equal Employment Opportunity Requirements which contains 5 new rule sections. With the adoption of these new rules, the single section formerly applying to equal employment opportunities, § 76.311, was removed.

Two cross references to the removed § 76.311 survive in § 76.305, the public inspection file rule. The cross references are amended to read correctly herein. (See Appendix item 16).

2. No substantive changes are made herein which impose additional burdens or remove provisions relied upon by licensees or the public. We conclude, for the reasons set forth above, that these revisions will serve the public interest.

3. These amendments are implemented by authority delegated by the Commission to the Chief, Mass Media Bureau. Inasmuch as these amendments impose no additional burdens and raise no issue upon which comments would serve any useful purpose, prior notice of rule making, effective date provisions and public procedure thereon are inapplicable pursuant to the Administrative Procedure Act. 5 U.S.C. 553(b)(3)(B).

4. Since a general notice of proposed rule making is not required, the Regulatory Flexibility Act does not apply.

5. Accordingly, it is ordered, That pursuant to section 4(i), 303(r) and 5(c)(1) of the Communications Act of 1934, as amended, and §§ 0.61 and 0.283 of the Commissions Rules, Parts 73, 74 and 76 of the FCC Rules and Regulations are amended as set forth below, effective on the date of publication in the **Federal Register.**

6. For further information on this *Order,* contact Steve Crane, (202) 632–5414, Mass Media Bureau.

List of Subjects

47 CFR Part 73

Radio broadcasting.

47 CFR Part 74

Television broadcasting.

47 CFR Part 76

Cable television.

Federal Communications Commission.

James C. McKinney,

Chief, Mass Media Bureau.

Parts 73, 74, and 76 of Title 47 of the Code of Federal Regulations are amended as follows:

1. The authority citation for Parts 73, 74 and 76 continues to read as follows:

Authority: 47 U.S.C. 154 and 303.

2. 47 CFR 73.45 is amended by revising paragraph (c)(1) and adding new paragraph (c)(2) to read as follows:

§ 73.45 AM antenna systems.

* * * * *

(c) * * *

(1) Whenever the measurements show that the antenna or common point resistance differs from that shown on the station authorization by more than 2%, FCC Form 302 must be filed with the information and measurement data specified in § 73.54(d).

(2) Whenever AM stations use direct reading power meters pursuant to § 73.51, notification to the FCC in Washington, DC must be filed in accordance with § 73.54(e).

3. 47 CFR 73.54 is amended by revising the introductory text of paragraph (d) and the text of paragraph (e) to read as follows:

§ 73.54 Antenna resistance and reactance measurements.

* * * * *

(d) Notification must be filed with the FCC in Washington, DC when determining power by the direct method pursuant to § 73.51 and must specify the antenna or common point resistance at the operating frequency. The following information must also be kept on file at the station:

* * * * *

(e) AM stations using direct reading power meters in accordance with § 73.51, can either submit the information required by paragraph (d) of this section or submit a statement indicating that such a meter is being used. Subsequent station licenses will indicate the use of a direct reading power meter in lieu of the antenna resistance value in such a situation.

4. 47 CFR 73.207, Minimum distance separation between stations, is amended by removing the table designated "Table B—Minimum Distance Separation Requirements in Kilometers (miles)" and retaining the table designated "Table B—Minimum Distance Separation Requirements in Kilometers"; and by revising (b)(2) to read as follows:

§ 73.207 Minimum distance separation between stations.

* * * * *

(b) * * *

(2) Under the Canada-United States FM Broadcasting Agreement, domestic U.S. allotments and assignments that are located within 320 kilometers (199 miles) of the common border must be separated from Canadian allotments and assignments by the following distances. Class C2 allotments and assignments must be considered Class B allotments and assignments when using this table.

* * * * *

5. 47 CFR 73.525 is amended by revising paragraph (b)(1) introductory text to read as follows:

§ 73.525 TV Channel 6 protection.

* * * * *

(b) *Existing NCE–FM Stations.* (1) A NCE–FM station license authorized to operate on channels 201–220 as of December 31, 1984, or a permittee, granted a construction permit for a NCE–FM station as of December 31,

1984, are not subject to this section unless they propose either:

* * * * *

6. 47 CFR 73.684 is amended by adding the following text to the end of paragraph (g) to read as follows:

§ 73.684 Prediction of coverage

* * * * *

(g) * * * In lieu of maps, the average terrain elevation may be computer generated, except in the cases of dispute, using elevations from a 30 second point or better topographic data file. The file must be identified and the data processed for intermediate points along each radial using linear interpolation techniques. The height above mean sea level of the antenna site must be obtained manually using appropriate topographic maps.

* * * * *

§ 73.1570 [Amended]

7. 47 CFR 73.1570, Modulation levels: AM, FM and TV aural, is amended by removing the Note following paragraph (b)(2)(ii).

8. 47 CFR 73.1690 is amended by revising paragraphs (b) (4) and (c) introductory text to read as follows:

§ 73.1690 Modification of transmission systems.

* * * * *

(b) * * *

(4) Change in the operating power from that specified on the station authorization.

* * * * *

(c) The following FM and TV station modifications may be made and operation commenced without prior authorization from the FCC, provided that the modifications would not possibly affect the operation of any co-located or nearby AM station. An application for license modification must be filed on FCC Form 302 within 10 days following completion of the changes. Equipment performance measurements are not required for applications covering changes described in paragraph (c) (1) and (2) of this section.

* * * * *

9. New § 73.4107, FM broadcast assignment, increasing availability of, is added to 47 CFR to read as follows:

§ 73.4107 FM broadcast assignments, increasing availability of.

(a) See, First Report and Order MM Docket 84–231, FCC 84–640, adopted December 19, 1984. 50 FR 3514, January 25, 1985.

(b) See, Second Report and Order, MM Docket 84–231, FCC 85–124, adopted March 14, 1985. 50 FR 15558, April 19, 1985.

(c) See, Memorandum Opinion and Order, MM Docket 84–231, FCC 86–76, adopted February 10, 1986. 51 FR 9210, March 18, 1986.

§ 73.4135 [Amended]

10. 47 CFR 73.4135, Interference to TV reception by FM stations, is amended by removing the Note following the text of this policy listing.

11. 47 CFR 73.4163 is amended by adding new paragraph (d) and by revising paragraphs (b) and (c) to read as follows:

§ 73.4163 Noncommercial nature of educational broadcast stations.

* * * * *

(b) See Order, BC Docket 21136, FCC 82–327 adopted July 15, 1982. 90 FCC 2d 895; 47 FR 36171, August 19, 1982.

(c) See Memorandum Opinion and Order, BC Docket 21136, FCC 84–105, adopted March 28, 1984. 97 FCC 2d 255; 49 FR 13534, April 5, 1984.

(d) See, Public Notice, FCC 86–161, dated April 11, 1986. 51 FR 21800, June 16, 1986.

12. New § 73.4266, is added to Title 47 CFR to read as follows:

§ 73.4266 Tender offer and proxy statements.

See *Policy Statement*, MM Docket 85–218, FCC 86–67, adopted January 30, 1986. 51 FR 9794, March 21, 1986.

13. 47 CFR 74.655 is amended by revising paragraph (e) to read as follows:

§ 74.655 Authorization of Equipment.

* * * * *

(e) An applicant for a TV broadcast auxiliary station may also apply for type acceptance or notification, as specified in paragraph (f) of this section, for an individual transmitter by following the procedures set forth in Subpart J of Part 2 of the FCC Rules and Regulations. Individual transmitters which are authorized will not normally be included in the FCC's Radio Equipment List.

14. 47 CFR 74.933 is amended by revising paragraph (a)(2) to read as follows:

§ 74.933 Remote control operation

(a) * * *

(2) An operator meeting the requirements of § 74.18 shall be on duty at the remote control position and in actual charge thereof at all times when the station is in operation.

* * * * *

15. 47 CFR 76.305 is amended by revising paragraphs (a) and (c) to read as follows:

§ 76.305 Records to be maintained locally by cable system operators for public inspection.

(a) *Records to be maintained.* The operator of every cable television system having 1000 or more subscribers shall maintain for public inspection a file containing a copy of all records which are required to be kept by § 76.205(d) (origination cablecasts by candidates for public office); § 76.221(f) (sponsorship identification); and § 76.79 (EEO records available for public inspection).

* * * * *

(c) The records specified in paragraph (a) of this section shall be retained for the periods specified in §§ 76.205(d), 76.221(f) and 76.79.

* * * * *

[FR Doc. 86–16316 Filed 7–21–86; 8:45 am]

BILLING CODE 6712-01-M

GENERAL SERVICES ADMINISTRATION

48 CFR Part 532

[APD 2800.12 CHGE 27]

General Services Administration Acquisition Regulation; Payment Due Date Clauses

Correction

In FR Doc. 86–14282, beginning on page 23062, in the issue of Wednesday, June 25, 1986, make the following corrections:

§ 532.11 [Amended]

1. On page 23063, second column, § 532.111(b)(2), second line, after "is" insert "for".

2. On page 23063, third column, § 532.111(f), last line, after "small" insert "purchase".

BILLING CODE 1505-01-M

INTERSTATE COMMERCE COMMISSION

49 CFR Part 1105

[Ex Parte No. 274 (Sub-No. 10)]

Environmental Notices In Abandonment and Rail Exemption Proceedings; Correction

AGENCY: Interstate Commerce Commission.

ACTION: Final rules; correction.

SUMMARY: At 51 FR 25206, July 11, 1986, the Commission modified its rules to require that notices of environmental

and energy matters be served when filing notices of exemption under 49 CFR 1150.31 and 1180.2(d); and to require carriers to certify that a notice of environmental and energy matters has been served on the designated State agency or agencies. That notice contained inadvertent errors in the text of the revised § 1105.11 which this notice corrects.

FOR FURTHER INFORMATION CONTACT: Donald J. Shaw, Jr. (202) 275–7245.

SUPPLEMENTARY INFORMATION: The final rules appearing at 51 FR 25207, July 11, 1986 are corrected as follows:

PART 1105—[CORRECTED]

As corrected, § 1105.11 is revised to read as follows:

§1105.11 Environmental notice.

A carrier filing a notice of intent to abandon a line under 49 CFR 1152.20(d), a notice of exemption under 49 CFR 1150.31, 1152.50, or 1180.2(d) or a petition for exemption pursuant to 49 U.S.C. 10505 [except when exemption is sought for an action normally not subject to environmental review under § 1105.6(c) of this part] shall serve upon the designated agency in each State a notice of environmental and energy matters, together with its notice or petition. The environmental notice must be in the form specified in the appendix to this section. When filing the notice or petition, a carrier must certify to the Commission that this environmental notice requirement has been satisfied.

Noreta R. McGee,
Secretary.

[FR Doc. 86–16399 Filed 7–21–86; 8:45 am]
BILLING CODE 7035-01-M

Proposed Rules

Federal Register
Vol. 51, No. 140
Tuesday, July 22, 1986

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Agricultural Marketing Service

7 CFR Part 967

Celery Grown in Florida; Proposed Handling Regulation

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule.

SUMMARY: This action would help Florida celery producers compete for a share of the U.S. celery market by proposing the establishment of an upper limit on the quantity of Florida celery that may be marketed fresh during the 1986–87 season. The establishment of a marketable quantity would encourage growers to assume the risks of planting celery and thus provide consumers with an adequate supply. The proposal was recommended by the Florida Celery Committee which works with the U.S. Department of Agriculture in administering the order.

DATE: Comments due August 21, 1986.

ADDRESS: Interested persons are invited to submit written comments concerning this proposal. Comments must be sent in duplicate to the Docket Clerk, Fruit and Vegetable Division, AMS, USDA, Room 2085, South Building, Washington, DC 20250. Comments should reference 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: Ronald L. Cioffi, Chief, Marketing Order Administration Branch, F&V, AMS, USDA, Washington, DC 20250, telephone: 202/447–5679.

SUPPLEMENTARY INFORMATION: This proposed rule has been reviewed under Departmental Regulation 1512–1 and Executive Order 12291 and has been determined to be a "non-major" rule under criteria contained therein.

Pursuant to requirements set forth in the Regulatory Flexibility Act (RFA), the Administrator of the Agricultural Marketing Service has determined that this action would not have a significant economic impact on a substantial number of 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 Agricultural Marketing Agreement Act, and rules issued thereunder, are unique in that they are brought about through group action of essentially small entities on their own behalf. Thus, both statutes have small entity orientation and compatibility.

The proposed rule is issued under Marketing Agreeement No. 149 and Marketing Order No. 967, both as amended, regulating the handling of celery grown in Florida. The marketing agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The proposal is based upon the recommendation and information submitted by the Florida celery committee and upon other available information.

The committee met on June 4, 1986, and recommended a marketable quantity of 6,789,738 crates of fresh celery for the 1986–87 season. This recommendation was based on an appraisal of the expected supply and prospective market demand. The recommended marketable quantity is about 26 percent more than the approximately 5.3 million crates expected to be marketed fresh during the 1985–86 season, and such allotment is also expected to be above actual shipments for the 1986–87 season. Additionally, a uniform percentage of 100 percent was proposed which would allow each producer registered pursuant to § 967.37(f) of the order to market 100 percent of their base quantities.

This recommendation would encourage Florida celery growers to assume the risks of planting celery and thus help to provide consumers with an adequate supply. As in past seasons, the limitation on the quanity of Florida celery handled for fresh shipment is not expected to restrict the quantity of Florida celery sold.

As required by § 967.37(d)(1) of the order, a reserve of 6 percent of the 1985–86 total base quantities is authorized for new producers and for increases by existing producers for the 1986–87 season. However, there were no applications for new or additional base submitted for the 1986–87 season.

List of Subjects in 7 CFR Part 967

Marketing agreements and orders, Celery, and Florida.

1. The authority citation for 7 CFR Part 967 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

2. It is proposed to add a new § 967.322 under Subpart-Rules and Regulations, to read as follows:

PART 967—FLORIDA CELERY

Subpart—Rules and Regulations

§ 967.322 Handling regulation; Marketable quantity; and uniform percentage for the 1986–87 season beginning August 1, 1986.

(a) The Marketable Quantity established under § 967.36(a) is 6,789,738 crates of clery.

(b) As provided in § 967.38(a), the Uniform Percentage shall be 100 percent.

(c) Pursuant to § 967.36(b), no handler shall handle any harvested celery unless it is within the Marketable Allotment of a producer who has a Base Quantity and such producer authorizes the first handler thereof to handle it.

(d) As required by § 967.37(d)(1) a reserve of 6 percent of the total Base Quantities is hereby authorized for:

(1) New producers; and

(2) Increases for existing Base Quantity holders.

(e) Terms used herein shall have the same meaning as when used in the said marketing agreement and order.

Dated: July 16, 1986.

Joseph A. Gribbin,

Director, Fruit and Vegetable Division, Agricultural Marketing Service.

[FR Doc. 86–16437 Filed 7–21–86; 8:45 am]

BILLING CODE 3410–02–M

7 CFR Parts 1006, 1007, 1011, 1012, 1013, 1046, 1093, 1094, 1096, 1098, and 1099

[Docket Nos. AO-366-A27 et al.]

Milk in the Georgia and Certain Other Marketing Areas; Tentative Decision on Proposed Amendments and Opportunity To File Written Exceptions to Tentative Marketing Agreements and to Orders; Correction

7 CFR Parts	Marketing area	Docket Nos.
1007	Georgia	AO-366-A27
1006	Upper Florida	AO-356-A25
1011	Tennessee Valley	AO-251-A30
1012	Tampa Bay	AO-347-A28
1013	Southeastern Florida	AO-286-A35
1046	Louisville-Lexington-Evansville	AO-123-A56
1093	Alabama-West Florida	AO-386-A6
1094	New Orleans-Mississippi	AO-103-A48
1096	Greater Louisiana	AO-257-A35
1098	Nashville, Tenessee	AO-184-A50
1099	Paducah, Kentucky	AO-183-A42

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Proposed rule; correction.

SUMMARY: This document corrects several errors appearing in a tentative decision on proposed amendents to 11 southeastern Federal milk marketing orders, published in the **Federal Register** on June 5, 1986 (51 FR 20446).

FOR FURTHER INFORMATION CONTACT: Robert F. Groene, Marketing Specialist, Dairy Division, Agricultural Marketing Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447–2089.

SUPPLEMENTARY INFORMATION: The tentative decision on proposed amendments to 11 southeastern Federal milk orders that was issued on May 28, 1986, and published in the **Federal Register** on June 5, 1986 (51 FR 20446) contained several errors. The corrections necessary to rectify such errors are as follows:.

1. On page 20446, second column, in the heading of the document, change "INTERIM FINAL DECISION" to "TENTATIVE DECISION" and change "INTERIM FINAL MARKETING" to "TENTATIVE MARKETING".

2. Page 20446, third column in the ACTION line, change "interim final" to "proposed".

3. On page 20446, third column, in the first sentence of the SUMMARY, change "interim final" to "tentative".

4. On page 20447, first column, in the first sentence of the PRELIMINARY STATEMENT, change "interim final decision" to "tentative decision" and change "interim final marketing" to "tentative marketing".

5. On page 20462, first column, in the first sentence of the *Order relative to handling*, change "effective date hereof" to "date the proposed amendments in this document become effective".

Signed at Washington, DC, on July 17, 1986.

Alan T. Tracy,

Acting Assistant Secretary, Marketing and Inspection Services.

[FR Doc. 86-16438 Filed 7-21-86; 8:45 am]

BILLING CODE 3410-02-M

7 CFR Parts 1006, 1007, 1011, 1012, 1013, 1046, 1093, 1094, 1096, 1098, and 1099

[Docket Nos. AO-366-A27 et al.]

Milk in the Georgia and Certain Other Marketing Areas; Interim Final Decision on Proposed Amendments and Opportunity To File Written Exceptions to Interim Final Marketing Agreements and to Orders

Correction

FR Doc. 86-12370 was published on page 20446 in the issue of Thursday, June 5, 1986. The document announced a tentative decision to modify the plant location adjustments to prices under 11 southeastern Federal milk marketing orders. It was published in the Rules section of the **Federal Register**. It should have appeared in the Proposed Rules section.

BILLING CODE 1505-02-M

7 CFR Parts 1006, 1007, 1011, 1012, 1013, 1030, 1032, 1033, 1036, 1040, 1046, 1049, 1050, 1064, 1065, 1068, 1076, 1079, 1093, 1094, 1096, 1097, 1098, 1099, 1102, 1106, 1108, 1120, 1124, 1125, 1126, 1131, 1132, 1134, 1135, 1136, 1137, 1138, and 1139

Milk in the Upper Florida and Certain Other Marketing Areas; Computation of Basic Class II Formula Price; Termination of Proceeding on Proposed Termination of Use of Edible Whey Factors, and Determination To Continue the Current Computation

7 CFR Parts and Marketing Areas

1006 Upper Florida
1007 Georgia
1011 Tennessee Valley
1012 Tampa Bay
1013 Southeastern Florida
1030 Chicago Regional
1032 Southern Illinois
1033 Ohio Valley
1036 Eastern Ohio-Western Pennsylvania
1040 Southern Michigan
1046 Louisville-Lexington-Evansville
1049 Indiana
1050 Central Illinois
1064 Greater Kansas City
1065 Nebraska-Western Iowa
1068 Upper Midwest
1076 Eastern South Dakota
1079 Iowa
1093 Alabama-West Florida
1094 New Orleans-Mississippi
1096 Greater Louisiana
1097 Memphis, Tennessee
1098 Nashville, Tennessee
1099 Paducah, Kentucky
1102 Fort Smith, Arkansas
1106 Southwest Plains
1108 Central Arkansas
1120 Lubbock-Plainview, Texas
1124 Oregon-Washington
1125 Puget Sound-Inland
1126 Texas
1131 Central Arizona
1132 Texas Panhandle
1134 Western Colorado
1135 Southwestern Idaho-Eastern Oregon
1136 Great Basin
1137 Eastern Colorado
1138 Rio Grande Valley
1139 Lake Mead

AGENCY: Agricultural Marketing Service, USDA.

ACTION: Termination of proceeding and Determination of current Class II price.

SUMMARY: This action terminates a proceeding on a proposal of the Department to terminate certain provisions relating to the computation of the Class II price in the above-listed 39 Federal milk orders. It also continues the use of equivalent whey processing cost and whey yield factors in computing the current basic Class II formula price. The Class II price, which applies in most cases to such products as cottage cheese, ice cream, yogurt, and cream, is determined each month through a formula. The formula provides, in part, for using certain pricing factors relating to edible dry whey as established under the dairy price support program. Because of recent changes in the support program, these pricing factors are no longer available. The proposed action would have eliminated the use of dry whey values in the Class II price computation.

Comments supporting and opposing the proposed termination were submitted. Because of the conflicting viewpoints among interested parties, it is concluded that the termination should not be implemented on the basis of this proceeding.

FOR FURTHER INFORMATION CONTACT: Maurice M. Martin, Marketing Specialist, Dairy Division, Agricultural Marketing Service, United States Department of Agriculture, Washington, D. C. 20250, (202) 447-7311.

SUPPLEMENTARY INFORMATION: Prior document in this proceeding:

Notice of Proposed Termination and Determination of current Class II price: Issued January 29, 1986; published February 4, 1986 (51 FR 4374).

This termination of proceeding is issued pursuant to the provisions of the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674).

Notice of proposed rulemaking was published in the Federal Register (51 FR 4374) concerning a proposed termination of certain provisions of the aforesaid marketing orders. Interested persons were afforded opportunity to file written data, views, and arguments thereon by February 19, 1986.

The following provisions of the orders regulating the handling of milk in the aforesaid marketing areas were proposed to be terminated:

7 CFR Provisions and Marketing Area

1006.19(d) and 1006.51a(a)(1)(iii)—Upper Florida
1007.20(d) and 1007.51a(a)(1)(iii)—Georgia
1011.20(d) and 1011.51a(a)(1)(iii)—Tennessee Valley
1012.19(d) and 1012.51a(a)(1)(iii)—Tampa Bay
1013.19(d) and 1013.51a(a)(1)(iii)—Southeastern Florida
1030.20(d) and 1030.51a(a)(1)(iii)—Chicago Regional
1032.20(d) and 1032.51a(a)(1)(iii)—Southern Illinois
1033.21(d) and 1033.51a(a)(1)(iii)—Ohio Valley
1036.20(d) and 1036.51a(a)(1)(iii)—Eastern Ohio-Western Pennsylvania
1040.21(d) and 1040.51a(a)(1)(iii)—Southern Michigan
1046.20(d) and 1046.51a(a)(1)(iii)—Louisville-Lexington-Evansville
1049.20(d) and 1049.51a(a)(1)(iii)—Indiana
1050.20(d) and 1050.51a(a)(1)(iii)—Central Illinois
1064.20(d) and 1064.51a(a)(1)(iii)—Greater Kansas City
1065.20(d) and 1065.51a(a)(1)(iii)—Nebraska-Western Iowa
1068.20(d) and 1068.51a(a)(1)(iii)—Upper Midwest
1076.20(d) and 1076.51a(a)(1)(iii)—Eastern South Dakota
1079.20(d) and 1079.51a(a)(1)(iii)—Iowa
1093.20(d) and 1093.51a(a)(1)(iii)—Alabama-West Florida
1094.20(d) and 1094.51a(a)(1)(iii)—New Orleans-Mississippi
1096.20(d) and 1096.51a(a)(1)(iii)—Greater Louisiana
1097.20(d) and 1097.51a(a)(1)(iii)—Memphis, Tennessee
1098.20(d) and 1098.51a(a)(1)(iii)—Nashville, Tennessee
1099.20(d) and 1099.51a(a)(1)(iii)—Paducah, Kentucky
1102.20(d) and 1102.51a(a)(1)(iii)—Fort Smith, Arkansas
1106.20(d) and 1106.51a(a)(1)(iii)—Southwest Plains
1108.20(d) and 1108.51a(a)(1)(iii)—Central Arkansas
1120.20(d) and 1120.51a(a)(1)(iii)—Lubbock-Plainview, Texas
1124.20(d) and 1124.51a(a)(1)(iii)—Oregon-Washington
1125.19(d) and 1125.51a(a)(1)(iii)—Puget Sound-Inland
1126.20(d) and 1126.51a(a)(1)(iii)—Texas
1131.20(d) and 1131.51a(a)(1)(iii)—Central Arizona
1132.20(d) and 1132.51a(a)(1)(iii)—Texas Panhandle
1134.19(d) and 1134.51a(a)(1)(iii)—Western Colorado
1135.19(d) and 1135.51a(a)(1)(iii)—Southwestern Idaho-Eastern Oregon
1136.19(d) and 1136.51a(a)(1)(iii)—Great Basin
1137.19(d) and 1137.51a(a)(1)(iii)—Eastern Colorado
1138.20(d) and 1138.51a(a)(1)(iii)—Rio Grande Valley
1139.19(d) and 1139.51a(a)(1)(iii)—Lake Mead

Statement of Consideration

This action terminates a proceeding to eliminate the use of dry whey values in the Class II price computation for 39 Federal milk orders. The whey value, incorporated in the gross value of cheddar cheese, is a factor used in computing the "basic Class II formula price", which in turn is the basis of the "tentative Class II price" that is announced for each month by the 15th day of the preceding month.

The prescribed formula set forth in the orders for computing the basic Class II formula price, as indicated above, includes determining the gross value of milk used to manufacture cheddar cheese. The gross value of cheddar cheese is the sum of the following computations:

(i) Multiply the cheddar cheese price by the yield factor used under the Price Support Program for cheddar cheese;

(ii) Multiply the butter price by the yield factor used under the Price Support Program for determining the butterfat component of the whey value in the cheese price computation; and

(iii) Subtract from the edible whey price the processing cost used under the Price Support Program for edible whey and multiply any positive difference by the yield factor used under the Price Support Program for edible whey.

Because of recent changes in the price support program, the processing cost and yield factor for edible dry whey are no longer being determined under that program and thus are not available for use under the Federal orders. The changes stemmed from the recently enacted Food Security Act of 1985, which precludes the use of any market value of whey in determining the purchase price for cheese under the price support program.

Possible options for dealing with the unavailability of certain pricing factors included amending the orders on the basis of a public hearing or terminating the use of a whey value in computing the basic Class II formula price which has been in effect since October 1981. For the 51-month period of October 1981 through December 1985, the average monthly impact of the whey pricing factor on the basic Class II formula price was .0033 cents per hundredweight. Since the whey value carried a relatively minor weight in the pricing formula, the Department recommended the termination option.

Interested parties were invited to comment on the proposed termination of provisions governing the use of whey value factors in computing the tentative Class II price. Comments were submitted by two dairy industry groups. Associated Milk Producers, Inc. (AMPI), a cooperative association that represents a large number of producers on the 39 markets, favored termination of the use of a whey value in computing the basic Class II formula price. In AMPI's opinion, such action would provide consistency between the price support program and the Federal order program without having an adverse impact on dairy farmer returns.

The Milk Industry Foundation (MIF), an organization of milk handlers, opposed the termination. MIF held the view that any issue that would change prices under the orders should be considered at an amendatory hearing.

Because of the conflict of views among interested parties, it is concluded that the termination should not be implemented on the basis of this proceeding. Accordingly, the proceeding begun in this matter on January 29, 1986, is hereby terminated.

Determination of Current Class II Price

It is appropriate, however, to continue the use of a whey value in computing the basic Class II formula price. As authorized under the orders, equivalent pricing factors were adopted for this purpose in a determination issued January 29, 1986, and published February 4, 1986 (51 FR 4374).

It is therefore ordered that a whey processing cost of 12.5 cents per pound and a yield factor of 5.5 pounds continue to be used as equivalent factors in determining any positive whey value in computing the basic Class II formula price under the above-named orders, effective upon issuance of this determination.

List of Subjects in 7 CFR Parts 1006 et al.

Milk marketing orders, Milk, Dairy products.

The authority citation for Parts 1006, 1007, 1011, 1012, 1013, 1030, 1032, 1033, 1036, 1040, 1046, 1049, 1050, 1064, 1065, 1068, 1076, 1079, 1093, 1094, 1096, 1097, 1098, 1099, 1102, 1106, 1108, 1120, 1124, 1125, 1126, 1131, 1132, 1134, 1135, 1136, 1137, 1138, 1139 continues to read as follows:

Authority: Secs. 1–19, 48 Stat. 31, as amended; 7 U.S.C. 601–674.

Signed at Washington, DC, on July 14, 1986

William T. Manley,

Deputy Administrator, Marketing Programs.

[FR Doc. 86–16238 Filed 7–21–86; 8:45 am]

BILLING CODE 3410-02-D

Farmers Home Administration

7 CFR Part 1944

Section 502 Rural Housing Loan Policies, Procedures, and Authorizations

AGENCY: Farmers Home Administration, USDA.

ACTION: Proposed rule.

SUMMARY: The Farmers Home Administration (FmHA) proposes to amend its regulation for section 502 rural housing loans to further define modest, adequate housing, and to include specific cost containment measures for the effective administration of the program.

This action is being taken to enable the Agency to more fully address the housing needs of very low income persons and families as required by the Housing Amendments of 1983, and at the same time reduce the overall cost of the program to the government.

The intended effect of this action is to include specific cost containment measures for the Section 502 Rural Housing Program. Minor changes include the addition of a definition for the word "family," a requirement that Form FmHA 431–3, "Household Financial Statement and Budget," be completed before loan approval for each Section 502 applicant, and instruction on how to handle cases when an error by an FmHA employee results in too little interest credit being granted. The latter had been erroneously removed from this Section.

DATES: Comments must be received on or before September 22, 1986.

ADDRESSES: Submit written comments in duplicate to the Office of the Chief, Directives Management Branch, Farmers Home Administration, U.S. Department of Agriculture, Room 6348, South Agriculture Building, 14th and Independence Avenue, SW., Washington, DC 20250. All written comments made pursuant to this notice will be available for public inspection at the above address.

FOR FURTHER INFORMATION CONTACT: Nancy Monesson, Senior Loan Specialist, Single Family Housing Processing Division, Farmers Home Administration, USDA, Room 5338-South Agriculture Building, Washington, DC 20250, Telephone 202–382–1474.

SUPPLEMENTARY INFORMATION: This proposed action has been reviewed under USDA procedures established in Departmental Regulation 1512–1 which implements Executive Order 12291 and has been classified as "nonmajor." This action will result in an annual effect on the economy of less than $100 million and will neither result in a major increase in cost or prices, nor adversely affect competition, employment, investment, productivity, innovation, or the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. There is no impact on proposed budget levels, and funding allocations will not be affected because of this action.

Discussion

1. A definition of the word "family" is proposed in combination with the word "household" in § 1944.2(j).

2. Section 1944.11 proposes to clarify the conditions under which a waiver can be granted for land in excess of a minimum adequate site.

3. Section 1944.16 proposes to include specific cost containment measures including:

a. Maximum dwelling size based on the number of persons who will occupy the dwelling.

b. How living area will be calculated for each design type house,

c. Certain amenities which will not be financed. Section 1944.16 also includes a requirement that the suitability of homes more than 30 years old be determined by the District Director.

4. Section 1944.26(a)(2) proposes to require that Form FmHA 431–3, "Household Financial Statement and Budget," be prepared before loan approval to determine the repayment ability of every 502 loan applicant:

5. Section 1944.34(h) proposes to include a statement regarding the correction of interest credit agreements when an error by an FmHA employee results in too little interest credit being granted.

This document has been reviewed in accordance with 7 CFR Part 1944, Subpart G, "Environmental Program." It is the determination of FmHA that the proposed action does not constitute a major Federal action significantly affecting the quality of the human environment and in accordance with the National Environmental Policy Act of 1969, Pub. L. 91–190, an Environmental Impact Statement is not required.

This program/activity is listed in the Catalog of Federal Domestic Assistance under No. 10.410. For the reasons set forth in the final rule related Notice to 7 CFR Part 3015, Subpart V, 48 FR 29115, June 24, 1983, this program/activity is excluded from the scope of Executive Order 12372 which requires intergovernmental consultation with State and local officials. This action does not directly affect any FmHA programs or project which are subject to intergovernmental consultation.

List of Subjects in 7 CFR Part 1944

Home improvement, Loan program—housing and community development, low and moderate income housing—rental, Mobile homes, Mortgages, Rural housing, Subsidies.

Therefore, FmHA proposes to amend Subpart A of Part 1944, Chapter XVIII, Title 7, Code of Federal Regulations as follows:

PART 1944—HOUSING

1. The authority citation for Part 1944 continues to read as follows:

Authority: 42 USC 1480; 7 CFR 2.23; 7 CFR 2.70.

Subpart A—Section 502 Rural Housing Loan Policies, Procedures and Authorizations

2. Section 1944.2 is amended by revising paragraphs (f) and (j) to read as follows:

§ 1944.2 Definitions.

* * * * *

(f) *Extended family.* A double family unit comprised of adult relatives who live together for reasons of physical dependency, economics, and/or social custom, who, under other circumstances, could maintain separate households. A typical example is: mother and father-in-law living with borrower, spouse, and their children.

* * * * *

(j) *Household or family.* The applicant, spouse, and all persons who will make the applicant's dwelling their primary residence for all or part of the

next 12 months (excluding fosterchildren and live-in aides).

* * * * *

3. Section 1944.11 is amended by revising paragraph (c); redesignating current paragraph (d) as paragraph (e); and adding a new paragraph (d) to read as follows:

§ 1944.11 Property requirements.

* * * * *

(c) A nonfarm tract on which a loan is to be made may not be larger than a minimum adequate site, which is the smallest area sufficient for the dwelling, an adequate water and/or waste disposal system, other related facilities, and a yard. Size limitations which represent a minimum adequate site are:

(1) House lots on scattered sites will be less than 1 acre.

(2) House lots within a subdivision environment will normally not exceed 10,000 square feet. However, some variation in lot size may be permitted to accommodate cluster housing concepts or other subdivision designs which maximize good land usage.

(d) Sites which exceed the limitations set forth in paragraph (c) (1) and (2) of this section must, in all cases, be authorized by the State Director, and the reasons and justifications must be recorded in the loan docket. The State Director may authorize a larger site only if:

(1) The determination has been made that no minimum adequate building site is available in the area, or

(2) The extra land does not qualify as a minimum adequate building site and the value of the total site is comparable to the value of a minimum adequate site in the area, and

(3) Zoning ordinances which require lots in excess of the limitations set forth in paragraph (c) (1) and (2) of this section were established because the additional land is needed to protect the water supply and/or provide an adequate waste disposal system, or the zoning complies with an established State or National environmental plan.

* * * * *

4. Section 1944.16 is revised to read as follows:

§ 1944.16 Building requirements.

(a) *Modest house.* All dwellings financed must provide decent, safe and sanitary housing, and be modest in size, design, and cost. Applicants should be counseled regarding the size and type of housing necessary to meet their needs. No dwelling will be designed or built to exceed the housing needs of the applicant/borrower.

(b) *Maximum gross square footage area limitations for new construction and purchase new:*

No. of occupants	Maximum No. of bedrooms	Maximum No. of baths	Maximum sq. ft. w/ neither basement nor carport [2]	Maximum sq. ft. w/ either a basement *or* a carport [2]
1–2	2	1	912	816
3–5	Up to 3	1	1,056	960
6–8	Up to 4	1½	1,200	1,104
[1] 9 or more		2		

[1] Large families for which a 4-bedroom, 1200 square foot house is inadequate may have additional bedrooms not to exceed 120 square feet each, including closets.
[2] A 10% increase in living area is permitted for zero lot-line townhouses.

(c) *Living area.* Living area or gross floor area is the square footage within the perimeter of the outside walls of the dwelling. Living area will be determined as follows:

(1) *Ranch on slab, crawl space, or totally below ground basement:* First floor excluding garage or carport, without deduction for any of the contained space.

(2) *Split Foyer, Bi-Level, etc.:* All finished and unfinished areas of all levels (heated and unheated) without deduction for any of the contained space.

(3) *Cape Cod.* All of the first floor, and all of the second floor area measured to the outside of the stud wall, excluding totally below ground basements.

(4) *Two Story Townhouses—zero lot-line.* The area, center to center of party walls, and outside of all exterior walls of all floors, excluding totally below ground basements.

(d) *Building designs and materials.* No FmHA office will require the use of any building and/or building materials which exceed the applicable development standards, or the fair quality as described in Marshall and Swift Residential Cost handbook, or other similar cost guide.

(e) *Design features.* Design features and/or amenities which will not be permitted in connection with new construction or purchase of a new dwelling include but are not limited to:

(1) Garage.

(2) A carport in addition to a basement.

(3) Single car carports which exceed 312 square feet.

(4) Non-living areas such as balconies, decks, patios or porches which exceed 50 square feet for the housing unit.

(5) Sliding glass doors or atrium doors.

(6) Bay windows.

(7) Components of the house, such as kitchen cabinets, bathroom fixtures, light fixtures, etc. which exceed "fair-quality" as described in Marshall and Swift Residential Cost handbook or some other similar cost guide.

(8) Fireplaces, except for those solid fuel burning devices authorized under paragraph (f)(3) of this section.

(9) Skylights, cathedral or vaulted ceilings.

(10) Recreation rooms/dens (in addition to living rooms).

(11) Fences (except for short privacy fences on zero lot lines, town house properties, etc. or when needed to block an undesirable view or provide protection from a potentially dangerous situation.

(12) decorative iron work which is not needed as a safety measure.

(13) Dishwashers.

(14) Central air conditioning systems separate and apart from heat pumps unless authorized by the State Director, in which case, a State Supplement must be issued outlining the conditions for approval.

(f) *Special features.* (1) Special design features necessary to accommodate the needs of disabled or handicapped persons may be included when necessary.

(2) Energy saving measures which exceed FmHA requirements and cost more than 1 percent of the market value of the property and solar energy systems may be used only after approval by the State Architect/Engineer and authorization by the State Director. Complex systems, such as active solar space heating or cooling, geothermal, hydropower, wind and photovoltaic, that could be considered unconventional, must be submitted to the National Office for concurrence prior to authorization by the State Director.

(3) Solid fuel burning devices may be authorized only if the loan approval official determines and documents that a dependable and economical fuel supply is available. All solid fuel burning devices must comply with MPS (4900.1, 610–1.1) and with Exhibit D, paragraph IV D 2. of Part 1924, Subpart A. To assure compliance and to remove uncertainties regarding safety and efficiency, solid fuel burning devices are authorized only after approval by the State Architect/Engineer and subsequent authorization by the State Director.

(4) A dwelling for an extended family as defined in § 1944.2(f) of this subpart may include bedroom area with an exterior entrance and an additional bathroom. This area should be designed in a manner that will not adversely affect the home's potential for resale.

(g) *Existing dwellings.* Applicants should be counseled regarding the type

of housing necessary to meet their needs. First consideration will be given to the purchase of an existing adequate but modest dwelling. In most cases, the cost of an existing dwelling including necessary repair and renovation is less than the cost of new construction. However, the cost advantage should not be offset by the cost of utilities and maintenance. Existing dwellings purchased with RH funds must be structurally sound, functionally adequate, either be in good repair or placed in good repair with loan funds and meet the standards required by § 1924.5(d)(1)(ii) of Subpart A of Part 1924 of this chapter. All existing dwellings must meet the thermal performance standards required in Exhibit D, paragraph IV B, of Subpart A of Part 1924 of this chapter. Existing dwellings to be financed will contain no more than 1,200 square feet (1008 square feet for a one or two member household) of living area measured in accordance with paragraph (c) of this section. One or two member households will be limited to a 2-bedroom house if available in the area. Exceptions to the square footage limitations apply when:

(1) The application is for refinancing, and the determination has been made that the house is modest in size, design and cost in the area.

(2) A larger house is necessary to meet the needs of the family in accordance with paragraph (b) of this section.

(3) The house is being transferred with assumption of a 502 loan, or a credit sale is being made, and the determination has been made that the house is considered modest in size, design, and cost in the area. In all cases, every effort will be made to provide housing which does not exceed the needs of the applicant/borrower.

(h) *Amenities in existing dwellings.* Existing properties may contain not more than 2 design features which are considered above modest, (such as those set forth in paragraph (e) of this section) for which a loan for new construction would not be made unless:

(1) The house is being transferred with assumption of a 502 loan, a credit sale is being made, or the applicant already owns the house and has filed an application to refinance and

(2) The amenities involved do not cause the property to be above modest.

(i) *Age.* Dockets for dwellings older than 30 years must be reviewed by the District Director to determine whether the house is suitable for the program. A statement will be entered in the running record of the casefile, signed by the District Director, regarding the decision of suitability. All houses older than 30 years must be inspected and certified by qualified persons for adequacy of the electrical system and the plumbing. The cost of these inspections and certifications will be borne by the seller.

(j) *Improvements.* Improvements financed with loan funds must be on land which, after loan closing, is part of a tract owned by the borrower in accordance with § 1924.15(a) of this Subpart, or on an easement appurtenant to such a tract.

(k) *Repairs.* Any dwelling repaired with RH funds must be structurally sound, functionally adequate, and be placed in good repair with loan funds. If the loan is not more than $7,500 and is scheduled for repayment in not more than 15 years from the date of the note, the dwelling may lack some equipment or features such as a complete bath, kitchen cabinets, closet, or completely finished interior in some rooms. Such dwellings must meet the housing needs of the applicant and provide decent, safe, and sanitary living conditions when the improvements financed with the loan are completed.

5. Section 1944.26 is amended by revising the introductory text of paragraphs (a)(2) and (f)(2) to read as follows:

§ 1944.26 Application processing.

(a) *Application forms.* * * *

(2) Form FmHA 431–3, "Household Financial Statement and Budget," will be completed for each low or very low-income Section 502 loan applicant, for each transfer with assumption and for each credit sale to an eligible applicant prior to loan approval. The form will be used to determine repayment ability. When preparing Form FmHA 431–3, the following will be considered:

* * * * *

(f) *Determining eligibility.* * * * (2) Repayment ability as outlined in § 1944.8(a)(2), will be evaluated on the circumstances surrounding the individual case including possible eligibility for interest credits as provided in § 1944.34. Form FmHA 431–3 will be completed by the applicant and the County Supervisor as set forth in paragraph (a)(2) of this section. Under no condition(s) will arbitrary guidelines or "rules of thumb" be used. If the applicant(s) can verify payment of a comparable or greater amount for housing costs for the previous 12 months, the applicant will be presumed to have repayment ability for the requested loan unless:

* * * * *

6. § 1944.34 is amended by revising paragraph (h)(2) to read as follows:

§ 1944.34 Interest credit.

* * * * *

(h) * * *

(2) *Correction of Interest Credit Agreement.* When an error by an FmHA employee results in too little interest credit being granted, a corrected agreement will be prepared effective the date of the error, if the error results in the granting of $5 or more per month or $60 or more per year less interest credit than the borrower was eligible to receive. In some cases, a Form FmHA 1944–6 showing the proper amount of interest credit which the borrower is entitled to receive, together with written authorization from the State Director to reapply any affected payments, will be submitted to the Finance Office to replace the incorrect agreement. The effective date of the corrected agreement will be the same as the agreement in error. The notation "Corrected in accordance with § 1944.34" will be entered on the face of the form. The Finance Office will cancel the incorrect Interest Credit Agreement as of its effective date. Payments made under the previous agreement will be reversed and reapplied at the adjusted interest rate of the new Interest Credit Agreement.

* * * * *

Dated: May 28, 1986.

Kathleen W. Lawrence,

Acting Undersecretary for Small Community and Rural Development.

[FR Doc. 86–16439 Filed 7–21–86; 8:45 am]

BILLING CODE 3410–07–M

Food Safety and Inspection Service

9 CFR Part 327

[Docket No. 85–010P]

Proportionate Sampling; Deletion of Provision

AGENCY: Food Safety and Inspection Service, USDA.

ACTION: Proposed rule.

SUMMARY: The Food Safety and Inspection Service (FSIS) is proposing to amend § 327.21 of the Federal meat inspection regulations. This section contains the provisions for inspection of imported chilled fresh or frozen boneless manufacturing meat; it also contains provisions allowing the use of proportionate sampling under certain conditions for these meat products. FSIS is proposing to delete all references to the use of proportionate sampling for boneless manufacturing meat because this form of sampling is outdated, outmoded and incompatible with the

Agency's Automated Import Inspection System. This action would assure that all imported meat products are inspected in a uniform manner and on an equitable basis.

DATE: Comments must be received on or before: September 22, 1986.

ADDRESS: Written comments to: Policy Office, ATTN: Annie Johnson, Room 3803, South Building, Food Safety and Inspection Service, U.S. Department of Agriculture, Washington, DC 20250. (See also "Comments" under Supplementary Information.)

FOR FURTHER INFORMATION CONTACT: Patricia Stolfa, Deputy Administrator, International Programs, Food Safety and Inspection Service, US. Department of Agriculture, Washington, DC 20250, (202) 447–3473.

SUPPLEMENTARY INFORMATION:

Executive Order 12291

The Administrator has determined in accordance with Executive Order 12291 that this proposed rule is not a "major rule." It will not result in an annual increase in costs or prices for consumers, individual industries, Federal, State or local government agencies, or geographic regions. It will not have a significant effect on competition, employment, investment, productivity, or on the ability of United States-based enterprises to compete with foreign-based enterprises in domestic or export markets. The proposed rule would only eliminate a current provision in the regulations that provides an unwarranted advantage for foreign producers and importers of boneless manufacturing meat that is not afforded producers and importers of other imported meat products.

Effect on Small Entities

The Administrator has made an initial determination that this proposed rule will not have a significant economic impact on a substantial number of small entities as defined by the Regulatory Flexibility Act, Pub. L. 96–354 (5 U.S.C. 601 *et seq.*) because it only serves to eliminate a current provision in the regulations that provides an unwarranted advantage for foreign producers and importers of boneless manufacturing meat that is not afforded producers and importers of other imported meat products.

Generally, rejected product is covered now by insurance or payment is not made until product passes inspection.

Comments

Interested persons are invited to submit written comments concerning this proposal. Please send your comments in duplicate to the Policy Office and refer to the docket number that appears in the heading of this document. All comments submitted in response to this proposal will be made available for public viewing in the Policy Office between 9 a.m. and 4 p.m., Monday through Friday.

Background

Under the Federal Meat Inspection Act (21 U.S.C. 620 *et seq.*), the Food Safety and Inspection Service (FSIS) is responsible for assuring that imported meat products meet the same standards that are applied to domestic meat products. FSIS performs this responsibility by conducting two primary activities: (1) The review of foreign inspection systems to evaluate and determine the at least "equal to" eligibility of countries wishing to export to the United States, and (2) port-of-entry reinspection of imported meat products to verify the effectiveness of foreign inspection programs.

In particular, under 327.6 of the Federal meat inspection regulations (9 CFR 327.6), all meat products offered for importation are subject to sampling and reinspection in conjunction with the risk-based programs of the Automated Import Information System (AIIS). The AIIS provides a data base which allows different ports-of-entry (POE) to share information on inspection results for all imported meat and poultry products. The AIIS also prescribes inspection types and intensities based on the individual plant's performance record and the nature and volume of the product shipped. In addition, the AIIS tracks the inspection record of a particular imported product at all POEs. If a problem is found in a product at one port, the system locates shipments from the same plant at other ports so that the AIIS can issue intensified inspection plans.

Port-of-entry inspection in the United States by FSIS is actually reinspection of product previously inspected in the country of origin and serves as a means for assuring that the foreign country's inspection system continues to produce products that meet standards "at least equal to" those applied to product produced by inspected establishments in the United States.

History of Proportionate Sampling

The use of proportionate sampling techniques for lots of boneless manufacturing meat was proprosed in August 1968 (33 FR 12259) and was adopted as a final rule on January 20, 1969. The purpose of this action according to the "Statement of Considerations" was to eliminate costly reinspections including resampling for boneless manufacturing meats. Past policy had allowed an importer whose lot had been refused entry to "sort out identifiable portions of the lot which contain the defects, reexport or render these portions incapable of use as human food, and resubmit the balance of the lot for reinspection (including resampling) for acceptance for entry . . . Equal protection will be afforded to consumers of meat products and unnecessary inspection costs will be avoided . . . when a portion of the lot offered for importation is identified as consisting of a different type of meat or as having been prepared in a different production run than the remainder of the lot. In such cases, an evaluation of the inspection findings for each portion separately will result in a more valid disposition of the product in each portion. The procedures are also appropriate in case of prolonged delay in unloading from ships any large lot of product consisting of several such portions offered for inspection." (33 FR 20033)

These regulations were promulgated in response to shipping practices then in existence. Formerly, it was a trade practice to bulk ship in boxes, in no particular order, various cuts of beef. These boxes were designated as containing "beef"; no further distinctions (i.e., specific cuts) were made. For example, products designated as "beef" could include sirloin tips, shanks and boneless manufacturing meat. Therefore, the bulk product was broken down into separate lots and sampled according to the proportions of each cut.

With the advent of containerized shipping practices, each product type could be and is now placed and identified in a separate container. In conjunction with shipping changes, FSIS began developing product codes for each type or cut and species of product being offered for importation. Since each type of product has a separate code, one code equals one lot of a singular product for inspection purposes. This code system effectively eliminates the need for breaking down and sampling bulk "beef" shipments.

GAO Review of Proportionate Sampling

On June 15, 1983, the Comptroller General issued report GAO/RECD–83–81, "Improved Management of Import Meat Inspection Program Needed," which included a recommendation that FSIS enforce an internal task force recommendation to end proportionate sampling. The Agency made a commitment to do so and subsequently

reported on its progress in accomplishing this. References to proportionate sampling have been deleted from the inspector's manual, and elimination of the practice has been stressed in training for import inspections. The final action necessary to complete this process is the rulemaking proposed here which would delete the now obsolete authorization for proportionate sampling.

Current Regulations and Practices

Current regulations have not been revised to reflect changed shipping practices and developments in the POE inspection system. Therefore, regulations now authorize propportionate sampling even though the need for such a procedure has disappeared.

Under § 327.21 of the current meat inspection regulations (9 CFR 327.21), importers are able to request special treatment for portions of refused entry lots of boneless beef which can be identified by different code marks, shift marks, or production runs. These portions cannot be the source of the defects which have caused rejection. For instance, if a lot composed of two types of boneless beef (e.g., shanks and rounds) is rejected due to defects discovered in randomly selected samples that came from only one of the types (e.g., shanks), § 327.21 permits the importer to sort out the rounds have them enter U.S. commerce as inspected and passed because no defects were found. An importer can also request such treatment on an initial product evaluation and inspection of a portion of a lot, when that portion is unloaded first with the remaining portion being delayed beyond a day.

Agency Policy

FSIS' policy is to treat all producers and products equitably during inspection. Currently, boneless manufacturing meat is the only product for which proportionate sampling may be performed. There is no justification for allowing this particular product a second chance to pass import inspection when all others must be accepted or refused entry strictly on the basis of the AIIS-determined sampling results.

The proportionate sampling provision provides an unwarranted advantage to foreign producers and importers of boneless manufacturing meat that is not afforded producers and importers of other imported meat products. In essence, producers and importers of imported boneless manufacturing meat have an advantage in the regulations which gives them a second chance to "pass for entry" part of a lot of refused entry product simply by redefining the lot. This is an anachronism that is inconsistent with FSIS Automated Import Inspection System, which prescribes the sampling of *all* imported products in a uniform manner and on an equitable basis.

The Proposal

FSIS is proposing to amend § 327.21 of the Federal meat inspection regulations by deleting all references to the use of proportionate sampling.

List of Subjects in 9 CFR Part 327

Meat inspection, Imported products.

PART 327—[AMENDED]

Accordingly, 9 CFR Part 327 would be amended as set forth below.

1. The authority citation for Part 327 is revised to read as follows:

Authority: 34 Stat. 1260, 79 Stat. 903, as amended, 81 Stat. 584, 84 Stat. 91, 438; 21 U.S.C. 71 *et seq.*

2. Paragraphs (c) and (d) would be removed and paragraph (b) of § 327.21 would be revised to read as follows:

§ 327.21 Special inspection procedures for chilled fresh or frozen boneless manufacturing meat.

* * * * *

(b) *Lots refused entry.* Reinspection (including resampling) will be provided for any lot of frozen boneless manufacturing meat which was refused entry under this section on the basis of the original evaluation of the sample thereof, upon appeal from the inspector's initial decision.

Done at Washington, DC on July 17,1986.

Donald L. Houston,

Administrator, Food and Safety and Inspection Service.

[FR Doc. 86-16386 Filed 7-21-86; 8:45 am]

BILLING CODE 3410-DM-M

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Ch. I

[Summary Notice No. PR-86-13]

Summary of Petitions Received and Dispositions of Petitions Denied or Withdrawn

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of petitions for rulemaking and of dispositions of petitons denied or withdrawn.

SUMMARY: Pursuant to FAA's rulemaking provisions governing the application, processing, and disposition of petitons for rulemaking (14 CFR Part 11), this notice contains a summary of certain petitions requesting the initiation of rulemaking procedures for the amendment of specified provisions of the Federal Aviation Regulations and of denials or withdrawals of certain pertitions previously received. The purpose of this notice is to improve the public's awareness of this aspect of FAA's regulatory activities. Neither publication of this notice nor the inclusion or omission of information in the summary is intended to affect the legal status of any petition or its final disposition.

DATES: Comments on petitions received must identify the petition docket number involved and be received on or before September 22, 1986.

ADDRESSES: Send comments on the petition in triplicate to: Federal Aviation Administration, Office of the Chief Counsel, Attn: Rules Docket (AGC-204), Petition Docket No. _____, 800 Independence Avenue, SW., Washington, DC 20591.

FOR FURTHER INFORMATION CONTACT: The petition, any comments received, and a copy of any final disposition are filed in the assigned regulatory docket and are available for examination in the Rules Docket (AGC-204), Room 916, FAA Headquarters Building (FOB-10A), Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 426-3644.

This notice is published pursuant to paragraph (b) and (f) of § 11.27 of Part 11 of the Federal Aviation Regulations (14 CFR Part 11).

Issued in Washington, DC on July 16, 1986.

John H. Cassady,

Assistant Chief Counsel, Regulations and Enforcement Division.

PETITIONS FOR RULEMAKING

Docket No.	Petitioner	Description of the petition
24984.....	Aircraft owners and pilots association.	Description of petition: To require that air carriers announce their intentions in advance of significantly increasing existing or planned flight operations at airports by more than 30 operations a day. At least a 6-month lead time should be allowed for this process. Regulations Affected: 14 CFR 121.97 and 121.117.

PETITIONS FOR RULEMAKING—Continued

Docket No.	Petitioner	Description of the petition
		Petitioner's Reason for Rule: The petitioner states that the surge of additional air carrier operations increases delays and often serves to preclude general aviation operations at many large airports. The proposed amendment would allow sufficient time for evaluation of factors such as noise, ground congestion, air traffic control facility capacity, delay, and economic impact on exiting users of the airports.

PETITIONS FOR RULEMAKING: WITHDRAWN OR DENIED

Docket No.	Petitioner	Description and disposition of the rule requested
24774	Aircraft owners & pilots association.	Description of Petition: To raise the altitude below which no aircraft may operate at more than 250 knots indicated airspeed from 10,000 feet to 12,500 feet MSL. Regulations Affected: 14 CFR 91.70(a). Denied 6/5/86.
23758	Academics of flight.	Description of Petition: To amend Appendix C of Part 63 of the Federal Aviation Regulations to allow flight engineer students not holding at least a commercial pilot certificate with an instrument rating, the option to substitute 10 hours of training in a simulator which meets the Phase I simulator requirements of Appendix H to Part 121 for the 5 hours of instruction in an airplane required by Appendix C (a)(3)(iv)(a). Regulation's Affected: 14 CFR Appendix C of Part 63 and Appendix H to Part 121. Denied 6/18/86.

[FR Doc. 86-16337 Filed 7-21-86; 8:45 am]
BILLING CODE 4910-13-M

14 CFR Parts 21, 23, and 25

[Docket No. 12337, Notice No. 23-ACE-17]

Special Conditions; Beech Model 300 and 1900 Airplanes With Electronic Flight Instrument Systems

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice to Amend Special Conditions No. 23-47-CE-5.

SUMMARY: This notice proposes to amend special conditions No. 23-47-CE-5 presently applicable to Beech 200, 300, and 1900 series airplanes to allow incorporation of Electronic Flight Instrument System (EFIS) in the Beech 300 and 1900 airplanes. These airplanes will have novel and unusual design features when compared to the state of technology envisaged in the airworthiness standards applicable to these airplanes when EFIS is installed. These novel and unusual design features include the use of cathode-ray tube electronic flight instrument system for which the applicable regulations do not contain adequate or appropriate airworthiness standards. This notice contains the additional safety standards which the Administrator considers necessary to establish a level of safety equivalent to that provided by the applicable airworthiness standards.

DATE: Comments must be received on or before August 21, 1986.

ADDRESS: Comments on this proposal may be mailed in duplicate to: Federal Aviation Administration, Office of the Regional Counsel, ACE-7, Attention: Rule Docket Clerk, Docket No. 12337, Room No. 1558, 601 East 12th Street, Kansas City, Missouri 64106. All comments must be marked: Docket No. 12337. Comments may be inspected in the Rules Docket weekdays, except Federal holidays, between 7:30 a.m. and 4:00 p.m.

FOR FURTHER INFORMATION CONTACT: David M. Warner, Aerospace Engineer, Regulations and Policy Office (ACE-110), Aircraft Certification Division, Central Region, Federal Aviation Administration, Room 1656, 601 East 12th Street, Federal Office Building, Kansas City, Missouri 64106; telephone (816) 374-5688.

SUPPLEMENTARY INFORMATION:

Comments invited

Interested persons are invited to participate in the making of these special conditions by submitting such written data, views, or arguments as they may desire. Communications should identify the regulatory docket or notice number and be submitted in duplicate to the address specified above. All communications received on or before the closing date for comments specified above will be considered by the Administrator before taking further rulemaking action on this proposal. Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this notice must include a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket No. 12337." The postcard will be dated stamped and returned to the commenter. The proposal's contained in this notice may be changed in light of the comments received. All comments received will be available, both before and after the closing date for comments, in the Rules Docket for examination by interested parties. A report summarizing each substantive public contact with FAA personnel concerned with this rulemaking will be filed in the docket.

The type certification basis for the Beech Models 300 and 1900 airplanes is as follows: Special Federal Aviation Regulation (SFAR) 41C, effective September 13, 1982; Part 23 of the Federal Aviation Regulations (FARs), effective February 1, 1985, through Amendment 23-9; Amendment 23-11; Amendment 23-14, §§ 23.143(a), 23.145(d), 23.153, 23.161(c)(3), 23.173(a), 23.175, 23.427, 23.441, and 23.445; Amendment 23-15, §§ 23.951(c) and 23.997(d); Amendment 23-23, § 23.1545(a); Amendment 23-26, §§ 23.967 and 23.1305(n); Special Conditions No. 23-47-CE-5, including Amendments Nos. 1, 2, and 3 dated November 15, 1982; Part 25 of the FAR, § 25.929, effective February 1, 1965; Amendment 25-23, § 25.1419; Amendment 25-41, § 25.831(d); Part 36 of the FARs, through Amendment 36-10; SFAR 27, through Amendment 27-4, and § 25.1419 when ice protection equipment is installed in accordance with the equipment list; and any other changes to Special Conditions No. 23-47-CE-5.

On April 9, 1986, Beech Aircraft Corporation, Wichita, Kansas, notified the FAA of their proposal for approval of installation of a Bendix EFS-10 Electronic Flight Instrument System (EFIS) on the Beech Model 300 airplane. This installation incorporates an electronic attitude director indicator (EADI) and electronic horizontal situation indicator (EHSI) in lieu of traditional mechanical or electro-mechanical displays providing similar information to the flight crew.

Special conditions may be issued and amended, as necessary, as part of the type certification basis if the Administrator finds that the airworthiness standards designated in accordance with § 21.101 do not contain adquate or appropriate safety standards because of novel or unusual design features of an airplane or installation. Special conditions, as appropriate, are issued in accordance with § 11.49, after public notice as required by §§ 11.28 and 11.29(b), effective October 14, 1980, and will become part of the type certification basis, as provided by § 21.101(b)(2).

The proposed type design of the Bendix EFS-10 EFIS installation in the Beech Model 300 airplane contains a number of novel or unusual design features not envisaged by the applicable Part 23 airworthiness standards. Special conditions are considered necessary because the airworthiness standards of

Part 23 do not contain adequate or appropriate safety standards for the novel or unusual design features of the Bendix EFS–10 EFIS installation in the Beech Model 300 airplane.

Special Conditions No. 23–47–CE–5 applicable to the Beech 300 are also applicable to the Beech 200 and 1900 airplanes. However, the requirements of SFAR 41C are applicable to the Beech 300 and 1900 airplanes, but are not applicable to the Beech 200 airplanes. Therefore, special conditions resulting from this notice will also be applicable to the Beech 300 and 1900 for installation of similar EFIS (not limited to the same manufacturer) without further amendment of the special conditions, but will not be applicable to the Beech 200 airplanes.

Beech has proposed cathode-ray tube (CRT) electronic display units for primary attitude, heading, and navigation cockpit displays. The cockpit instrument panel configuration would feature three EFIS displays, an electronic attitude director indicator (EADI) and electronic horizontal situation indicator (EHSI) on the left instrument panel and a multi-function display in the center panel. All other displays; i.e., airspeed, altitude, vertical speed, etc., will be conventional instruments. An optional configuration would provide for an EADI and EHSI on the copilot's side.

Emissive color on a CRT display will inevitably appear different than reflective colors on conventional electro-mechanical displays. Different intensities and color temperatures of ambient illumination will also affect the perceived colors. Therefore, display legibility must be adequate for all cockpit lighting conditions including direct sunlight.

Features of this system are novel and unusual relative to the applicable airworthiness requirements. Current small airplane airworthiness requirements are based on "single-fault" or "fail-safe" concepts and, when promulgated, the FAA did not envision use of complex, safety-critical systems in small airplanes. The current small airplane requirements envisioned instruments that were single function; i.e., a failure would cause loss of only one instrument function, although several instrument functions may have been housed in a common case.

Flight instruments for the pilot are required to be grouped in front of the pilot so deviation from looking forward along the airplane flight path is minimized when the pilot shifts from viewing the flight path to viewing the flight instruments.

For instrument flight, the airplane must be equipped with the minimum flight instruments listed in the operating rules. This minimum listing of instruments includes all instruments that have long been accepted as the minimum for continued safe flight. Back-up instruments for these instruments are not required by the small airplane airworthiness requirements because the FAA has long accepted that the small airplanes could be safely flown following a single instrument failure. The basic airman certification program for an instrument flight rules (IFR) rating has long included the required demonstration of ability to fly the airplane safely following failure of any one of the previously cited instruments and has not required as a basic IFR rating requirement, that all IFR rated airmen must demonstrate abilities using other back-up instruments.

A special condition is proposed which would allow installation of electronic displays that feature design characteristics where a single malfunction or failure could affect more than one primary instrument, display, or system. The proposed special condition would also provide requirements to assure adequate reliability of system design functions that are determined to be essential for continued safe flight and landing of the airplane.

In installations where electronic displays take the place of traditional instruments, the reliability must not be less than that of the traditional instruments. This is in regard to the collective reliability of the traditional instruments rather than the reliability of a single traditional instrument. For this reason, the proposed special condition includes requirements for identifying complex, safety critical systems, and defines requirements needed for their certification.

The proposed special condition will also require a detailed examination of each item of equipment/component of the electronic display system, and installation of the system, to determine if the airplane is dependent upon its function for continued safe flight and landing, or if its failure would significantly reduce the capability of the airplane or the ability of the crew to cope with these adverse operating conditions. Each component of the installation identified by such an examination as being critical to the safe operation of the airplane would be required to meet the proposed special condition.

The present § 23.1309 has been used as a means of evaluating systems since being incorporated into 14 CFR Part 23 by Amendment 23–14, dated December 20, 1973. The "no-single-fault" or "fail-safe" concept of § 23.1309, along with experience based on service-proven designs and good engineering judgment have have been used to successfully evaluate most airplane systems and equipment. However, the FAA is finding it difficult to apply the "single fault" concept as a means of determining the effect or likelihood of certain failure conditions to complex systems like those proposed for the Bendix EFS–10 EFIS installation. Therefore, the FAA considers it necessary to include the proposed additional system analysis requirements in the certification basis. This will also allow the use of the latest available "rational method" of safety analysis of the systems to assure a level of safety intended in the applicable requirements.

The development of rational methods for safety assessment of systems is based on the premise that an inverse relationship exists between the probability of a failure condition and its effect on the airplane. This is, the more serious the effect, the lower the probability must be that the related failure condition will occur.

Use of these rational methods for safety assessment of systems do not mandate use of numerical analysis. An applicant may use numerical analysis to assist in showing compliance but, in many cases, adequate data is not available for preparing a stand-alone numerical analysis for showing compliance. Therefore, in small airplane certification, a rational analysis based on identification of failure modes and their consequences is frequently better substantiation of compliance with the various required levels of system reliability than a numerical analysis alone.

If it is determined that the airplane includes systems that perform more critical functions, it will be necessary to show that those systems meet more stringent requirements. Systems that perform a function that is needed for continued safety of flight and landing of the airplane, whose failure would be catastrophic, would be required to meet requirements that establish either that there will be no failures of that system, or that a failure is extremely improbable.

The special condition also requires that the occurrence of systems failures which would significantly reduce the airplane's capability, or the ability of the crew to cope with adverse operating conditions, and thereby be potentially catastrophic, be improbable. It is recognized that any system(s) failure will reduce the airplane's or crew's

capability by some degree, but that reduction may not be of the degree as to lead to potentially catastrophic results.

The proposed special condition provides reliability requirements which are based on the critically of the system's function and will provide the standards needed for certification of complex safety-critical systems being proposed for installation in Model 300 airplane, or for similar installations in the Beech Model 2900 airplane. The special conditions proposed in this notice vary from those proposed for other small airplanes because of differences in the airworthiness requirements applicable to the various affected airplanes.

The FAA has considered the features proposed by Beech for the EFIS installation in the Beech Model 300 airplane and has concluded that, notwithstanding the existing small airplane requirements which did not envision the use of such complex or critical systems, special conditions can be promulgated for the affected systems, in lieu of applicable requirements, that will provide the intended level of safety. Accordingly, the special conditions are proposed. Conclusion.

This action affects only specified model series airplanes. It is not a rule of general applicability and applies only to the series and models of airplanes identified in these proposed special conditions.

List of Subjects in 14 CFR Parts 21, 23, and 25

Aviation safety, Aircraft, Air transportation, and Safety.

The authority citation for these Special Conditions is as follows:

Authority: Secs. 313(a), 601, and 603 of the Federal Aviation Act of 1958; as amended (49 U.S.C. 1354(a), 1421, and 1423); 49 U.S.C. 106(g) (Revised Pub. L. 97-449, January 12, 1983); 14 CFR 21.16 and 21.101; and 14 CFR 11.28 and 11.49.

The Proposed Special Conditions

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration proposes the following special conditions as an amendment to Special Conditions No. 23-47-CE-5 applicable to the Beech 300 and 1900 series airplanes equipped with an electronic flight instrument system (EFIS).

9. In addition to Appendix A of Part 135 and in lieu of § 23.1309(b) and applicable requirements of Part 23 of the Federal Aviation Regulations to the contrary, for instruments, systems, and installations whose design incorporates electronic displays that feature design characteristics where a single malfunction or failure could affect more than one primary instrument display or system, and/or system design functions that are determined to be essential for continued safe flight and landing of the airplane, the following special condition applies:

(a) Systems and associated components must be examined separately and in relation to other airplane systems to determine if the airplane is dependent upon its function for continued safe flight and landing, and if its failure would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions. Each system and each component identified by this examination upon which the airplane is dependent for continued safe flight and landing, or whose failure would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operation conditions, must be designed and examined to comply with the following additional requirements:

(1) The occurrence of any single failure or probable combination of failures under any anticipated operating condition which would prevent the continued safe flight and landing of the airplane must be shown to be extremely improbable, or it must be shown such failures will not occur.

(2) The occurrence of any other single failure or probable combination of failures under any anticipated operation condition which would significantly reduce the capability of the airplane or the ability of the crew to cope with adverse operating conditions must be shown to be improbable.

(3) Warning information must be provided to alert the crew to unsafe system operating conditions and to enable them to take appropriate corrective action. This warning information must not tend to initiate crew action which would create additional hazards.

(4) Compliance with the requirements of this special condition must be shown by analysis and, where necessary, by appropriate ground, flight, or simulator tests. The analysis must consider:

(i) Modes of failure, including malfunction and damage from forseeable sources;

(ii) Consequence of a single failure or probable combination of failures (latent or undetected);

(iii) Appropriate levels of reliability as determined by the severity of consequence;

(iv) The resulting effects on the airplane and occupants, considering the state of flight and operating conditions; and

(v) The crew warning cues, corrective action required, and the capability of detecting faults.

(5) Numerical analysis may be used to support the engineering examination.

(b) Electronic display units, including those incorporating more than one function, may be installed in lieu of mechanical or electro-mechanical instruments if:

(1) The display units:

(i) Are easily legible under all lighting conditions encountered in the cockpit, including direct sunlight;

(ii) In any normal mode of operation do not inhibit the primary display of attitude; and

(iii) Incorporate sensory cues for the pilot that are equivalent to those in the instrument being replaced by the electronic display units.

(2) The display units, including their systems and installations, must be designed so that one display of information essential to safety and successful completion of the flight will remain available to the pilot, without need for immediate action by any crewmember for continued safe operation, after any single failure or probable combination of failures that is not shown to comply with paragraph (a)(1) of this special condition.

Issued in Kansas City, Missouri on July 11, 1986.

Jerold M. Chavkin,

Acting Director, Central Region.

[FR Doc. 86-16340 Filed 7-21-86; 8:45 am]

BILLING CODE 4910-13-M

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14 CFR Part 73

[Airspace Docket No. 86-SWA-24]

Proposed Alteration of Restricted Area R-5803 Chambersburg, PA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to expand the size of Restricted Area R-5803 Chambersburg, PA, from a 2,400-foot radius circular area to a 5,500-foot radius area centered on the present location at the Letterkenny Army Depot. The change is required because the Department of the Army has determined that the existing area is not large enough to adequately protect aircraft from activities conducted at the Depot. The proposed expansion will fully enclose within the restricted area the safety buffer zones for an ordnance disposal pit and functional equipment test firing range and will ensure that aircraft flying in the vicinity are kept at a safe distance from the facility.

DATES: Comments must be received on or before September 8, 1986.

ADDRESSES: Send comments on the proposal in triplicate to: Director, FAA, Eastern Region, Attention: Manager, Air Traffic Division, Docket No. 86-AWA-24, Federal Aviation Administration, JFK International Airport, The Fitzgerald Federal Building, Jamaica, NY 11430.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue SW., Washington, D.C.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace and Aeronautical Information Requirements Branch (ATO–240), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 426–3656.

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, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket 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. 86–AWA–24." The postcard will be date/time stamped and returned to the commenter. All communications received 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 the 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.

Comments are specifically invited on the overall regulatory, aeronautical, economic and energy aspects of the rule that might suggest the need to modify the rule. Send comments on environmental and land use aspects to: Commander, Letterkenny Army Depot, Attn: SDSLE–SFEN, Chambersburg, PA 17201–4150.

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 Information Center, APA–430, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 426–8058. Communications must identify the notice number of this RPRM. Persons interested in being placed on a mailing list for future NPRM's should also request a copy of Advisory Circular No. 11–2 which describes the application procedure.

The Proposal

The FAA is considering an amendment to § 73.58 of Part 73 of the Federal Aviation Regulations (14 CFR Part 73) to expand the size of restricted Area R–5803 Chambersburg, PA, from a 2,400-foot radius circular area to a 5,500-foot radius area. The Department of the Army has determined that aircraft flying near the Letterkenny Army Depot should remain at least 5,500 feet from the facility to ensure adequate protection from the ordnance disposal and firing activities contained therein. Section 73.58 of Part 73 of the Federal Aviation Regulations was republished in Handbook 7400.6B dated January 2, 1986.

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 73

Aviation safety, Restricted areas.

The Proposed Amendment

PART 73—[AMENDED]

Accordingly, pursuant to the authority delegated to me, Part 73 of the Federal Aviation Regulations (14 CFR Part 73) is amended, as follows:

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

Authority. 49 U.S.C. 1348(a), 1354(a), 1510, 1522; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69.

§ 73.58 [Amended]

2. § 73.58 is amended as follows:

R–5803 Chambersburg, PA [Amended]

By removing the present boundary description and substituting the following:

Boundaries. A circular area with a 5,500-foot radius centered at lat. 40°02'29"N., long. 77°44'20"W.

Issued in Washington, DC, on July 14, 1986.

Harold H. Downey,

Acting Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 86–16341 Filed 7–21–86; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 75

[Airspace Docket No. 86–AWP–15]

Proposed Alteration of Jet Route J–143, CA

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to realign Jet Route J–143 between Point Reyes, CA, and Roseburg, CA. The purpose of this realignment would enable the Oakland Center and Seattle Center to incorporate radar sectors into their oceanic operations and establish en route spacing. This action would improve traffic flow between Seattle, WA, and San Francisco, CA, by reducing en route delays and controller workload. This action would also provide north/south one way jet routes and apportion air traffic operation between two Air Route Traffic Control Centers (ARTCC).

DATES: Comments must be received on or before September 8, 1986.

ADDRESSES: Send comments on the proposal in triplicate to: Director, FAA, Western-Pacific Region, Attention: Manager, Air Traffic Division, Docket No. 86–AWP–15, Federal Aviation Administration, P.O. Box 92007, Worldway Postal Center, Los Angeles, CA 90009.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue SW., Washington, DC.

An informal docket may also be examined during normal business hours at the office of the Regional Air Traffic Division.

FOR FURTHER INFORMATION CONTACT: Peter DiVenere, Airspace and Air Traffic Rules Branch (ATO–230), Airspace-Rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation

Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 426–8783.

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, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket 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. 86–AWP–15." The postcard will be date/time stamped and returned to the commenter. All communications received 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 the 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 Information Center, APA–430, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 426–8058. Communications must identify the notice 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. 11–2 which describes the application procedure.

The Proposal

The FAA is considering an amendment to Part 75 of the Federal Aviation Regulations (14 CFR Part 75) to realign Jet Route J–143 to improve traffic flow between Seattle, WA, and San Francisco, CA. The realigned J–143 and the current alignment of J–501 would provide north/south one way routes that would enhance traffic flow. This action would also eliminate en route delays and reduce controller workload by apportioning traffic between two ARTCCs radar sectors. Section 75.100 of Part 75 of the Federal Aviation Regulations was republished in Handbook 7400.6B dated January 2, 1986.

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 75

Aviation safety, Jet Routes.

The Proposed Amendment

PART 75—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend Part 75 of the Federal Aviation Regulations (14 CFR Part 75) as follows:

1. The authority citation for Part 75 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1354(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (Revised Pub. L. 97–449, January 12, 1983); 14 CFR 11.69.

2. § 75.100 is amended as follows:

J–143 [Revised]

From Point Reyes, CA, via Mendocino, CA; Roseburg, OR; Eugene, OR; The Dalles, OR; to Spokane, WA.

Issued in Washington, DC, on July 14, 1986.

Harold H. Downey,

Manager, Airspace-Rules and Aeronautical Information Division.

[FR Doc. 86–16342 Filed 7–21–86; 8:45 am]

BILLING CODE 4910–13–M

14 CFR Part 75

[Airspace Docket No. 86–ASO–19]

Proposed Alteration of Jet Routes—South Carolina

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Notice of proposed rulemaking.

SUMMARY: This notice proposes to realign Jet Routes J–79, J–121 and J–174 all of which are located in the vicinity of Charleston, SC. The current alignment of these jet routes between Jacksonville, FL, and Charleston has created an unnecessary dogleg. This action would eliminate that dogleg thereby reducing excessive radar vectors and resultant controller workload.

DATES: Comments must be received on or before September 8, 1986.

ADDRESSES: Send comments on the proposal in triplicate to: Director, FAA, Southern Region, Attention: Manager, Air Traffic Division, Docket No. 85–ASO–19, Federal Aviation Administration, P.O. Box, 20636, Atlanta, GA 30320.

The official docket may be examined in the Rules Docket, weekdays, except Federal holidays, between 8:30 a.m. and 5:00 p.m. The FAA Rules Docket is located in the Office of the Chief Counsel, Room 916, 800 Independence Avenue SW., Washington, DC.

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 Air Traffic Rules Branch (ATO–230), Airspace-rules and Aeronautical Information Division, Air Traffic Operations Service, Federal Aviation Administration, 800 Independence Avenue SW., Washington, DC 20591; telephone: (202) 426–8783.

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 overll regulatory, economic, environmental, and energy aspects of the proposal. Communications should identify the airspace docket 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. 86-ASO-19." The postcard will be date/time stamped and returned to the commenter. All communications received 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 the 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 Information Center, APA-430, 800 Independence Avenue SW., Washington, DC 20591, or by calling (202) 426-8058. 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. 11-2 which describes the application procedure.

The Proposal

The FAA is considering an amendment to part 75 of the Federal Aviation Regulations (14 CFR Part 75) to realign Jet Routes J-79, J-121 and J-174 as direct routes between Stary Intersection, GA, and the Charleston, SC, VORTAC. These routes are presently established on the Charleston, SC, 214° radial which results in an unnecessary dogleg. Realignment of the route would eliminate an unnecessary dogleg and reduce excessive radar vectors. Realignment of the route would reduce controller workload and improve the efficiency of the ATC system by permitting direct jet route navigation rather than radar vectors. Section 75.100 of Part 75 of the Federal Aviation Regulations was republished in Handbook 7400.6B dated January 2, 1986.

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 75

Aviation safety, Jet routes.

The Proposed Amendment

PART 75—[AMENDED]

Accordingly, pursuant to the authority delegated to me, the Federal Aviation Administration proposes to amend part 75 of the Federal Aviation Reglations (14 CFR part 75) as follows:

1. The authority citation for Part 75 continues to read as follows:

Authority: 49 U.S.C. 1348(a), 1510; Executive Order 10854; 49 U.S.C. 106(g) (revised Pub. L. 97-449, January 12, 1983); 14 CFR 11.69.

§ 75.100 [Amended]

2. § 75.100 is amended as follows:

J-79 [Amended]

By removing the words "Ormond Beach, FL; INT Ormond Beach 360° and Jacksonville, FL, 020° radials thence Charleston, SC, 214° radials; Charleston;" and by substituting the words "Ormond Beach, FL; INT Ormond Beach 360° T (360° M) and Charleston, SC 207° T (212° M) radials; Charleston;"

J-174 [Amended]

By removing the words "From Jacksonville, FL; via INT Jacksonville 020° and Charleston, SC 214° radials; Charleston;" and by substituting the words "From Jacksonville, FL, via INT Jacksonville 020° T (023° M) and Charleston, SC 207° T (219° M) radials; Charleston;"

J-121 [Amended]

By removing the words "From Jacksonville, FL via INT Jacksonville 020° and Charleston, SC, 214° radials; Charleston; " and by substituting the words "From Jacksonville, FL, via INT Jacksonville 020° T (023° M) and Charleston, SC, 207° T (220° M) radials; Charleston;"

Issued in Washington, DC, on July 14, 1986.

Harold H. Downey,

Acting Manager, Airspace—Rules and Aeronautical Information Division.

[FR Doc. 16343-86 Filed 7-21-86; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 141

Proposed Customs Regulations Amendment Relating to Entry Documentation Filing

AGENCY: U.S. Customs Service, Department of the Treasury.

ACTION: Proposed rule.

SUMMARY: This document proposes to amend the Customs Regulations to provide an optional procedure under which importers could file entry documentation at one port to be analyzed by Customs to determine if an examination of the cargo is necessary. If no examination is necessary, the merchandise could be released when it arrives, even at another port. This would enable importers to obtain an expedited release of their merchandise. Expediting the clearance of cargo would benefit importers, carriers, and Customs.

DATE: Comments must be received on or before September 22, 1986.

ADDRESS: Comments (preferably in triplicate) may be addressed to, and inspected at, the Regulations Control Branch, Room 2426, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229.

FOR FURTHER INFORMATION CONTACT: Operational Aspects: Jerrald O. Worley, Office of Cargo Enforcement and Facilitation, (202-566-8151); Legal Aspects: Jerry C. Laderberg, Entry Procedures and Penalties Division, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, DC 20229 (202-566-5765).

SUPPLEMENTARY INFORMATION:

Background

Parts 141 through 144, Customs Regulations (19 CFR Parts 141-144), govern the entry of imported merchandise. Release of the merchandise from Customs custody is secured by filing the entry documentation required by §§ 142.3 *et seq.*, Customs Regulations (19 CFR 142.3 *et seq.*).

If merchandise is imported at one port and the importer of record desires to have the merchandise delivered to another port (usually where the importer's premises are located), there are two alternatives available to the importer. He may make entry by submitting entry documentation at the port where the merchandise has arrived, either in person or through an agent, to obtain release of the merchandise at

that port. He then makes arrangements for transportation of the merchandise to the inland location, free of any Customs control or custody of the merchandise. Alternatively, the importer may make arrangements at the port of arrival to have the merchandise transported under Customs bond from that port to the destination port, utilizing the transportation in-bond procedures of §§ 18.1 *et seq.*, Customs Regulations (19 CFR 18.1 *et seq.*). These procedures entail using a Customs bonded carrier for the transportation process and complying with the documentary and sealing requirements of Parts 18 and 24, Customs Regulations (19 CFR Parts 18, 24). When the merchandise arrives at the destination port, the importer makes entry by filing the appropriate documentation. He then may obtain release of the merchandise.

Under a program known as PAIRED (Port of Arrival Immediate Release and Enforcement Determination), which has been tested at a number of locations in the U.S., importers are allowed to file entry documentation at one port, usually an inland or interior location, to be analyzed by Customs to determine if an examination of the cargo is necessary. With the permission of the district director at the inland port, the importer files such documentation as is necessary to enable Customs to decide if the merchandise may be released or if it must be retained in Customs custody for reasons such as examination or extraction of a sample for an admissibility determination, verification of manifest, etc. The documentation is usually submitted before the merchandise has arrived in the U.S. Then, if no examination or extraction is required, the importer or broker is notified that the shipment can be released upon arrival. The shipment may then proceed directly to its intended destination without going to another Customs port for further Customs processing. Thus, the importer will receive his shipment more expeditiously and with fewer transportation costs.

Customs experience with the PAIRED program, which is voluntary on the part of importers, has demonstrated that it benefits importers and carriers by expediting the delivery of merchandise and reducing congestion at the port of arrival. Approximately 80% of all entries under PAIRED are released immediately at the port of arrival, without the need for examination of the merchandise or in-bond transportation to another port. It benefits Customs by reducing the costs and expenditures of manpower and other resources for maintaining the transportation in-bond system.

Section 484(a)(2)(A), Tariff Act of 1930, as amended (19 U.S.C. 1484(a)(2)(A)), requires that an entry be filed at a place within the Customs-collection district where merchandise covered by the entry will be released from Customs custody. Release occurs whenever Customs determines that it has no further need to maintain actual custody of the merchandise. Under the PAIRED program, this occurs at the port where the entry documentation is filed (usually an inland port). Entry filing at an inland port and release of the merchandise by the appropriate Customs officer at that port (which order is thereby conveyed to the arrival port) is therefore consistent with 19 U.S.C. 1484(a)(2)(A).

Examination of merchandise entered under the PAIRED program may occur either at the port of arrival or the port of destination of the merchandise. Such examination is authorized by (Section 499, Tariff Act of 1930, as amended (19 U.S.C. 1499). Pending the examination, the merchandise may not be released from Customs custody.

Proposal

To implement the PAIRED program in all Customs districts, it is proposed to amend § 141.63, Customs Regulations (19 CFR 141.63), relating to the submission of entry documentation for preliminary review. A new paragraph (c) would be added to § 141.63, allowing an importer to request the district director to approve the filing of entry documentation at a port other than the port of arrival of the merchandise, to obtain release of the merchandise at the port of arrival. The use of this procedure would be optional on the part of the importer.

Comments

Before adopting this proposal, consideration will be given to any written comments timely submitted to Customs. Comments submitted will be available for public inspection in accordance with the Freedom of Information Act (5 U.S.C. 552), § 1.4, Treasury Department Regulations (31 CFR 1.4), and § 103.11(b), Customs Regulations (19 CFR 103.11(b)), on regular business days between the hours of 9:00 a.m. and 4:30 p.m. at the Regulations Control Branch, Room 2426, Customs Headquarters, 1301 Constitution Avenue, NW., Washington, DC 20229.

Regulatory Flexibility Act

Pursuant to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), it is certified that, if adopted, the proposed amendment will not have a significant economic impact on a substantial number of small entities. Accordingly, it is not subject to the regulatory analysis or other requirements of 5 U.S.C. 603 and 604.

Executive Order 12291

This document does not meet the criteria for a "major rule" as specified in section 1(b) of E.O. 12291. Accordingly, no regulatory impact analysis has been prepared.

Drafting Information

The principal author of this document was Susan Terranova, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

List of Subjects in 19 CFR Part 141

Customs duties and inspection, Imports, Entry documentation filing.

Proposed Amendment

It is proposed to amend Part 141, Customs Regulations (19 CFR Part 141), as set forth below.

PART 141—ENTRY OF MERCHANDISE

1. The authority citation for Part 141 would continue to read as follows:

Authority: 19 U.S.C. 66, 1448, 1484, 1624.

2. It is proposed to amend § 141.63 by adding a new paragraph (c) to read as follows:

§ 141.63 Submission of entry summary documentation for preliminary review.

* * * * *

(c) *For merchandise entered other than at port of arrival.* If merchandise is to arrive or has arrived at one port and the importer wishes to file his entry documentation at another port to which the merchandise is destined, he may do so upon approval of the district director at the port of destination. The district director at the destination port may then authorize release of the merchandise, after its importation at the port of arrival, or postpone its release if he believes it is necessary for examination or other purposes.

William von Raab,

Commissioner of Customs.

Approved: July 2, 1986.

Francis A. Keating,

Assistant Secretary of the Treasury.

[FR Doc. 86-16414 Filed 7-21-86; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Social Security Administration

20 CFR Parts 404 and 416

[Regulations No. 4 and No. 16]

Social Security Benefits and Supplemental Security Income; Continued Payment of Benefits During Appeal

Correction

In FR Doc. 86–11449 beginning on page 18611 in the issue of Wednesday, May 21, 1986, make the following corrections:

1. On page 18612, in the first column, in the **FOR FURTHER INFORMATION CONTACT:** caption in the last line, the telephone number should read "(301) 594–7459".

2. On page 18613, in the first column, in the fourth line, "such" was misspelled.

3. On page 18613, in the first column, in the third complete paragraph, in the third line, "determination" was misspelled; in the fifteenth line, "there" should read "these".

4. Also on page 18613, in the first column, in the fourth complete paragraph, in the seventh line, "termination" should read "determination", in the second column, in the seventh line, "of" should read "or".

5. On page 18613, in the third column, in the fourth paragraph, in the seventh line, "consideration" should read "reconsideration".

6. On page 18615, in the first column, in the second line, "in" should read "on"; in the third column, in the first complete paragraph, in the eighth line, "bet" should read "be".

§ 404.1597a [Corrected]

7. On page 18616, in the third column, in the third complete paragraph, in § 404.1597a(b)(1), in the seventh line, "on" should read "or".

8. On page 18617, in the first column, in § 404.1597a(b)(3)(i), in the eighth line, "Appeal" should read "Appeals"; after the eleventh line, insert "for further action); or (ii) the month before the month no timely request for a reconsideration or a hearing before an administrative law judge".

9. On page 18617, in the first column, in § 404.1597a(c)(1), in the fourth line, "your" should read "our".

10. Also on page 18617, in the second column, in § 404.1597a(e), in the tenth line, "continuing" should read "continued".

§ 416.996 [Corrected]

11. On page 18619, in the second column, in § 416.996(a), the sixth line should read, "have existed, or to no longer be disabling,"; in the third column, in paragraph (a)(2)(ii), in the third line, "of" should read "or".

BILLING CODE 1505-01-M

Food and Drug Administration

21 CFR Part 155

[Docket No. 86N-0175]

Canned Dry Peas; Advance Notice of Proposed Rulemaking on the Possible Amendment of U.S. Standards of Identity, Quality, and Fill of Container

Correction

In FR Doc. 86–12092, beginning on page 19566, in the issue of Friday, May 30, 1986, make the following correction:

§ 155.170 [Amended]

On page 19568, third column, § 155.170 (a)(2) (xiii) (*d*), second line, "eight" should read "weight".

BILLING CODE: 1505-01-M

DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 256

Outer Continental Shelf Minerals and Rights-of-Way Management; General

AGENCY: Minerals Management Service, Interior.

ACTION: Proposed rule.

SUMMARY: The proposed rule amends the regulation requiring publication in the **Federal Register** of a notice of availability in lieu of a proposed notice of sale (PNOS), thereby reducing annual publication costs to the Minerals Management Service (MMS).

DATE: Comments must be hand-delivered or postmarked no later than August 21, 1986.

ADDRESS: Comments should be mailed or hand-delivered to the Department of the Interior; Minerals Management Service; 12203 Sunrise Valley Drive; Mail Stop 646, Room 6A110; Reston, Virginia 22091; Attention: Norman J. Hess.

FOR FURTHER INFORMATION CONTACT: Norman J. Hess, Telephone: (703) 648–7816.

SUPPLEMENTARY INFORMATION: Currently, the PNOS is published in the **Federal Register**, and copies of the PNOS are also made available by MMS to lessees or other interested parties free of charge upon request; therefore, publication of the PNOS in the **Federal Register** is unnecessary.

The MMS proposes to amend § 256.29(c) requiring the publication in the **Federal Register** of a notice of availability of the PNOS in lieu of publishing the PNOS in the **Federal Register**, thereby reducing annual publication costs to MMS by approximately $28,925.

The Department of the Interior (DOI) has determined that this action does not constitute a major Federal action affecting the quality of the human environment; therefore, an environmental impact statement is not required.

The DOI also determined that this document is not a major rule under Executive Order 12291 because the annual economic effect is less than $100 million.

The DOI also certifies that the rule will not have a significant effect on a substantial number of small entities under the Regulatory Flexibility Act (5 U.S.C. 601 et seq.) as the entities that engage in offshore activities are not considered small due to the technical complexity and financial resources necessary to conduct offshore activities.

This rule does not contain information collection requirements which require approval by the Office of Management and Budget under 44 U.S.C. 3501 et seq.

Author. The document was prepared by Mario Rivero, Offshore Rules and Operations Division, Minerals Management Service.

List of Subjects in 30 CFR Part 256

Administrative practice and procedure; Continental shelf; Government contracts; Oil and gas exploration; Pipelines; Public lands-mineral resources; Public lands-rights-of-way; Reporting and recordkeeping requirements; Surety bonds.

Dated: May 28, 1986.

William D. Bettenberg,

Director, Minerals Management Service.

PART 256—[AMENDED]

For the reasons set forth above, 30 CFR Part 256 is proposed to be amended as follows:

1. The authority citation for Part 256 continues to read as follows:

Authority: Secretarial Order 3071, Amendment No. 1, May 10, 1982, and the Outer Continental Shelf Lands Act, 43 U.S.C. 1331 et seq., as amended, 92 Stat. 629.

§ 256.29 [Amended]

2. Section 256.29(c) is amended by adding the phrase "a notice of its availability shall" after the phrase "any affected State and."

[FR Doc. 86-16360 Filed 7-21-86; 8:45 am]
BILLING CODE 4310-MR-M

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[A-5 FRL-3051-3]

Approval and Promulgation of Implementation Plans; Indiana

AGENCY: Environmental Protection Agency (USEPA).

ACTION: Proposed rulemaking.

SUMMARY: USEPA is proposing approval of a revision to the Indiana State Implementation Plan (SIP) for Carbon Monoxide (CO). The revision pertains to a revised CO plan for Marion County, Indiana. USEPA's action is based upon a revision which was submitted by the State in response to a February 24, 1984 notice of SIP deficiency issued under section 110(a)(2)(H) of the Clean Air Act (Act).

DATE: Comments on this revision and on the proposed USEPA action must be received by September 22, 1986.

ADDRESSES: Copies of the SIP revision are available at the following addresses for review: (It is recommended that you telephone Anne E. Tenner, at (312) 886-6036, before visiting the Region V office.)

U.S. Environmental Protection Agency, Region V, Air and Radiation Branch (5AR-26), 230 South Dearborn Street, Chicago, Illinois 60604

Indiana Air Pollution Control Division, Indiana State Board of Health, 1330 West Michigan Street, Indianapolis, Indiana 46206

Comments on this proposed rule should be addressed to: (Please submit an original and three copies, if possible.)

Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604

FOR FURTHER INFORMATION CONTACT: Anne E. Tenner, (312) 886-6036.

SUPPLEMENTARY INFORMATION: Indiana's proposed revision to the Marion County CO plan is discussed in this notice in nine sections. They are: I. Background Information; II. Air Quality Analysis; III. Emission Inventory; IV. Modeling and Demonstration of Attainment; V. Control Strategies; VI. Maintenance of the NAAQS; VII. Demonstration of Reasonable Further Progress; VIII. USEPA Technical Review and Determination; and IX. Conclusion.

I. Background Information

The 1977 Clean Air Act Amendments added new Part D to Title I of the Act. Under this part, the States were required to revise their SIPs for all nonattainment areas and to submit the revisions to USEPA by January 1, 1979. The revised plans were to provide for attainment of the National Ambient Air Quality Standards (NAAQS) by December 31, 1982, unless the States demonstrated that they could not attain the CO or ozone NAAQS by that date despite the implementation of all reasonable available control measures. If USEPA approved a plan showing attainment could not be achieved by December 31, 1982, the attainment date for CO or ozone could be extended up to December 31, 1987.

In the May 19, 1981, **Federal Register** (46 FR 27339), USEPA approved the 1979 Indiana CO SIP for Marion County. This plan was designed to show attainment of the CO NAAQS by December 31, 1982.

However, significant CO exceedances were monitored in Marion County during 1981 and 1982. Because of these, USEPA notified the State of Indiana on February 24, 1984, that the Marion County CO SIP was inadequate. USEPA required that a SIP revision be submitted within one year following the notice of SIP deficiency. The SIP deficiency notice was issued in accordance with USEPA policy appearing in the November 2, 1983, (48 FR 50686) **Federal Register.** In addition, this submittal was to conform to the USEPA's "Guidance Document for the Correction of Part D SIP's for Nonattainment Areas", which was released on January 27, 1984. This document referenced the original transportation control plan elements which were published in the January 22, 1981, (46 FR 7182) **Federal Register.**

The State of Indiana, in response to USEPA's notification, submitted a revised CO SIP for Marion County on March 4, 1985. USEPA reviewed this technical information and requested additional information. As a result, additional supplemental technical information was submitted to USEPA on October 7, 1985. In addition, the State of Indiana submitted its transportation control measures portion of the CO SIP on February 12, 1985.

II. Air Quality Analysis

Three CO monitors were located in the CO nonattainment area during the period of 1981 thru 1983 (the base period of the SIP). During this period, the 8-hour CO standard of 9 parts per million (ppm) averaged over 8 hours (not to be exceeded more than once per year) was only violated at the L.S. Ayres site which is located at the intersection of 1 West Washington and Meridian. The highest second-high CO concentration monitored at this site was 11.7 ppm recorded in June 1981. No violations of the one hour standard were recorded at any of the monitoring sites.

The second highest concentration monitored at 1 West Washington in 1983 was 11.1 ppm. The State, however, considers this concentration to be questionable for several reasons. First, it occurred during the afternoon of Thanksgiving Day. There was little traffic in the nonattainment area because of the holiday. As a result, the source of the high CO concentration is not certain. Second, a sudden pronounced increase in the hourly concentrations was noted between 3 p.m. (with a concentration of 0.9 ppm) and 4 p.m. (with a concentration of 13.2 ppm). The submittal includes a duplication of the strip chart which supports the observation of the Indianapolis Air Pollution Control Division (APCD) that the monitor may have been unstable or malfunctioning on this day. If the November 24, 1983, 8-hour concentration is discredited, the second-high concentration of 11.7 ppm, monitored in 1981, becomes the constraining CO concentration from a control standpoint.

III. Emission Inventory

The Indianapolis APCD developed the CO emission inventory for the post-1982 SIP. It was assumed that major stationary source emissions of CO had a negligible impact on the CO concentrations in the nonattainment area because no such sources were known to be located near this area. The post-1982 SIP only addresses the mobile source CO emissions in the nonattainment area and in the Central Business District (CBD). The SIP shows that the CO concentration patterns in the nonattainment area point to the existence of intersection-specific problem areas (hotspots) rather than to an areawide problem. Despite this, the SIP includes both a demonstration of attainment based on a rollback of CBD mobile source CO emissions as well as a demonstration of attainment based on hotspot microscale dispersion modeling.

An emission inventory was developed for specific intersections as well as for the CBD. The mobile source emissions inventory was developed using USEPA's mobile source emissions factor models, MOBILE 2.5 and MOBILE 3. Due to timing constraints, the Indianapolis APCD used MOBILE 2.5 for the initial intersection-specific (hotspot) analysis. An updated hotspot analysis submitted on October 7, 1985, used MOBILE 3 as required by USEPA. The SIP does include a comparison of the results from MOBILE 2.5 with those from MOBILE 3 for the CBD emissions total.

The annual and worst-case daily CBD mobile source emission factors were calculated for 1981, 1983 thru 1987, and 1995. These factors took into account the impact of the Federal Motor Vehicle Emission Control Program (FMVCP), but ignored other impacts such as the committed Transportation Control Measures (TCM's).

In regard to the base period and projected traffic levels, the plan notes that current (base period) and projected Vehicle Miles Traveled (VMT) were difficult to determine due to the limited amount of available traffic count data. Currently, each major CBD intersection receives one 48-hour traffic count every 3 years. There has been no continuous counting at a permanent site to provide detailed traffic trend data.

The Indianapolis APCD determined through the use of available traffic count data that despite the recent significant commercial growth in the downtown area, no upward trend in VMT was observed during the past decade. Excluding year-to-year variations, no overall increases in traffic levels are evident in the data. Nonetheless, the plan assumes a 1 percent per year growth rate for the VMT between 1981 and 1987. This assumption is consistent with the same assumption used by the Indianapolis Department of Transportation for short term planning purposes.

Based on the use of a travel demand model for 1981, the Indianapolis APCD determined that the CBD had an average daily VMT of 395,400 VMT. Projecting the traffic demand to the year 2,000 and accounting for both the assumed VMT growth rate and the impacts of planned traffic improvement projects, the Indianapolis APCD determined that the CBD VMT would increase by 27.7 percent between 1981 and the year 2000, giving an average annual growth rate of 1.4 percent. This growth rate was used to determine the 1995 VMT level. The same growth rates were applied to all arterials in the CBD.

The available data, predicts that a 25.8 percent drop in annual CBD CO emissions will occur between 1981 (the base year of the rollback analysis) and 1987.

IV. Modeling and Demonstration of Attainment

The Marion County CO plan approaches the CO demonstration of attainment in several ways. First, assuming the data for the L.S. Ayres site are the worst-case concentrations for the CBD, the SIP discusses a rollback analysis of the total CBD emissions. The highest second-high 8-hour CO concentration (11.7 ppm) in 1981 at the L.S. Ayres site was usd in the rollback analysis.

Second, recognizing the hotspot nature of the emissions within the nonattainment area, the plan describes the results of an intersection-specific dispersion analysis using CALINE3. This later analysis was updated in the October, 7, 1985, submittal. The CALINE3 line source dispersion model along with intersection-specific emission estimates by traffic link segments were used to calculate CO concentrations at twelve major intersections in the CO nonattainment area. These intersections were selected because either they had associated CO monitors or because they suffered from notable traffic congestion.

The hotspot modeling indicated that five intersections had the potential to violate the CO NAAQS in 1983. These intersections are: Pennsylvania and Washington: Delaware and Ohio; Meridian and 11th Street; Delaware and Michigan; and Delaware and Washington. Based on the modeling, none of these interesection have the potential to violate the CO NAAQS in 1986. The modelled worst-case intersection in 1986 was the intersection of Delaware and Ohio, for which an 8-hour concentration of 8.9 ppm was calculated.

USEPA had reviewed some of the initial CO modeling and expressed concern over several aspects of the modeling. The additional modeling data (second series) submitted on October 7, 1985, addressed USEPA's technical concerns on the first series of modeling. In the second series of modeling, the twelve intersections considered in the first modeling series were screened to determine which intersections were located in street canyons. Two intersections, Washington/Meridian and Pennsylvania/Market were found to be street canyon locations. For these two intersections, 1983 and 1987 concentrations were calculated using a street canyon algorithm given in USEPA's indirect source evaluation guideline (EPA–450/4–78–001). The following 8-hour concentrations were calculated for Washington/Meridian: 12.0 ppm in 1983 and 9.0 ppm in 1987; and for Pennsylvania-Market 11.8 ppm in 1983 and 8.8 ppm in 1987.

The results of the revised CALINE3 modeling showed no violations of the 8-hour CO NAAQS for 1987 at any of the five modelled intersections.

The highest 1987 8-hour concentration modelled was 7.5 ppm at the intersection of Pennsylvania and Washington. Both the CBD emission rollback analysis and the hotspot modeling results imply that the CO NAAQS will be attained in the nonattainment area by December 31, 1987.

V. Control Strategies

The State of Indiana submitted its transportation control measures portion of the Marion Country Co plan on February 12, 1985. The SIP included a commitment to implement a one-way pair project involving Washington and Maryland Streets in the CBD. This project is expected to provide better signal timing progression on Washington Street, to increase the average speed of traffic, and to shorten queue lengths significantly. The Maryland Street project was completed in 1985. The Washington Street project is scheduled for completion in August 1986.

This control measure will result in smoother traffic flow along Washington resulting in higher average vehicle speeds. The projected impact of the higher speeds was included in the modeling analysis for 1987. Higher vehicle speeds lead to significantly lower CO emissions rates. The number of traffic lanes on Washington Avenue will be reduced while maintaining the existing street width, which will also lead to improvements in traffic flow. Marion County also expects the FMVCP to have a significant downward effect on CO emissions from mobile sources. All the other transportation elements in the 1979 SIP have been implemented.

VI. Maintenance of the National Ambient Air Quality Standards (NAAQS)

In order to assure maintenance of the CO NAAQS, a comparison was made between the anticipated increase in the traffic volume and the predicted change in the fleet composite CO emission factor for the CBD during the period of 1987 to 1995. A 27.6 percent reduction in the emission factor is expected between 1987 and 1995. The CBD VMT is expected to increase by 13.5 percent uniformly throughout the CBD. Therefore, continued improvement in the downtown CO concentrations and maintenance of the NAAQS is expected to occur after 1987.

VII. Demonstration of Reasonable Further Progress

The CO SIP submittal contains the anticipated yearly CO emission reductions in the CBD along with the yearly reduction needed to meet USEPA's "straight line" reasonable further progress (RFP) requirement. The data indicate that RFP was achieved in the CBD after 1984 and will be maintained through 1987.

The SIP also presents a graphical CO RFP demonstration for the worst-case hotspot intersection. This graphical presentation demonstrates that RFP will be achieved and maintained at this intersection through 1987.

VIII. USEPA Technical Review and Determination

USEPA's review of the ambient monitor strip chart record for November 24, 1983, supports the Indianapolis APCD view that this second-high concentration at the L.S. Ayers site should be discredited due to probable montitor instability. USEPA has determined that the appropriate second-high 8-hour design concentration should be 11.7 ppm, which was monitored in 1986.

It should be noted that USEPA does not agree with the manner in which the State calculated the CBD-wide CO emission rates. Vehicles travel at different speeds within the CBD. As may be noted from the speed-specific emission factors listed in the Indiana SIP revision, emission factors do not vary linearly with speed. The use of a single average vehicle speed to calculate a CBD total emission rate may lead to an incorrectly calculated emission rate. USEPA believes that it would have been more technically correct to have determined the VMT distribution as a function of vehicle speed with the CBD emission rate based on this VMT distribution. However, review of the speed-specific emission rates indicates that these emission rates drop by approximately the same percentage between 1983 and 1986 regardless of vehicle speed. The same result is assumed to be the case between 1981 and 1987. As a result, the use of a single, average speed rather than a VMT-speed distribution to calculate the CBD total emission rate should have little effect on the results of the rollback analysis, which is only sensitive to the percentage change in emissions. Therefore, USEPA does agree with the general results of the analysis.

USEPA has determined that the SIP has successfully demonstrated attainment of the CO NAAQS by December 31, 1987. Assuming that the L.S. Ayres site has the worst-case CO concentration site in the CBD, the rollback analysis shows CO emissions must be reduced by 22.8 percent from the 1981 CBD total. The SIP demonstrates a 24.5 percent emission reduction by 1987 based on daily emissions, or a 25.8 percent emission reduction by 1987 based on annual emissions.

USEPA's review of the hotspot analysis as revised in the October 7, 1985, submittal shows that a demonstration of attainment by December 31, 1987, has been successfully made for the worst-case intersections. The ambient monitoring from the three sites does support the view that the CO nonattainment problem in downtown Indianapolis is hotspot in nature and, therefore, by developing an approvable plan for the hotspot problems, Indiana has assured the attainmenmt and maintenance of the CO NAAQS throughout the nonattainment area. Additionally, USEPA has determined that the Marion County CO SIP appropriately demonstrates RFP towards attainment of the CO NAAQS.

IX. Conclusion

USEPA proposes to approve the Marion County CO SIP as demonstrating attainment of the NAAQS by December 31, 1987, and RFP in the existing nonattainment area. USEPA also proposes to approve the adopted Transportation Control Measure (TCM).

Under 5 U.S.C. 605(b), the Administrator has certified that SIP approvals do not have a significant impact on a substantial number of small entities. (See 46 FR 8709).

The Office of Management and Budget has exempted this rule from the requirements of section 3 of Executive Order 12291.

Authority: 42 U.S.C. 7401–7642.

Dated: March 27, 1986.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 86–16388 Filed 7–21–86; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Part 60

[AD-FRL-3052-9]

Standards of Performance for New Stationary Sources; Industrial-Commercial-Institutional Steam Generating Units

AGENCY: Environmental Protection Agency (EPA).

ACTION: Rescheduling of Public Hearing and Extension of Public Comment Period.

SUMMARY: On June 19, 1986, new source performance standards were proposed to limit sulfur dioxide emissions from new industrial-commercial-institutional steam generating units of more than 100 million Btu/hr heat input capacity (51 FR 22384). On June 24, 1986, the Council of Industrial Boiler Owners requested that the public hearing be rescheduled and the public comment period be extended. As a result, as noted below, the public hearing has been rescheduled to September 4, 1986, and the close of the public comment period has been extended to October 2, 1986.

DATES: *Comments.* Comments on the proposed standards must be received by October 2, 1986.

Public Hearing. A public hearing will be held on September 4, 1986, beginning at 10:00 a.m.

Request to Speak at Hearing. Persons wishing to present oral testimony must request to speak at the public hearing by calling Ann Eleanor at (919) 541–5578 by August 8, 1986.

ADDRESSES: *Public Hearing:* The public hearing will be held at EPA's Office of Administration Auditorium, Research Triangle Park, North Carolina.

Docket: Docket No. A–83–27 containing supporting information used in developing the proposed standards is available for public inspection and copying between 8:00 a.m. and 4:00 p.m., Monday through Friday, at EPA's Central Docket Section, West Tower Lobby, Gallery 1, Waterside Mall, 401 M Street, SW., Washington, DC 20460. A reasonable fee may be charged for copying.

FOR FURTHER INFORMATION CONTACT: Mr. Fred Porter or Ms. Dianne Byrne, Standards Development Branch, Emission Standards and Engineering Division (MD–13), U.S. Environmental Protection Agency, Research Triangle Park, North Carolina 27711. Telephone: (919) 541–5578.

Dated: July 14, 1986.

Don R. Clay,

Acting Assistant Administrator for Air and Radiation.

[FR Doc. 86–16390 Filed 7–21–86; 8:45 am]

BILLING CODE 6560-50-M

40 CFR Part 81

[A-5-FRL-3053-3]

Designation of Areas for Air Quality Planning Purposes; Attainment Status Designations: Indiana

AGENCY: U.S. Environmental Protection Agency.

ACTION: Proposed rule.

SUMMARY: USEPA proposes to change the designation for St. Joseph and Elkhart Counties, Indiana, from nonattainment to attainment for ozone. This proposal was initiated by a request from the State of Indiana to redesignate this area. USEPA is proposing to approve the request based on ambient air quality data and the emissions data submitted by the State.

DATE: Comments on this revision and on the proposed USEPA action must be received by September 22, 1986.

ADDRESSES: Copies of the redesignation request, technical support documents and the supporting air quality data are available at the following addresses:

U.S. Environmental Protectioin Agency, Region V, Air and Radiation Branch (5AR-26), 230 S. Dearborn Street, Chicago, Illinois 60604

Indiana Air Pollution Control Division, Indiana State Board of Health, 1330 West Michigan Street, Indianapolis, Indiana 46206

Comments on this propsed rule should be addressed to: (Please submit an original and three copies, if possible.)

Gary Gulezian, Chief, Regulatory Analysis Section, Air and Radiation Branch (5AR-26), U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604

FOR FURTHER INFORMATION CONTACT: Annie E. Tenner, (312) 886-6036

SUPPLEMENTARY INFORMATION: Under section 107(d) of the Clean Air Act (Act), the Administrator of USEPA has promulgated the National Ambient Air Quality Standards (NAAQS) attainment status for each area of every State. See 43 FR 8962 (March 3, 1978) and 40 CFR Part 81. These area designations may be revised whenever the date warrant, provided USEP's criteria are met for redesignations. St. Joseph and Elkhart Counties were designated nonattainment for ozone in the March 3, 1978, rulemaking.

Ozone Redesignation Criteria

USEPA's designation policy, as contained in the "Guideline for the Interpretation of Ozone Air Quality Standards" (EPA-450/4-79-003), provides that the NAAQS for ozone is violated when the annual average expected number of daily exceedances of the standard (0.12 parts per million (ppm), 1 hour average) is greater than one (1.0) at any monitoring site in the area under consideration. A daily exceedance occurs when the maximum hourly ozone concentration during a given day exceeds 0.124 ppm.

USEPS's policy for ozone redesignation requests is also discussed in the following memoranda:

1. December 7, 1979, from Richard G. Rhoads to the Directors of Air and Hazardous Materials Divisions, Region I-X "Criteria for Ozone Redesignations Under section 107."

2. April 21, 1983, from Sheldon Meyers to Directors of Air Management Divisions, "Section 107 Designation Policy Summary."

3. December 23, 1983, from G.T. Helms to Chiefs of Air Program Branchs, Region I-X, "Section 107 Questions and Answers."

The provisions of this policy which apply to Indiana's redesignation request can be summarized as follows:

1. Generally, the most recent 3 years of quality-assured ozone monitoring data at least are to be considered.

2. The designation given for an area applies to whole counties only. No subdivision of a county is allowed. Urban areas must have a single designation, with the designation area including the entire urbanized area and fringe areas of development.

3. The nonattainment area should be of sufficient size to include all significant impacting volatile organic compound (VOC) emission sources.

4. The State Implementation Plan (SIP) for the area must be fully approved and finally implemented.

St. Joseph and Elkhart Counties Ozone Redesignation Requests

On December 22, 1983, the State of Indiana submitted a redesignation request to USEPA proposing to redesignate St. Joseph and Elkhart Counties from nonattainment to attainment for ozone. USEPA reviewed this submittal and proposed to disapprove this request in the August 3, 1984 (49 FR 31093), **Federal Register.**

On February 8, 1985, the State of Indiana officially withdrew its December 22, 1983, redesignation request, which had been based on 3 years (1981-1983) of ozone monitoring data. Instead, the February 8, 1985, submittal requested USEPA to redesignate St. Joseph and Elkhart Counties to attainment based on 4 years of ozone data (1981-1984) from the two Indiana sites in the area. This revised redesignation request was accompanied by documentation on VOC emissions in the area. The documentation in this redesignation request includes 1981 through 1984 ozone monitoring data for the two Indiana downwind sites, Children's Hospital and Harris Township, Fire Station, and 1984 data for one upwind site in Walkerton, Indiana. The data show that multiple exceedances of the ozone standard have been recorded at the two downwind sites. Both sites have expected exceedances rates of 1.1 per year based on 3 years of data. However, if 4 years of data are considered, both sites have an average expected exceedance rate of 0.8 per year, which is not a violation of the NAAQS.

The State submitted emission inventory data for a baseline year of 1983 and for the extrapolated years of 1981, 1982, 1984 and 1990. The point source VOC and NOx emissions were taken from Indiana's Emission Inventory Survey (EIS) computer data base. The documentation includes emissions for each facility and for major process types within each facility. The documentation also includes reported days of operation in 1983 for each facility.

The 1983 mobile source emissions for St. Joseph, Elkhart and Berrien (Michigan) Counties were based on Vehicle Miles Traveled and Vehicle Hours Traveled, as reported by the Michiana Area Council of Governments (MACOG) for various roadway types. Area source VOC and NOx emission estimates were produced following, where possible, USEPA guidelines contained in "*Procedures for the Preparation of Emission Inventories for Volatile Organic Compounds*", Volume I, EPA-450/2-77-028.

On November 7, 1984, the State of Indiana adopted Reasonably Available Control Technology (RACT) I and II regulations, for St. Joseph and Elkhart Counties. These regulations were approved by USEPA in the February 10, 1986, (51 FR 4912) **Federal Register**, and this approval lifted the Section 110(a)(2)(I) growth restriction. Because compliance with these regulations is required by December 31, 1986, the projected emissions for 1990 include the projected impacts from these controls.

Discussion of Redesignations Based on More Than 3 Years of Ambient Data

The December 7, 1979, policy memorandum from Richard G. Rhoads states that the procedures outlined in the "Guideline for the Interpretation of Ozone Air Quality Standards" should be used in reviewing and/or making Section 107 redesignation requests for

ozone. The April 21, 1983, Sheldon Meyers' policy memorandum requires that all available information relative to the attainment status of an area should be reviewed. The issue of particular concern in the St. Joseph and Elkhart Counties redesignation request is the maximum number of years of ozone data per site that may be considered in the designation review.

The February 8, 1985, redesignation request from the State is based on the most recent 4 years of ozone data. USEPA's Guideline for Interpretation of Ozone Air Quality Standards states that increasing the number of years in the review increases the stability of the resulting average annual number of exceedances. The guideline points out that considering more years of ozone data minimizes the impacts of variations in meteorology. The guideline implies that the review of air quality data for designation purposes should not be biased by the effects of atypical meteorology. As many years as possible should be considered to dampen the effects of atypical meteorology. However, in evaluating the appropriate number of years of ambient data to use, one must also consider the impact in the area of changes in the emissions and ambient concentrations of ozone precursors, i.e., VOCs and oxides of nitrogen (NOx). Where these emissions may be demonstrated to be constant or decreasing over time, then it is appropriate to consider as many years of ambient data as possible to average out the effects of variations in meteorology.

Analysis of St. Joseph and Elkhart Counties Redesignation Request

USEPA reviewed the data submitted by the State and determined that additional information was needed. As discussed in USEPA's technical support document, USEPA adjusted and supplemented the State's emissions data. It then reassessed the corrected emissions.

USEPA's analysis showed that VOC emissions have decreased in the three county area (St. Joseph and Elkhart Counties in Indiana and Berrien County in Michigan) between 1981 and 1984. Additional emissions reductions will occur by 1990. This emission reduction will, in part, be due to the combined impact of the implementation of RACT and the continued implementation of the Federal Motor Vehicle Control Program (FMVCP).

If emissions are decreasing with time, and meteorology is essentially constant, ozone concentrations should decrease. As indicated in USEPA's guidelines, it is desirable to average out meteorological effects by considering as many years of data as possible, provided such data are representative of current and future conditions. Therefore, in the case of the St. Joseph and Elkhart Counties area, USEPA believes it appropriate to consider the most recent 4 years of ozone data in the calculation of expected exceedances. Based on 4 years of data, the South Bend area has an average expected exceedance rate of less than 1.0 per year. With respect to continuing maintenance of the ozone NAAQS, the FMVCP and the final implementation of RACT will produce further VOC emission reductions in the future. USEAP believe these reductions are necessary to provide for the continued maintenance of the ozone NAAQS with reasonable certainty.

As stated earlier, USEPA's policy requires that an area's SIP be fully approved and finally implemented before an area can be redesignated. Therefore, although USEPA is proposing to approve Indian's redesignation request today, it will not take final action to approve the redesignation request until the St. Joseph and Elkhart County SIP for ozone is finally implemented. Thus, subsequent to the December 31, 1986, compliance deadline imposed by the RACT I and II Regulations, the State must provide evidence that the approved control strategy has been finally implemented. USEPA will not take final action to approve this designation unless the State provides evidence that the approved control strategy has been implemented.

Additionally, USEPA is continuing to review ambient montoring data from St. Joseph and Elkhart Counties. In 1985, no excursions of the standard were recorded. Violations of the standard are not anticipated in the future in St. Joseph and Elkhart Counties. However, if one occurs before USEPA goes to final rulemaking on this redesignation, USEPA will reconsider the approvability of Indiana's redesignation request.

All interested persons are invited to submit written comment on the proposed redesignation. Written comments received by the data specified above will be considered in determining whether USEPA will approve the redesignation. After review of all comments submitted, the Administrator of USEPA will publish in the **Federal Register** the Agency's final action on the redesignation.

Under 5 U.S.C. 605(b), the Administrator has certified that redesignations do not have a significant economic impact on a substantial number of small entities (See 46 FR 8709).

The Office of Management and Budget has exempted this rule from the requirements of Section 3 of Executive Order 12291.

Authority: 42 U.S.C. 7401–7642.

Dated: September 11, 1985.

Valdas V. Adamkus,

Regional Administrator.

[FR Doc. 86–16409 Filed 7–21–86; 8:45 am]

BILLING CODE 6560-50-M

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40 CFR Parts 704 and 721

[OPTS-50552 AND OPTS-82026; FRL-3008-7]

11-Aminoundecanoic Acid; Proposed Determination of Significant New Use; Submission of Notice of Manufacture, Import, or Processing

AGENCY: Environmental Protection Agency (EPA).

ACTION: Proposed rule.

SUMMARY: EPA is proposing a significant new use rule (SNUR) under section 5(a)(2) of the Toxic Substances Control Act (TSCA) that would require persons to notify EPA at least 90 days before commencing the manufacture, import, or processing of 11-aminoundecanoic acid (11–AA) (CAS Number 2432–99–7) for any use other than as an intermediate in the manufacture of nylon 11 in an enclosed process. EPA believes that this action is necessary because 11–AA may be hazardous to human health, and any use of 11–AA other than as an intermediate in the manufacture of nylon 11 in an enclosed process may result in significant human exposure. The notice required by this rule would furnish EPA with the information needed to evaluate an intended use, and the opportunity to protect against potentially adverse exposure to the chemical substance.

EPA is also proposing under section 8(a) of TSCA that manufacturers, importers, and processors of 11–AA who are not covered by the SNUR notification requirements notify EPA of prospective manufacture, import, or processing of this chemical substance. This reporting rule would allow EPA to track the manufacture, import, processing, and end uses of this substance, and to investigate the health and environmental impacts of such activities. Small businesses that manufacture, import, or process 11–AA would be exempt from the section 8(a) reporting rule.

DATE: Written comments on this proposed rule should be submitted by September 22, 1986.

ADDRESS: Comments should bear the docket control numbers OPTS–50552 and OPTS–82026 and should be submitted to: TSCA Public Information Officer (TS–793), Office of Toxic Substances, Environmental Protection Agency, NE–G004, 401 M St., SW., Washington, DC 20460.

All written comments on this proposed rule will be available for public inspection in Rm. E–107 at the address given above from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays.

FOR FURTHER INFORMATION CONTACT: Edward A. Klein, Director, TSCA Assistance Office (TS–799), Office of Toxic Substances, Environmental Protection Agency, Rm. E–543, 401 M St., SW., Washington, DC 20460,
Toll free: (800–424–9065),
In Washington, DC: (554–1404),
Outside the USA: (Operator–202–554–1404).

SUPPLEMENTARY INFORMATION:

I. Authority

The Agency is proposing this rule pursuant to sections 5(a)(2) and 8(a) of TSCA, 15 U.S.C. 2604(a)(2) and 2607(a).

Section 5(a)(2) of TSCA authorizes EPA to determine that a use of a chemical substance is a significant new use. This determination is made by rule after consideration of all relevant factors, including those listed in section 5(a)(2). Once EPA determines a use to be a significant new use, persons must, under section 5(a)(1)(B), submit a notice to EPA at least 90 days before they commence the manufacture, import, or processing of the substance for that use.

Persons subject to this SNUR would comply with the same notice requirements and EPA regulatory procedures as submitters of premanufacture notices (PMNs) under section 5(a)(1)(A) of TSCA. In particular, these requirements include the information submission requirements of section 5(b) and (d)(1), the exemptions authorized by section 5(h)(1), (2), (3), and (5), and the regulations at 40 CFR Part 720. Once EPA receives a SNUR notice, the Agency may take regulatory action under section 5(e), 5(f), 6, or 7 to control the activities for which it has received a SNUR notice. If EPA does not take action, section 5(g) of TSCA requires the Agency to explain in the **Federal Register** its reasons for not taking action.

Persons who intend to export a substance identified in a proposed or final SNUR are subject to the export notification provisions of TSCA section 12(b). The regulations that interpret section 12(b) appear at 40 CFR Part 707.

Persons who intend to import a substance identified in a final SNUR are subject to the TSCA section 13 import certification requirements, which are codified at 19 CFR 12.118 through 12.127 and 127.28. The EPA policy in support of the import certification requirements appears at 40 CFR Part 707.

Section 8(a) of TSCA authorizes the Administrator to promulgate rules which require such person (other than a small manufacturer, importer, or processor) who manufactures, imports, or processes or who proposes to manufacture, import, or process a chemical substance to submit such reports as the Administrator may reasonably require.

II. Applicability of General Provisions

In the **Federal Register** of September 5, 1984 (49 FR 35011), EPA promulgated general provisions applicable to SNURs (40 CFR Part 721, Subpart A). April 22, 1986, EPA proposed revisions to the general provisions (51 FR 15104), some of which would apply to this proposed SNUR. General provisions applicable to section 8(a) rules were published in the **Federal Register** of May 25, 1983 (40 CFR Part 704, Subpart A). EPA is proposing that these general provisions apply to this rule. The general provisions are discussed in detail in the cited **Federal Register** documents and interested persons should refer to those documents for further information.

III. Summary of This Proposed Rule

A. Significant New Use Rule

EPA is proposing to designate any use of 11–AA other than as an intermediate in the manufacture of nylon 11 in an enclosed process as a significant new use of this chemical substance. This proposed rule would require persons who intend to manufacture, import, or process 11–AA for this significant new use to notify EPA at least 90 days before beginning such manufacture, import, or processing.

The notice is generally subject to the same statutory requirements and procedures as a premanufacture notice (PMN) submitted under section 5(a)(1)(A) of TSCA. In particular, these include the information submission requirements of sections 5(b) and (d)(2), and the exemptions authorized by section 5(h). Once EPA has received a significant new use notice, EPA may take regulatory action pursuant to section 5(e), 5(f), 6, or 7 to control the substance. If no action is taken, section 5(g) requires the Agency to explain in the **Federal Register** its reasons for not taking action.

11–AA is a known carcinogen for which there is no known use other than as an intermediate in the manufacture of nylon 11. This manufacture takes place in an enclosed process. 11–AA is not subject to any Federal regulation that would notify the government of activities that might result in adverse exposures to this substance or provide a regulatory mechanism that could protect human health from potentially adverse exposures before they occurred.

EPA believes that the significant new use and associated manufacture, import, or processing of 11–AA have a high potential to increase the magnitude and duration of exposure to this substance and to change the type or form of exposure from that which currently exists. Also, given the toxicity of this chemical substance, the reasonably anticipated situations that could result in exposure, and the lack of sufficient existing regulatory controls, individuals could be exposed to 11–AA at levels which may result in adverse effects.

The consideration of these factors has resulted in EPA's decision to propose that any use of 11–AA other than as an intermediate in the manufacture of nylon 11 in an enclosed process be designated a significant new use of this chemical substance. Persons intending to manufacture, import, or process 11–AA for this significant new use would be required to notify EPA 90 days before they begin manufacture, import, or processing. Advance notification will allow EPA the opportunity to evaluate the risks related to an intended activity and to protect against adverse exposures to 11–AA before they can occur.

B. Section 8(a) Rule

The proposed SNUR described above will ensure EPA is notified in the event that 11–AA is manufactured, imported, or processed for any use other than as an intermediate in the manufacture of nylon 11 in an enclosed process. However, persons who manufacture or import 11–AA would not be required to report to EPA if the 11–AA they were manufacturing or importing was to be used as an intermediate in the manufacture of nylon 11 in an enclosed process. Persons could also process 11–AA as an intermediate in the manufacture of nylon 11 in an enclosed process, but certain portions of the processing operation (such as raw material transfer) could result in potentially high human exposures.

EPA is concerned that 11–AA manufacturing, importing, and processing activities associated with the ongoing use could present the

opportunity for human exposure to this chemical substance. Because the SNUR would not provide notification of manufacturing, importing, and processing activities associated with the ongoing use, and because this substance is a possible human health hazard, EPA believes it is necessary to require reporting under TSCA section 8(a) for those ongoing 11–AA activities which would not be covered by the SNUR.

Therefore, EPA is proposing that persons who intend to manufacture, import, or process 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process be required to notify EPA within 30 days after making a firm management decision to commit financial resources for the manufacturing, importing, or processing of 11–AA. Persons who initiated manufacturing, importing, or processing 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process during the time period between July 22, 1986 and the effective date of the final rule would be required to notify EPA within 30 days of the effective date.

Persons who manufactured, imported, or processed 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process at any time during the three years before July 22, 1986 would be exempt from reporting. EPA is providing this exemption because the Agency has had the opportunity to evaluate ongoing 11–AA activities, and has found that adequate steps are currently being taken to minimize human exposure.

Small manufacturers (including importers) as described at 40 CFR 704.3 would be exempt from reporting. Processors meeting the same size standards as those described for small manufacturers at 40 CFR 704.3 would also be exempt from reporting (see proposed § 704.25(a)(4)).

EPA proposes to require that persons subject to the section 8(a) rule submit a PMN Form (EPA Form 7710–25). A copy of that form can be found at 40 CFR Part 720, Appendix A.

IV. Discussion of Chemical Substance

A. Production and Use Data

EPA reviewed both the TSCA Chemical Substance Inventory data base and other information sources to identify current manufacturers, importers, and processors of 11–AA. The review indicates that one company imports about 9 million pounds of 11–AA into the U.S. each year for the manufacture of the polyamide nylon 11. Nylon 11 is the substance formed by the polymerization of 11–AA, and is also known as poly(imino(1-oxo-1,11-undecanediyl)) (CAS Number 25035–04–5). There is no known manufacturer of 11–AA in the United States.

The entire import amount of 11–AA is processed to produce nylon 11, except for possibly small amounts for research and development. Nylon 11 is used to manufacture automobile parts, industrial fabrics, wire and cable coverings, and powder coatings.

B. Health Effects

Results of a National Toxicology Program (NTP) carcinogenesis bioassay on 11–AA published in May 1982 demonstrated limited evidence that 11–AA is carcinogenic in laboratory animals. Under the conditions of the bioassay, 11–AA was carcinogenic for male F344 rats, inducing neoplastic nodules in the liver and transitional cell carcinomas in the urinary bladder at a statistically significant ($p<0.01$) level. The substance was not carcinogenic for the female F344 rat. No clear evidence was found for the carcinogenicity of 11–AA in $B6C3F_1$ mice of either sex, although an increase in malignant lymphomas in male mice may have been associated with the administration of 11–AA. Other effects of 11–AA included a dose-related decrease in mean body weight gain and survival for male rats and mice of each sex, hyperplasia of transitional epithelium of the kidney and urinary bladder in rats of each sex, and mineralization of the kidney in mice of each sex.

EPA published Proposed Guidelines for Carcinogen Risk Assessment in the **Federal Register** of November 23, 1984 (49 FR 46294). These proposed guidelines define as a possible human carcinogen agents exhibiting: ". . . (a) definitive malignant tumor response in a single well-conducted experiment, (b) marginal tumor response in studies having inadequate design or reporting, (c) benign but not malignant tumors with an agent showing no response in a variety of short-term tests for mutagenicity, and (d) marginal responses in a tissue known to have a high and variable background rate. . . ."

A limited review of the results of the NTP carcinogenesis bioassay on 11–AA indicates that the substance has been found to induce a definitive malignant tumor response in male rats, and may therefore be a possible human carcinogen according to the Agency's proposed guidelines for carcinogen risk assessment.

Results from the NTP bioassay also demonstrate that 11–AA is capable of causing chronic and subchronic non-oncogenic effects in laboratory animals. For these reasons, EPA has concluded that exposure to the substance may present a risk of injury to human health.

C. Past and Current Exposures

The only known potential human exposure to 11–AA occurs during the manufacture of nylon 11. 11–AA is imported in 1,000 kg valved bags from which the 11–AA is pneumatically transferred to storage silos at the nylon 11 manufacturing facility. These valved bags are designed and constructed to prevent the release of 11–AA. When needed, the 11–AA is transferred from the storage silo via a closed piping system to a closed, pressurized ractor vessel where the production of nylon 11 occurs. Between 20 and 25 employes are potentially exposed to 11–AA. Workers engaged in processing 11–AA to nylon 11 are required to wear safety glasses, face-shields, safety shoes, longsleeved shirts, rubber or cotton gloves, along with suitable respirators whenever exposure to 11–AA is possible. The plant is equipped with hooded exhaust areas and local exhaust at points of potential worker exposure to 11–AA.

During the manufacture of nylon 11, monomeric 11–AA is expected to be fully polymerized. It is therefore unlikely that persons will be exposed to 11–AA in products containing nylon 11.

D. Regulatory Background

11–AA is not subject to any Federal regulation that limits exposure to humans or the environment. Excluding this proposed rule, no Federal regulations have been proposed or promulgated that would allow a governmental entity an opportunity to evaluate the potential human exposure to 11–AA originating from its manufacture, import, and processing, and to protect human being from potentially adverse exposures before they occur.

V. Alternatives

Before proposing this rule, EPA considered alternative regulatory actions.

1. One alternative would be to promulgate only a section 8(a) reporting rule for this substance. Under such a rule, EPA could require any person to report to EPA before manufacturing, importing, or processing 11–AA. However, the use of only section 8(a) rather than combined section 8(a)/SNUR authority has drawbacks. Small businesses would be exempt from reporting under section 8(a). Considering the toxicity of 11–AA, even relatively small manufacture, import, or processing activities could result in adverse exposures to this substance. In addition,

if EPA received a report under section 8(a) indicating that a person intended to manufacture, import, or process this substance, the Agency could not take immmediate action under section 5(e) or (f) as it can under a SNUR, and therefore would not be able to act quickly to protect against an adverse exposure to this substance. Rather, in a situation such as this, EPA would have to consider regulating the substance under TSCA section 6 or rquesting under section 9 that another agency regulate it, each of which would require a lengthy separate action before the exposure could be controlled.

Under the proposed combined section 8(a)/SNUR, the drawbacks described above still exist, but to a lesser extent. EPA would not be able to take immediate action under section 5(e) or 5(f) for persons who manufacture, import, or proces 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process. These manufacturers, importers, and processors would also be subject to the small business exemption provided by section 8(a). However, these limitations would not apply to persons who manufacture, import, or process 11–AA for any use other than as an intermediate in the manufacture of nylon 11 in an enclosed process.

2. The Agency also has the authority to regulate substances under section 6 of TSCA. However, the Agency may regulate under section 6 only if there is a reasonable basis to conclude that the manufacture, processing, distribution in commerce, use, or disposal of a chemical substance or mixture "presents or will present" an unreasonable risk of injury to human health or the environment. There is insufficient information about prospective manufacturing, importing, or processing operations at this time to perform a reasoned evaluation of the health or environmental effects of these activities. Therefore, the Agency cannot state with certaintly that these activities would present an unreasonable risk and cannot, at this time, reguate 11–AA under section 6.

If the Agency receives section 8(a) reports for 11–AA which indicate that the substance, as manufactured, imported, or processed "presents or will present" an unreasonable risk of injury to human health or the environment, EPA will take action under section 6 or 9 as appropri ate.

VI. Applicability of Proposal to Uses Occurring Before Promulgation of Final Rule

EPA finds that the intent of section 5(a)(1)(B) is best served by determining whether a use is a significant new use as of the proposal date of the SNUR rather than after the promulgation of a final rule. If uses begun during the proposal period of the SNUR were not considered new, it would be extremely difficult for the Agency to establish significant new use notice requirements. Any person could defeat the SNUR by initiating the proposed significant new use before the rule becomes final.

EPA recognizes that this interpretation of section 5 may disrupt the commercial activities of persons who begin the manufacture, import, or processing of 11–AA for the proposed significant new use during the proposal period. However, this proposal puts them on notice of the potential disruption, and they proceed at their own risk.

VII. Test Data and Other Information

Although EPA has a considerable amount of test data on the potential adverse effects of 11–AA to human health, EPA lacks data on the potential adverse effects of 11–AA to the environment. EPA recognizes that, under TSCA section 5(a)(2), a person is not required to develop any particular test data before submitting a notice. Rather, persons are only required to submit test data in their possession or control and to describe any other data known to or reasonably ascertainable by them. However, in view of the potential risks that may be posed by a significant new use of 11–AA, EPA encourages notice submitters under the SNUR to conduct tests that would permit a reasoned evaluation of the substance's toxic potential to the environment when utilized for an intended use.

Notices submitted with such test data would improve EPA's ability to make a reasoned evaluation of the environmental effects of 11–AA. Test data should be developed in accordance with TSCA Good Laboratory Practices Standards at 40 CFR Part 792.

In addition to environmental effects test data, EPA encourages notice submitters to develop and submit relevant exposure data on this substance. Notices submitted with such exposure data would improve EPA's ability to make an evaluation of the human exposure potential when 11–AA is utilized for an intended significant new use. EPA encourages persons to consult with the Agency before selecting a testing protocol.

Finally, EPA urges persons to submit information on potential benefits of this substance and information on risks posed by the substance compared to risks posed by potential substitutes.

VIII. Economic Impact

The Agency has evaluated the potential costs of establishing SNUR and section 8(a) reporting requirements for 11–AA. The only direct costs that will definitely occur as a result of the promulgation of this rule will be EPA's costs of issuing and enforcing the rule. The estimated cost to the Agency for issuing this rule is $10,500 to $20,500. The Agency will also incur enforcement costs, but these costs cannot be quantified at this time.

After promulgation of this rule, the Agency believes there are two possible courses of action for a person who intends to manufacture, import, or process 11–AA: (1) File a notice with information describing the method of controlling exposures that would mitigate health and environmental concerns; or, (2) not initiate the manufacturing, importing, or processing activity.

In some circumstances it may be cost-effective for a person to file a notice with data that show there exist means of controlling exposures (e.g., personal protective equipment or engineering controls) that would mitigate EPA's health concerns. In this case, the company incurs the costs of filing a notice ($1,400 to $8,000) and possibly the cost of utilizing exposure controls that, without the existence of the rule, would not have been used. These costs cannot be quantified at this time, since industrial processes and exposure controls vary among companies. The company may also incur up to a 3.2 percent reduction in profits due to delays in manufacture or processing and the cost of regulatory follow-up, if any.

A person may find the cost of controlling exposures too expensive to justify the manufacture, import, or processing of 11–AA. This outcome would not result in any direct costs, but the prospective manufacturer, importer, or processor may lose beneifts that would have been derived from such manufacture, import, or processing of 11–AA. EPA cannot quantify these potential lost benefits because EPA cannot reasonably anticipate the future level of use of this chemical substance, the profit margins of these uses, and other related factors.

The Agency has not attempted to quantify the benefits of the proposed rule or of the outcomes. In general, benefits will accrue if the proposed action leads to the identification and control of unreasonable risks before adverse effects can occur.

IX. Rulemaking Record

EPA has established a record for this rulemaking (docket control numbers OPTS–50552 and OPTS–82026). The record includes basic information considered by the Agency in developing this proposed rule. EPA will supplement the record with additional information at it is received. The record now includes the following:

1. Economic analysis of the proposed rule for 11–AA.
2. A chemical hazard information profile for 11–AA.
3. The NTP carcinogenesis bioassay on 11–AA.

The Agency will accept additional materials for inclusion in the record at any time between this proposal and designation of the complete record.

EPA will identify the complete rulemaking record by the date of promulgation. A public version of this record is available in the OTS Public Information Office, from 8 a.m. to 4 p.m., Monday through Friday, except legal holidays. The Public Information Office is located in Rm. NE–6004, 401 M St. SW., Washington, DC.

X. Regulatory Assessment Requirements

A. Executive Order 12291

Under Executive Order 12291, EPA must judge whether a regulation is "major" and therefore requires a regulatory impact analysis. The Agency has determined that this proposed rulemaking is not "major" because it will not have an effect of $100 million or more on the economy. EPA also anticipates that this proposed rulemaking will not have a signficant effect on competition, costs, or prices.

This regulation was submitted to the Office of Management and Budget (OMB) for review as required by Executive Order 12291.

B. Regulatory Flexibility Act

Under the Regulatory Flexibility Act, 5 U.S.C. 605(b), EPA certifies that this proposed rule, if promulgated, will not have a significant impact on a substantial number of small businesses.

The Agency cannot determine whether parties affected by the proposed SNUR are likely to be small businesses. However, because EPA has no evidence of recent commercial manufacture, import, or processing of 11–AA other than the manufacture of nylon 11 in an enclosed process, EPA believes that few manufacturers, importers, or processors will submit significant new use notices. Therefore, although the costs of preparing a notice under the SNUR provisions might be significant for some small businesses, the number of such businesses affected is not expected to be substantial.

The 8(a) rule will exempt "small" manufacturers (as defined in 40 CFR 704.4) and "small" processors from reporting on this chemical substance. Therefore, in accordance with the Regulatory Flexibility Act (Pub. L. 95–354), EPA has determined that this proposed rule will not have a significant economic impact on a substantial number of small entities.

C. Paperwork Reduction Act

OMB has approved the information collection requirements contained in this proposed rule under the provisions of the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 *et seq.* and has assigned OMB Control Numbers 2070–0067 and 2070–0038. Comments on these requirements should be submitted to the Office of Information and Regulatory Affairs of OMB, marked Attention: Desk Officer for EPA. The final rule package will respond to any OMB or public comments on the information collection requirements.

List of Subjects in 40 CFR Parts 704 and 721

Chemicals, Environmental protection, Hazardous substances, Recordkeeping and reporting requirements, Significant new uses.

Dated: July 11, 1986.

John A. Moore,

Assistant Administrator for Pesticides and Toxic Substances.

Therefore, it is proposed that 40 CFR Chapter I be amended as follows:

PART 704—[AMENDED]

1. In Part 704:

a. The authority citation for Part 704 would continue to read as follows:

Authority: 15 U.S.C. 2607(a).

2. By adding a new § 704.25 to read as follows:

§ 704.25 11-Aminoundecanoic acid.

(a) *Definitions.* (1) "11–AA" means the chemical substance 11-aminoundecanoic acid, CAS Number 2432–99–7.

(2) "Enclosed process" means a process that is designed and operated so that there is no intentional release of a chemical substance. In an enclosed process, only fugitive or inadvertent releases occur, and special measures are taken to prevent worker exposure and environmental contamination.

(3) "Nylon 11" is the chemical substance poly(imino(1-oxo-1,11-undecanediyl)), CAS Number 25035–04–5.

(4) "Small processor" means a processor that meets either the standard in paragraph (a)(4)(i) of this section or the standard in paragraph (a)(4)(ii) of this section.

(i) *Fist standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company, if any, are less than $40 million. However, if the annual processing volume of a particular chemical substance at any individual site owned or controlled by the processor is greater than 45,400 kilograms (100,000 pounds), the processor shall not qualify as small for purposes of reporting on the processing of that chemical substance at that site, unless the processor qualifies as small under paragraph (a)(4)(ii) of this section.

(ii) *Second standard.* A processor of a chemical substance is small if its total annual sales, when combined with those of its parent company (if any), are less than $4 million, regardless of the quantity of the particular chemical substance processed by that company.

(iii) *Inflation index.* EPA will use the Inflation Index described in the definition of "small manufacturer" set forth in § 704.3, for purposes of adjusting the total annual sales values of this small processor definition. EPA will provide notice in the **Federal Register** when changing the total annual sales values of this definition.

(b) *Persons who must report.* Except as provided in paragraph (c) of this section, the following persons are subject to the rule:

(1) Persons who manufacture or propose to manufacture 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process.

(2) Persons who import or propose to import 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process.

(3) Persons who process or propose to process 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process.

(c) *Persons not subject to this rule.* The following persons are not subject to this rule:

(1) Small manufacturers (includes importers) as described in § 704.3.

(2) Small processors.

(3) Persons described in § 704.5.

(4) Persons who manufactured, imported, or processed 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process at any time during the 3-year period ending July 22, 1986.

(d) *What information to report.* Persons identified in paragraph (b) of this section must submit a

Premanufacture Notice Form (EPA Form 7710–25) as described at CFR Part 720, Appendix A.

(e) *When to report.* (1) Persons who intend to manufacture, import, or process 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process must notify EPA within 30 days after making a firm management decision to commit financial resources for the manufacturing, importing, or processing of 11–AA.

(2) Persons who initiated manufacturing, importing, or processing of 11–AA for use as an intermediate in the manufacture of nylon 11 in an enclosed process during the time period between July 22, 1986 and [the effective date of the final rule] must notify EPA by [30 days after the effective date].

(f) *Recordkeeping.* Persons subject to the reporting requirements of this section must retain documentation of information contained in their reports for a period of 5 years from the date of submission of the report.

(g) *Where to send reports.* Reports must be submitted by certified mail to the United States Environmental Protection Agency, Document Processing Center, P.O. Box 2070, Rockville, MD 20852. ATTN: 11–AA Notification.

PART 721—[AMENDED]

(2). In Part 721:

a. The authority citation for Part 721 would continue to read as follows:

Authority: 15 U.S.C. 2604 and 2607.

b. By adding a new § 721.109 to read as follows:

§ 721.109 11-Aminoundecanoic acid.

(a) *Chemical substance and significant new use subject to reporting.* (1) The chemical substance 11-aminoundecanoic acid, CAS Number 2432–99–7, is subject to reporting under this section for the significant new use described in paragraph (a)(2) of this section.

(2) The significant new use is any use other than as an intermediate in the manufacture of nylon 11 in an enclosed process.

(b) *Specific requirements.* The provisions of Subpart A of this Part apply to this section except as modified by this paragraph.

(1) *Definitions.* In addition to the definitions in § 721.3, the following definitions apply to this section:

(i) "Enclosed process" means a process that is designed and operated so that there is no intentional release of a chemical substance. In an enclosed process, only fugitive or inadvertent releases occur, and special measures are taken to prevent worker exposure and environmental contamination.

(ii) "Nylon 11" is the chemical substance poly(imino(1-oxo-1,11-undecanediyl)), CAS Number 25035–04–5.

(2) [Reserved].

[FR Doc. 86–16393 Filed 7–21–86; 8:45 am]
BILLING CODE 6560–50–M

FEDERAL COMMUNICATIONS COMMISSION

47 CFR Part 1

[Gen. Docket No. 86–225; FCC 86–284]

Ex Parte Communications and Presentations in Commission Proceedings

AGENCY: Federal Communications Commission.

ACTION: Notice of proposed rulemaking.

SUMMARY: FCC institutes a rulemaking proceeding which proposes changes to the Subpart H, Part 1 of the Commission's Rules and Regulations relating to ex parte communications and presentations governing Commission proceedings. The purpose is to undertake a thorough review of the rules in order to clarify and streamline ex parte practice and procedure.

DATES: Comments must be received on or before September 2, 1986, and Reply Comments must be received on or before September 17, 1986.

ADDRESS: Secretary's Office, Room 222, Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Steve Bailey or Susan Steiman, Administrative Law Division, Office of General Counsel, Washington, DC 20554, (202) 254–6530 or 632–6990.

SUPPLEMENTARY INFORMATION: This is a summary of the commission's notice of proposed rulemaking, Gen. Docket No. 86–225, adopted June 5, 1986, and released July 9, 1986.

The full text of this commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (room 230), 1919 M Street, Northwest, Washington, DC. The complete text of this decision may also be purchased from the Commission's Copy Contractor, International Transcription Service, (202) 857–3800, 2100 M Street, Northwest, Suite 140, Washington, DC 20037.

Summary of Notice of Proposed Rulemaking

1. The Notice of Proposed Rulemaking invites comment on proposed changes to Commission's rules, regulations, and policies which govern the making of ex parte communications in Commission proceedings. The purpose of the ex parte rules is to ensure that agency proceedings are decided on the merits of a public record developed in the proceeding rather than communications shrouded in secrecy and to ensure the adequacy and completeness of a record to enable effective judicial review of the agency's action. An important objective is to establish procedures that allow the Commission sufficient flexibility to obtain necessary information and evidence for reasoned decisionmaking.

2. The major purposes of this rulemaking are to simplify the rules by making them easier to understand and apply, to clarify their applicability in areas where questions have arisen, and to remedy problems which have occurred under the present rules.

3. Besides recasting the existing provisions into a simpler format, the Commission is proposing the following major changes:

—to make clear that the ex parte prohibitions apply to presentations both *to* and *from* decision-making personnel in restricted proceedings;

—to redefine decision-making personnel to include any agency person "who is or may reasonably be expected to be involved" in the decision-making process in the proceeding;

—to clarify that "formal oppositions," not informal oppositions or objections, will trigger more stringent ex parte procedures applicable to restricted proceedings;

—to clarify that the less-restrictive "permit but disclose" ex parte procedures that now apply to informal rulemaking proceedings also apply to any proceeding instituted by a notice of inquiry which could lead to a change in policy intended to be binding as a matter of law;

—to clarify that *any* presentations, whether ex parte or not, are prohibited in non-restricted proceedings from the time that any such proceeding is placed on the Sunshine Agenda for Commission consideration;

—to clarify that status inquiries, *whether solicited or not,* are exempt from the prohibitions on ex parte presentations;

—to clarify that tariff proceedings under section 203, 204, or 205 of the Communications Act are exempt

unless they have been set for investigation or designated for hearing;
—to apply ex parte restraints to all "contested" adjudicative proceedings which are opposed; and
—to provide that the Managing Director shall provide notice to parties to a proceeding when a prohibited ex parte presentation has occurred but shall *not* be required to serve copies of the prohibited presentation except if he determines that there are public interest reasons that warrant disclosure of such information.

4. The Commission also proposes certain other clarifications, simplications, and modifications of its ex parte rules, procedures, and policies as indicated in Appendix "A".

5. This is a non-restricted notice and comment rule-making proceeding. *See* § 1.1231 of the Commission's Rules, 47 CFR 1.1231, for rules governing permissible *ex parte* contacts.

6. As required by section 603 of the Regulatory Flexibility Act, the Commission has prepared an initial regulatory flexibility analysis ("IRFA") of the expected impact of these proposed policies and rules on small entities. The IRFA is available with the full text of the Commission's decision.

7. The proposal contained herein has been analyzed with respect to the Paperwork Reduction Act of 1980 (44 U.S.C. 3501 *et al.*) and found to contain no significant new or modified form, information collection and/or record-keeping, labeling, disclosure, or record retention requirements; and should not result in a material increase or decrease in burden hours imposed on the public.

8. Authority for this proposed rule-making is contained in sections 4(i), 4(j), 303(r) and 409 of the Communications Act of 1934, as amended (47 U.S.C. 153(i), 153(j), 303(r) and 409). Pursuant to §§ 1.415 and 1.419 of the Commission's rules, interested parties may file comments on or before September 2, 1986 and reply coments on or before Septembe 17, 1986. All relevant and timely comments will be considered by the Commission before final action is taken in this proceeding. In reaching its decision, the Commission may take into consideration information and ideas not contained in the comments, provided that such information or a writing indicating the nature and source of such information is placed in the public file, and provided that the Commission's reliance on such information is noted in the Report and order.

9. To file formally in this proceeding, participants must file an original and five copies of all comments, reply comments, and supporting documents. If participants want each Commissioner to receive a personal copy of their comment, an original plus eleven copies must be filed. Persons wishing to participate informally may submit one copy of their comments, stating thereon the docket number of this proceeding. Comments and reply comments should be sent to the Office of the Secretary, Federal Communications Commission, 1919 M Street. NW., Washington, DC 20554. Comments and reply comments will be made available for public inspection during regular business hours in the Dockets Public Reference Room (Room 239) at that address. For additional information on this proceeding, contact Steve Bailey, Office of the General Counsel, (202) 254–6530.

List of Subjects in 47 CFR Part 1

Administrative practice and procedure.

Federal Communications Commission.
William J. Tricarico,
Secretary.

Proposed Rule Amendments

PART 1—[AMENDED]

Part 1 (Practice and Procedure) of Chapter I of Title 47 of the Code of Federal Regulations is amended as follows:

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

Authority: Sections 4, 303, 409, 48 Stat. 1066, 1082, 1096, as amended; 47 U.S.C. 154, 303, 409.

2. Subpart H is revised to read as follows:

Subpart H—Ex Parte Communications

General

Sec.
1.1200 Introduction.
1.1202 Definitions.

General Exemptions

1.1204 General exemptions.

Non-Restricted Proceedings

1.1206 Non-restricted proceedings; ex parte presentations generally permissable but subject to disclosure.

Restricted Proceedings

1.1208 Restricted proceedings.

Prohibition of Solication of Ex Parte Presentations

1.1210 Prohibition on solication of ex parte presentations.

Procedures for Handling of Prohibited Ex Parte Presentations Sanctions

1.1212 Procedures for handling of prohibited ex parte presentations

Sec.
1.1214 Disclosure of information/concerning violations of this subpart
§ 1.1216 Introduction.

Subpart H—Ex Parte Communications

General

§ 1.1200 Introduction.

(a) *Purpose.* To ensure that the Commission's decisional processes are fair, impartial, and otherwise comport with the concept of due process, the Commission has prescribed rules and regulations governing ex parte communications. These rules and regulations, which are designed to deter improper communications and maintain the utmost public confidence in Commission proceedings, specify minimum standards of conduct and procedures to be followed with regard of ex parte presentations in Commission proceedings and provide for the imposition of sanctions for violations of these standards and procedures.

(b) *General Applicability.* These rules set forth the ex parte requirements that apply in various types of Commission proceedings. Following § 1.1202 (Definitions), the rules describe three general classes of FCC proceedings. First, § 1.1204(a) lists types of proceedings in which there are no ex parte restrictions. In these proceedings, parties and Commission decision makers may communicate freely, without regard to the prohibitions and disclosure requirements of these ex parte rules. Next, § 1.1206(c) lists proceedings that are classified as "non-restricted." In non-restricted proceedings, parties and Commission decision makers are permitted to engage in ex parte communications but certain disclosure requirements must be met. In addition, in non-restricted proceedings certain periods are set aside during which all communication with Commission personnel is prohibited. *See* § 1.1206(b). Finally, § 1.1208(c) lists proceedings that are classified as "restricted." In restricted proceedings, ex parte communications are generally prohibited. In addition, the prohibitions and requirements applicable to "restricted" and "non-restricted" proceedings are subject to certain general exceptions, which are listed in § 1.1204(b). Therefore, § 1.1204(b) should always be examined to determine whether a seemingly prohibited ex parte communication may be permissible.

Note.—Inquiries concerning the propriety of ex parte communications should be directed to the Office of General Counsel.

§ 1.1202 Definitions.

(a) *Presentation.* Any communication directed to the merits or outcome of a proceeding. Excluded from this term is a communication inadvertently or casually made and which only relates incidentally to the merits or outcome of the proceeding, or an inquiry or request for information relating solely to the status of a proceeding.

Note.—A status inquiry which states or implies a preference for a particular party or position in a proceeding, or which states why timing is important to a particular party, or in any other manner as a means, direct or indirect, to address the merits or outcome of a proceeding is an ex parte presentation.

(b) *Ex parte presentation.* Any presentation made to decision-making personnel and, in restricted proceedings, any presentation to or from decision-making personnel which (1) If written, is not served on the parties to the proceeding or (2) If oral, is made without advance notice to the parties to the proceeding and without opportunity for them to be present.

Note.—Comments and reply comments in informal rule making proceedings pursuant to §§ 1.415 and 1.419 are not considered ex parte presentations even if they are not served on other parties.

(c) *Decision-making personnel.* Any member, officer or employee of the Commission who is or may reasonably be expected to be involved in the decisional process in the proceeding. Unless otherwise specified, such persons usually include the Commissioners, their assistants, and other professional personnel of the Commission. Any person who has been made a party to a proceeding or who otherwise has been excluded from the decisional process shall not be treated as a decision-maker with respect to that proceeding. Thus, any person designated as part of a separated trial staff shall not be considered a decision-making person in the designated proceeding. Unseparated Bureau or Office staff who may reasonably be expected to become involved in the decisional process of the proceeding shall be considered decision-making personnel.

(d) *Adjudicative proceeding.* A proceeding, other than a rule making (including a tariff proceeding involving future rates or practices), initiated upon the Commission's own motion or by the filing of an application, formal complaint, waiver request, petition for special relief, or other similar pleading that involves an authorization or action pertaining to specific entities or persons.

(e) *Formal opposition.* A pleading opposing the grant of a particular application, waiver request, petition for special relief or other request for Commission action which meets the following requirements:

(1) The caption and text of the pleading make it unmistakably clear that the pleading is intended to be a formal opposition;

(2) The pleading is served upon the other parties to the proceeding; and

(3) The pleading is timely filed.

(f) *Sunshine Agenda period.* For purposes of this subpart, the Sunshine Agenda period is defined as that period of time between which a draft order proposing a substantive disposition of the proceeding is placed on the Sunshine Agenda and the Commission

(1) Releases a final order, or

(2) Issues a public notice stating that the matter has been deleted from the Sunshine Agenda, or

(3) Issues a public notice stating that the matter has been returned to the staff for further consideration, whichever one of the above occurs first.

General Exemptions

§ 1.1204 General exemptions.

(a) *Proceedings in which no ex parte restrictions apply.* Subject to the provisions of § 1.1208(b), there are no ex parte restraints or disclosure requirements in the following types of proceedings:

(1) Any adjudicative proceeding as defined in § 1.1202(d) unless it

(i) Is formally opposed; or;

(ii) Involves mutually exclusive applications; or

(iii) Has been designated for hearing, *see* Section 1.1208(c)(1)(i);

Note.—In proceedings exempted by § 1.1204(a) ex parte communications are permissible only between the Commission and the formal party involved.

(2) A pending petition for rule making unless it involves the allotment of a channel in the radio broadcast or television broadcast services and is formally opposed, see § 1.1208(c)(2);

(3) A notice of inquiry proceeding unless the Commission states otherwise, *see* § 1.1206(c)(2);

(4) A request for information which is filed pursuant to the Freedom of Information Act, 5 U.S.C. 552, unless it is formally opposed, *see* § 1.1206(c)(6);

(5) A proceeding involving an informal complaint against a carrier under Section 208 of the Communications Act (see § 1.711 of the Rules) unless it has been designated for hearing; or

(6) A tariff proceeding under section 203, 204, or 205 of the Communications Act unless it has been set for investigation or designated for hearing, *see* §1.1206(c)(5).

(b) *Exempt Ex Parte Presentations.* The following types of ex parte presentations are exempt from the prohibitions and requirements in Section 1.1206 (non-restricted proceedings) and § 1.1208 (restricted proceedings):

(1) The presentation is authorized by statute or by the Commission's Rules, *see, e.g.,* § 1.333(d);

(2) The presentation is made by or to the General Counsel or his staff and concerns judicial review of a matter which has ben decided by the Commission;

(3) The presentation directly relates to an emergency in which the safety of life is endangered or substantial loss of property is involved;

(4) The presentation involves a military or foreign affairs function of the United States or involves classified security information;

(5) The presentation is requested by the Commission staff for the clarification or adduction of evidence or for resolution of issues in an adjudicatory proceeding which has not been designated for hearing or in a non-restricted proceeding, provided that any new written information elicited from such a communication and not already reflected in the record of the proceeding shall be served upon the other parties to the proceeding. A summary of any oral information elicited from such a communication and not already reflected in the record of the proceeding shall be served upon the other parties to the proceeding. Any such request made by Commission staff shall not be deemed an ex parte presentation.

Non-Restricted Proceedings

§ 1.1206 Non-restricted proceedings; ex parte presentations generally permissible but subject to disclosure.

(a) Except during the Sunshine Agenda period (*see* § 1.1206(b)), ex parte presentations are permissible in non-restricted proceedings if the following disclosure requirements are met:

(1) *Written ex parte presentations made by persons outside the Commission.* Any person who makes or submits a written ex parte presentation shall provide on the same day it is made or submitted a copy of its under separate cover to the Commission's Secretary for inclusion in the public record. The presentation must indicate on its face the docket number of the particular proceeding(s) to which it relates and that a copy of it has been submitted to the Secretary.

(2) *Oral ex parte presentations made by persons outside the Commission.* Any person who in making an oral ex parte presentation presents data or

arguments that are not already reflected in that person's written comments or in an ex parte presentation previously filed in that proceeding by that person shall provide on the day of the oral presentation a written memorandum to the Secretary (with a copy to the Commissioner or staff member involved) which summarizes the data and arguments.

(3) *Ex parte presentations requested by persons within the Commission and spontaneous ex parte presentations.* A decision making persons who requests an ex parte presentation or is involved in a spontaneous ex parte presentation should ensure that the presentation is reflected in the public record before the Commission issues a final order in the relevant proceeding. Any person who makes a presentation under this paragraph shall comply with the requirements of paragraph (a)(1) of this section or paragraph (a)(2) of this section whichever is applicable.

(4) *Filing of ex parte presentations.* The Commission's Secretary shall place in the public file or record of the proceeding written ex parte presentations and memoranda reflecting oral ex parte presentations.

(b) Unless exempted under § 1.1204(b), the making of any presentation, whether ex parte or not, is prohibited during the Sunshine Agenda period. *See* § 1.1202(f).

(c) Unless otherwise ordered by the Commisison, a non-restricted proceeding includes:

(1) An informal rule making proceeding conducted under section 553 of the Administrative Procedure Act (upon Commission adoption of a notice of proposed rulemaking), unless the proceeding concerns the allotment of a specific channel in the radio or television broadcast services, § 1.1208(c)(2);

(2) An inquiry proceeding (upon Commission adoption of a notice of inquiry) where the Commission specifically states the proceeding is nonrestricted because it contemplates adoption of a binding policy determination;

(3) A petition or request for declaratory ruling at the time a formal opposition to the petition has been filed;

(4) A rule making proceeding conducted pursuant to sections 201(a), 213(a), 221(c) or 222 of the Communications Act or sections 201(c)(2) or 201(c)(5) of the Communications Satellite Act of the 1962, if the proceeding has been formally opposed or has been set for investigation by the Commission.

(5) A tariff proceeding which has been set for investigation by the Commission under section 204 or 205;

Note.—Proceedings under the statutory provisions listed in §§ 1.1206(c)(4) and 1.1206(c)(5) that pertain primarily to *past* rates or practices of common carriers may be adjudicative proceedings subject to the provisions of section 1.1208. *See* 5 U.S.C. 551(4); 47 U.S.C. 409(c)(1)(2)(d); *AT&T v. FCC*, 449 F.2d 439 (2d Cir. 1971).

(6) A proceeding involving a request for information filed pursuant to the Freedom of Information Act, 5 U.S.C. 552, upon the filing of a formal opposition to the request.

Restricted Proceedings

§ 1.1208 Restricted proceedings.

(a) Unless exempted under § 1.1204(b), ex parte presentations are prohibited in restricted proceedings. The prohibition continues in effect until the proceeding has been decided or a settlement or agreement by the parties has been approved by the Commission and such decision or approval is no longer subject to reconsideration by the Commission or to review by any court.

(b) No person shall make an ex parte presentation in a proceeding even though the proceeding is not restricted if

(1) That person intends to file a mutually exclusive application which would cause the proceeding to become restricted; or

(2) That person intends to file an opposition or objection which would cause the proceeding to become restricted.

Note.—Informal complaint proceedings under Section 208 are not governed by § 1.1208(b)(2) until a formal complaint is filed.

(c) Unless governed by § 1.1204 or § 1.1206, the following are restricted proceedings:

(1)(i) Any adjudicative proceeding, including any proceeding conducted pursuant to section 303(1) (classification and qualifications of radio station operators); section 303(m) (suspension of radio licenses); sections 308 and 309 (application for licenses); section 310 (holding and transfer of licenses); section 312 (administrative sanctions); section 315 (facilities for candidates for public office); section 316 (modification of construction permits or licenses) of the Communications Act; cable television special relief or waiver proceedings; or

(ii) Any proceeding under section 206 (liability of carriers for damages); section 207 (recovery of damages); section 208 (complaints); section 212 (interlocking directorates); section 214(a) or 214(d) (line extensions); section 221(a) (telephone consolidations and acquisitions); section 224(b)(1) (pole attachments) of the Communications Act; or

(iii) Any proceeding under sections 201(c)(6), (7), (9) or 304(f) of the Communications Satellite Act of 1962;

from the day on which any of the following has occurred:

(A) The release of an order designating the proceeding for hearing (unless a hearing has been subsequently waived pursuant to § 1.92 of this chapter);

(B) The filing of a formal opposition or formal complaint;

(C) The release of a public notice apprising the public of the filing of a mutually exclusive application *provided, however,* that if a person has actual knowledge that a mutually exclusive application has been filed prior to the release of the public notice, that person is prohibited from making an ex parte presentation from the moment of such actual knowledge. The term "public notice" as used in this subsection means the public notice issued at regular intervals listing all applications and major amendments thereto which have been tendered (or, in non-broadcast services, accepted) for filing. (*See* §§ 1.564(c), 1.962(e) and 21.27(b) of this chapter.) When the Commission issues a specific public notice stating that there is a possibility of conflict between the applications, then the term "public notice" shall refer the specific public notice rather than that issued at regular intervals.

(2) An informal rule making proceeding concerning the allotment of a channel in the radio broadcast or television broadcast services (*see Sangamon Valley Television Corporation v. United States*, 269 F. 2d 221, 224 (D.C. Cir. 1959)) at the time of adoption of the notice of proposed rule making or the filing of an opposition to a petition for rule making, whichever is earlier;

(3) Any other proceeding which the Commission designates as restricted.

Prohibition on Solicitation of Ex Parte Presentations

§ 1.1210 Prohibition on solicitation of ex parte presentations.

No person shall solicit or encourage others to make any ex parte presentation which he or she is prohibited from making under the provisions of this subpart.

Procedures for Handling of Prohibited Ex Parte Presentations

§ 1.1212 Procedures for handling of prohibited ex parte presentations.

(a) If a prohibited oral ex parte presentation is initiated, the person to whom it is addressed shall advise the person initiating it that such presentation is prohibited and terminate the discussion.

(b) If a prohibited oral ex parte presentation has been made, the Commission personnel to whom the presentation was made shall forward to the Managing Director a statement containing the following information:

(1) The name of the proceeding.

(2) The name and address of the person making the presentation and that person's relationship (if any) to the parties to the proceeding or their attorneys.

(3) The date and time of the presentation, its duration, and the circumstances (telephone, personal interview, casual meeting, etc.) under which it was made.

(4) A brief summary of the presentation.

(5) Whether the person making the presentation persisted in doing so after having been advised that the presentation was prohibited.

(6) The date and time at which the statement was prepared.

(c) Written ex parte presentations which are prohibited shall be forwarded by the person receiving them to the Managing Director. If the circumstances in which such a presentation was made are not apparent from the presentation itself, a statement describing those circumstances shall be submitted to the Managing Director with the presentation.

(d) Prohibited *written* ex parte presentations, all statements and correspondence relating thereto, all statements and correspondence relating to prohibited *oral* ex parte presentations shall be placed in a public file which shall be associated with, but not made a part of, the file or record of the proceeding to which the presentations pertain. In a proceeding which has not yet been designated for hearing, no such presentations, statements or correspondence relating thereto, shall be considered in determining the merits of the proceeding except upon notice and disclosure to the parties to the proceeding. Once a proceeding has been designated for hearing, such materials may be considered in determining the merits of a restricted proceeding only if they are made a part of the record of the proceeding.

(e) If the Managing Director determines that an ex parte presentation is prohibited by this subpart, he shall notify the parties to the proceeding that a prohibited ex parte presentation has occurred. If the Managing Director determines that there are public interest reasons which warrant disclosure of the prohibited presentation, he shall serve upon the parties to the proceeding copies of the presentation or, if it was oral, a summary of the presentation, as well as any statements or correspondence describing the circumstances in which it was made. Service by the Managing Director shall not be deemed to cure any violation of the rules against prohibited ex parte presentations.

(f) If circumstances satisfy the Managing Director that notice of a prohibited presentation under paragraph (e) of this section would be unduly burdensome because the parties to the proceeding are numerous, he may (in lieu of notice to the parties) issue a public notice that a prohibited presentation has been made in the proceeding. Where a determination has been made that disclosure of the prohibited presentation would be appropriate under paragraph (e) of this section and circumstances satisfy the Managing Director that service of copies of the prohibited presentation would be unduly burdensome because the parties to the proceeding are numerous or because the materials relating to the presentation are voluminous, he may issue a public notice that copies of the presentation and/or materials relating to it are available for public inspection.

(g) A copy of any statement describing the circumstances in which any prohibited ex parte presentation was made shall be forwarded to the person who made the presentation. Within 10 days thereafter, the person who made the presentation may file with the Managing Director a notarized statement regarding the presentation and the circumstances in which it was made. If the Managing Director deems it appropriate, he shall serve copies of the notarized statement upon parties to the proceeding.

§ 1.1214 Disclosure of information concerning violations of this subpart.

Any party to a proceeding or any Commission employee who has substantial reason to believe that any violation of this subpart has been solicited, attempted, or committed, shall promptly advise the Managing Director in writing of all the facts and circumstances concerning the matter which are known to him.

Sanctions

§ 1.1216 Sanctions.

(a) *Parties.* (1) Upon notice and hearing, any party to a restricted proceeding who directly or indirectly violates or causes the violation of any provision of this subpart, or who fails to advise the Managing Director of the facts and circumstances concerning any such violation, may be disqualified from further participation in that proceeding. Such alternative or additional sanctions as may be appropriate may be imposed.

(2) To the extent consistent with the interests of justice and the public, a party who has violated or caused the violation of any provision of this subpart may be required to show cause why his claim or interest in the proceeding should not be dismissed, denied, disregarded, or otherwise adversely affected.

(b) *Commission personnel.* Violations of the provisions of this subpart by Commission personnel shall be disposed of in accordance with Administrative Order No. 10 and the penalties therein specified.

(c) *Other persons.* Such sanctions as may be appropriate under the circumstances shall be imposed upon other persons who violate the provisions of this subpart.

(d) The sanctions outlined in paragraphs (a)(1), (b), and (c) of this section shall also apply in non-restricted rulemaking proceedings, but the sanction outlined in paragraph (a)(2) shall not apply in such proceedings.

[FR Doc. 86-15898 Filed 7-21-86; 8:45 am]
BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 86-302, RM-5304]

Radio Broadcasting Services; Marshfield, MO

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Ladco Communications, Inc., requesting the substitution of FM Channel 284C2 for 285A at Marshfield, Missouri, and modification of the Class A license for Station KTOZ-FM, Marshfield, to reflect the higher class of channel. The allocation could provide Marshfield with a first Class C2 channel.

DATES: Comments must be filed on or before September 8, 1986, and reply

comments on or before September 23, 1986.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultant, as follows: Eugene T. Smith, 715 G Street, SE., Washington, DC 20003, (Counsel for the petitioner).

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 86–302, adopted July 3, 1986, and released July 16, 1986. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 86–16425 Filed 7–21–86; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 86–303, RM–5236]

Radio Broadcasting Services; Pleasant Hope, MO

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition filed by Charles Williams, seeking the allotment of FM Channel 238C2 to Pleasant Hope, Missouri, as that community's first broadcast service.

DATES: Comments must be filed on or before September 8, 1986, and reply comments on or before September 23, 1986.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultant, as follows: James J. McGillan, Barry Fleischman, Finley, Kumble, Wagner, Heine, Underberg, Manley & Casey, 1120 Connecticut Avenue, NW., Washington, DC 20036 (counsel for the petitioner).

FOR FURTHER INFORMATION CONTACT: Kathleen Scheuerle, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 86–303, adopted July 3, 1986, and released July 16, 1986. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 86–16426 Filed 7–21–86; 8:45 am]

BILLING CODE 6712-01-M

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47 CFR Part 73

[MM Docket No. 85–305, RM–5248]

Radio Broadcasting Services; Aberdeen, SD

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: Action taken herein proposes the allocation of Channel 294C1 to Aberdeen, South Dakota, as the community's third local commercial FM service, at the request of ALROX, Inc.

DATES: Comments must be filed on or before September 8, 1986, and reply comments on or before September 23, 1986.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioner, or their counsel or consultant, as follows: Clifford M. Harrington, Esq., Neil S. Ende, Esq., Fisher, Wayland, Cooper, and Leader, 1255–23rd Street, NW., Suite 800, Washington, DC 20037–1125. (Counsel to petitioner).

FOR FURTHER INFORMATION CONTACT: Leslie K. Shapiro, Mass Media Bureau, (202) 634–6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 86–305, adopted July 3, 1986, and released July 23, 1986. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857–3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 86-16427 Filed 7-21-86; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 86-304, RM-5318]

Radio Broadcasting Services; Wilmington, VT

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by Robin Rothschild proposing the allotment of FM Channel 264A to Wilmington, Vermont, as that community's first FM services.

DATES: Comments must be filed on or before September 8, 1986, and reply comments on or before September 23, 1986.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultant, as follows: Steven J. Pena, Gurman, Kurtis & Black, Chartered, 1730 M Street, NW., Suite 700, Washington, DC 20036 (Counsel for petitioner).

FOR FURTHER INFORMATION CONTACT: Patricia Rawlings, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 86-304, adopted July 3, 1986, and released July 16, 1986. The full test of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW, Suite 140, Washington DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contacts are prohibited in Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, see 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Radio broadcasting.

Federal Communications Commission.

Mark N. Kipp,

Chief, Allocations Branch, Mass Media Bureau.

[FR Doc. 86-16428 Filed 7-21-86; 8:45 am]

BILLING CODE 6712-01-M

47 CFR Part 73

[MM Docket No. 86-301, RM-5311]

Television Broadcasting Services: Panama City, FL

AGENCY: Federal Communications Commission.

ACTION: Proposed rule.

SUMMARY: This document requests comments on a petition by National Hispanic Broadcasters Association which seeks to assign UHF television Channel 62 to Panama City, Florida, as its fourth commerical service.

DATES: Comments must be filed on or before September 8, 1986, and reply comments on or before September 23, 1986.

ADDRESS: Federal Communications Commission, Washington, DC 20554. In addition to filing comments with the FCC, interested parties should serve the petitioners, or their counsel or consultant, as follows: Mr. Carlos Ortiz, National Hispanic Broadcasters Association, P.O. Box 1975, San Benito, Texas 78586 (petitioner).

FOR FURTHER INFORMATION CONTACT: Montrose H. Tyree, (202) 634-6530.

SUPPLEMENTARY INFORMATION: This is a summary of the Commission's Notice of Proposed Rule Making, MM Docket No. 86-301, adopted July 3, 1986, and released July 16, 1986. The full text of this Commission decision is available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, NW., Washington, DC. The complete text of this decision may also be purchased from the Commission's copy contractors, International Transcription Service, (202) 857-3800, 2100 M Street, NW., Suite 140, Washington, DC 20037.

Provisions of the Regulatory Flexibility Act of 1980 do not apply to this proceeding.

Members of the public should note that from the time a Notice of Proposed Rule Making is issued until the matter is no longer subject to Commission consideration or court review, all *ex parte* contracts are prohibited in Federal Communication Commission proceedings, such as this one, which involve channel allotments. See 47 CFR 1.1231 for rules governing permissible *ex parte* contact.

For information regarding proper filing procedures for comments, See 47 CFR 1.415 and 1.420.

List of Subjects in 47 CFR Part 73

Television broadcasting.

Federal Communications Commission.

Mark N. Lipp,

Chief, Allocations Branch, Policy and Rules Division, Mass Media Bureau.

[FR Doc. 85-16429 Filed 7-21-85; 8:45 am]

BILLING CODE 6712-01-M

Notices

Federal Register
Vol. 51, No. 140
Tuesday, July 22, 1986

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 COMMERCE

Agency Forms Under Review by the Office of Management and Budget

DOC has submitted to OMB for clearance the following proposals for collection of information under the provisions of the Paperwork Reduction Act (44 U.S.C. Chapter 35).

Agency: International Trade Administration
Title: General Licenses (RCS)
Form number: Agency—15 CFR 371.12; OMB—N/A
Type of request: Revision of a currently approved collection
Burden: 100 respondents; 50 recordkeeping hours
Needs and uses: The Department of Commerce requires that vessels and aircraft in international operation retain records showing that the fuels used were not derived from the Naval Petroleum Reserves. Export of petroleum products produced from any other crude oil are permitted under the General Licenses provided that documentary evidence is retained. Documentation is subject to audits. This license is specifically for vessels or planes of U.S. or Canadian registry.
Affected Public: Busineses or other for-profit institutions, small businesses or organizations
Frequency: Recordkeeping
Respondent's obligation: Required to obtain or retain a benefit
OMB desk officer: Sheri Fox 395–3785

Agency: International Trade Administration
Title: General Licenses-Plane Stores
Form number: Agency—EAR 371.10; OMB—N/A
Type of request: Revision of a currently approved collection
Burden: 1,400 respondents; 700 recordkeeping hours
Needs and uses: Operators of aircraft in international operation are required to retain records showing that the fuels used were not derived from the Naval Petroleum Reserves. Documentation is subject to audit. This license is for aircraft of U.S. or foreign registry departing the U.S.
Affected Public: Businesses or other for-profit institutions, small businesses or organizations
Frequency: Recordkeeping
Respondent's obligation: Required to obtain or retain a benefit
OMB desk officer: Sheri Fox 395–3785

Agency: International Trade Administration
Title: General Licenses-Ship Stores
Form number: Agency—EAR 371.9; OMB—N/A
Type of request: Revision of a currently approved collection
Burden: 1,600 respondents; 800 recordkeeping hours
Needs and uses: Operators of vessels in international operation are required to retain records showing that the fuels used were not derived from the Naval Petroleum Reserves which is prohibited by the Naval Petroleum Reserves Production Act. Documentary evidence is requested and is subject to audit. This license is for vessels of any registry.
Affected Public: Business or other for-profit institutions, small businesses or organizations
Frequency: Recordkeeping
Respondent's obligation: Required to obtain or retain a benefit
OMB desk officer: Sheri Fox 395–3785

Agency: International Trade Administration
Title: United States and Foreign Commercial Service End-User Survey
Form number: Agency—ITA 728P; OMB—N/A
Type of request: New collection
Burden: 280 respondents; 70 reporting hours
Needs and uses: Data will be used to determine degree of satisfaction with US&FCS services.
Affected Public: State or local governments, businesses and other for-profit institutions, small businesses or organizations
Frequency: On occasion
Respondent's obligation: Voluntary
OMB desk officer: Sheri Fox 395–3785

Agency: International Trade Administration
Title: Request for Proposal for International Freight Forwarding Services
Form number: Agency—ITA 729P; OMB—N/A
Type of request: New collection
Burden: 50 respondents; 250 reporting hours
Needs and uses: Services are required for handling cargos from the United States to Commerce-sponsored exhibitions overseas. The information received will be used to select international freight forwarders to handle shipments for exhibitors.
Affected Public: Businesses or other for-profit institutions
Frequency: Biennially
Respondent's obligation: Voluntary
OMB desk officer: Sheri Fox 395–3785

Agency: National Bureau of Standards
Title: Time and Frequency User Survey
Form number: Agency—NBS–1220; OMB—N/A
Type of request: New collection
Burden: 9,000 respondents; 2,250 reporting hours
Needs and uses: The information from users of NBS time and frequency dissemination services will be used for evaluating the effectiveness of present services and planning for new services to meet unfullfilled needs.
Affected Public: Individuals, businesses or other for-profit institutions, federal agencies or employees
Frequency: One-time only
Respondent's obligation: Voluntary
OMB desk officer: Sheri Fox 395–3785

Copies of the above information collection proposals can be obtained by calling or writing DOC Clearance Officer, Edward Michals, (202) 377–4217, Department of Commerce, Room 6622, 14th and Constitution Avenue NW., Washington, DC 20230.

Written comments and recommendations for the proposed information collections should be sent to Sheri Fox, OMB Desk Officer, Room 3235, New Executive Office Building, Washington, DC 20503.

Dated: July 16, 1986.

Edward Michals,

Departmental Clearance Officer, Information Management Division, Officer of Information Resources Management.

[FR Doc. 86–16405 Filed 7–21–86; 8:45 am]
BILLING CODE 3510-CW-M

International Trade Administration

Brigham Young University; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC.

Docket Number: 86–203. Applicant: Brigham Young University, Provo, UT 84602. Instrument: Annular Diffusion Denuder with Accessories. Manufacturer: Gruppo Flow S.P.A., Italy. Intended Use: See notice at 51 FR 19242.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument can separate and collect gas-phase nitric acid with high efficiency and operates at flow rates up to 20 liters per minute. This capability is pertinent to the applicant's intended purpose. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86–16401 Filed 7–21–86; 8:45 am]

BILLING CODE 3510-DS-M

Cornell University; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR 301). Related records can be reviewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 86–197. Applicant: Cornell University, Ithaca, NY 14853–1504. Instrument: Mass Spectrometer, Model VG Sector with Accessories. Manufacturer: VG Isotopes Ltd., United Kingdom. Intended Use: See notice at 51 FR 19242.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reason: The foreign instrument is equipped with a fully automated multiple collector system capable of providing an external precision on Neodymium (300 ng) of 0.003%. This capability is pertinent to the applicant's intended purposes. We know of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intend use.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86–16402 Filed 7–21–86; 8:45 am]

BILLING CODE 3510-DS-M

Harvard University; Decision on Application for Duty-Free Entry of Scientific Instrument

This decision is made pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 AM and 5:00 PM in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC.

Docket Number: 85–309. Applicant: Harvard University, Cambridge, MA 01238. Instrument: Monodisperse Aerosol Generator. Manufacturer: Lavoro E Ambiente, Italy. Intended Use: See notice at 50 FR 45646.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as it is intended to be used, is being manufactured in the United States.

Reasons: The foreign instrument is capable of producing aerosols with a uniform size of about 1.0 micrometer and a concentration of at least 5.8×10^4 particles per cubic centimeter. The National Institutes of Health advises in its memorandum dated April 3, 1986 that (1) this capability is pertinent to the applicant's intended purpose and (2) it knows of no domestic instrument or apparatus of equivalent scientific value to the foreign instrument for the applicant's intended use. We know of no other instrument or apparatus of equivalent scientific value to the foreign instrument which is being manufactured in the United States.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86–16403 Filed 7–21–86; 8:45 am]

BILLING CODE 3510-DS-M

University of Pennsylvania; Consolidated Decision on Applications for Duty-Free Entry of Electron Microscopes

This is a decision consolidated pursuant to section 6(c) of the Educational, Scientific, and Cultural Materials Importation Act of 1966 (Pub. L. 89–651, 80 Stat. 897; 15 CFR 301). Related records can be viewed between 8:30 A.M. and 5:00 P.M. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue NW., Washington, DC.

Docket Number: 86–177. Applicant: University of Pennsylvania, Philadelphia, PA 19104. Instrument: Electron Microscope, Model JEM–400EX. Manufacturer: JEOL, Japan. Intended Use: See notice at 51 FR 15820. Instrument Ordered: November 8, 1985.

Docket Number: 86–187. Applicant: Juniata College, Huntingdon, PA 16652. Instrument: Electron Microscope, Model H–300. Manufacturer: Hitachi, Japan. Intended Use: See notice at 51 FR 17382. Instrument Ordered: August 14, 1985.

Docket Number: 86–190. Applicant: Harvard University, Cambridge, MA 02138. Instrument: Electron Mircoscope, Model JEM–1200EX/SEG with Accessories. Manufacturer: JEOL, Ltd., Japan. Intended Use: See notice at 51 FR 18922. Instrument Ordered: February 28, 1986.

Docket Number: 86–193. Applicant: U.S. Army Institute of Dental Research, Washington, DC 20307–5300. Instrument: Electron Microscope, Model EM 10 CRSTSE with Accessories. Manufacturer: Carl Zeiss, Inc., West Germany. Intended Use: See notice at 51 FR 17383. Instrument Ordered: February 24, 1986.

Docket Number: 86–194. Applicant: University of Wisconsin-Milwaukee, Milwaukee, WI 53201. Instrument: Electron Microscope, Model H–600 CR/CR with Accessories. Manufacturer: Hitachi, Japan. Intended Use: See notice at 51 FR 18922. Instrument Ordered: December 10, 1985.

Docket Number: 86–198. Applicant: The Medical College of Wisconsin, Milwaukee, WI 53226. Instrument: Electron Microscope, Model H–600–3 with Accessories. Manufacturer: Hitachi, Ltd., Japan. Intended Use: See

notice at 51 FR 18922. Instrument Ordered: February 7, 1986.

Docket Number: 86–199. Applicant: University of Medicine and Dentistry of New Jersey, Piscataway, NJ 08854. Instrument: Electron Microscope, Model CM 12/STEM with Accessories. Manufacturer: N.V. Philips, The Netherlands. Intended Use: See notice at 51 FR 18923. Instrument Ordered: March 4, 1986.

Comments: None received.

Decision: Approved. No instrument of equivalent scientific value to the foreign instrument, for such purposes as these instruments are intended to be used, was being manufactured in the United States at the time the instruments were orderd.

Reasons: Each foreign instrument is a conventional transmission electron microscope (CTEM) and is intended for research or scientific educational uses requiring a CTEM. We know of no CTEM, or any other instrument suited to these purposes, which was being manufactured in the United States either at the time of order of each instrument or at the time of receipt of application by the U.S. Customs Service.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86–16404 Filed 7–21–86; 8:45 am]

BILLING CODE 3510-DS-M

Notice of Applications for Duty-Free Entry of Scientific Instruments

Pursuant to section 6(c) of the Educational, Scientific and Cultural Materials Importation Act of 1966 (Pub. L. 89–651; 80 Stat. 897; 15 CFR 301), we invite comments on the question of whether instruments of equivalent scientific value, for the purposes for which the instruments shown below are intended to be used, are being manufactured in the United States.

Comments must comply with § 301.5(a) (3) and (4) of the regulations and be filed within 20 days with the Statutory Import Programs Staff, U.S. Department of Commerce, Washington, DC 20230. Applications may be examined between 8:30 A.M. and 5:00 P.M. in Room 1523, U.S. Department of Commerce, 14th and Constitution Avenue, NW., Washington, DC.

Docket Number: 86–021R. Applicant: National Bureau of Standards, Electricity Division, Building 220, Room B258, Gaithersburg, MD 20899. Instrument: Superconducting Magnet System. Manufacturer: Cryogenic Consultants Limited, United Kingdom. Original notice of this resubmitted application was published in the **Federal Register** of November 6, 1985.

Docket Number: 86–090R. Applicant: Brookdale Hospital Medical Center, Linden Boulevard and Rockaway Parkway, Brooklyn, NY 11212. Instrument: Electron Microscope, Model EM 109 with Accessories. Manufacturer: Carl Zeiss, West Germany. Original notice of this resubmitted application was published in the **Federal Register** of February 20, 1986.

Docket Number: 86–219R. Applicant: St. Vincent's Hospital and Medical Center New York, 153 W. 11th Street, New York, NY 10011. Instrument: Electron Microscope, Model EM 109 with Accessories. Manufacturer: Carol Zeiss, West Germany. Intended use: The instrument is intended to be used for research into the cause and mechanisms of amyotrophic lateral sclerosis. Specimens of nervous and muscle tissues (motor cortex, Ammon's horn, nucleus basalis of Meynert, brain stem, cervical, thoracic and lumbar spinal cord and the spinal roots from the cervical and lumbar areas) will be removed at autopsy and processed for light and electron microscopy. In addition, the instrument will be used for residency training in electron microscopy. Original of this resubmitted application was Received By Commissioner of Customs on April 2, 1986.

Docket Number: 86–248. Applicant: University of Cincinnati, College of Medicine, 231 Bethesda Avenue, Cincinnati, OH 45267–0529. Instrument: Electron Microscope, Model H–600 CR/CR. Manufacturer: Hatachi Ltd., Japan. Intended use: The instrument will be used for research of the following: the ischemic heart ultrastructure, coupling substructure and cell junctions, interstitial ischemia, absorption and distribution of heavy metals, Ca++ control of cardiac myofibrils, age related arterial changes, structure and function of sarcoplasmic reticulum, structure of human plasma apolipoproteins and pathology of environmental pollutants in the lung. In addition, the instrument will be extensively use by graduate students, residents and research fellows for their training in the field of pathology. Application received by Commissioner of Customs: June 30, 1986.

Docket Number: 86–249. Applicant: University of Illinois, 601 S. Morgan, Chicago, IL 60607. Instrument: Electron Microscope, Model JEM–100CX with Accessories. Manufacturer: JEOL Co., Ltd., Japan. Intended use: The instrument will be used for examination of internal structures of metals, semiconductors and ceramics. Application received by Commissioner of Customs: June 30, 1986.

Docket number: 86–250. Applicant: Veterans Administration Medical Center, Cell Biology Section 151-E, 4150 Clement Street, San Francisco, CA 94121. Instrument: Electron Microscope, Model EM 10CA. Manufacturer: Carl Zeiss, West Germany. Intended use: Research devoted to the study of normal structure and function of the liver and intestine and the changes that occur under certain physiological and pathological conditions. Current investigations include: The Role of growth factors in liver generation, the effect of transforming growth factors on the liver, the role of binding proteins for distribution of thyroid hormones in the liver, the function and localization of fatty acid binding protein in the liver, intestinal immune response to cholera toxin and giardiasis, development of the intestinal immune system in the fetus and neonate, the contribution of the liver to the intestinal immune response, and the effects of aging on intestinal immunity. The objectives of these various projects are to further basic knowledge of how the liver and intestinal immune system operate in health and disease. Applications received by Commissioner of Customs: June 30, 1986.

Docket number: 86–253. Applicant: University of Notre Dame, Radiation Laboratory, Notre Dame, IN 46556. Instrument: Laser System with Accessories. Manufacturer: Lumonics, Inc., Canada. Intended use: The instrument will be used in numerous experiments involving both simple free radicals in water solution as well as radicals and excited states derived from complex molecules such as porphyrins to understand the kinds of processes which may occur when radicals and excited states absorb light. Application received by Commissioner of Customs: July 1, 1986.

Docket number: 86–254. Applicant: Baylor College of Medicine, One Baylor Plaza, Houston, TX 77030. Instrument: Electron Microscope, Model CM 10/PC with Accessories. Manufacturer: N.V. Philips, The Netherlands. Intended use: The instrument will be used in a variety of studies involving viral pathogenesis and oncogenesis; for example: (i) Investigations of the pathological changes induced by several strains of rotaviruses in mouse and rabbit intestines, (ii) studies of rotavirus morphogenesis and antigenic properties in cultured cells, (iii) identification of enteric viruses in stool samples and in concentrates of environmental samples, (iv) studies of AIDS virus

cytopathology in cultured lymphoid cells, (v) analysis of pathological changes induced in human and chimpanzee livers by non-A, non-B hepatitis virus, (vi) localization of SV40 antigens within productively infected and oncogenically transformed cells and (vii) localization of age-specific proteins within quiescent and senescent fibroblasts. In addition, the microscope will be used for routine evaluation of virus stocks for purity and virus particle concentration. The instrument will also be used for educational purposes in the Experimental Virology course and for research training of graduate students or postdoctoral fellows whose interests include microscopy. Application received by Commissioner of Customs: July 3, 1986.

Docket number: 86–255. Applicant: University of Wisconsin, Geology Department, 105 Garfield Avenue, Eau Claire, WI 54701. Instrument: Electromagnetic Geophysical Survey Instrument, Model EM34–3. Manufacturer: Geonics Limited, Canada. Intended use: The instrument is intended to be used for educational purposes in the courses Geol 315—Hydrogeology and Geol 334—Geophysics to determine if groundwater contaminant plume exists downgradient of the Seven Mile Creek Landfill and to determine the configuration of buried bedrock channels of the Chippewa River. Applications received by Commissioner of Customs: July 3, 1986.

Docket number: 86–256. Applicant: University of California at Irvine, Department of Anatomy, Irvine, CA 92717. Instrument: Electron Microscope, Model CM 10 with Accessories. Manufacturer: N.V. Philips, The Netherlands. Intended use: Study of the structure of the brain, lungs, and developing cartilage of mammals. Specific experiments will include: An analysis of the morphology of animal brains that display focal and genetic epilepsy, an analysis of neuronal connections in the hippocampus, a temporal lobe structure in the brain involved with memory and emotions, the structural analysis of bone, cartilage and lung development, the morphological localization of neurotransmitters to neurons in the hippocampus and cerebral cortex, and an analysis of axons in the peripheral nerves. These studies will provide important knowledge about the structure and function of the brain and spinal cord as well as the development of bone, cartilage and lung. Application received by Commissioner of Customs: July 3, 1986.

Docket number: 86–257. Applicant: Albany Medical School, Department of Physiology, 47 New Scotland Avenue, NY 12208. Instrument: Rapid Kinetics Accessories for Spectrophotometer/Spectrofluorometer, Model SFA–11. Manufacturer: Hi-Tech Scientific Ltd., United Kingdom. Intended use: The instrument is an accessory to an existing spectrofluorometer which is being used to study the binding of divalent cations to the protein actin. Application received by Commissioner of Customs: July 3, 1986.

Docket number: 86–258. Applicant: Duke University Medical Center, P.O. Box 3177, 350 Bell Building, Durham NC 27710. Instrument: Electron Microscope, Model CM 10/PC with Accessories. Manufacturer: N.V. Philips, The Netherlands. Intended use: The instrument is intended to be used for studies of experimental and control rat lung, dog lung, baboon lung and other animal tissues to determine the amounts of injury to the lungs after various levels of exposure to O_2, NO_2 and asbestos. Application received by Commissioner of Customs: July 3, 1986.

(Catalog of Federal Domestic Assistance Program No. 11.105, Importation of Duty-Free Educational and Scientific Materials)

Frank W. Creel,

Director, Statutory Import Programs Staff.

[FR Doc. 86–16400 Filed 7–21–86; 8:45 am]

BILLING CODE 3510-DS-M

DEPARTMENT OF DEFENSE

Office of the Secretary

DOD Advisory Group on Electron Devices; Advisory Committee Meeting

SUMMARY: Working Group D (Production) of the DoD Advisory Group on Electron Devices (AGED) announces a closed session meeting.

DATE: The meeting will be held at 1000, Tuesday, August 19, 1986.

ADDRESS: The meeting will be held at Palisades Institute for Research Services, Inc., 2011 Crystal Drive, Suite 307, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: Thomas Henion, AGED Secretariat, 201 Varick Street, New York, 10014.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group D meeting will be limited to review of research and development programs which the military propose to initiate with industry, universities or in their laboratories. The Working Group D area includes all production aspects of critical electronic components for the defense electronic supply base; the transition of components from research and development into production, e.g., manufacturing technology; policy and acquisition steps necessary to insure that there is a sufficient domestic supply base for critical electronic components; and steps necessary to insure the continuing availability of skilled people to support the critical electronic component supply base. The review will include classified program details throughout.

In accordance with section 10(d) of Pub. L. 92–463, as amended, (5 U.S.C. App. II section 10(d) (1982)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly, this meeting will be closed to the public.

Dated: July 17, 1986.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 86–16465 Filed 7–21–86; 8:45 am]

BILLING CODE 3810-01-M

DOD Advisory Group on Electron Devices; Advisory Committee Meeting

SUMMARY: Working Group B (Microelectronics) of the DoD Advisory Group on Electron Devices (AGED) announces an Annual Report Ad Hoc Committee closed session meeting.

DATE: The meeting will be held at 0900, Monday, 18 August 1986.

ADDRESS: The meeting will be held at Palisades Institute for Research Services, Inc., 2011 Crystal Drive, Suite 307, Arlington, Virginia 22202.

FOR FURTHER INFORMATION CONTACT: Becky Terry, AGED Secretariat, 2011 Crystal Drive, Arlington, Virginia 22202.

SUPPLEMENTARY INFORMATION: The mission of the Advisory Group is to provide the Under Secretary of Defense for Research and Engineering, the Director, Defense Advanced Research Projects Agency and the Military Departments with technical advice on the conduct of economical and effective research and development programs in the area of electron devices.

The Working Group B meeting will hold discussions concerning the preparation of the 1986 AGED Annual

Report. The Microelectronics area includes such programs as integrated circuits, charge coupled devices and memories. The review will include classified program details throughout.

In accordance with section 10(d) of Pub. L. 92–463, as amended, (5 U.S.C. App. II section 10(d) (1982)), it has been determined that this Advisory Group meeting concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly, this meeting will be closed to the public.

Dated: July 17, 1986.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 86–16466 Filed 7–21–86; 8:45 am]

BILLING CODE 3810-01-M

Defense Science Board Task Force on Multi-National FOFA

ACTION: Notice of advisory committee meetings.

SUMMARY: The Defense Science Board Task Force on Multi-National FOFA will meet in closed session on August 21, 1986 in the Pentagon, Arlington, Virginia.

The mission of the Defense Science Board is to advise the Secretary of Defense and the Under Secretary of Defense for Research and Engineering on scientific and technical matters as they affect the perceived needs of the Department of Defense. At this meeting the Task Force will continue to review, in detail, classified material associated with conventional military capabilities in NATO with a view toward future U.S. and NATO requirements.

In accordance with section 10(d) of the Federal Advisory Committee Act, Pub. L. 92–463, as amended (5 U.S.C. App. II, (1982)), it has been determined that this DSB Panel meeting, concerns matters listed in 5 U.S.C. 552b(c)(1) (1982), and that accordingly this meeting will be closed to the public.

Dated: July 17, 1986.

Patricia H. Means,

OSD Federal Register Liaison Officer, Department of Defense.

[FR Doc. 86–16467 Filed 7–21–86; 8:45 am]

BILLING CODE 3810-01-M

Department of the Air Force

USAF Scientific Advisory Board; Meeting

July 15, 1986.

The USAF Scientific Advisory Board Aircraft Cross-Matrix Panel will meet at Headquarters Military Airlift Command, Scott AFB, IL, on August 13, 1986, from 8:00 am to 5:00 p.m.

The purpose of the meeting is for MAC to brief the Airlift Cross-Matrix Panel on technical, programmatic and organizational issues of importance to HQ MAC. Additionally, this is an orientation for the new panel members.

The meeting concerns matters listed in section 552b(c) of Title 5, United States Code, specifically subparagraph (1) thereof, and accordingly, will be closed to the public.

For further information, contact the Scientific Advisory Board Secretariat at 202–697–8845.

Patsy J. Conner,

Air Force Federal Register Liaison Officer.

[FR Doc. 86–16357 Filed 7–21–86; 8:45 am]

BILLING CODE 3910-01-M

Department of the Army

Intent To Prepare an Environmental Impact Statement (EIS); Proposed Mission Expansion/Multiple Construction at Camp Grayling Army National Guard Training Site, Michigan

AGENCY: National Guard Bureau, DOD/Department of Military Affairs, Michigan, National Guard.

ACTION: Notice of intent to prepare an environmental impact statement: proposed mission expansion/multiple construction at Camp Grayling Army National Guard Training Site, Michigan.

SUMMARY: 1. *Proposed Action*—Camp Grayling Army National Guard Training Site is a state owned/operated, federally funded installation. Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the National Guard Bureau and the Michigan Department of Military Affairs intend acting as co-lead agencies, to prepare an Environmental Impact Statement on the proposed master plan construction and mission expansion at Camp Grayling, Michigan. The proposal will include renovation and rehabilitation of existing facilities, range improvements, construction of facilities, development of ranges and associated maneuver areas, and increased training site utilization. The Environmental Impact Statement will address environmental considerations of the various alternatives for the construction/mission expansion at Camp Grayling. The document will display direct and indirect environmental impacts, both beneficial and detrimental. Environmental impacts addressed will include those affecting air quality, noise, physical setting, natural resources, land use, waste disposal, water resources, cultural resources, and social and economic resources.

2. *Alternatives*—Various alternatives are being developed for consideration regarding the master plan/mission expansion at Camp Grayling. The Environmental Impact Statement will include an evaluation of the environmental and socioeconomic impacts on the military reservation and neighboring communities. The following constitutes a tentative list of those alternatives to be considered in the Draft EIS:

(1) No Action (status quo)

(2) Relocation of Actions

(3) Alternative Site Locations

3. *Scoping Process*—The National Guard Bureau will utilize the scoping process, as outlined by the Council on Environmental Quality Regulations (40 CFR 1500–1508) implementing NEPA, to determine potentially significant issues related to the proposed master plan/mission expansion at Camp Grayling. To initiate the formal scoping process, interested individuals, governmental agencies, and private organizations are invited to submit information and comments on this proposed action for consideration by the National Guard Bureau and possible incorporation into the EIS. Particularly solicited is information that would assist the National Guard Bureau in analyzing the potential environmental consequences of the proposed action. This includes information on other environmental studies planned or completed in the area surrounding Camp Grayling; environmental issues which the Environmental Impact Statement should consider; and major impacts associated with the proposed action and recommended mitigation measures. Concerned individuals and agencies can express their views either by writing to the designated point of contact or participating in a public scoping meeting to be held at a convenient location near Camp Grayling. Adequate notice will be published in the local area newspapers at a later date to inform interested parties of the exact place and time of the scoping meeting. The notice will also be mailed to select groups, individuals, agencies, and those responding to this Notice of Intent desiring to be informed of the details of the upcoming public scoping meeting. The purpose of the public scoping meeting is (1) to provide a description of the proposed action; (2) to identify potential impacts and issues that should be included in the EIS; (3) to identify other review coordination or permit requirements associated with the proposal; and (4) to discuss the role of

the EIS in the development of the proposed action. Questions and comments regarding the scope of the environmental analysis should be directed to: LTC Edgar E. Wilkins, Jr., Michigan Army National Guard, 2500 S. Washington Avenue, Lansing, Michigan 56345.

To ensure that comments regarding this proposal are considered in a timely manner, all correspondence should be received at the address above no later than 15 days following the public scoping meeting in order to be considered in the draft EIS.

4. *Draft Environmental Impact Statement preparation*—The draft EIS is expected to be available to the public during April 1987. When the draft EIS is completed, a public notice of its availability for review will be announced in order that interested parties may comment on the document. If warranted, notice providing a schedule for a public hearing to solicit public response to the document will also be announced. Persons desiring to be placed on a mailing list to receive additional information regarding the scoping process and copies of the draft EIS and final EIS may contact LTC Edgar E. Wilkins, Jr. at the address above or by telephoning (517) 483–9644.

John O. Roach,

Army Liaison Officer with the Federal Register.

[FR Doc. 86–16373 Filed 7–21–86; 8:45 am]

BILLING CODE 3710–08–M

Intent To Prepare an Environmental Impact Statement (EIS); Proposed Mission Expansion/Multiple Construction at Camp Ripley Army National Guard Training Site, Minnesota

AGENCY: National Guard Bureau, DOD/ Department of Military Affairs, Minnesota National Guard.

ACTION: Notice of intent to prepare an environmental impact statement: proposed mission expansion/multiple construction at Camp Ripley Army National Guard Training Site, Minnesota.

SUMMARY: 1. *Proposed Action*—Camp Ripley Army National Guard Training Site is a state owned/operated, federally funded installation. Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the National Guard Bureau and the Minnesota Department of Military Affairs intend acting as co-lead agencies, to prepare an Environmental Impact Statement on the proposed master plan construction and mission expansion at Camp Ripley, Minnesota. The proposal will include renovation and rehabilitation of existing facilities, range improvements, construction of facilities, development of ranges and associated maneuver areas, and increased training site utilization. The Environmental Impact Statement will address environmental consideration of the various alternatives for the construction/mission expansion at Camp Ripley. The document will display direct and indirect environmental impacts, both beneficial and detrimental. Environmental impacts addressed will include those affecting air quality, noise, physical setting, natural resources, land use, waste disposal, water resources, cultural resources, and social and economic resources.

2. *Alternatives*—various alternatives are being developed for consideration regarding the master plan/mission expansion at Camp Ripley. The Environmental Impact Statement will include an evaluation of the environmental and socioeconomic impacts on the military reservation and neighboring communities. The following constitutes a tentative list of those alternatives to be considered in the Draft EIS:

(1) No Action (status quo)
(2) Relocation of Actions
(3) Alternative Site Locations

3. *Scoping Process*—The National Guard Bureau will utlize the scoping process, as outlined by the Council on Environmental Quality Regulations (40 CFR 1500–1508) implementing NEPA, to determine potentially significant issues related to the proposed master plan/ mission expansion at Camp Ripley. To Initiate the formal scoping process, interested individuals, governmental agencies, and private organizations are invited to submit information and comments on this proposed action for consideration by the National Guard Bureau and possible incorporation into the EIS. Particularly solicited is information that would assist the National Guard Bureau in analyzing the potential environmental consequences of the proposed action. This includes information on other environmental studies planned or completed in the area surrounding Camp Ripley; environmental issues which the Environmental Impact Statement should consider; and major impacts associated with the proposed action and recommended mitigation measures. Concerned individuals and agencies can express their views either by writing to the designated point of contact or participating in a public scoping meeting to be held at a convenient location near Camp Ripley. Adequate notice will be published in local area newspapers at a later date to inform interested parties of the exact place and time of the scoping meeting. The notice will also be mailed to select groups, individuals, agencies, and those responding to this Notice of Intent desiring to be informed of the details of the upcoming public scoping meeting. The purpose of the public scoping meeting is (1) to provide a description of the proposed action; (2) to identify potential impacts and issues that should be included in the EIS; (3) to identify other review coordination or permit requirements associated with the proposal; and (4) to discuss the role of the EIS in the development of the proposed action. Questions and comments regarding the scope of the environmental analysis should be directed to: LTC Wayne A Johnson, Office of Architect and Engineer, P.O. Box 348, Camp Ripley, Little Falls, MN 56345–0348.

To ensure that comments regarding this proposal are considered in a timely manner, all correspondence should be received at the address above no later than 15 days following the public scoping meeting in order to be considered in the draft EIS.

4. *Draft Environmental Impact Statement Preparation*—The draft EIS is expected to be available to the Public during January 1987. When the draft EIS is completed, a public notice of its availability for review will be announced in order that interested parties may comment on the document. If warranted, notice providing a schedule for a public hearing to solicit public response to the document will also be announced. Persons desiring to be placed on a mailing list to receive additional information regarding the scoping process and copies of the draft EIS and final EIS may contact LTC Wayne A. Johnson at the address above or by telephoning (612) 632–6631, extension 314.

John O. Roach,

Army Liaison Officer with the Federal Register.

[FR Doc. 86–16374 Filed 7–21–86; 8:45 am]

BILLING CODE 3710–08–M

Intent To Prepare an Environmental Impact Statement (EIS); Proposed Mission Expansion/Multiple Construction at Camp Shelby Army National Guard Training Site, Mississippi

AGENCY: National Guard Bureau, DOD/ Department of Military Affairs,

Mississippi Military Department, Mississippi National Guard.

ACTION: Notice of Intent to prepare an environmental impact statement: proposed mission expansion/multiple construction at Camp Shelby Army National Guard Training Site, Mississippi.

SUMMARY: 1. *Proposed Action.*—Camp Shelby Army National Guard Training Site is a state owned/operated, federally funded installation. Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969, the National Guard Bureau and the Mississippi Military Department intend action as co-lead agencies, to prepare an Environmental Impact Statement on the proposed master plan construction and mission expansion at Camp Shelby, Mississippi. The proposal will include renovation and rehabilitation of existing facilities, range improvements, construction of facilities, development of ranges and associated maneuver areas, and increased training site utilization. The Environmental Impact Statement will address environmental considerations of the various alternatives for the construction/mission expansion at Camp Shelby. The document will display direct and indirect environmental impacts, both beneficial and detrimental. Environmental impacts addressed will include those affecting air quality, noise, physical setting, natural resources, land use, waste disposal, water resources, cultural resources, and social and economic resources.

2. *Alternatives.*—Various alternatives are being developed for consideration regarding the master plan/mission expansion at Camp Shelby. The Environmental Impact Statement will include an evaluation of the environmental and socioeconomic impacts on the military reservation and neighboring communities. The following constitutes a tentative list of those alternatives to be considered in the Draft EIS:

(1) No Action (status quo)
(2) Relocation of Actions
(3) Alternative Site Locations

3. *Scoping Process*—The National Guard Bureau will utilize the scoping process, as outlined by the Council on Environmental Quality Regulations (40 CFR 1500–1508) implementing NEPA, to determine potentially significant issues related to the proposed master plan/mission expansion at Camp Shelby. To initiate the formal scoping process, interested individuals, governmental agencies, and private orgainzations are invited to submit information and comments on this proposed action for consideration by the National Guard Bureau and possible incorporation into the EIS. Particularly solicited is information that would assist the National Guard Bureau in analyzing the potential environmental consequences of the proposed action. This includes information on other environmental studies planned or completed in the area surrounding Camp Shelby; environmental issues which the Environmental Impact Statement should consider; and major impacts associated with the proposed action and recommended mitigation measures. Concerned individuals and agencies can express their views either by writing to the designated point of contact or participating in a public scoping meeting to be held at a convenient location near Camp Shelby. Adequate notice will be published in local area newspapers at a later date to inform interested parties of the exact place and time of the scoping meeting. The notice will also be mailed to select groups, individuals, agencies, and those responding to this Notice of Intent desiring to be informed of the details of the upcoming public scoping meeting. The purpose of the public scoping meeting is (1) to provide a description of the proposed action; (2) to identify potential impacts and issues that should be included in the EIS; (3) to identify other review coordination or permit requirements associated with the proposal; and (4) to discuss the role of the EIS in the development of the proposed action. Questions and comments regarding the scope of the environmental analysis should be directed to: LTC Samuel K. McLellan, Office of the Adjutant General, Mississippi Military Department, Post Office Box 5027, Jackson, Mississippi 39216–1027.

To ensure that comments regarding this proposal are considered in a timely manner, all correspondence should be received at the address above no later than 15 days following the public scoping meeting in order to be considered in the draft EIS.

4. *Draft Environmental Impact Statement preparation*—The draft EIS is expected to be available to the public during January 1987. When the draft EIS is completed, a public notice of its availability for review will be announced in order that interested parties may comment on the document. If warranted, notice providing a schedule for a public hearing to solicit public response to the document will also be announced. Persons desiring to be placed on a mailing list to receive additional information regarding the scoping process and copies of the draft EIS and final EIS may contact LTC Samuel K. McLellan at the address above or by telephoning (601) 949–6238.

John O. Roach,

Army Liaison Officer with the Federal Register.

[FR Doc. 86–16375 Filed 7–21–86; 8:45 am]

BILLING CODE 3710–08–M

Intent To Prepare a Supplemental Environmental Impact Statement for the Production of the Phosphorus Based Chemicals Required for the Binary Munitions Program

AGENCY: Department of the Army, Department of Defense.

ACTION: Notice of Intent to prepare a supplemental environmental impact statement in which the alternatives announced in prior notices (47 FR 6318, 50 FR 2706 and 50 FR 12853 for QL production, and 50 FR 21916 for DC production) will be combined for analysis in one statement.

SUMMARY: 1. The Department of the Army intends to pursue the production of the phosphorus based binary chemical precursors for the Department of Defense's Binary Munitions Programs as a combined acquisition strategy. In support of this strategy, the Department of the Army will address both production alternatives for QL, a nonlethal precursor binary chemical, and for DC, a chemical intermediate used to manufacture DF, another nonlethal precursor binary chemical, in one Supplemental Environmental Impact Statement.

2. Five sites are under consideration as manufacturing alternatives for the chemical intermediate, DC. The sites are Newport Army Ammunition Plant, Newport, Indiana; Vertac Chemical Corporation at West Helena, Arkansas; Olin Chemical Corporation at Lake Charles, Louisiana; and the U.S. Army Phosphate Development Works, Muscle Shoals, Alabama; as specified in the previous announcement, in addition to Pine Bluff Arsenal, Arkansas. Pine Bluff Arsenal had been previously eliminated as an alternative due to initial facilitization cost estimates. It is now being reconsidered as part of the combined acquisition strategy evaluation to identify the most economical alternative.

Three sites are under consideration as manufacturing alternatives for the precursor chemical QL. The sites are Vertac Chemical Corporation and Newport Army Ammunition Plant, as specified in the previous announcements, in addition to Pine Bluff

Arsenal. Production at Pine Bluff Arsenal would require the addition of a process unit to produce the chemical intermediate, methyl phosphonous dichloride (SW) which is no longer readily available, commercially.

These three alternate sites are also potential candidates for dual QL and DC production. The environmental impact of these multiple operations will be addressed in the Supplemental Environmental Impact Statement. Newport Army Ammunition Plant and Pine Bluff Arsenal are also being considered for potential disposal facilities for existing unitary chemical agents stored at these locations, January 28, 1986, 51 FR 3492. The document will also consider the potential effect of disposal operations since these facilities may be collocated with binary production facilities at these locations.

Therefore, the Department of the Army is presently planning on combining all impact analyses involving the production of phosphorus based binary chemicals in one Supplemental Environmental Impact Statement. The Supplemental Environmental Impact Statement will be a tier to the Final Environmental Impact Statement, "Programmatic Environmental Impact Statement, Binary Chemical Munitions Program," December 4, 1981 (46 FR 60230, 60643). In addition to a Draft Supplemental Impact Statement for the alternative identified above, the Final Supplemental Environmental Impact statement will reference the Draft Supplemental Environmental Statement "Binary Program Alternatives, Production of QL at the Newport Army Ammunition Plant, Indiana or the Vertac Chemical Corporation, West Helena, Arkansas Plant Site," May 28, 1985 (50 FR 21645).

3. Under the previous notices, the Army has been following the scoping processes as outlined by the Council on Environmental Quality Regulations (40 CFR 1500—1508). Meetings have been held in Alabama, Arkansas, Indiana and Louisiana with interested persons, including community representatives and Federal, state, and local environmental agencies. The Army will conduct information update meetings in Arkansas, Alabama, and Indiana, the sites impacted by the integrated acquisition strategy, with representatives of the regulatory agencies, civic leaders, or any other interested community representatives. Such meetings are tentatively scheduled for the July-August 1986 time frame.

In order to provide an opportunity for public input to the scoping process, interested individuals and organizations are encouraged to submit information and comments for consideration by the Army and possible incorporation in the combined statement. Particularly solicited is information that would assist the Army in determining community concerns and issues related to the Pine Bluff Arsenal site and in the analysis, in greater depth, of potential environmental consequences of multiple operations at the three candidate sites.

4. Questions and comments regarding the scope of the analysis and/or specific issues which should be addressed in the analysis should be submitted to Mr. James M. Allingham, U.S. Army Chemical Research, Development and Engineering Center, ATTN: SMCCR-IN, Aberdeen Proving Ground, MD 21010-5423, telephone (301) 671-4345. Comments and suggestions should be received by August 22, 1986, to be considered for incorporation in the Draft Supplemental Environmental Impact Statement. Persons desiring to be placed on a mailing list to receive additional information regarding the proposed meetings and copies of the draft and final statements may contact Mr. Allingham at the address or telephone indicated above.

Lewis D. Walker,

Deputy for Environmental, Safety and Occupational Health, OASA(I&L).

[FR Doc. 86-16412 Filed 7-21-86; 8:45 am]

BILLING CODE 3710-08-M

DELAWARE RIVER BASIN COMMISSION

Commission Meeting, Public Hearing and Announcement of Water Quality Program

Notice is hereby given that the Delaware River Basin Commission will hold a public hearing on Wednesday, July 30, 1986 beginning at 1:30 p.m. in the Auditorium of the Delaware Department of Natural Resources and Environmental Control at 89 Kings Highway, Dover, Delaware. The hearing will be part of the Commission's regular business meeting which is open to the public.

An informal pre-meeting conference among the Commissioners and staff will be open for public observation at about 11:00 a.m. at the same location.

The subjects of the hearing will be as follows:

Proposed Amendment to the Water Code and Administrative Manual—Part III Water Quality Regulations. Notice was given in the June 17, 1986 **Federal Register**, Vol. 51, No. 116, p. 21928 that the Commission would hold a public hearing on July 30, 1986 to receive comments on a proposed amendment to the *Water Code of the Delaware River Basin* and *Administrative Manual—Part III Water Quality Regulations* providing for temporary suspension of stream bacterial criteria for Delaware River Zones 2, 3 and 4. The proposed amendment is needed to conduct a two-year monitoring program to assess the impact of changes in disinfection requirements. During the first year, discharges in Zones 2-4 would not be required to disinfect from October through April. During the second year, continuous disinfection would be required for the entire year.

Application for Approval of the Following Projects Pursuant to Article 10.3, Article 11 and/or Section 3.8 of the Compact:

1. *Peter Manetas D-81-40 RENEWAL.* An application for the renewal of a ground water withdrawal project to supply up to 38 million gallons (mg)/30 days of water to the applicant's agricultural irrigation system from Pond Nos. 1, 2 and 3. Commission approval on September 3, 1981 was limited to five years will expire unless renewed. The applicant requests that the total withdrawal from all ponds remain limited to 38 mg/30 days. The project is located in Fairfield Township, Cumberland County, New Jersey.

2. *Stuart L. Reed, Jr. D-81-44 RENEWAL.* An application for the renewal of a ground water withdrawal project to supply up to 20 mg/30 days of water to the applicant's sod farm from an irrigation well. Commission approval on September 3, 1981 was limited to five years and will expire unless renewed. The applicant requests that the total withdrawal from all wells be increased from 14 mg/30 days to 20 mg/30 days. The project is located in Washington Township, Mercer County, New Jersey.

3. *Muhlenberg Township Authority D-81-46 CP RENEWAL.* An application for the renewal of a ground water withdrawal project to supply up to 19 mg/30 days of water to the applicant's distribution system from Well No. 13. Commission approval on September 3, 1981 was limited to five years and will expire unless renewed. The applicant requests that the total withdrawal from all wells remain limited to 151.2 mg/30 days. The project is located in Muhlenburg Township, Berks County, Pennsylvania.

4. *Borough of Media D-86-10 CP.* An application to construct new sedimentation basins at the Borough of Media Water Filtration Plant located at U.S. Route 1 and Elwyn Road, in Middletown Township, Delaware County, Pennsylvania. The existing basins will be modified to allow for the collection and treatment of all

sedimentation tank sludge and filter backwash. The maximum wastewater discharge will be 0.083 million gallons per day (mgd). The discharge to Ridley Creek will meet PADER standards of 30 mg/1 or less of suspended solids.

5. *Thomas & Betts Corporation D–86–24.* An application to modify an approved wastewater treatment project (D–75–53 and D–79–77) located in East Rockhill Township, Bucks County, Pennsylvania. The applicant currently pumps 30 gallons per minute (gpm) of TCE-contaminated ground water from two wells for industrial purposes and control of the contamination. The ground water is treated by an air stripper to remove TCE. The process wastewater (15 gpm) flows to Pennridge Wastewater Treatment Authority, and the remaining 15 gpm is discharged to the East Branch Perkiomen. This discharge contains less than 4.5 ppb TCE.

6. *Larchmont Farms Inc. D–86–37.* An application for approval of a ground water withdrawal project which includes the renewal of approval to operate Well No. 1, abandonment of Well No. 2 and operation of new Well Nos. 2 and 3 in Salem and Burlington Counties, New Jersey. New Jersey Certification has limited the total withdrawal from all three wells and an existing pond to 100 mg per month.

7. *Great Bear Hydropower, Inc. D–86–46.* An application to rehabilitate an existing 530 kW hydroelectric generating station at the Columbia Dam on the Paulins Kill in Knowlton Township, Warren County, New Jersey. The applicant has negotiated a 50-year lease with the owner, New Jersey Department of Environmental Protection. The powerhouse was abandoned in 1955 due to flood damage. The dam is located on the Paulins Kill at River Mile 207–0.3, adjacent to the Town of Columbia. The dam, which was constructed in 1909, has a 62.4 mg (197 acre foot) storage capacity.

8. *Fluidized Energy Frackville Associates D–86–48.* An application for approval of a surface water withdrawal project to provide 43.77 mg/30 days of water for a proposed steam/electric cogeneration facility. The project is located in Mahonoy Township, Schuylkill County, Pennsylvania. The project will withdraw approximately 1.459 mgd of acid mine drainage and pretreat it for use as boiler feed water and cooling tower blowdown. Approximately 0.492 mgd of process waste water will be treated to NPDES permit limits and discharged back to the pit.

Documents relating to these items may be examined at the Commission's offices. Preliminary dockets are available in single copies upon request. Please contact David B. Everett. Persons wishing to testify at this hearing are requested to register with the Secretary prior to the hearing.

Public Information Notice

Water Quality Program

The Commission is preparing its water quality program for the fiscal year ending September 30, 1987. Notice of this action is given in accordance with the requirements of the Federal Clean Act, as amended. The proposed program will involve a variety of activities in the areas of planning, surveillance, compliance monitoring, regional, coordination, use attainability assessment, wasteload allocations and public participation. While the proposed program is not subject to public hearing by the Commission, it may be examined by interested individuals at the Commission's offices upon request. The public review and comment period will begin July 16, 1986 and end August 8, 1986. Contact Seymour P. Gross at the Commission.

Richard C. Albert,

Acting Secretary.

July 15, 1986.

[FR Doc. 86–16363 Filed 7–21–86; 8:45 am]

BILLING CODE 6360–01–M

DEPARTMENT OF EDUCATION

Office of Special Education and Rehabilitative Services

Application Notice for New Awards Under the Program of Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Severely Handicapped Individuals in Supported Employment for Fiscal Year 1986

Programmatic and Fiscal Information

The purpose of this application notice is to inform potential applicants of fiscal and programmatic information and the closing date for transmittal of new applications for the Program of Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Severely Handicapped Individuals in Supported Employment. Awards are made under this program for the purpose of stimulating the development and provision of supported employment services on a statewide basis for severely handicapped individuals. Eligible applicants are State and public and other nonprofit agencies and organizations. The authority for this program is section 311(a)(1) of the Rehabilitation Act of 1973, as amended.

The amount of funds available under this grant program for supported employment projects in fiscal year 1986 is $8,613,000. It is expected that these funds will support about 18 new supported employment projects.

These estimates do not bind the U.S. Department of Education to a specific number of grants or to the amount of any grant, unless that amount is otherwise specified by statue or regulations.

It is expected that new projects funded under this program in fiscal year 1986 will be approved for project periods of up to 60 months.

Closing Date for Transmittal of Applications

Applications for new grant awards must be mailed or hand-delivered on or before August 21, 1986.

Applications sent by mail must be addressed to the U.S. Department of Ecucation, Application Control Center, Attention: CFDA No. 84.128A, 400 Maryland Avenue SW., Washington, DC 20202.

Each late applicant will be notified that its application will not be considered.

Applications that are hand-delivered must be taken to the U.S. Department of Education, Application Control Center, Room 3633, Regional Office Building #3, 7th and D Streets SW., Washington, DC.

The Application Control Center will accept hand-delivered applications between 8:00 am and 4:30 pm (Washington, DC time) daily, except Saturdays, Sundays, and Federal holidays.

Applicable Regulations

Regulations applicable to this program include the following: (a) Education Department General Administration Regulations (EDGAR) (34 CFR Parts 74, 75, 77 and 78); and (b) The regulations governing the Program of Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Severely Handicapped Individuals in 34 CFR Parts 369 and 373. (Note particularly §§ 373.14 and 373.31 which apply specifically to supported employment demonstration projects.)

Application Forms

Application forms and program information packages are expected to be available July 22, 1986. These may be obtained by writing the Office of Developmental Programs, Rehabilitation Services Administration, U.S. Department of Education, 400 Maryland

Avenue SW., Room 3332, Mary E. Switzer Building, MS–2312, Washington, DC 20202, Telephone (202) 732–1343.

Futher Information

For futher information contact Roseann Rafferty, Office of Developmental Programs, Rehabilitation Services Administration, U.S. Department of Education, 400 Maryland Avenue SW., Room 3322, Mary E. Switzer Building, MS–2312, Washington, DC 20202, Telephone (202) 732–1349.

Program Authority

29 U.S.C. 777a(a)(1).

(Catalog of Federal Domestic Assistance Number 84.128A Special Projects and Demonstrations for Providing Vocational Rehabilitation Services to Severely Handicapped Individuals)

Dated: July 17, 1986.

Madeleine Will,

Assistant Secretary for Special Education and Rehabilitative Services.

[FR Doc. 86–16442 Filed 7–21–86; 8:45 am]

BILLING CODE 4000–01–M

Office of Elementary and Secondary Education

Education Consolidation and Improvement Act of 1981; Intent To Repay to the Washington Superintendent of Public Instruction Funds Recovered as a Result of a Final Audit Determination

AGENCY: Department of Education.

ACTION: Notice of Intent To Award Grantback Funds.

SUMMARY: Notice is given that, under Section 456 of the General Education Provisions Act (GEPA), the U.S. Secretary of Education (Secretary) intends to repay under a grantback arrangement to the Washington Superintendent of Public Instruction, the State educational agency (SEA), an amount equal to 75 percent of the funds recovered by the U.S. Department of Education (Department) as a result of a final audit determination. This notice describes the SEA's plan for the use of the grantback funds and the terms and conditions under which the Secretary intends to make these funds available.

DATES: All written comments must be received on or before August 21, 1986.

ADDRESS: All written comments should be submitted to Dr. James Spillane, Director, Division of Program Support, Compensatory Education Programs, U.S. Department of Education, 400 Maryland Avenue, SW., (Room 5004, ROB–3–Mail Stop 3580), Washington, DC 20202.

FOR FURTHER INFORMATION CONTACT: Dr. James Spillane. Telephone: (202) 245–9846.

SUPPLEMENTARY INFORMATION:

A. Background

During fiscal year 1982, the SEA conducted an audit of the school year 1980–81 program that was operated by the Washington State Department of Corrections and funded under Title I of the Elementary and Secondary Education Act. Section 151 of the Title I statute provided that a State agency which was directly responsible for providing free public education for children in institutions for neglected or delinquent children or in adult correctional institutions was entitled to receive a grant to meet the special educational needs of these children.

On the basis of the State audit, the Assistant Superintendent, Financial Services, Office of the Washington Superintendent of Public Instruction, issued a final audit determination on April 25, 1983, concluding that the Department of Corrections had misspent $23,822 in Title I funds by serving ineligible students over the age of 21. This was a violation of 45 CFR 116c.2 (1979) which limited eligible children under this program to persons under 21 years of age.

In July 1983, the Department of Corrections paid the SEA for the misspent funds and the SEA repaid $23,822 to the Department in August 1983.

B. Authority for Awarding a Grantback

Section 456(a) of GEPA (20 U.S.C. 1234e(a)) provides that whenever the Secretary has recovered funds following a final audit determination with respect to an applicable program, the Secretary may consider those funds to be additional funds available to that program and may arrange to repay to the SEA or local educational agency (LEA) affected by that determination an amount not to exceed 75 percent of the recovered funds. The Secretary may enter into this "grantback" arrangement if the Secretary determines that—

(1) The practices and procedures of the SEA or LEA that resulted in the audit determination have been corrected, and that the SEA or LEA is in all other respects in compliance with the requirements of the applicable program;

(2) The SEA has submitted to the Secretary a plan for the use of the funds to be awarded under the grantback arrangement which meets the requirements of the applicable program and, to the extent possible, benefits the population that was affected by the misexpenditures that resulted in the audit exceptions; and

(3) The funds to be awarded under the grantback arrangement, if used in accordance with the SEA's plan, would serve to achieve the purposes of the program under which the funds were originally granted.

C. Request for Repayment of Funds Awarded Under a Grantback Arrangement

On April 16, 1986, the SEA submitted a formal written request for repayment of $17,866 (75 percent of the $23,822 repaid to the Department as a result of the final audit determination) under a grantback arrangement. Additional documents were forwarded by the SEA to the Department on May 20, 1986. With its request for grantback funds, the SEA provided assurances that the practices and procedures of the SEA and the State agency that had resulted in the final audit determination have been corrected and that the SEA and State agency are in all other respects in compliance with the requirements of Chapter 1 of the Education Consolidation and Improvement Act of 1981 (Chapter 1). Also included with the SEA's request was a detailed budget relating to the expenditure of Chapter 1 funds to be awarded under the grantback arrangement.

D. Plan for Use of Funds Awarded Under a Grantback Arrangement

In accordance with section 456(a)(2) of GEPA, the SEA submitted a plan for use of Chapter 1 funds, made available under the grantback, to serve children under 21 years of age in adult correctional institutions operated by the Department of Corrections.

The grantback funds will be used in the current Chapter 1 program during the months of August and September 1986. During the current project year, it is expected that approximately 63 students will be served in the Chapter 1 reading program, 115 students in the mathematics program, 110 students in the language arts program, and 88 students will receive counseling services. The grantback funds will pay the salaries of 3.21 full-time equivalent staff members to continue these services during the months of August and September. The compensatory services funded by Chapter 1 supplement the Department of Corrections' education program.

The SEA's plan proposes to use the funds to be repaid under the grantback arrangement to meet the special educational needs of children in adult correctional institutions. While the final

audit determination resulted from improper expenditures of Title I funds, Chapter 1 supersedes Title I. The SEA's proposal reflects adherence to the requirements of Chapter 1, which, like Title I, is designed to serve children in neglected or delinquent institutions or in adult correctional institutions operated or supported by a State agency.

E. The Secretary's Determinations

Based upon a thorough review of the SEA's request for the repayment of funds under section 456 of GEPA, including the SEA's discharge of its payment obligations to the Department in August 1983, the SEA's assurances described in Part C of this notice, and the SEA's plan and budget describing the use of funds, the Secretary makes the following determinations:

(1) The SEA and the State agency have corrected the practices and procedures that resulted in the final audit determination, and they are in all other respects in compliance with the requirements of the Chapter 1 program;

(2) The SEA has submitted a plan on behalf of the State agency for the use of the funds to be awarded under the grantback arrangement that meets the requirements of the Chapter 1 program and, to the extent possible, benefits the Chapter 1 children who were affected by the misexpenditures that resulted in the audit exception; and

(3) The funds to be awarded under the grantback arrangement, if used in accordance with the SEA's plan, would serve to achieve the purposes of the Chapter 1 program.

These determinations are based upon the best information available to the Secretary at the present time. If this information is not accurate or complete, the Secretary is not precluded from taking appropriate administrative action.

F. Notice of the Secretary's Intent To Enter Into a Grantback Arrangement

Section 456(d) of GEPA requires, at least 30 days prior to entering into an arrangement to award funds under a grantback, that the Secretary publish in the **Federal Register** a notice of his intent to do so, and the terms and conditions under which the payment will be made.

In accordance with this requirement, notice is given that the Secretary intends to make available under a grantback arrangement to the SEA an amount equal to 75 percent of the funds the Department has recovered as a result of the final audit determination. The Secretary bases his intention to enter into a grantback arrangement under section 456 of GEPA on his determinations outlined in Part E of this notice, and the repayment by the SEA of all the funds owed to the Department as a result of the final audit determination.

G. Terms and Conditions Under Which Payment Under the Grantback Arrangement Will Be Made

Section 456(b) of GEPA provides that any payments made under a grantback arrangement shall be subject to the terms and conditions that the Secretary deems necessary to accomplish the purposes of the affected program. The SEA agrees to comply with the following terms and conditions under which payment under the grantback arrangement will be made:

(1) Funds awarded under the grantback will be spent in accordance with—

(a) All applicable statutory and regulatory requirements;

(b) The plan that the SEA submitted and any amendments to that plan that are approved by the Secretary; and

(c) The budget that was submitted with the plan and any amendments to that budget that are approved by the Secretary.

(2) In accordance with section 456(c) of GEPA and the SEA's plan, all funds received under the grantback arrangement will be obligated by September 30, 1986.

(3) The SEA must, not later than January 1, 1987, submit a report to the Secretary which indicates that the funds awarded under the grantback have been spent in accordance with the SEA's proposed plan and budget.

(4) Separate accounting records will be maintained documenting the expenditures of funds awarded under the grantback arrangement.

Invitation to Comment

The Secretary invites public comments on this notice of intent to award funds under grantback arrangement to the Washington Superintendent of Public Instruction. Interested persons may send written comments to Dr. James Spillane at the address at the beginning of this notice. All comments must be received on or before August 21, 1986.

(Catalog of Federal Domestic Assistance No: 84.013, State Operated Programs for Neglected and Delinquent Children)

Dated: Jully 16, 1986.

William J. Bennett,

Secretary of Education.

[FR Doc. 86-16443 Filed 7-21-86; 8:45 am]

BILLING CODE 4000-01-M

DEPARTMENT OF ENERGY

Economic Regulatory Administration

Proposed Consent Order; Horizon Petroleum Co.

AGENCY: Economic Regulatory Administration, DOE.

ACTION: Notice of proposed consent order and opportunity for comment.

SUMMARY: The Economic Regulatory Administration [ERA] of the Department of Energy [DOE] announces a proposed Consent Order with Horizon Petroleum Company [Horizon] concerning crude oil resales by the firm, and provides an opportunity for public comment on the terms and conditions of the proposed Consent Order.

DATE: Comments by August 21, 1986.

ADDRESS: Send comments to: Horizon Consent Order Comments, Carl A. Corrallo, Solicitor, Economic Regulatory Administration, U.S. Department of Energy, 1000 Independence Avenue, SW., Room 3H-017; Mail Code RG-43, Washington, DC 20585.

FOR FURTHER INFORMATION CONTACT: Jeffrey R. Whieldon, Associate Solicitor, Economic Regulatory Administration, U.S. Department of Energy, 1000 Independence Avenue, SW., Room 3H-017; Mail Code RG-43, Washington, DC 20585 (202) 252-4235. (Copies of the Consent Order may be obtained free of charge by writing or calling this office).

SUPPLEMENTARY INFORMATION: On May 23, 1986, the ERA executed a proposed Consent Order with Horizon for $1,932,917. Under 10 CFR 204.199(b), a proposed Consent Order which involves the sum of $500,000 or more, excluding interest and penalties, becomes effective no sooner than thirty days after publication of a notice in the **Federal Register** requesting comments concerning the proposed Consent Order. Although ERA has signed and tentatively accepted the proposed Consent Order, the ERA may, after consideration of the comments it receives, withdraw its acceptance and, if appropriate, attempt to negotiate a modification of the Consent Order or issue the Consent Order as signed.

I. Background

Horizon Petroleum Company [Horizon] was involved in crude oil reselling activities during the period of April 1, 1977 through January 27, 1981 [audit period]. DOE conducted an audit to determine Horizon's compliance during the audit period and, as a result, issued a Notice of Proposed Violation for the period May 1977 through

September 1978 alleging a total of $3,518,858.65 in violation of Part 212 of the federal petroleum price and allocation regulations. Horizon disputes these alleged violations and, depending on the eventual outcome of these disputes, the alleged violation could be less than $3,518,858.65. ERA has preliminarly agreed to the settlement amount after assessing the litigation risks associated with establishing the alleged violations. In these circumstances, it is the opinion of ERA that a lump sum payment of $1,932,917 by Horizon is a satisfactory compromise of the audit.

II. The Consent Order

The proposed Consent Order has been entered into to resolve all civil and administrative disputes, claims, and causes of action by DOE relating to Horizon's compliance in its crude oil resales during the audit period. Although Horizon contends that in all respects it correctly construed and applied the applicable regulations, Horizon has entered into this proposed Consent Order to avoid the expense of litigation and the disruption of business. DOE believes the Consent Order is in the public interest and provides a satisfactory resolution of the issues raised by its audit.

III. Refunds

Under the Consent Order, Horizon will pay the sum of $1,932,917, within thirty days of the effective date of the Consent Order. The Administrator of ERA (or his designee) shall direct that these monies be deposited in a suitable account and ERA will petition DOE's Office of Hearings and Appeals to implement special refund procedures pursuant to 10 CFR Part 205, Subpart V, to distribute the monies.

In consideration for Horizon's performance under the Consent Order, the DOE agrees not to pursue any civil claims against Horizon that the DOE may have arising out of the matters covered by the Consent Order.

The foregoing provisions for payment of the refund amount were established because ERA was unable to readily identify the ultimate injured parties due to the nature of the alleged violations.

IV. Submission of Written Comments

Interested persons are invited to submit written comments concerning the terms and conditions of this Consent Order to the address given above. Comments should be identified on the outside of the envelop and on the documents submitted with the designation "Comments on Horizon Consent Order." The ERA will consider all comments it receives by 4:30 p.m. CST, thirty (30) days after the date of publication of this notice. Any information or data considered confidential by the person submitting it must be identified as such in accordance with the procedures in 10 CFR 205.9(f).

Issued in Washington, DC, on the 15th day of July 1986.

Carl A. Corrallo,

Solicitor, Economic Regulatory Administration.

[FR Doc. 86-16383 Filed 7-21-86; 8:45 am]

BILLING CODE 6450-01-M

Energy Information Administration

Alternative Fuel Price Ceilings and Incremental Price Threshold for High Cost Natural Gas

The Natural Gas Policy Act of 1978 (NGPA) (Pub. L. 95-621) signed into law on November 9, 1978, mandated a new framework for the regulation of most facets of the natural gas industry. In general, under title II of the NGPA, interstate natural gas pipeline companies are required to pass through certain portions of their acquisition costs for natural gas to industrial users in the form of a surcharge. The statute requires that the ultimate costs of gas to the industrial facility should not exceed the cost of the fuel oil which the facility could use as an alternative.

Pursuant to title II of the NGPA, section 204(e), the Energy Information Administration (EIA) herewith publishes for the Federal Energy Regulatory Commission (FERC) computed natural gas ceiling prices and the high cost gas incremental pricing threshold which are to be effective August 1, 1986. These prices are based on the prices of alternative fuels.

FOR FURTHER INFORMATION CONTACT: Leroy Brown, Jr., Department of Energy, Energy Information Administration, 1000 Independence Avenue, SW., Room BE-034, Washington, DC 20585, Telephone: (202) 252-6077.

Section I

As required by FERC Order No. 50, computed prices are shown for the 48 contiguous States. The District of Columbia's ceiling is included with the ceiling for the State of Maryland. FERC, by an Interim Rule issued on April 2, 1981, in Docket No. RM79-21, revised the methodology for calculating the monthly alternative fuel price ceilings for State regions. Under the revised methodology, the applicable alternative fuel price ceiling published for each of the contiguous States shall be the lower of the alternative fuel price ceiling for the State or the alternative fuel price ceiling for the multistate region in which the State is located.

The price ceiling is expressed in dollars per million British Thermal Units (BTU's). The method used to determine the price ceilings is described in Section III.

State	Dollard per million Btu's
Alabama	1.45
Arizona [1]	1.33
Arkansas [1]	1.61
California	1.28
Colorado [2]	1.55
Connecticut [1]	1.59
Delaware [1]	1.63
Florida	1.30
Georgia	1.47
Idaho [2]	1.55
Illinois	1.62
Indiana [1]	1.74
Iowa [1]	1.92
Kansas	1.78
Kentucky [1]	1.74
Louisiana	1.46
Maine [1]	1.59
Maryland [1]	1.63
Massachusetts	1.52
Michigan [1]	1.74
Minnesota [1]	1.92
Mississippi	1.45
Missouri	1.48
Montana [2]	1.55
Nebraska [1]	1.92
Nevada [1]	1.33
New Hampshire [1]	1.59
New Jersey [1]	1.63
New Mexico [1]	1.61
New York	1.56
North Carolina [1]	1.57
North Dakota [1]	1.92
Ohio	1.58
Oklahoma [1]	1.61
Oregon [1]	1.33
Pennsylvania [1]	1.63
Rhode Island [1]	1.59
South Carolina [1]	1.57
South Dakota [1] [2]	1.92
Tennessee	1.48
Texas [1]	1.61
Utah [2]	1.55
Vermont [1]	1.59
Virginia [1]	.57
Washington [1]	1.33
West Virginia	1.71
Wisconsin [1]	1.74
Wyoming [2]	1.55

[1] Region based price as required by FERC Interim Rule, issued on April 2, 1981, in Docket No. RM-79-21.
[2] Region based price computed as the weighted average price of Regions E, F, G, and H.

Section II. Incremental Pricing Threshold for High Cost Natural Gas

The EIA has determined that the volume-weighted average price for No. 2 distillate fuel oil landed in the greater New York City Metropolitan area during May 1986 ws $18.53 per barrel. The EIA has implemented a procedure to partially compensate for the two-month lag between the end of the month for which data are collected and the beginning of the month for which the incremental pricing threshold becomes effective. The prices found in *Platt's*

Oilgram Price Report are given for each trading day in the form of high and low prices for No. 2 fuel oil in Metropolitan New York and Northern New Jersey. A lag adjustment factor was calculated using the average of the low posted price for these two areas for the ten trading days ending July 15, 1986, and dividing that price by the corresponding average price computed from prices published by Platt's for the month of May 1986. This lag adjustment factor was applied to the April price yielding $14.25 per barrel. In order to establish the incremental pricing threshold for high cost natural gas, as identified in the NGPA, Title II, section 203(a)(7), this price was multiplied by 1.3 and converted to its equivalent in millions of BTU's by dividing by 5.8. Therefore, the incremental pricing threshold for high cost natural gas, effective August 1, 1986, is $3.19 per million BTU's.

Section III. Method Used To Compute Price Ceilings

The FERC, by Order No. 50, issued on September 29, 1979, in Docket No. RM79–21, established the basis for determining the price ceilings required by the NGPA. FERC also, by Order No. 167, issued in Docket No. RM81–27 on July 24, 1981, made permanent the rule that established that only the price paid for No. 6 high sulfur content residual fuel oil would be used to determine the price ceilings. In addition, the FERC, by Order No. 181, issued on November 6, 1981, in Docket No. RM81–28, established that price ceilings should be published for only the 48 contiguous States on a permanent basis.

A. Data Collected

The following data were required from all companies identified by the EIA as sellers of No. 6 high sulfur content (greater than 1 percent sulfur content by weight) residual fuel oil: for each selling price, the number of gallons sold to large industrial users in the months of March 1986, April 1986, and May 1986.[3] All reports of volume sold and price were identified by the State into which the oil was sold.

B. Method Used To Determine Alternative Price Ceilings

(1) Calculation of Volume-Weighted Average Price

The prices which will become effective August 1, 1986, (shown in Section I) are based on the reported price of No. 6 high sulfur content residual fuel oil, for each of the 48 contigious States, for each of the 3 months, March 1986, April 1986, and May 1986. Reported prices for sales in March 1986 were adjusted by the percent change in the nationwide volume-weighted average price from March 1986 to May 1986. Prices for April 1986 were similarly adjusted by the percent change in the nationwide volume-weighted average price from April 1986 to May 1986. The volume-weighted 3-month average of the adjusted March 1986 and April 1986, and the reported May 1986 prices were then computed for each State.

(2) Adjustment for Price Variation

States were grouped into the regions identified by the FERC (see Section III.C). Using the adjusted prices and associated volumes reported in a region during the 3-month period, the volume-weighted standard deviation of prices was calculated for each region. The volume-weighted 3-month average price (as calculated in Section III.B.(1) above) for each State was adjusted downward by two times this standard deviation for the region to form the adjusted weighted average price for the State.

(3) Calculation of Ceiling Price

The lowest selling price within the State was determined for each month of the 3-month period (after adjusting up or down by the percent change in oil prices at the national level as discussed in Section III.B.(1) above). The products of the adjusted low price for each month times the State's total reported sales volume for each month were summed over the 3-month period for each State and divided by the State's total sales volume during the 3 months to determine the State's average low price. The adjusted weighted average price (as calculated in Section III.B.(2)) was compared to this average low price, and the higher of the values was selected as the base for determining the alternative fuel price ceiling for each State. For those States which had no reported sales during one or more months of the 3-month period, the appropriate regional volume-weighted alternative fuel price was computed and used in combination with the available State data to calculate the State alternative fuel price ceiling base. The State's alternative fuel price ceiling base was compared to the alternative fuel price ceiling base for the multistate region in which the State is located and the lower of these two prices was selected as the final alternative fuel price ceiling base for the State. The appropriate lag adjustment factor (as discussed in Section III.B.4) was then applied to the alternative fuel price ceiling base. The alternative fuel price (expressed in dollars per gallon) was mulitplied by 42 and divided by 6.3 to estimate the alternative fuel price ceiling for the State (expressed in dollars per million BTU's).

There were insufficient sales reported in Region G for the months of March 1986, April 1986, and May 1986. The alternative fuel price ceilings for the States in Region G were determined by calculating the volume-weight average price ceilings for Region E, Region F, Region G, and Region H.

(4) Lag Adjustment

The EIA has implemented a procedure to partially compensate for the two-month lag between the end of the month for which data are collected and the beginning of the month for which ceiling prices become effective. It was determined that *Platt's Oilgram Price Report* publication provides timely information relative to the subject. The prices found in *Platt's Oilgram Price Report* publication are given for each trading day in the form of high and low prices for No. 6 residual oil in 20 cities throughout the United States. The low posted prices for No. 6 residual oil in these cities were used to calculate a national and a regional lag adjustment factor. The national lag adjustment factor was obtained by calculating a weighted average price for No. 6 high sulfur residual fuel oil for the the trading days ending July 15, 1986, and dividing that price by the corresponding weighted average price computed from prices published by Platt's for the month of May 1986. A regional lag adjustment factor was similarly calculated for four regions. These are: one for FERC Region A and B combined; one for FERC Region C; one for FERC Regions D, E, and G combined; and one for FERC Regions F and H combined. The lower of the national or regional lag factor was then applied to the alternative fuel price ceiling for each State in a given region as calculated in Section III.B.(3).

Listing of States by Region

States were grouped by the FERC to form eight distinct regions as follows:

Region A	*Region B*
Connecticut	Delaware
Maine	Maryland
Massachusetts	New Jersey
New Hampshire	New York
Rhode Island	Pennsylvania
Vermont	

[3] Large Industrial User—A person/firm which purchases No. 6 fuel oil in quantities of 4,000 gallons or greater for consumption in a business, including the space heating of the business premises. Electric utilities, governmental bodies (Federal, State, or Local), and the military are excluded.

Region C	*Region D*
Alabama	Illinois
Florida	Indiana
Georgia	Kentucky
Mississippi	Michigan
North Carolina	Ohio
South Carolina	West Virginia
Tennessee	Wisconsin
Virginia	

Region E	*Region F*
Iowa	Arkansas
Kansas	Louisiana
Missouri	New Mexico
Minnesota	Oklahoma
Nebraska	Texas
North Dakota	
South Dakota	

Region G	*Region H*
Colorado	Arizona
Idaho	California
Montana	Nevada
Utah	Oregon
Wyoming	Washington

Issued in Washington, DC, July 17, 1986.

L.A. Pettis,

Deputy Administrator, Energy Information Administration.

[FR Doc. 86-16469 Filed 7-21-86; 8:45 am]

BILLING CODE 6450-01-M

Federal Energy Regulatory Commission

[Docket No. RP86-102-001]

Equitable Gas Company, a Division of Equitable Resources, Inc.; Compliance Filing

July 16, 1986.

Take notice that on July 3, 1986, Equitable Gas Company, a Division of Equitable Resources, Inc. (Equitable) tendered for filing the following tariff sheets to its FERC Gas Tariff in compliance with the Commission's order of June 30, 1986, in this docket.

First Revised Volume No. 1

Thirteenth Revised Sheet No. 1
First Revised Sheet No. 1-A.

Original Volume No. 3

Substitute Original Sheet No. 4
Substitute Original Sheet No. 8
Substitute Original Sheet No. 25
Substitute Original Sheet No. 26

Equitable states that copies of this filing have been served on all its jurisdictional customers and affected state regulatory commissions. Equitable requests waiver of all Commission rules and regulations as may be necessary to permit the tendered tariff sheets to become effective July 1, 1986.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of practice and procedure (18 CFR 385.214, 385.211). All such motions or protests should be filed on or before July 23, 1986. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-16420 Filed 7-21-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. CP86-619-000]

Florida Gas Transmission Co.; Application

July 17, 1986.

Take notice that on July 15, 1986, Florida Gas Transmission Company (FGT), P.O. Box 1188, Houston, Texas 77001 filed in Docket No. CP86-619-000 an application pursuant to section 7(c) of the Natural Gas Act for a limited-term certificate of public convenience and necessity with pre-granted abandonment authorizing FGT to transport natural gas on behalf of its, producer/suppliers in western Louisiana and Texas or, in the alternative, for a waiver of the Commissions Regulations to permit FGT to transport gas for such producers on a limited term basis under section 311 of the Natural Gas Policy Act (NGPA) without becoming an open-access pipeline under the Commission's Order No. 436, all as more fully set forth in the application on file and open to public inspection.

FGT states that under the Regulations of the United States Department of Transportation (DOT), it is required to hydrostatically test approximately 40 miles of its main transmission line located downstream of FGT's Compressor Station No. 7 (Station 7) in Acadia Parish, Louisiana. FGT further states that such requirement was made necessary by an increase in the population density in the immediate vicinity of the pipeline. Such testing, it is indicated, must be completed prior to the winter heating season. FGT explains that the segment of the pipeline to be tested is at a point on FGT's system where no looping exists. Thus, it is asserted, the pipeline testing will require a total shut-down of all FGT's producer/suppliers whose contracts provide for delivery of gas west of Station 7, which includes all of FGT's producers in western Louisiana and Texas. FGT anticipates that the testing procedures and any associated repairs or further maintenance which may be required could take approximately 4 to 6 weeks.

To compensate for the temporary loss of volumes from the affected producers, FGT states that it has arranged for continued deliveries to its customers during the shut-down through an emergency delayed exchange involving up to 200,000 Mcf per day with Southern Natural Gas Company, Houston Pipeline Company, and Enron Oil and Gas Company under Subpart I of Part 284 of the Commission's Regulations. In addition FGT indicates that it will offer shut-in producers the opportunity to sell to FGT from other sources during the force majeure period if deliveries can be made to FGT at points on its system east of the pipeline segment to be tested.

In order to assist its producer/suppliers west of Station 7 FGT requests authority to transport on a limited-term basis on behalf of those producer/suppliers, or their designees, gas which is dedicated to FGT under long-term contracts and which is subject to being shut in by the force majeure on FGT's system related to DOT's mandated testing. FGT proposes to receive the gas at existing points of delivery under its gas purchase contracts with its producers and to redeliver the gas to existing points of interconnection on its system with the facilities of other pipeline systems or with the facilities of other buyers. FGT is requesting authority to transport exclusively NGPA gas (which is not subject to certificate requirements), released by FGT, for a four to six week span during the duration of the force majeure testing, with pregranted abandonment at the end of such period.

Since the gas which FGT proposes to transport would be sold on the short-term spot market, FGT indicates that it cannot specify volumes or other specifics for each transaction. For this reason FGT further proposes flexible authority to receive and deliver gas west

of its Station 7 as well as for maximum volumes up to the deliverability of the wells dedicated.

For the transportation service FGT proposes to charge a facility charge of $126.00 per billion Btu equivalent plus $40.00 per billion Btu equivalent for each 100 miles of forward haul. The total minimum rate proposed is $69.00 per billion Btu equivalent. These rates, it is asserted, are the same as those contained in FGT's WDTS Rate Schedule which became effective July 1, 1986, as authorized by Commission order June 27, 1986, in Docket No. RP86–84–000. FGT states that because the proposed services would be limited to the western portion of its system, the rates in FGT's Western Division Transportation Service Rate Schedule are appropriate since they cover comparable service.

In the alternative to a section 7(c) certificate, FGT requests that the Commission waive § 284.7, 284.8, 284.9, 284.10 and such other of the Regulations as are necessary under Part 284 to permit FGT to transport gas on a limited-term basis under section 311 of the NGPA during the period of force majeure without becoming subject to all of the requirements of Order No. 436. For the emergency period in question, FGT states that it would agree to provide nondiscriminatory open-access transportation at all receipt and delivery points on its system west of Station 7. It is explained that rates identical to the WDTS rate would be charged for such service.

In order to implement transportation concurrently with the beginning of pipeline testing, FGT requests a shortened notice period and consideration of the application pursuant to the shortened procedure provided for by Rule 802 of the Commission's Rules of practice and procedure.

Any person desiring to be heard or to make any protest with reference to said application should on or before July 28, 1986, 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.

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 application 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 FGT to appear or be represented at the hearing.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86–16424 Filed 7–21–86; 8:45 am]

BILLING CODE 6717–01–M

[Docket Nos. ER86–595–000 et al.]

The Kansas Power and Light Company et al; Electric Rate and Corporate Regulation Filings

July 16, 1986.

Take notice that the following filings have been made with the Commission:

1. The Kansas Power and Light Company

[Docket No. ER86–595–000]

Take notice that on July 10, 1986, The Kansas Power and Light Company (KPL) tendered for filing a newly executed renewal contract dated June 30, 1986 with the City of Wamego, Kansas (Wamego) for wholesale service to that community. KPL states that this contract permits the City of Wamego to receive service under rate schedule WTU–12/83 designated Supplement No. 9 to R.S. FERC No. 184. The proposed effective date is July 1, 1986. The proposed contract change provides essentially for the ten year extension of the original terms of the presently approved contract. In addition, KPL states that copies of the contract have been mailed to the City of Wamego and the State Corporation Commission.

Comment date: July 29, 1986, in accordance with Standard Paragraph E at the end of this document.

2. New England Power Company

[Docket Nos. ER85–647–006 and ER86–239–003]

Take notice that on July 10, 1986, New England Power Company (NEP) tendered for filing a Compliance Refund Report and supporting documentation that effectuates the terms of Offers of Settlement in these proceedings that 1) resolves the treatment of test generation prior to commercial operation of the Millstone #3 unit, and 2) refunds amounts collected through base rates during the period March 1, 1986 through April 22, 1986.

NEP states that appropriate refunds, including interest, were made on June 27, 1986.

Comment date: July 29, 1986, in accordance with Standard Paragraph E at the end of this notice.

3. Pacific Power & Light Company, an Assumed Business Name of PacifiCorp

[Docket No. ER86–597–000]

Take notice that on July 11, 1986, Pacific Power & Light Company (Pacific), an assumed business name of PacifiCorp, tendered for filing Revision No. 2 to Exhibit C and Revision No. 3 to Exhibit D to Contract No. 14–03–29245, between Pacific and the Bonneville Power Administration (BPA), electric power and energy, and changes in the points of connection for emergency exchange of electric power and energy between Pacific and BPA, respectively.

Pacific requests this rate schedule to become effective at 2400 hours on November 30, 1985, which is the effective date of commencement of sevice.

Copies of the filing were supplied to the Public Utility Commissioner of Oregon and to BPA.

Comment date: July 29, 1986, in accordance with Standard Paragraph E at the end of this notice.

4. Public Service Company of Oklahoma

[Docket No. ER86–596–000]

Take notice that on July 11, 1986, Public Service Company of Oklahoma ("PSO") tendered for filing an amendment to the Facilities Agreement between PSO and Western Farmers Cooperative. PSO proposes that the amendment be made effective as of January 1, 1986 and, accordingly, seeks waiver of the notice requirements of the Federal Power Act. PSO states that the changes reflected in the amendment are minor in nature, specifically a change in the maximum load for one point of delivery.

Copies of the filing have been sent to the Oklahoma Corporation Commission

and to Western Farmers Electric Cooperative.

Comment date: July 29, 1986, in accordance with Standard Paragraph E at the end of this notice.

5. Southwestern Public Service Company

[Docket No. ER86-594-000]

Take notice that on July 9, 1986, Southwestern Public Service Company (Southwestern) tendered for filing an Experimental Interruptible Irrigation Rider proposed to be made applicable to two of its full requirements customers' FERC Electric Service Tariffs, specifically Bailey County Electric Cooperative Association (FERC Rate Schedule No. 86) and South Plains Electric Cooperative, Incorporated (FERC Rate Schedule No. 96).

Southwestern, Bailey County Electric Cooperative Association (Bailey), and South Plains Electric Cooperative, Inc. (South Plains) have determined that an experimental interruptible service rider may be beneficial to all parties and that a one-year experiment to test the efficacy of an interruptible rate is appropriate.

Comment date: July 30, 1986, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. 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 (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. Protests will be considered by the Commission in determinig 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-16417 Filed 7-21-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket Nos. ID-2241-000 et al.]

John Justin et al.; Interlocking Directorate Applications

July 16, 1986.

Take notice that the following filings have been made with the Commission:

1. John Justin

[Docket Nos. ID-2241-000]

Take notice that on July 3, 1986, John Justin tendered for filing an application for authority to hold certain interlocking positions:

Position	Name of corporation	Classification
Director	Texas-New Mexico Power Company.	Public Utility.
Director	Ceramic Cooling Tower Company.	Electrical Equipment Supplier.
Director	TNP Enterprises, Inc.	Public Utility Holding Company (parent of Texas-New Mexico Power Company).
Chairman of the Board & CEO.	Justin Industries, Inc.	Parent of Ceramic Cooling Tower Company.

Comment date: August 11, 1986, in accordance with Standard Paragraph E at the end of this notice. 2. Kenneth J. Douglas

[Docket No. ID-2242-000]

Take notice that on July 8, 1986, Kenneth J. Douglas tendered for filing an application for authority to hold certain interlocking positions:

Position	Name of corporation	Classification
Director	Centel Corporation	Public Utility.
Director	American National Bank and Trust Company of Chicago (Bank).	Foreign Affiliate Authorized to Underwrite Securities.
Director	American National Corporation.	Parent of American National Bank and Trust Company of Chicago.

Applicant states that a foreign affiliate of Bank is authorized to and does participate in the marketing or underwriting of securities of a public utility. Bank is not so authorized. However, to the extent necessary, applicant seeks authorization to continue to hold the designated positions in all three companies.

Comment date: August 11, 1986, in accordance with Standard Paragraph E at the end of this notice.

Standard Paragraphs

E. 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 (18 CFR 385.211 and 385.214). All such motions or protests should be filed on or before the comment date. 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.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-16418 Filed 7-21-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RP86-98-001]

Michigan Gas Storage Co.; Compliance Filing

July 16, 1986.

Take notice that on July 3, 1986, Michigan Gas Storage Company (Storage Company) tendered for filing the following tariff sheets to its FERC Gas Tariff, Original Volume No. 2 in compliance with the Commissioner's order of June 30, 1986, in this docket:

First Revised Sheet No. 9
First Revised Sheet No. 21
First Revised Sheet No. 41

According to § 381.103(b)(2)(iii) of the Commission's regulations (18 CFR § 381.103(b)(2)(iii)), the date of filing is the date on which the Commission receives the appropriate filing fee, which in the instant case was not until July 14, 1986.

Storage Company states that these sheets are filed solely to meet the Commission's direction that Storage Company submit tariff sheets eliminating (1) the "use or lose" provision under its firm transportation rate, and (2) a requirement of a $500 prepayment for transportation service.

Any person desiring to be heard or to protest said filing should file a motion to intervene or a protest with the Federal Energy Regulation Commission, 825 North Capitol Street NE., Washington, DC 20426, in accordance with Rules 214 and 211 of the Commission's Rules of practice and procedure (18 CFR 385.214, 385.211). All such motions or protests should be filed on or before July 23, 1986. Protest 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.

Kennety F. Plumb,

Secretary.

[FR Doc. 86-16422 Filed 7-21-86; 8:45 am]

BILLING CODE 6717-01-M

[Docket No. RM85-1-000]

Regulation of Natural Gas Pipelines After Partial Wellhead Decontrol (Transcontinental Gas Pipe Line Corporation) (Natural Gas Pipeline Company of America); Order Granting Requests for Clarification

Issued July 17, 1986.

Before Commissioners: Anthony G. Sousa, Acting Chairman; Charles G. Stalon, Charles A. Trabandt and C.M. Naeve.

On February 25, 1986, Transcontinental Gas Pipe Line Corporation filed a request for clarification of the transitional provisions of Order No. 436[1] as they apply to 26 transportation transactions performed by Transco under former §§ 284.102 and 284.221 of the Commission's Regulations.

On May 21, 1986, Natural Gas Pipeline Company of America filed a request for clarification of the order issued in *Black Marlin Pipeline Company, 35 FERC ¶ 62,196 (April 29, 1986).*

Since the petitions of Transco and Natural address an identical issue, we will consider the petitions simultaneously. Transco's and Natural's requests will be granted.

Transco

Transco Energy Marketing Company (Temco), an affiliate of Transco, was formed to purchase gas from a variety of sources and sell the gas to its customers. Temco operates on a "pool" concept and does not "match specific producers with specific customers." Instead, Temco purchases gas from "spot" sources that enter into and drop out of the pool from time to time.

Transco has entered into numerous transportation agreements with Temco's customers in order to transport gas from receipt points with Temco to the customers. Transco states that "from an administrative standpoint, the only feasible type of transportation agreement . . . to use in connection with transporting such gas would be one which would not require an amendment every time a source in the Temco pool is either deleted or added." Transco has submitted contractual language that purports to reflect the language used in the transportation agreements. In essence, the language states that the Temco customer has requested Transco to receive certain quantities of gas "at the existing points of interconnection between Transco and T[emco] [p]roducer [s]ellers" and deliver the gas on an interruptible basis to the customer at an existing point of connection between Transco and the customer.

Transco states that the 26 transportation transactions commenced before October 9, 1985. Transco also states that there have been no changes since October 9 in delivery points to Temco's customers. Transco does admit that it has added and deleted receipt points with the Temco producer sellers since October 9. Finally, Transco states that its ST docket reports to the Commission contain a list of receipt points with the Temco producer sellers that is updated from time to time.

Transco submits that we should grant clarification because the transportation for Temco's customers does not require "an agreement in writing or any amendment in order to delete or add sources of gas." This factor, argues Transco, distinguishes the instant case from *Air Products and Chemicals, Inc.*, 34 FERC ¶ 61,139 (1986), where we found that a contract clause that permitted the parties to add unspecified delivery points merely committed them to amend their written agreement at a later date.

On April 1, 1986, Citizens Energy Corporation, a marketer to low-income consumers and a competitor of Temco, filed a motion opposing Transco's request for clarification. Citizens disagrees with Transco's interpretation of the *Air Products* decision, contending that the effect of Transco's transportation agreements is to amend the agreements *"pro tanto"* after October 9, 1985.[2] Citizens contends that "Transco's effort here is simply a transparent attempt to obtain the flexible authority which the Commission has consistently denied others." Citizens also contends that Transco has been adding and deleting receipt points since October 9. According to Citizens, "Transco has assumed the risks that its interpretation of the Commission's regulations are wrong [and] may be knowingly violating Commission regulations by not offering non-discriminatory [s]ection 311 transportation at the same time that it amends it[s] receipt points."

Citizens further alleges that Transco is using Temco controlled transportation to meet its competitive requirements "while denying such transportation to local distribution customers or to others whose gas would compete with its own sales." Citizens contends that Transco is operating with "virtual impunity" outside of the principles of Order No. 436 and *Maryland People's Counsel* v. *FERC*, 761 F.2d 768 (D.C. Cir. 1985), *modified*, 768 F.2d 450 (D.C. Cir. 1985), and *Maryland People's Counsel* v. *FERC*, 761 F.2d 780 (D.C. Cir. 1985), *mandate stayed*, 768 F.2d 1354 (D.C. Cir. 1985). Citizens also contends that Transco's non-displacement policy dating back to 1983 has been found unduly discriminatory and in violation of the Natural Gas Act, citing an initial decision in *Transcontinental Gas Pipe Line Corporation*, Docket No RP83-137-011, 33 FERC ¶ 63,035 (November 8, 1985).

Citizens request that the Commission require Transco to provide non-discriminatory transportation under Order No. 436 as a remedy for adding and deleting receipt points after October 9. Citizens further requests that Transco not be allowed to cease section 311 transportation for a period "reasonably related to its violation." According to Citizens, no other remedy will benefit Transco's customers who "are now and have been for over three years denied transportation."

Transco has filed two responses to Citizens' motion. In its first response, Transco states that its arguments distinguishing *Air Products* from the instant case have been misrepresented by Citizens. Transco also claims that Citizens creates confusion by suggesting that the agreements for which transition treatment is sought are either between Temco and the producers or Temco and Transco. Transco states that the agreements at issue are between Transco and its shippers, *i.e.*, Temco's customers.

In its second response, Transco denies that its delivery points to Temco's customers have changed since October 9, 1985, and denies that it has engaged in any wrongful action that brings it within the provisions of Order No. 436. Transco states that it *"is continuing to operate under its transportation agreements in a manner identical to the operation under such agreements prior to October 9, 1985."* (Emphasis in Transco's motion.) Transco argues that Citizens' "sweeping allegations" would be more appropriate in a complaint that would more fully advise Transco of the specifics of Citizens' charges. Finally, Transco states that the initial decision in Docket No. RP83-137-011 does not take effect until it is upheld by the Commission.

Natural

Natural requests clarification of language contained in the *Black Marlin* order. In *Black Marlin*, the Director of the Office of Pipeline and Producer Regulation amended a certificate to

[1] 33 FERC ¶ 61,007 (1985), FERC Statutes and Regulations ¶ 30,665 (1985).

[2] In its motion, Citizens incorrectly asserts that the transportation contracts for which Transco seeks transition treatment are between Temco and Transco.

authorize Black Marlin to transport gas from a new supplier. Specifically, the language in the order for which Natural seeks clarification states that "a change in the supplier of gas is a change in a term or condition of service and therefore considered to be initiation of new service." Natural contends that this language "appears broad enough to encompass all 'grandfathered' transportation arrangements involving a change in the underlying suppliers." Natural argues that "changes in suppliers which do not require an existing transportation contract to be amended should not be deemed initiation of new service." Finally, Natural contends that the language in *Black Marlin* is "unworkable" because the "transporter often has no knowledge of who the underlying suppliers are [and] is usually unable to monitor when or if changes are made concerning the suppliers."

Discussion

In previous orders, we have held that amending a transportation agreement after October 9, 1985, will result in the initiation of a new transportation transaction under Order No. 436. *J.R. Simplot Company*, 33 FERC ¶ 61,379 (1985); *Hadson Gas Systems, Inc.*, 33 FERC ¶ 61,142 (1985), *reh'g denied*, 34 FERC ¶ 61,039 (1986); *Panhandle Eastern Pipe Line Company*, 33 FERC ¶ 61,139 (1985). We have also held that a written transportation agreement that permits the parties to add mutually agreeable points after October 9, 1985 merely commits the parties to amend their agreement at a later date. *Air Products and Chemicals, Inc.*, 34 FERC ¶ 61,139 (1986). In contrast, we have granted transitional treatment where a transportation agreement does not have to be amended after October 9, 1985 in order to connect new wells to an existing transportation transaction. *Sohio Petroleum Company*, 33 FERC ¶ 61,448 (1985) (transition treatment was granted because service commenced before October 9 and because no amendment to the transportation contract was necessary); *Osborn Heirs Company*, 35 FERC ¶ 61,181 (May 8, 1986) (transition treatment was granted because service commenced before October 9, because there was no change in the volumes of gas transported or in the central receipt point, and because no amendment to the transportation contract was necessary).

In the instant case, Transco seeks clarification that it can add new receipt points with Temco after October 9, 1985 under the terms of its transportation contracts with the Temco customers. As in *Sohio* and *Osborn*, no amendment to the pre-October 9 transportation agreement is necessary in order to attach the new points. Accordingly, we will grant Transco's request by clarifying that receipt points can be added to a transportation transaction after October 9 where the transporation agreement does not have to be amended.

Citizens has alleged that delivery points to the Temco customers have changed since October 9, 1985. Citizens' charges are not substantiated, and Transco has denied the allegation. For these reasons, we will not address the issue of changed delivery points because that question is beyond the scope of Transco's request for clarification.

For the same reasons that applied to Transco, Natural's request for clarification is granted, *i.e.*, a change in suppliers that does not require a pre-October 9, 1985 transportation agreement to be amended is not deemed initiation of new service that would subject a transporter to the conditions of Order No. 436. By the Commission.

Kenneth F. Plumb,

Secretary.

[FR Doc. 86-16419 Filed 7-21-86; 8:45 am]

BILLING CODE 6717-01-M

ENVIRONMENTAL PROTECTION AGENCY

[SW-FRL-3052-7]

Hazardous Waste Disposal Facilities; Availability of Information

AGENCY: U.S. Environmental Protection Agency.

ACTION: Notice of availability of information.

SUMMARY: The Environmental Protection Agency today announces the availability of a guidance document entitled "Interim Status Surface Impoundments—Retrofitting Variances." This document provides guidance to owners and operators of surface impoundments who are subject to requirements under section 3005(j) of the Resource Conservation and Recovery Act (RCRA) as amended by the Hazardous and Solid Waste Amendments (HSWA) of 1984. Section 3005(j) requires impoundments, which were in existence on November 8, 1984, to be retrofitted to meet double-liner design standards, unless the owner or operator obtains an exemption from the retrofitting requirements. If the impoundment is not retrofitted or exempted by November 8, 1988, it must stop receiving hazardous waste. This document discusses the four exemptions and presents the Agency's recommendations on what information owners and operators should provide if they are seeking an exemption.

ADDRESS: A copy of this document is available for reading at the EPA Library and Subtitle C Docket (Room S-212), both located at 401 M Street SW., Washington, DC 20460, as well as at all Regional Office libraries, Monday through Friday, during the hours of 9:30 a.m. to 3:30 p.m. Copies of this document are available for purchase through NTIS, U.S. Department of Commerce, Springfield, Virginia 22161, (703) 487-4600. NTIS publication number for this document is PB 86212263.

FOR FURTHER INFORMATION CONTACT: RCRA Hotline at (800) 424-9346 (toll free) or at (202) 382-3000. For technical information, contact Paul Cassidy, Office of Solid Waste (WH-565-E), U.S. Environmental Protection Agency, 401 M Street SW., Washington, DC 20460, at (202) 382-4658.

SUPPLEMENTARY INFORMATION: Section 3005(j) of RCRA, as amended by HSWA, requires that each surface impoundment in existence on the date of enactment (November 8, 1984) of HSWA, and qualifying for the authorization to operate under interim status, shall not receive, store, or treat hazardous waste after November 8, 1988, unless such impoundment is in compliance with the requirements of section 3004(o)(1)(A). Section 3004(o)(1)(A) is a reference to the minimum technological standards that require double liners and a leachate collection system. Section 3005(j) allows four exemptions to the retrofitting requirements; these are in paragraphs (j)(2), (3), (4), and (13).

The first exemption, in paragraph (j)(2), requires that the impoundment (1) have a liner for which there is no evidence of leakage, (2) be in compliance with applicable ground-water monitoring requirements for facilities with permits, and (3) be located more than one-quarter mile from an underground source of drinking water.

The second exemption, in paragraph (j)(3), requires that the impoundment be (1) part of a waste water treatment system that utilizes aggressive biological treatment, (2) in compliance with applicable ground-water monitoring requirements for facilities with permits, and (3) part of a facility that is in compliance with Best Available Technology (BAT) effluent limitations; or part of a facility that is in compliance with a Best Practicable Technology (BPT) permit and achieving significant

degradation of toxic pollutants and hazardous constituents. These permit technologies are NPDES permits under the Clean Water Act.

The third exemption, in paragraph (j)(4), requires that the impoundment be located, designed, and operated so that there will be no migration of any hazardous constituent into ground water or surface water at any future time.

The last exemption, in paragraph (j)(13), requires that the owner or operator of an impoundment seeking this exemption has entered into an agreement or order with a State, prior to October 1, 1984, which mandates corrective action. The corrective action should protect human health and the environment as effectively as the minimum technological standards.

This guidance document explains the Congressional intent behind this amendment, discusses the Agency's implementation policies, and recommends the information that owners and operators should submit for each of the four exemptions.

J.W. McGraw,

Acting Assistant Administrator for Solid Waste and Emergency Response.

[FR Doc. 86-16392 Filed 7-21-86; 8:45 am]

BILLING CODE 6560-50-M

[SAB FRL-3052-8]

Science Advisory Board; Ecological Risk Assessment Research Review Subcommittee; Open Meeting—August 7-8, 1986

Under Pub. L. 92-463, notice is hereby given of a meeting of the Science Advisory Board's Ecological Risk Assessment Research Review Subcommittee on August 7-8, 1986 at the Georgia Center for Continuing Education at S. Carlton and Lumpkin Streets, Athens, Georgia. The meeting will begin at 8:30 a.m. on August 7 and will adjourn at approximately 2:30 p.m. on August 8, 1986.

The purpose of the meeting will be to discuss and evaluate the current and proposed Agency research program for ecological risk assessment. The EPA program is presented in an Office of Research and Development document entitled: "Research Plan for Ecological Risk Assessment". The specific agenda issues include: Decision Support Systems for Environmental Risk Assessment; Environmental Transport and Transformation; Uptake, Toxicokinetics, and Effects on Biota; and Population and Ecosystem Effects Analysis. The Subcommittee will receive background briefings on each of these issues.

The meeting is open to the public. Any member of the public wishing to attend, obtain information, or submit written comments should contact Dr. Terry F. Yosie, Director, Science Advisory Board or Mrs. Joanna Foellmer located at 401 M Street SW., Washington, DC 20460 or call (202) 382-4126 by close of business August 1, 1986.

Dated: July 19, 1986.

Terry F. Yosie,

Director Science Advisory Board.

[FR Doc. 86-16391 Filed 7-21-86; 8:45 am]

BILLING CODE 6560-50-M

FEDERAL COMMUNICATIONS COMMISSION

[FCC 86-315]

Licensee of Station KNBP-212 in the Business Radio Service; Data Com, Inc., et al.

AGENCY: Federal Communications Commission.

ACTION: Declaratory ruling.

SUMMARY: The Commission has ruled that the multiple licensed one-way paging system operated by Data Com is a private land mobile service and is therefore preempted from regulation by the Louisiana Public Service Commission by the Communications Act.

EFFECTIVE DATE: July 22, 1986.

ADDRESS: Federal Communications Commission, 1919 M Street, NW., Washington, DC 20554.

FOR FURTHER INFORMATION CONTACT: Nia Chirigos Cresham, Private Radio Bureau, Land Mobile and Microwave Division, Rules Branch, (202) 634-2443.

SUPPLEMENTARY INFORMATION:

In the Matter of Data Com, Inc.; and American Welding Supply, Inc., Licensee of Station KNBP-212 in the Business Radio Service.

This is a summary of the commission's declaratory ruling, adopted July 7, 1986 and released July 14, 1986. The full texts of commission decisions are available for inspection and copying during normal business hours in the FCC Dockets Branch (Room 230), 1919 M Street, Northwest, Washington, DC. The complete text of this decision may also be purchased from the Commission's Copy Contractor, International Transcription Service, (202) 857-3800, 2100 M Street, Northwest, Suite 140, Washington, DC 20037.

Summary of Declaratory Ruling

1. On October 26, 1982, the Louisiana Public Service Commission (PSC) found Data Com, Inc., the equipment supplier of a multiple licensed business radio system to be operating "for hire" as defined by the Louisiana Revised Statutes without the required certificate of convenience and necessity from the PSC. The PSC issued a cease and desist order against the Data Com system. Data Com and American Welding Supply, Inc., a licensee of the system, asked the Commission to rule that the Data Com system is a private land mobile service preempted from state regulation by the Communications Act.

2. In its Declaratory Ruling on the status of the Data Com system the Commission described the system as a multiple licensed one-way paging system. Each user is eligible and licensed by the Commission in the Business Radio Service pursuant to 47 CFR 90.75 and 90.185. The licensees lease the transmitter, equipment and pagers from Data Com. In order for a licensee to receive a page, the caller must call an answering service and leave a message. An employee of the answering service then accesses the transmitter to initiate a page by use of a private radio frequency control link.

3. The issue before the Commission was whether the Data Com system qualified as a private land mobile radio system pursuant to the Communications Act of 1934, as amended. The Commission applied the test set forth section 331(c)(1) of the Communications Act (47 U.S.C. 332(c)(1)) to determine whether the Data Com system was functioning as a private land mobile service by examining the method by which the radio system was interconnected with the telephone network and whether it was reselling a telephone exchange or interexchange service. In its Declaratory Ruling the Commission found the Data Com system was *not* interconnected with the telephone network because the callers can not access the transmitter from the telephone network. The transmitter is used only by the multiple licensees to receive pages initiated by the answering service. Therefore, the Commission found the Data Com system to be a private land mobile radio system within the meaning of section 331(c)(1) of the Communications Act.

4. The Commission also applied section 331(c)(3) of the Act which provides that no state or local government shall have any authority to impose any rate or entry regulation upon any private land mobil service.

Accordingly, the Commission stated in the Declaratory Ruling that the cease and desist order issued by the Louisiana PSC was without force and effect.

Ordering Clause

5. Accordingly, it is hereby declared, that the private radio system licensed to American Welding Supply, Inc., et al., and serviced by Data Com, Inc. and Tri-City Answering Service, Inc. is duly licensed under the Communications Act of 1934, as amended, to offer private land mobile radio service; that the offering described herein is properly classified as private land mobile radio service within the scope of section 331(c)(1) of the Communications Act of 1934, as amended in the Communications Amendments Act of 1982; and that any entry or rate regulations of such offering by a state or local government are without force and effect pursuant to section 331(c)(3) of the amended Act.

6. The authority for this action is contained in sections 1, 3(gg), 4(i), 4(j), 303(r) and 331(c) of the Communications Act of 1934, as amended.

Federal Communications Commission.
William J. Tricarico,
Secretary.
[FR Doc. 86-16424 Filed 7-21-86; 8:45 am]
BILLING CODE 6712-01-M

Public Information Collection Requirement Submitted to Office of Management and Budget for Review

July 16, 1986.

The Federal Communications Commission has submitted the following information collection requirement to the Office of Management and Budget for review and clearance under the Paperwork Reduction Act of 1980, 44 U.S.C. 3501 et seq.

Copies of the submission are available from Jerry Cowden, Federal Communications Commission, (202) 632-7513. Persons wishing to comment on this information collection should contact David Reed, Office of Management and Budget, Room 3235 NEOB, Washington, DC 20503, (202) 395-7231.

OMB Number: 3060-0288
Title: Section 78.33, Special temporary authority
Action: Extension
Respondents: Cable Television Relay Service (CARS) stations
Estimated Annual Burden: 100 Responses; 400 Hours.

Federal Communications Commission.
William J. Tricarico,
Secretary.
[FR Doc. 86-16430 Filed 7-21-86; 8:45 am]
BILLING CODE 6712-01-M

FEDERAL EMERGENCY MANAGEMENT AGENCY

FEMA Advisory Board; Continuation

In accordance with the provisions of the Federal Advisory Committee Act (5 U.S.C. App. I), GSA Regulation 41 CFR 101.6, and FEMA Regulation 44 CFR Part 12, the Director of the Federal Emergency Management Agency (FEMA) has determined that the continuation of the FEMA Advisory Board is in the public interest in connection with the performance of duties imposed on the Agency by law.

As the principal advisory body to the Director, the objective of the Board is to continue to provide him with independence advice on the adequacy of FEMA plans and programs in areas of civil emergencies, such as natural or man-made disasters, mobilization of resources and stabilization of the economy during crisis or war, civil defense and continuity of government measures during conflict, post-conflict resources management for national reconstitution, and other civil emergency roles assigned by Acts of Congress or by Executive Order.

The Board will draw on the expertise of its members and other sources (e.g., FEMA emergency plans and programs analyses, interrelated activities of other Agencies) to continue to provide advice and make recommendations to the Director. In addition to its evaluating role on FEMA high priority civil preparedness programs, the Board will continue to provide advice concerning mission priorities, methodology for addressing objectives, training-education exercise programs, and new concepts related to emergency preparedness.

The Board functions solely as an advisory body, and complies fully with the provisions of the Federal Advisory Committee Act.

The Board consists of 20 members that have been appointed by the Director. This membership assures a balanced representation of experts in areas of natural disasters and national security, such as physical scientists and engineers, sociologists, political scientists, and economic experts drawn from universities, industry, nonprofit organizations, etc. The members will serve at the discretion of the Director for a 2-year term.

Interested persons are invited to submit comments regarding the recommendation to continue the FEMA Advisory Board. Such comments, as well as any inquires, may be addressed to the Rules Docket Clerk, Federal Emergency Management Agency, Washington, DC 20472.

Dated: July 17, 1986.
Julius W. Becton, Jr.,
Director.
[FR Doc. 86-16372 Filed 7-21-86; 8:45 am]
BILLING CODE 6718-01-M

FEDERAL HOME LOAN BANK BOARD

Lincoln Savings and Loan Association, Portland, OR; Appointment of Receiver

Notice is hereby given that pursuant to the authority contained in section 406(c)(1)(B) of the National Housing Act, as amended, 12 U.S.C. 1729(c)(1)(B) (1982), the Federal Home Loan Bank Board appointed the Federal Savings and Loan Insurance Corporation as sole receiver for Lincoln Savings and Loan Association, Portland, Oregon, on July 14, 1986.

Dated: July 16, 1986.
Jeff Sconyers,
Secretary.
[FR Doc. 86-16351 Filed 7-21-86; 8:45 am]
BILLING CODE 6720-01-M

FEDERAL MARITIME COMMISSION

Ocean Freight Forwarder License; Applicants; Morris Knudsen Engineers, Inc., and Transfreight International Freight Services, Inc.

Notice is hereby given that the following persons have filed applications for licenses as ocean freight forwarders with the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and 46 CFR Part 510.

Persons knowing of any reason why any of the following persons should not receive a license are requested to contact the Office of Freight Forwarders, Federal Maritime Commission, Washington, D.C. 20573.

Morris Knudsen Engineers, Inc.
180 Howard Street
San Francisco, CA 94105
Officers:
Richard E. Kohne, President/Director
Robert A. Tinstman, Executive Vice President/Director
David L. Backus, Senior Vice President
William L. Kelley, Senior Vice President
Robert B. Christensen, Senior Vice President/Director
Alex W. Conger, Senior Vice President
Mack A. Redford, Vice President/General Counsel
Gurmukh S. Sarkaria, Senior Vice President

E. Bailey Nicks, Senior Vice President
Samuel H. Crossland, Vice President/Secretary
Joseph F. McKee, Executive Vice President/Director
W. Bert Corbett, Senior Vice President
Walter C. Bell, Vice President-Management Services
Ruric H. Bendio, Vice President-District Operations
Warren M. Emerson, Vice President
James A. Bowden, Treasurer
Gilbert S. Quick, Controller
Jack K. Lemley, Director
Bates C. Burnell, Director
G. William Gilfillan, Director
William J. Deasy, Director
R. K. Woodhead, Director

Transfreight International Freight Services, Inc.
5477 N.W. 72nd Avenue
Miami, FL 33166
Officers:
Alberto Hernandez, President/Director
Ana T. Guerra, Vice President/Director

Dated: July 17, 1986.

Joseph C. Polking,

Secretary.

[FR Doc. 86-16354 Filed 7-21-86; 8:45 am]

BILLING CODE 6730-01-M

Ocean Freight Forwarder License; Revocations; Traco International et al.

Notice is hereby given that the following ocean freight forwarder licenses have been revoked by the Federal Maritime Commission pursuant to section 19 of the Shipping Act of 1984 (46 U.S.C. app. 1718) and the regulations of the Commission pertaining to the licensing of ocean freight forwarders, 46 CFR Part 510.

License No.: 2775
Name: Darrell W. Naquin dba Traco International
Address: 5261 Laurel Street, New Orleans, LA 70115
Date Revoked: June 26, 1986
Reason: Failed to maintain a valid surety bond

License No.: 2649
Name: Golero Freight Forwarding, Inc.
Address: 7811 NW. 72nd Avenue, Medley, FL 33166
Date Revoked: June 26, 1986
Reason: Failed to maintain a valid surety bond

License No.: 2413
Name: A & A International Freight Forwarders, Inc.
Address: 4200 N. 29th Terrace, Hollywood, FL 33020
Date Revoked: June 29, 1986
Reason: Failed to maintain a valid surety bond

License No.: 2979
Name: Lucille A. Battle dba Galt Services
Address: 5207 Newton Street, #102, Bladensburg, MD 20710
Date Revoked: July 3, 1986
Reason: Failed to maintain a valid surety bond

License No.: 2642
Name: Kanguro Express, Inc.
Address: 8329 NW. 66th Street, Miami, FL 33166
Date Revoked: July 7, 1986
Reason: Requested revocation voluntarily

License No.: 339
Name: Hampton Roads Shipping Corporation
Address: World Trade Center, Suite 320, Norfolk, VA 23514
Date Revoked: July 15, 1986
Reason: Surrendered license voluntarily

Eugene P. Stakem,

Deputy Director, Bureau of Tariffs.

[FR Doc. 86-16353 Filed 7-21-86; 8:45 am]

BILLING CODE 6730-01-M

FEDERAL RESERVE SYSTEM

Bankers Trust New York Corp. et al.; 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 August 6, 1986.

A. Federal Reserve Bank of New York (William L. Rutledge, Vice President), 33 Liberty Street, New York, New York 10045:

1. *Bankers Trust New York Corporation*, New York, New York; to engage *de novo* in providing data processing and related activities as described in § 225.25(b)(7) of the Board's Regulation Y.

2. *Midland Bank PLC*, London, England; to engage *de novo* through its subsidiary, Crocker Trust Company, San Francisco, California, in performing functions or activities that may be performed by a trust company, pursuant to § 225.25(b)(3) of the Board's Regulation Y.

Board of Governors of the Federal Reserve System, July 16, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-16355 Filed 7-21-86; 8:45 am]

BILLING CODE 6210-01-M

Conrad Bancorporation 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 August 13, 1986.

A. **Federal Reserve Bank of Chicago** (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Illinois 60690:

1. *Conrad Bancorporation,* Conrad, Iowa; to become a bank holding company by acquiring 100 percent of the voting shares of First State Bank, Conrad, Iowa.

2. *Firstbank of Illinois Co.,* Springfield, Illinois; to acquire 100 percent of the voting shares of Elliot Bancorp, Inc., Jacksonville, Illinois, and thereby indirectly acquire Elliot State Bank, Jacksonville, Illinois; Illinois Bancorporation, Inc., and thereby indirectly acquire United Bank of Collinsville, both of Collinsville, Illinois; Hamilton Bancgroup & Co., St. Louis, Missouri, and thereby indirectly acquire United Illinois Bank, Dahlgren, Illinois; Franklin Bancgroup & Co., St. Louis, Missouri, and thereby indirectly acquire United Illinois Bank, Benton, Illinois; Kaskaskia Bancgroup & Co., St. Louis, Missouri, and thereby indirectly acquire United Illinois of New Athens, New Athens, Illinois; Troy Bancgroup & Co., St. Louis, Missouri, and thereby indirectly acquire United Illinois Bank, Troy, Illinois, Union Bancgroup & Co., St. Louis , Missouri, and thereby indirectly acquire United Illinois Bank, Cobden, Illinois. The comment period on this application ends August 11, 1986.

3. *Security Bancorp, Inc.,* Southgate, Michigan; to acquire 100 percent of the voting shares of Old Kent Bank of Almont, Almont, Michigan.

4. *The First State Bank of Thornton, Iowa Employees' Stock Ownership Plan and Trust,* Thornton, Iowa; to become a bank holding company by acquiring 51 percent of the voting shares of Thornton Bancshares, Inc., Thornton, Iowa, and thereby indirectly acquiring The First State Bank of Thornton, Thornton, Iowa.

B. **Federal Reserve Bank of Kansas City** (Thomas M. Hoenig, Vice President) 925 Grand Avenue, Kansas City, Missouri 64198:

1. *Limestone Bancshares, Inc.,* Sand Springs, Oklahoma; to become a bank holding company by acquiring 100 percent of the voting shares of Limestone National Bank, Sand Springs, Oklahoma.

Board of Governors of the Federal Reserve System, July 16, 1986.

James McAfee,

Associate Secretary of the Board.

[FR Doc. 86-16356 Filed 7-21-86; 8:45 am]

BILLING CODE 6210-01-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control

Chronic and Sentinel Disease Surveillance System; Program Announcement and Notice of Availability of Funds for Fiscal Year 1986

The Centers for Disease Control (CDC), announces that competitive applications are being accepted to assist State and Local Departments of Health in establishing, developing, and maintaining a Chronic and Sentinel Disease Surveillance System. The Catalog of Federal Domestic Assistance number is 13.283.

Authority

This program is authorized under section 301 of the Public Health Service Act.

Availability of Funds

It is expected that approximately $200,000 will be available in Fiscal Year 1986 to fund up to three awards. Awards will be funded with a 12-month budget period and a 3-year project period. It is planned that at least $200,000 will be available each year. Continuation awards within the project periods will be made on the basis of satisfactory progress in meeting project objectives and availability of funds. The funding estimate outlined above may vary and is subject to change.

Eligible Applicants

The official Health Departments of the several States of the United States, the District of Columbia, the Commonwealth of Puerto Rico, any territory or possession of the United States, or any agency or instrumentality of a State exclusive of local governments.

Type of Assistance

Awards resulting from this announcement will be cooperative agreements.

Objectives and Collaborative Activities

A. Objectives

1. Develop chronic and sentinel disease surveillance programs through hospital discharge data and other corroborative secondary data sources such as medical examiner's data, vital statistics data, or environmental exposure data.

2. Overcome obstacles preventing 100% coverage of hospital discharge abstract data.

B. Cooperative Activities

1. Recipient Activities

a. Design and develop a project plan to be made a part of this agreement, for the conduct of population-based chronic disease surveillance based on hospital discharge data and other appropriate information. The project plan will cover all aspects of this study including the implementation schedule, the selection of geographic areas to be included, the collection of discharge data, training of surveillance staff, instrument development, verification of data collected by abstractors, and data entry and analyses.

b. Develop, establish and maintain a chronic and sentinel disease surveillance system utilizing existing data sources such as hospital discharge and other morbidity data, mortality data, disease registries, and veterinary morbidity data.

c. Develop specific plans for:

(1) Assessing the incidence and prevalence of chronic disease,

(2) Identifying areas of potential environmental exposures that may be related to or precipitate various chronic diseases,

(3) Developing and implementing analysis strategies, and

(4) Evaluating the impact of long-term interventions based on continued monitoring of incidence data, and

(5) Following up individuals warranting further investigation because of unusual disease patterns or potential toxic exposures or both.

d. Conduct statistical and epidemiologic analysis of study data and interpret, present, and publish surveillance efforts.

e. Establish a reporting procedure to advise local health departments and local citizens of study findings and their implications.

f. Establish a method to locate and follow-up individual patients when it is scientifically indicated. This will include providing a means for sequentially contacting the hospital, attending physician, and ultimately the patient access to more detailed information such as in a case-control study.

2. Centers for Disease Control (CDC) Activities

a. Provide technical assistance in the development of all phases of the project plan including: surveillance program

design, designation, and selection of defined population-base, identification of hospitals, design of instrument for data collection; evaluation of interventions including environmental exposure mitigation; training of surveillance staff; and data entry and analysis.

b. Provide technical assistance in the assessment and collection of morbidity and mortality data and in the development of the overall surveillance system.

c. Collaborate on the compilation of specified information in a periodic and standardized manner using uniform data elements, coding, and analytical techniques.

d. Provide epidemiologic and other technical assistance in both the planning and implemetation of all phases of the surveillance program.

e. Coordinate with the States and local jurisdictions on the development of appropriate descriptive and analytical techniques to make each data system available nationally for chronic disease surveillance.

Reports

Annual technical and financial status reports are required no later than 30 days after the end of each budget period. Final financial status and progress reports are required 90 days after the end of a project period.

Applications

A. Copies—Place of Submission

The original and two copies of the application should be submitted on Form PHS 5161–1 by August 20, 1986 to: Grants Management Branch, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305.

Application forms may be obtained from the above address.

B. Deadlines

Applications shall be considered as meeting the deadline if they are either:

1. Received on or before the deadline date, or

2. Sent on or before the deadline date and received in time for submission to the independent review group. (Applicants should request a legibly-dated U.S. Postal Service postmark or obtain a legibly-dated receipt from a commercial carrier or U.S. Postal Service. Private metered postmarks shall not be acceptable as proof of timely mailing.)

C. Late Applications

Applications which do not meet the criteria in either paragraph 1 or 2 immediately above are considered late applications and will not be considered in the current competition and will be returned to the applicant.

D. Reviews

Applications are not subject to review as governed by Executive Order 12372, Intergovernmental Review of Federal Programs.

Review Criteria

Applications will be reviewed and evaluated based on the evidence submitted which specifically describes the applicant's ability to meet the following criteria:

A. Adequacy and completeness of the project plan and methodology, including a proposed schedule for accomplishing the activities and objectives.

B. The qualifications and time allocation of the applicant's staff and the type and quality of facilities, equipment and administrative support for the project.

C. How closely objectives of the application fit the objective for which applications were invited. More specifically, the selection of award sites will be based on the potential for establishing a viable system, the percentage of discharges anticipated in a given area, the potential for environmental exposures to produce diseases, and the potential for timely assessment and analysis of data. This data base might include such elements as hospital and patient identification, patient demographic information, patient admission and discharge information, and information related to diagnoses and procedures performed.

D. Documentation that the area covered by the application is population-based and focuses on a population which meets the overall needs for these surveillance systems, i.e., population 500,000 or more, in a geographically defined area and including 90% or more of hospital discharges in that area.

E. Documentation that local resources include a developed public health delivery system, available census and vital data, or the commitment and potential to establish this necessary delivery system.

F. Documentation for follow-up capacity including contacting and informing the appropriate hospital, attending physician and finally the patient for follow-up information such as in a case-control study when scientifically indicated.

G. Documentation that the population-based geographic area has at least one source of environmental pollution (e.g., toxic waste site, source of industrial pollution, or contaminated aquifer).

H. Documentation that areas proposed represent a complete jurisdiction (e.g., a State, county, group of counties, or city), and must be population-based (i.e., encompass an area defined in the 1980 census).

Content of Application

Applicants are required to include a narrative which must:

A. Briefly describe the applicant's understanding of the requirements, problems, objectives, complexities, and interactions required of this cooperative agreement.

B. Describe how the applicant will develop and implement this project including a time schedule.

C. Document the ability to provide the staff, knowledge, and resources to perform their part of this project, and describe the approach to be used in carrying out their responsibilities.

D. Identify and provide the qualifications and time allocations of the existing staff and staff to be assigned to this project, and the facilities/capabilities, office space, necessary equipment, and support staff resources available for the performance of this project.

E. Specify how the project will be administered, including the organizational structure.

F. Describe plans to publish results and designate responsibilities for scientific publications and authors, summary documents, news releases, etc.

Information

Information on application procedures, copies of application forms, and other material may be obtained from: Mr. Luther DeWeese, Grants Management Specialist, Procurement and Grants Office, Centers for Disease Control, 255 East Paces Ferry Road, NE., Room 321, Atlanta, Georgia 30305, (404) 262–6575 or FTS 236–6575.

Technical assistance may be obtained from the Division of Chronic Disease Control:

Matthew M. Zack, M.D., Chief, Cancer Branch, Division of Chronic Disease Control, Center for Environmental Health, Centers for Disease Control, Atlanta, Georgia 30333, (404) 452–4068 or FTS 236–4086

Gary Ford Stein, M.D., M.O.H., Medical Epidemiologist, Division of Chronic Disease Control, Center for Environmental Health, Centers for Disease Control, Atlanta, Georgia 30333, (404) 454–4377 or FTS 236–4377.

Dated: July 16, 1986.

Robert L. Foster,

Acting Director, Office of Program Support, Centers for Disease Control.

[FR Doc. 86-16384 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-18-M

Food and Drug Administration

[Docket No. 86F-0255]

Buckman Laboratories, Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Buckman Laboratories, Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of poly[oxyethylene (dimethyliminio) ethylene (dimethyliminio)ethylene dichloride] as an antimicrobial agent in starch in the manufacture of paper and paperboard products for food-contact use.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF-335), 200 C St. SW., Washington, DC 20204, 202-472-5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5B3835) has been filed by Buckman Laboratories, Inc., 1256 North McLean Blvd., P.O. Box 8305, Memphis, TN 38108, proposing that § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) be amended to provide for the safe use of poly[oxyethylene (dimethyliminio)ethylene(dimethyliminio) ethylene dichloride] as an antimicrobial agent in starch in the manufacture of paper and paperboard products for food-contact use.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16364 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86F-0280]

Canandaigua Wine Co., Inc.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that the Canandaigua Wine Co., Inc., has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener in alcoholic beverages containing wine with ethanol content below 7 percent volume per volume.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C Street SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 6A3942) has been filed by Canandaigua Wine Co., Inc., 116 Buffalo St., Canandaigua, NY 14424, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in alcoholic beverages containing wine with ethanol content below 7 percent volume per volume.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16368 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86F-0281]

Holland American Wafer Co.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Holland American Wafer Co. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of aspartame as a sweetener in wafer cookies.

FOR FURTHER INFORMATION CONTACT: Carl L. Giannetta, Center for Food Safety and Applied Nutrition (HFF-334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202-426-8950.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5)), notice is given that a petition (FAP 6A3912) has been filed by Holland American Wafer Co., 3300 Roger B. Chaffee Dr. SE., Grand Rapids, MI 49508, proposing that § 172.804 *Aspartame* (21 CFR 172.804) be amended to provide for the safe use of aspartame as a sweetener in wafer cookies.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16367 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86F-0221]

Nebraska Department of Economic Development; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Nebraska Department of Economic Development has filed a petition proposing that the food additive regulation for sucrose fatty acid esters be amended to provide for the safe use of vegetable oils as a source of fatty acids in the manufacture of sucrose fatty acid esters.

FOR FURTHER INFORMATION CONTACT: John W. Gordon, Center for Food Safety and Applied Nutrition (HFF-334), Food

and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–426–5487.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 5A3859) has been filed on behalf of Nebraska Department of Economic Development, c/o Commonwealth Bldg., 1625 K St. NW., Washington, DC 20006, proposing that § 172.859 *Sucrose fatty acid esters* (21 CFR 172.859) be amended to provide for the safe use of vegetable oils as a source of fatty acids in the manufacture of sucrose fatty acid esters.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in accordance with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–16365 Filed 7–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 86F–0274]

Union Carbide Corp.; Filing of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that Union Carbide Corp. has filed a petition proposing that the food additive regulations be amended to provide for the safe use of glutaraldehyde as a slimicide in the manufacture of paper and paperboard that may contact food.

FOR FURTHER INFORMATION CONTACT: Edward J. Machuga, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration 200 C St. SW., Washington, DC 20240, 202–472–5690.

SUPPLEMENTARY INFORMATION: Under the Federal Food, Drug, and Cosmetic Act (sec. 409(b)(5), 72 Stat. 1786 (21 U.S.C. 348(b)(5))), notice is given that a petition (FAP 6B3943) has been filed by Union Carbide Corp., Bound Brook, NJ 08805, proposing that § 176.300 *Slimicides* (21 CFR 176.300) be amended to provide for the safe use of glutaraldehyde as a slimicide in the manufacture of paper and paperboard that contact food.

The potential environmental impact of this action is being reviewed. If the agency finds that an environmental impact statement is not required and this petition results in a regulation, the notice of availability of the agency's finding of no significant impact and the evidence supporting that finding will be published with the regulation in the **Federal Register** in according with 21 CFR 25.40(c), as published in the **Federal Register** of April 26, 1985 (50 FR 16636).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center of Food Safety and Applied Nutrition.

[FR Doc. 86–16369 Filed 7–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 83F–0263]

Westvaco; Withdrawal of Food Additive Petition

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the withdrawal without prejudice of a petition (FAP 3B3728) proposing that the food additive regulations be amended to provide for the safe use of mono-, di-, or tri-(1-phenylethyl)phenol, ethoxylated, sulfosuccinated, sodium salt as an emulsifier in the manufacture of paper and paperboard.

FOR FURTHER INFORMATION CONTACT: Julius Smith, Center for Food Safety and Applied Nutrition (HFF–335), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 19, 1983 (48 FR 37714), FDA published a notice that it had filed a petition (FAP 3B3728) from Westvaco Corp., P.O. Box 70848, Charleston Heights, SC 29405, that proposed to amend § 176.170 *Components of paper and paperboard in contact with aqueous and fatty foods* (21 CFR 176.170) of the food additive regulations to provide for the safe use of mono-, di-, tri-(1-phenylethyl)phenol, ethoxylated, sulfosuccinated, sodium salt as an emulsifer in the manufacture of paper and paperboard. Westvaco Corp. has not withdrawn the petition without prejudice to a future filing (21 CFR 171.7).

Dated: July 11, 1986.

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86–16366 Filed 7–21–86; 8:45 am]

BILLING CODE 4160–01–M

[Docket No. 84P–0281]

Canned Green Beans Deviating From Identity Standard; Further Amendment of Temporary Permit for Market Testing

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a temporary permit issued to the Friday Canning Corp., and Continental Can Co., Inc., to market test experimental packs of canned green beans containing added zinc chloride is being further amended to reflect that the test product is to be manufactured at one additional plant.

DATE: The expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking.

FOR FURTHER INFORMATION CONTACT: Catharine R. Calvert, Center for Food Safety and Applied Nutrition (HFF–214), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–485–0121.

SUPPLEMENTARY INFORMATION: A temporary permit was issued under the provisions of 21 CFR 130.17 to the Friday Canning Corp., 150 West First St., P.O. Box 129, New Richmond, WI 54017, and Continental Can Co., Inc., 800 Connecticut Ave., P.O. Box 5410, Norwalk, CT 06856 (formerly 51 Harbor Plaza, Box Number 10004, Stamford, CT 06904–2004), to market test canned green beans containing added zinc chloride to retain the color of the test product (up to 75 parts per million of zinc in the finished food). The permit was issued in order to facilitate market testing of foods that deviate from the requirements of the standards of identify promulgated under section 401 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 341). Notice of issuance of the temporary permit to the Friday Canning Corp., and Continental Can Co., Inc., was published in the **Federal Register** of September 20, 1984 (49 FR 36925).

Continental Can Co., Inc., jointly with other sponsors, submitted a petition to amend 21 CFR 155.120 to provide for the

use of zinc chloride for stabilization of color. At the same time, the Friday Canning Corp., and Continental Can Co., Inc., jointly submitted a request to extend and amend their temporary permit to increase the number of cases of test product for the marketing test. A notice of an extension and amendment of the temporary permit to increase the number of cases of test product was published in the **Federal Register** of March 13, 1986 (51 FR 8709).

Continental Can Co., Inc., on behalf of the Friday Canning Corp., has requested that the temporary permit be amended to permit the test product to be manufactured at an additional plant. Accordingly, FDA, under the provisions of 21 CFR 130.17(f), is further amending the temporary permit to indicate that, in addition to the plant located at Cambria, WI 53923, the test product is to be manufactured at the Friday Canning Corp. plant located at Gillett, WI 54124.

All other conditions and terms of this permit remain the same. The expiration date of the permit will be either the effective date of a final rule for any proposal to amend the standard of identity for canned green beans which may result from the petition, or 30 days after termination of such rulemaking.

Dated: July 10, 1986

Sanford A. Miller,

Director, Center for Food Safety and Applied Nutrition.

[FR Doc. 86-16370 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

[Docket No. 86M-0270]

Ethicon, Inc.; Premarket Approval of PDS™ (Polydioxanone), Dyed and Clear Monofilament Synthetic Absorbable Sutures

AGENCY: Food and Drug Administration.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing its approval of a supplemental application by Ethicon, Inc., Somerville, NJ, for premarket approval, under the Medical Device Amendments of 1976, of the PDS™ (polydioxanone) Dyed and Clear Monofilament Synthetic Absorbable Sutures. After reviewing the recommendation of the General and Plastic Surgery Devices Panel, FDA's Center for Devices and Radiological Health (CDRH) notified the applicant of the approval of the supplemental application.

DATE: Petitions for administrative review by August 21, 1986.

ADDRESS: Written requests for copies of the summary of safety and effectiveness data and petitions for administrative review to the dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Kenneth A. Palmer, Center for Devices and Radiological Health (HFZ-410), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7238.

SUPPLEMENTARY INFORMATION: On March 8, 1985, Ethicon, Inc., Somerville, NJ 08876, submitted to CDRH a supplemental application for premarket approval of the PDS™ (polydioxanone) Dyed and Clear Monofilament Synthetic Absorbable Sutures for an additional indicated use for these previously approved devices (46 FR 59311; December 4, 1981). Ethicon, Inc., requested approval for use of the devices in pediatric cardiovascular tissue where growth is expected to occur.

PDS™ sutures are available as sterile, monofilament dyed (violet) strands in sizes 9-0 to 2 (metric size 0.3 to 5), and as sterile, monofilament dyed (blue) strands in sizes 10-0 to 7-0 (metric size 0.2 to 0.5) in a variety of lengths with a variety of needles. Sterile monofilament dyed (violet) sutures, sizes 4-0 to 1 (metric size 1.5 to 4) are also available attached to control release removable needles. Sterile, monofilament, clear suture strands are available in sizes 7-0 to 1 (metric size 0.5 to 4) in a variety of lengths with permanently attached needles.

On March 25, 1985, the General and Plastic Surgery Devices Panel, an FDA advisory committee, reviewed and recommended approval of the supplemental application. On June 6, 1986, CDRH approved the supplemental application by a letter to the applicant from the Director of the Office of Device Evaluation, CDHR. With FDA's approval of the supplemental application, the indicated uses of these devices read as follows: PDS ™ (polydioxanone) Dyed and Clear Monofilament Synthetic Absorbable Sutures are indicated for use in all types of soft tissue approximation, including use in pediatric cardiovascular tissue where growth is expected to occur and ophthalmic surgery. PDS ™ suture is not indicated in adult cardiovascular tissue, microsurgery, and neural tissue. These sutures are particularly useful where the combination of an absorbable suture and extended wound support (up to 6 weeks) is desirable.

A summary of the safety and effectiveness data on which CDRH based its approval is on file in the Dockets Management Branch (address above) and is available from that office upon written request. Requests should be identified with the name of the device and the docket number found in brackets in the heading of this document.

A copy of all approved labeling is available for public inspection at CDRH—contact Kenneth A. Palmer (HFZ-410), address above.

Opportunity for Administrative Review

Section 515(d)(3) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(d)(3)) authorizes any interested person to petition, under section 515(g) of the act (21 U.S.C. 360e(g), for administrative review of CDRH's decision to approve this supplemental application. A petitioner may request either a formal hearing under Part 12 (21 CFR Part 12) of FDA's administrative practices and procedures regulations or a review of the application and CDRH's action by an independent advisory committee of experts. A petition is to be in the form of a petition for reconsideration under § 10.33(b) (21 CFR 10.33(b)). A petitioner shall identify the form of review requested (hearing or independent advisory committee) and shall submit with the petition supporting data and information showing that there is a genuine and substantial issue of material fact for resolution through administrative review. After reviewing the petition, FDA will decide whether to grant or deny the petition and will publish a notice of its decision in the **Federal Register.** If FDA grants the petition, the notice will state the issue to be reviewed, the form of review to be used, the persons who may participate in the review, the time and place where the review will occur, and other details.

Petitioners may, at any time on or before August 21, 1986, file with the Dockets Management Branch (address above) two copies of each petition and supporting data and information, identified with the name of the device and the docket number found in brackets in the heading of this document. Received petitions may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

This notice is issued under the Federal Food, Drug, and Cosmetic Act (secs. 515(d), 520(h), 90 Stat. 554-555, 571 (21 U.S.C. 360e(d), 360j(h))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Director, Center for Devices and Radiological Health (21 CFR 5.53).

Dated: July 14, 1986.

John C. Villforth,

Director, Center for Devices and Radiological Health.

[FR Doc. 86-16371 Filed 7-21-86; 8:45 am]

BILLING CODE 4160-01-M

Drug Abuse Advisory Committee; Renewal

Correction

In FR Doc. 86-14152 appearing on page 22981, in the second column, in the issue of Tuesday, June 24, 1986, make the following correction:

In the **SUMMARY:** caption, in the seventh and eighth lines, "Pub. L. 92-464" should read "Pub. L. 92-463".

BILLING CODE 1505-01-M

Science Advisory Board to the National Center for Toxicological Research; Renewal

Correction

In FR Doc. 86-14156 appearing on page 22982, in the first column, in the issue of Tuesday, June 24, 1986, make the following correction:

In the **DATE:** caption, in the second line, "June 4" should read "June 2".

BILLING CODE 1505-01-M

Docket No. 83P-0274]

Health Industry Manufacturers Association; Cardiopulmonary Bypass Oxygenator; Denial of Petition for Reclassification

Correction

In FR Doc. 86-12099, beginning on page 19608, in the issue of Friday, May 30, 1986, make the following correction:

On page 19609, first column, first complete paragraph, fifteenth line, "520 (b) (3)" should read "520 (h) (3)".

BILLING CODE 1505-01-M

DEPARTMENT OF THE INTERIOR

Bureau of Land Management

[F-85316]

Alaska; Notice of Proposed Withdrawal and Opportunity for Public Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Notice.

SUMMARY: The Bureau of Land Management proposes to withdraw 40,462 acres of public land near the Nigu River, Alaska, until a study and analysis of resource values is made to support a final decision on disposition. This notice closes the land for up to 2 years from entry and location for metalliferous minerals. The land has been and will remain closed to all forms of appropriation under the public land laws and from location and entry under the mining laws.

DATE: Comments and requests for a public meeting should be received by October 20, 1986.

ADDRESS: Comments and meeting requests should be sent to: Alaska State Director, Bureau of Land Management, 701 C Street, Box 13, Anchorage, Alaska 99513.

FOR FURTHER INFORMATION CONTACT: Mary Jane Clawson, BLM Alaska State Office, 907-271-5060.

On July 15, 1986, a petition was approved allowing the Bureau of Land Management to file an application to withdraw the following described public land from entry and location for metalliferous minerals, subject to valid existing rights:

Kateel River Meridan

T. 30 N., R. 13 E.,
Those portions of secs. 1 and 2 lying outside the Gates of the Arctic National Park and Wilderness; that portion of sec. 3 lying outside the Gates of the Arctic National Park and Wilderness and the Noatak National Preserve and Wilderness; that portion of sec. 12 lying outside the Gates of the Arctic National Park and Wilderness.

T. 31 N., R. 13 E.,
Secs. 1 to 4, inclusive; secs. 5 and 8 lying outside the National Petroleum Reserve in Alaska (NPR-A); secs. 9 to 16, inclusive; that portion of sec. 17 lying outside the NPR-A; that portion of sec. 20 lying outside the Noatak National Preserve and Wilderness and outside the NPR-A; secs. 21 to 26, inclusive; those portions of secs. 27, 28, 29 and 34 lying outside the Noatak Preserve and Wilderness; secs. 35 and 36.

T. 30 N., R. 13 E.,
Sec. 2, W½W½; secs. 3, 4, and 5; those portions of secs. 6 and 7 lying outside the Gates of the Arctic National Park and Wilderness; secs. 8, 9, and 10; sec. 11, W½W½; sec. 14, W½W½; sec. 15; those portions of secs. 16, 17, 18, 19, 20, 21, 22, and 23 lying outside the Gates of the Arctic National Park and Wilderness.

T. 31 N., R. 14 E.,
Sec. 2, W½W½; secs. 3 to 10, inclusive; sec. 11, W½W½; sec. 14, W½W½; secs. 15 to 22, inclusive; sec. 23, W½W½; sec. 26, W½W½; sec. 27 to 34, inclusive; sec. 35, W½W½.

The area described contains approximately 40,462 acres.

The purpose of the proposed withdrawal is to protect the land until a Resource Management Plan is completed to support a final decision on the disposition of the land.

For a period of 90 days from the date of publication of this notice, all persons who wish to submit comments, suggestions, or objections in connection with the proposed withdrawal may present their views in writing to the Alaska State Director of the Bureau of Land Management.

Notice is hereby given that an opportunity for a public meeting is afforded in connection with the proposed withdrawal. All interested persons who desire a public meeting for the purpose of being heard on the proposed withdrawal must submit a written request to the Alaska State Director within 90 days from the date of publication of this notice. Upon determination by the authorized officer that a public meeting will be held, a notice of the time and place will be published in the **Federal Register** at least 30 days before the scheduled date of the meeting.

The application will be processed in accordance with the regulations set forth in 43 CFR Part 2300.

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 will be permitted during this segregative period are licenses, permits, 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 lands, and the segregation shall not have the effect of authorizing any use of the lands by the Bureau of Land Management.

Robert W. Arndorfer,

Deputy State Director for Conveyance Management.

[FR Doc. 86-16434 Filed 7-21-86; 8:45 am]

BILLING CODE 4310-JA-M

[A 20346-L]

Realty Action; Exchange of Public Lands; Pima County, AZ

AGENCY: Bureau of Land Management (BLM), Interior.

ACTION: Exchange of public lands, Pima County, Arizona.

BLM proposes to exchange public land with the State of Arizona in order to achieve more efficient management of

the public land through consolidation of ownership.

The following public land is being considered for disposal by exchange pursuant to sec. 206 of the Federal Land Policy and Management Act of October 21, 1976, 43 U.S.C. 1716.

Gila and Salt River Meridan, Arizona

T. 15 S., R. 15 E.,
Section 15, W½SW¼, SE¼SW¼
Containing 120 acres, more or less.

Final determination on disposal will await completion of an environmental analysis.

In accordance with the regulations of 43 CFR 2201.1(b), publication of this notice will segregate the public lands, as described in this Notice, from appropriation under the public land laws, including the mining laws, but not the mineral leasing laws or Geothermal Steam Act.

The segregation of the above described lands shall terminate upon issuance of a document conveying such lands or upon publication in the **Federal Register** of a notice of termination of the segregation; or the expiration of two years from the date of publication, whichever occurs first.

For a period of forty-five (45) days, interested parties may submit comments to the District Manager, Phoenix District Office, 2015 West Deer Valley Road, Phoenix, Arizona 85027.

Dated: July 10, 1986.

Marlyn V. Jones,

District Manager.

[FR Doc. 86-16406 Filed 7-21-86; 8:45 am]

BILLING CODE 4310-32-M

[CA-060-06-7122-10-1018; CA 18780]

Realty Action; Proposed Exchange of Public and Private Lands Riverside County, CA

Correction

In **Federal Register** Doc. 86-4434 appearing on page 7340 in the issue of Monday, March 3, 1986, make the following correction:

In the first column, in the second land description for "San Bernardino Meridian," "Sec. 2," delete the period at the end of the third line, then add a comma and "SW¼."

Dated: July 16, 1986.

Bary A. Freet,

Acting District Manager.

[FR Doc. 86-16432 Filed 7-21-86; 8:45 am]

BILLING CODE 4310-40-M

[ID-030-06-4322-15]

Idaho Falls District Grazing Advisory Board; Meeting

AGENCY: Bureau of Land Management, Interior.

ACTION: Meeting of the Idaho Falls district grazing advisory board.

SUMMARY: The Idaho Falls District Grazing Advisory Board will meet Tuesday, August 26, 1986. Notice of this meeting is in accordance with Pub. L. 92-463. The meeting will begin at 9 a.m. at the Idaho Falls District Office on 940 Lincoln Road, Idaho Falls, Idaho. The meeting is open to the public; public comments on agenda items will be accepted from 11:00 to 11:30 a.m.

The agenda items are: an Overview of the Functions of the Grazing Advisory Board, Election of Officers and FY 87 Range Improvement Projects Funding.

Summary minutes of the meeting will be kept in the District Office and will be available for public inspection and reproduction during business hours (7:45 a.m. to 4:30 p.m.) within 30 days after the meeting.

FOR FURTHER INFORMATION CONTACT: O'dell A. Frandsen, Bureau of Land Management, 940 Lincoln Road, Idaho Falls, Idaho 83401; Telephone: (208) 529-1020.

W. Bernard Jansen,

Acting District Manager.

July 10, 1986.

[FR Doc. 86-16359 Filed 7-21-86; 8:45 am]

BILLING CODE 4310-GG-M

Minerals Management Service

Development Operations Coordination Document; Phillips Petroleum Co.

AGENCY: Minerals Management Service, Interior.

ACTION: Notice of the Receipt of a Proposed Development Operations Coordination Document (DOCD).

SUMMARY: Notice is hereby given that Phillips Petroleum Company has submitted a DOCD describing the activities it proposes to conduct on Lease OCS 0757, Block 118, West Cameron Area, offshore Louisiana. Proposed plans for the above area provide for the development and production of hydrocarbons with support activities to be conducted from

an onshore base located at Grand Chenier, Louisiana.

DATE: The subject DOCD was deemed submitted on July 10, 1986.

ADDRESSES: A copy of the subject DOCD is available for public review at the Office of the Regional Director, Gulf of Mexico OCS Region, Minerals Management Service, 1420 South Clearview Pkwy., Room 114, New Orleans, Louisiana (Office Hours: 9 a.m. to 3:30 p.m., Monday through Friday).

FOR FURTHER INFORMATION CONTACT: Michael J. Tolbert; Minerals Management Service; Gulf of Mexico OCS Region; Field Operations; Plans, Platform and Pipeline Section; Exploration/Development Plans Unit; Phone (505) 736–2867.

SUPPLEMENTARY INFORMATION: The purpose of this Notice is to inform the public, pursuant to section 25 of the OCS Lands Act Amendments of 1978, that the Minerals Management Service is considering approval of the DOCD and that it is available for public review.

Revised rules governing practices and procedures under which the Minerals Management Service makes information contained in DOCDs available to affected States, executives of affected States, local governments, and other interested parties became effective December 13, 1979, (44) FR 53685). Those practices and procedures are set out in revised § 250.34 of Title 30 of the CFR.

Dated: July 14, 1986.

J. Rogers Pearcy,

Regional Director, Gulf of Mexico OCS Region.

[FR Doc. 86–16407 Filed 7–21–86; 8:45 am]

BILLING CODE 4310-MR-M

INTERSTATE COMMERCE COMMISSION

[Finance Docket No. 30764]

Arkansas and Missouri Railroad Co. et al.; Exemption

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts the following transactions from the prior approval requirements of: (1) 49 U.S.C. 10901, for the acquisition from Burlington Northern Railroad Company and operation by Arkansas and Missouri Railroad Company (AMR) of a railroad line extending from Monett, MO (milepost 282.08) to South Fort Smith, AR (milepost 422.50) and a branch line known as the Bentonville Branch extending between milepost 332.07 and milepost 338.21; (2) 49 U.S.C. 11301, for the issuance by AMR of up to $750,000 and $400,000, respectively, in debt and equity securities; and (3) 49 U.S.C. 11343, for the continuance in control by J.A. Hannold of AMR and the Maryland and Delaware Railroad, subject to standard employee protective conditions.

DATES: These exemptions will be effective on July 28, 1986. Petitions to reopen must be filed by August 13, 1986.

ADDRESSES: Send pleadings referring to Finance Docket No. 30764 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423

(2) Petitioner's representative: R. Lawrence McCaffrey, Jr., Suite 800, 1350 New York Avenue, NW, Washington, DC 20005–4797.

FOR FURTHER INFORMATION CONTACT: Donald Shaw, Jr., (202) 275–7245.

SUPPLEMENTARY INFORMATION: Additional information is contained in the full decision. To purchase a copy of it write to T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289–4357 (DC Metropolitan area) or toll free (800) 424–5403.

Decided: June 30, 1986.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre, and Lamboley. Vice Chairman Simmons dissented in part with a separate expression. Commissioner Lamboley dissented and will submit a separate expression at a later date.

Noreta R. McGee,

Secretary.

[FR Doc 86–16397 Filed 7–17–86; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB–26 (Sub-No. 34X)]

Southern Railway Co. and Southern Railway; Carolina Division—Abandonment and Discontinuance of Service in New York and Cherokee Counties, SC

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Commission exempts from prior approval under 49 U.S.C. 10903, *et seq.*, the abandonment by Southern Railway-Carolina Division of and the discontinuance of service by Southern Railway Company over 18.3 miles of track in New and Cherokee Counties, SC, subject to standard labor protective conditions.

DATES: This exemption is effective on August 21, 1986. Petitions to stay must be filed by August 6, 1986, and petitions for reconsideration must be filed by August 18, 1986.

ADDRESSES: Send pleadings referring to Docket No. AB–26 (Sub-No. 34X) to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423

Petitioner's representative: Nancy S. fleischman, 1050 Connecticut Avenue, NW., Suite 740, Washington, DC 20036

FOR FURTHER INFORMATION CONTACT: Donald J. Shaw, Jr., (202) 275–7245.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision, write to T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289–5403 (DC Metropolitan area), or toll-free (800) 424–5403.

Decided: July 14, 1986.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre, and Lamboley.

Noreta R. McGee,

Secretary.

[FR Doc. 86–16398 Filed 7–21–86; 8:45 am]

BILLING CODE 7035-01-M

[Finance Docket No. 30779]

Rochester and Southern Railroad, Inc., and Genesee and Wyoming Industries, Inc.—Exemption

AGENCY: Interstate Commerce Commission.

ACTION: Notice of exemption.

SUMMARY: The Interstate Commerce Commission exempts (1) from the prior approval requirements of 49 U.S.C. 10901, (a) the acquisition by the Rochester and Southern Railroad, Inc. (RS), of about 103 miles of rail line, owned by the Buffalo, Rochester and Pittsburgh Railway Company (BRP) and operated by the Baltimore and Ohio Railroad Company (B&O), between Rochester, NY (milepost 0.00) and Ashford, NY (milepost 93.63), between milepost 0.00 and milepost 6.90 (the Rochester Belt line), and between milepost 0.00 and milepost 2.27 (the Silver Lake Branch); and (b) the acquisition by RS of trackage rights over 14.3 miles of rail line, owned by BRP and operated by B&O, between Ashford (milepost 93.63) and East Salamanca, NY (milepost 107.93); (2) from the prior approval requirements of 49 U.S.C. 11301, the issuance by RS of 10,000 shares of common stock in connection with its acquisition and operation of the lines descried above; and (3) from the prior approval requirements of 49 U.S.C. 11343, continuation in control and management of RS by Genesee and Wyoming Industries, Inc., subject to standard employee protective conditions.

DATES: These exemptions will be effective on July 31, 1986. Petitions to reopen must be filed by August 8, 1986.

ADDRESSES: Send pleadings referring to Finance Docket No. 30779 to:

(1) Office of the Secretary, Case Control Branch, Interstate Commerce Commission, Washington, DC 20423

(2) Petitioners' representative: James B. Gray, Jr., 700 Midtown Tower, Rochester, NY 14604.

FOR FURTHER INFORMATION CONTACT: Donald Shaw, Jr., (202) 275–7693.

SUPPLEMENTARY INFORMATION: Additional information is contained in the Commission's decision. To purchase a copy of the full decision write to T.S. InfoSystems, Inc., Room 2229, Interstate Commerce Commission Building, Washington, DC 20423, or call 289–4357 (DC Metropolitan area) or toll free (800) 424–5403.

Decided: June 27, 1986.

By the Commission, Chairman Gradison, Vice Chairman Simmons, Commissioners Sterrett, Andre, and Lamboley. Vice Chairman Simmons concurred in the result. Commissioner Lamboley dissented in part with a separate expression.

Noreta R. McGee,

Secretary.

[FR Doc. 86–16352 Filed 7–21–86; 8:45 am]

BILLING CODE 7035-01-M

DEPARTMENT OF JUSTICE

Antitrust Division

Proposed Termination of Final Decree; NCR Corp.

Notice is hereby given that NCR Corporation ("NCR"), formerly known as the The National Cash Register Company, has filed with the United States District Court for the Southern District of Ohio a motion to terminate the final decree in *United States v. The National Cash Register Company*, In Equity No. 6802; and the Department of Justice ("Department"), in a stipulation also filed with the Court, has consented to termination of the decree, but has reserved the right to withdraw its consent for at least seventy (70) days after the publication of this notice. The compliant in this case (filed on December 4, 1911) alleged a conspiracy to restrain trade, an attempt to monopolize and a successful monopolization of the cash register industry through a variety of tactics designed to harass and intimidate competitors.

The decree (entered on February 1, 1916) enjoins NCR and 17 individuals from engaging in the conduct that promoted the filing of the complaint, including, among other things: (1) Persuading and purchaser of a competitor's cash register to break his contract; (2) engaging in corporate espionage or inducing a competitor's employee to disclose trade secrets; (3) inducing a competitor's employee or a dealer in competitive cash registers to leave the service of the competitor in return for employment at NCR; (4) making statements about a competitor's solvency or responsibility or about the efficiency of a competing cash register for the purpose of preventing the sale of competing cash registers; (5) intimidating competitors or prospective investors in competitors with certain types of product comparisons or statements of purported losses suffered by the competitors in their efforts to compete with NCR; and (6) acquiring a competitor's business without first obtaining the Court's permission.

The Department has filed with the Court a memorandum setting forth the reasons why the Department believes that termination of the decree would serve the public interest. Copies of the complaint and final decree, NCR's notice papers, the stipulation containing the Government's consent, the Department's memorandum and all further paper filed with the Court in connection with this motion will be available for inspection in the Legal Procedure Unit of the Antitrust Division, Room 7233, Department of Justice, 10th Street and Pennsylvania Avenue, NW., Washington, DC 20530 (telephone: 202–633–2481), and at the Office of the Clerk of the United States District Court for the Southern District of Ohio, Western Division, 200 West Second Street, Dayton, Ohio 45402. Copies of any of these materials may be obtained from the Legal procedure Unit upon request and payment of the coping fee set by Department of Justice regulations.

Interested persons may submit comments regarding the proposed termination of the decree to the Department. Such comments must be received within sixty (60) days, and will be filed with the Court. Comments should be addressed to John A. Weedon, Chief, Cleveland Field Office, Antitrust Division, United States Department of Justice, 995 Celebrezze Federal Building, Cleveland, Ohio 44199 (telephone: 216–522–4070).

Dated: July 16, 1986.

Joseph H. Widmar,

Director of Operations, Antitrust Division.

[FR Doc. 86–10468 Filed 7–21–86; 8:45 am]

BILLING CODE 4410-01-M

Immigration and Naturalization Service

Productivity Improvement Reviews (A–76)

AGENCY: Immigration and Naturalization Service, Justice.

ACTION: Notice of Productivity Improvement Reviews.

FOR FURTHER INFORMATION CONTACT: Robert A. Anderson, Director, Office of Program Inspection, 425 I Street, NW., Washington, DC 20536, (202) 633–4097.

SUPPLEMENTARY INFORMATION: In accordance with OMB Circular No. A–76 and the September 27, 1984 memorandum to the President's Council on Management Improvement, the Immigration and Naturalization Service will be conducting productivity improvement reviews at its various field offices and its Central Office to develop the most efficient organization (MEO) and to determine whether activities should remain in-house, be cross-

serviced by other Federal agencies, or be contracted out. Appearing below is a schedule of productivity reviews to be conducted in calendar years 1985 through 1987. As a result of these on-site studies, other worksite locations might be affected.

Study	Starting date	Location
1. Motor vehicle maintenance.	February 1986	San Diego, CA. El Paso, TX.
2. Mail and file services/data transcription and keypunch.	April 1986	New York, NY. St. Albans, VT. Los Angeles, CA. San Francisco, CA. Dallas, TX. Phoenix, AZ. Washington, DC. Boston, MA. Detroit, MI. Miami, FL.
3. ADP	June 1986	Washington, DC. Burlington, VT.
4. Accounting	May 1986	Washington, DC.

Dated: July 15, 1986.

Alan C. Nelson,

Commissioner, Immigration and Naturalization Service.

[FR Doc. 86-16385 Filed 7-21-86; 8:45 am]

BILLING CODE 4410-10-M

LEGAL SERVICES CORPORATION

One-Time Grant Award: Announcement; American Corporate Counsel Institute

AGENCY: Legal Services Corporation.

ACTION: Announcement of intention to award a one-time grant.

SUMMARY: The Legal Services Corporation (LSC) announces its intention to award a one-time, non-recurring grant of $50,000 to the American Corporate Counsel Institute (ACCI). This grant will be for a one-year term. It will be awarded pursuant to authority conferred by sections 1006(a)(1)(B) and 1006(A)(3) of the Legal Services Corporation Act of 1974, as amended, in response to an unsolicited proposal submitted by ACCI for assistance in continuing ACCI's Corporate Pro Bono Activation Program. The grant will not be subject to automatic refunding rights or entitled to any rights, including hearing rights, under section 1011 of the LSC Act, as amended, or LSC regulations promulgated thereunder.

This public notice is issued pursuant to section 1007(F) of the LSC Act, with a request for comments and recommendations within a period of thirty (30) calendar days from date of publication of this Notice. The grant award will not become effective and no grant funds will be distributed prior to expiration of this thirty day period.

DATE: All comments and recommendations must be received by the Program Development and Substantive Support Division within the Office of Field Services of the Legal Services Corporation within thirty (30) calendar days of publication of this notice.

FOR FURTHER INFORMATION CONTACT: Legal Services Corporation, Charles T. Moses, III, Esq., Assistant Manager, Program Development and Substantive Support Division, Office of Field Services, 400 Virginia Avenue SW., Washington, DC 20024-2751 (202) 863-1837.

SUPPLEMENTARY INFORMATION: The American Corporate Counsel Institute (ACCI), a 501(c)(3) corporation, was established by the American Corporate Counsel Association (ACCA) to support the Association's work in the field of education, research and community service concentrating in pro bono activation. the ACCI/ACCA Pro Bono Program was originally funded by LSC in October, 1983; this will be the third grant award to ACCI. This Pro Bono Program performs a variety of activities to stimulate the development and expansion of corporation law department pro bono projects. The Program activates pro bono commitments by attorneys employed by corporation law departments as well as from outside counsel retained by corporations. These corporation sponsored projects provide direct civil legal assistance to poor individuals and generally work cooperatively with local LSC-funded field programs.

James H. Wentzel,

President, Legal Services Corporation.

[FR Doc. 86-16410 Filed 7-21-86; 8:45 am]

BILLING CODE 6820-35-M

NUCLEAR REGULATORY COMMISSION

[Docket No. 50-341]

Detroit Edison Co. and Wolverine Power Supply Cooperative, Inc.; Environmental Assessment and Finding of No Significant Impact

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an exemption from the requirements of § 50.44(c)(3)(i) of 10 CFR Part 50 to the Detroit Edison Company (DECo or licensee), holder of Facility Operating License No. NPF-43 which authorizes operation of the Fermi-2 facility. The facility is a boiling water reactor and is located in Monroe County, Michigan.

Environmental Assessment

Identification of the Proposed Action

The exemption would allow inerting of the containment in response to the requirements of 10 CFR Part 50.44 to be postponed from six months after initial criticality until either the completion of the 100 percent thermal power trip tests or until 120 effective full power days of core burn-up is achieved, whichever is earlier. The exemption is in accordance with the licensee's request dated October 9, 1985, and supplemented on November 13, 1985.

The Need for the Proposed Action

The exemption is needed to permit completion of the startup test program with a non-inerted containment. A non-inerted containment during startup testing would facilitate containment entries on an as-needed frequency for identifying and correcting potential safety problems and would also provide greater safety to personnel entering the containment during this period.

Environmental Impacts of the Proposed Action

The increment of environmental impact is related to the potentially increased consequences of an accident sequence which would have been mitigated by an inerted containment. However, the regulatory requirement from which an exemption is sought anticipated that the startup test program could be completed within six months and, consequently, the risk resulting from the core fission product inventory which would build up over the relatively short period of the power ascension test program while the containment was not inerted, was acceptable. While the regulation contemplated a six-month period to complete the startup test program, recent BWR startup test programs have proven to actually require an average of about eleven months. The Fermi-2 plant, due to its entended shutdown for the last nine months after completing almost all of the five percent power testing program, clearly was not able to complete the startup test program prior to six months after initial criticality as required by 10 CFR 50.44. (Initial criticality was achieved on June 21, 1985.) With the simple stretch in time proposed in the subject exemption, no significant increase in core inventory occurs and about the same effective core history is experienced as was contemplated in the applicable portion of the regulations. This limitation on the fission product inventory in the Fermi-2 reactor core is assured by a restriction, contained in

the proposed exemption, on the integrated power history.

With regard to potential non-radiological impacts, the proposed exemption involves systems located entirely within the restricted areas as defined in 10 CFR Part 20. It does not affect non-radiological plant effluents and, by minimizing the energy requirements required to obtain the nitrogen used in purging the containment, may have a positive environmental impact. Therefore, the Commission concludes there are no significant adverse non-radiological environmental impacts associated with the proposed exemption.

Alternative to the Proposed Action

Because the staff has concluded that there is no measurable environmental impact associated with the exemption, any alternative to the exemption will have either no impact or a greater environmental impact.

The principal alternative would be to deny the requested exemption. This would not reduce the environmental impacts of plant operation. Further, without the requested exemption, considerable delay will be incurred as the containment is deinerted and reinerted before and after containment entries by plant personnel. Some risk to plant personnel will also be encountered. At this point in the test program of the Fermi-2 facility, this process of deinerting and reinerting would significantly extend the time to complete the startup test phase and would produce unwarranted delays in power ascension.

Alternative Use of Resources

The action in the granting of this exemption does not involve the use of resources not previously considered in connection with the "Final Environmental Statement related to the Operation of Enrico Fermi Atomic Power Plant, Unit No. 2." (NUREG–0769) dated August 1981.

Agencies and Persons Consulted

The NRC staff reviewed the licensee's requests that support the requested exemption. The NRC staff did not consult other agencies or persons.

Finding of No Significant Impact

The Commission has determined not to prepare an environmental impact statement for the requested exemption.

Based upon the forgoing environmental assessment, we conclude that the requested action will not have a significant effect on the quality of the human environment.

For further details with respect to this action, see the requests for the exemption as listed herein, which are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555 and at the Monroe County Library, South Custer Road, Monroe, Michigan 48161.

Dated at Bethesda, Maryland, this 16th day of July 1986.

For the Nuclear Regulatory Commission.

Elinor G. Adensam,

Director, BWR Project Directorate No. 3, Division of BWR Licensing.

[FR Doc. 86–16446 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–238]

Renewal of Amended Facility License; State of South Carolina Patriots Point Development Authority and the U.S. Maritime Administration

The U.S. Nuclear Regulatory Commission (the Commission) has issued Amendment No. 11 to Facility License No. NS–1 for the State of South Carolina Patriots Point Development Authority and the U.S. Maritime Administration (the licensees) which renews the license for possession, but not operation (possession-only) of the nuclear reactor aboard the N.S. Savannah. The renewed Facility License No. NS–1 will expire on July 15, 1996.

The amended license complies 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. Those findings are set forth in the license amendment. Opportunity for hearing was afforded in the notice of the proposed issuance of this renewal in the **Federal Register** on January 6, 1986 at 51 FR 460. No request for a hearing or petition for leave to intervene was filed following notice of the proposed action.

The Commission has prepared a Safety Evaluation for the renewal of Possession Only License No. NS–1 and has, based on that evaluation, concluded that the licensee can continue to possess the facility without endangering the health and safety of the public.

For further details with respect to this action, see (1) the application for amendment dated August 20, 1985, (2) the Finding of No Significant Environmental Impact, (3) Amendment No. 11 to Possession Only License No. NS–1, (4) the Commission's related Safety Evaluation and (5) the Environmental Assessment. These items are available for public inspection at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555.

Dated at Bethesda, Maryland, this 15th day of July 1986.

For the Nuclear Regulatory Commission.

Herbert N. Berkow,

Director, Standardization and Special Projects Directorate, Division of PWR Licensing–B.

[FR Doc. 86–16455 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

[Docket Nos. 50–266 and 50–301]

Wisconsin Electric Power Co. (Point Beach Nuclear Plant Unit Nos. 1 and 2); Issuance of Director's Decision

The Office of Nuclear Reactor Regulation has considered pursuant to 10 CFR 2.206 alleged equipment qualification deficiencies at the Point Beach Nuclear Plant, Unit Nos. 1 and 2, identified in the "Comments on Rule Regarding Environmental Qualification of Electrical Equipment: Removal of June 30, 1982 Deadline" filed with the Commission by Stephen Proudman of Wisconsin's Environmental Decade, Inc., (Petitioner) on August 10, 1984. The Petitioner included as a concern that specific items of electrical equipment for certain facilities had not been found environmentally qualified in a Technical Evaluation Report prepared by the Franklin Research Center for the NRC in 1982.

Upon review of information pertaining to these items and the information provided by the Petitioner, the Director of the Office of Nuclear Reactor Regulation has determined that the concerns identified by the Petitioner have been adequately addressed. The reasons for the Director's conclusions are contained in the "Director's Decision Under 10 CFR 2.206" (DD–86–09) which is available for inspection in the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555 and the local public document room for the Point Beach Nuclear Plant, Unit No. 1 and 2 located at the Joseph P. Mann Public Library, 1516 Sixteenth Street, Two Rivers, Wisconsin.

A copy of the decision will be filed with the Office of the Secretary of the Commission for the Commission's review in accordance with 10 CFR 2.206(c). As provided in this regulation, the decision will become the final action of the Commission twenty-five (25) days after issuance, unless the Commission

on its own motion institutes review of the decision within that time.

For the Nuclear Regulatory Commission.
Dated at Bethesda, Maryland, this 14th of July, 1986.

Richard H. Vollmer,
Acting Director, Office of Nuclear Reactor Regulation.

[FR Doc. 86-16452 Filed 7-21-86; 8:45 am]
BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards; Subcommittee on Extreme External Phenomena; Meeting

The ACRS Subcommittee on Extreme External Phenomena will hold a meeting on August 6, 1986, Room 1046, 1717 H Street, NW., Washington, DC.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Wednesday, August 6, 1986—8:30 a.m. Until the Conclusion of Business

The Subcommittee will conduct a workshop to review the importance of seismic risk to nuclear power plants. Seismic hazard will be the principal topic to be discussed.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Dr. Richard Savio (telephone 202/634-3267) between 8:15 A.M. and 5:00 P.M. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: July 16, 1986.

Morton W. Libarkin,
Assistant Executive Director for Project Review.

[FR Doc. 86-16450 Filed 7-21-86; 8:45 am]
BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards; Subcommittee on Improved LWR Designs; Meeting

The ACRS Subcommittee on Improved LWR Designs will hold a meeting on August 5, 1986, Room 1046, 1717 H Street, NW., Washington, DC.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, August 5, 1986—2:00 P.M. until 6:00 P.M.

The Subcommittee will discuss the Standardization Policy Statement.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Herman Alderman (telephone 202/634-1413) between 8:15 A.M. and 5:00 P.M. Persons planning to attend this meeting are urged to contact one of the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: July 17, 1986.

Morton W. Libarkin,
Assistant Executive Director for Project Review.

[FR Doc. 86-16448 Filed 7-21-86; 8:45 am]
BILLING CODE 7590-01-M

Advisory Committee on Reactor Safeguards; Subcommittee on Metal Components; Meeting

The ACRS Subcommittee on Metal Components will hold a meeting on August 4, 1986, at the Battelle Pacific Northwest Laboratories (PNL), Battelle Avenue in the Battelle Auditorium Lobby, Richland, WA.

The entire meeting will be open to public attendance.

The agenda for subject meeting shall be as follows:

Monday, August 4, 1986—8:30 A.M. Until the Conclusion of Business

The Subcommittee will review the steam generator integrity program. In addition, the integrated Fracture Mechanics/Nondestructive Examination and other PNL programs will be discussed.

Oral statements may be presented by members of the public with concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff members as far in advance as practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements

and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Elpidio Igne (telephone 202/634–1414) between 8:15 A.M. and 5:00 P.M. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: July 17, 1986.

Morton W. Libarkin,

Assistant Executive Director for Project Review.

[FR Doc. 86–16447 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards; Subcommittee on Reactor Operations; Meeting

The ACRS Subcommittee on Reactor Operations will hold a meeting on August 4, 1986, Room 1046, 1717 H Street, NW., Washington, DC.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Monday, August 4, 1986—1:00 P.M. until the conclusion of business

The Subcommittee will review recent events at operating plants.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee may exchange preliminary views regarding matters to be considered during the balance of the meeting. The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Herman Alderman (telephone 202/634–1414) between 8:15 A.M. and 5:00 P.M. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: July 16, 1986.

Morton W. Libarkin,

Assistant Executive Director for Project Review.

[FR Doc. 86–16451 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

Advisory Committee on Reactor Safeguards; Subcommittee on Reliability Assurance; Meeting

The ACRS Subcommittee on Reliability Assurance will hold a meeting on August 5, 1986, Room 1046, 1717 H Street, NW., Washington, DC.

The entire meeting will be open to public attendance.

The agenda for the subject meeting shall be as follows:

Tuesday, August 5, 1986—8:30 A.M. Until the Conclusion of Business

The Subcommittee will review the final resolution of USI A–46, "Seismic Qualification of Equipment in Operating Plants." The Subcommittee will also hear a briefing by the Vendor Program Branch NRC's Office of Inspection and Enforcement on the status of a generic check valve program.

Oral statements may be presented by members of the public with the concurrence of the Subcommittee Chairman; written statements will be accepted and made available to the Committee. Recordings will be permitted only during those portions of the meeting when a transcript is being kept, and questions may be asked only by members of the Subcommittee, its consultants, and Staff. Persons desiring to make oral statements should notify the ACRS staff member named below as far in advance as is practicable so that appropriate arrangements can be made.

During the initial portion of the meeting, the Subcommittee, along with any of its consultants who may be present, may exchange preliminary views regarding matters to be considered during the balance of the meeting.

The Subcommittee will then hear presentations by and hold discussions with representatives of the NRC Staff, its consultants, and other interested persons regarding this review.

Further information regarding topics to be discussed, whether the meeting has been cancelled or rescheduled, the Chairman's ruling on requests for the opportunity to present oral statements and the time allotted therefor can be obtained by a prepaid telephone call to the cognizant ACRS staff member, Mr. Richard Major (telephone 202/634–1414) between 8:15 A.M. and 5:00 P.M. Persons planning to attend this meeting are urged to contact the above named individual one or two days before the scheduled meeting to be advised of any changes in schedule, etc., which may have occurred.

Dated: July 17, 1986.

Morton W. Libarkin,

Assistant, Executive Director for Project Review.

[FR Doc. 86–16449 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–373 and 50–374]

Commonwealth Edison Co.; La Salle County Station, Units 1 and 2; Denial of Amendments to Facility Operating License and Opportunity for Hearing

The U.S. Nuclear Regulatory Commission (the Commission) has denied in part requests by the licensee for amendments to Facility Operating License Nos. NPF–11 and NPF–18, issued to the Commonwealth Edison Company (licensee), for operation of the La Salle County Station, Units 1 and 2 located in La Salle County, Illinois. The Notice of Consideration of Issuance of Amendments was published in the **Federal Register** on April 9, 1986 (51 FR 12247).

The amendments proposed by the licensee would change the Technical Specifications: (a) To add fire detectors in fire zones 2C, 4C2, 3C, 4C3, and 6E to Unit 1 to demonstrate compliance with Operating License NPF–11 License Condition 2.C.(25)(c); and (b) for Units 1 and 2 to delete the Action Statement 3.3.7.9b. The licensee's reason for this proposed item b change is that: a) they will have the required special fire watch patrol at least once per hour in each such area with a deficient number of fire detection instruments, and b) this change is consistent with the General Electric (GE) Standard Technical Specifications (STS). However, the presence of the required special fire watch (3.3.7.9a) does not address the requirement for returning instruments to operable status or submitting a Special Report to describe the actions taken to restore the operability, the cause of the inoperability, and plans and schedule for restoring the instruments status if instruments are not operable after 14 days. In addition, the proposed change

is not consistent with the present GE STS, NUREG–0123, Revision 3 which requires return of instruments to an operable status or the Special Report previously described. We discussed the deficiencies above with representatives of the licensee by phone. They acknowledged using outdated standard Technical Specifications. Further, the licensee concluded that modifying their request to include the excluded section of the Standard Technical Specification was not necessary at this time since they intended to withdraw all fire related Technical Specifications in accordance with the voluntary aspect given in Generic Letter 86–10, "Implementation of Fire Protection Requirements". The staff, therefore, denied the deletion of Technical Specification 3.3.7.9b on the basis of the above. Therefore, the licensee must abide by the previously issued Action Statement 3.3.7.9b.

By Aug. 21, 1986, the licensee may demand a hearing with respect to the denials described above and any person whose interest may be affected by this proceeding may file a written petition for leave to intervene.

A request for a hearing or petition for leave to intervene must comply with the requirements of the Commission's Rules of Practice, 10 CFR Part 2, and must be filed with the Secretary of the Commission, Washington, DC 20555, Attention: Docketing and Service Branch, or may be delivered to the Commission's Public Document Room, 1717 H Street NW., Washington, DC, by the above date.

A copy of any petitions should also be sent to the Executive Legal Director, U.S. Nuclear Regulatory Commission, Washington, DC 20555, and to Nicholas Reynolds, Esquire, Bishop, Liberman, Cook, Purcell and Reynolds, 1200 Seventeenth Street NW., Washington, DC 20036.

For further details with respect to this action, see application for amendments dated March 4, 1986, as supplemented on March 20, 1986, which are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC 20555, and at the Public Library of Illinois Valley Community College, Rural Route No. 1, Oglesby, Illinois 61348.

Dated at Bethesda, Maryland this 16th day of July 1986.

For the Nuclear Regulatory Commission.

Elinor G. Adensam,

Director, BWR Project Directorate No. 3, Division of BWR Licensing.

[FR Doc. 86–16453 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–142]

Finding of No Significant Environmental Impact Regarding Proposed Order Authorizing Dismantling of the Reactor and Disposition of Component Parts; the University of California at Los Angeles

The Nuclear Regulatory Commission is considering issuance of an Order authorizing the University of California at Los Angeles to dismantle the UCLA Argonaut Reactor Facility on its campus in Los Angeles, California and to dispose of the reactor components in accordance with the application dated October 29, 1985, as supplemented.

The Order would authorize Phase I of the dismantling of the facility and disposal of the components in accordance with the application for decontamination and dismantling, dated October 29, 1985, as supplemented. Opportunity for hearing was afforded by the Proposed Issuance of Orders Authorizing Disposition of Component Parts and Termination of Facility License published in the **Federal Register** on September 24, 1984 at 49 FR 37484.

Finding of No Significant Environmental Impact

The Commission has determined not to prepare an Environmental Impact Statement for the proposed action. The Commission has prepared an Environmental Assessment of this action, dated July 14, 1986, and has concluded that the proposed action will not have a significant effect on the quality of human environment.

Summary of Environmental Impacts

The environmental impacts associated with the dismantling and decontamination operations are discussed in an Environmental Assessment associated with this action, dated July 14, 1986. The operations are calculated to result in a total radiation exposure for workers for the entire Phase I of the project to be less than 10 person-rem. The Environmental Assessment concluded that the operation will not result in any significant environmental impacts on air, water, land or biota in the area, and that an Environmental Impact Statement need not be prepared. These conclusions were based on the fact that all proposed operations are carefully planned and controlled, all contaminated components will be removed, packaged, and shipped offsite, and that the radioactive wastes from the facility are within the limits of 10 CFR Part 20 and are as low as is reasonable achievable (ALARA).

For further details with respect to this proposed action, see the application for dismantling, decontamination and license termination dated October 29, 1985, as supplemented, the Environmental Assessment, and the Safety Evaluation prepared by the staff. These documents and this Finding of No Significant Environmental Impact are available for public inspection at the Commission's Public Document Room, 1717 H Street NW., Washington, DC 20555. Copies may be obtained upon request addressed to the U.S. Nuclear Regulatory Commission, Washington, DC 20555, ATTENTION: Director, Division of PWR Licensing-B.

Dated at Bethesda, Maryland this 14th day of July 1986.

For the Nuclear Regulatory Commission.

Herbert N. Berkow,

Director, Standardization and Special Projects Directorate, Division of PWR Licensing-B.

[FR Doc. 86–16445 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–320; License No. DPR–73; EA 84–137]

General Public Utilities Nuclear Corporation (Three Mile Island, Unit No. 2); Prehearing Conference

Counsel for the parties are directed to appear at a prehearing conference beginning at 1:00 P.M. on Wednesday, July 30, 1986 at the Commission's Hearing Room, Fifth Floor, 4350 East-West Highway, Bethesda, Maryland.

The purpose of the prehearing conference is to consider identification of issues, need for discovery, and any other matters attendant to prehearing and hearing requirements. The prehearing conference is open to the public.

Bethesda, Maryland, July 16, 1986.

Ivan W. Smith,

Administrative Law Judge.

[FR Doc. 86–16454 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

[Docket No. 50–341]

Detroit Edison Co., Wolverine Power Supply Cooperative, Inc.; Amendment to Facility Operating License and Proposed No Significant Hazards Consideration Determination

The U.S. Nuclear Regulatory Commission (the Commission) is considering issuance of an amendment to Facility Operating License No. NPF–43, issued to Detroit Edison Company (the licensee), for operation of the

Fermi-2 facility located in Monroe County, Michigan.

The proposed amendment would change a portion of the Fermi-2 Technical Specifications to allow a higher value for the undervoltage relay setpoints at which the supply of emergency power for Division I is automatically switched from the preferred source (i.e., the 120 kilovolt grid) to the onsite power supply (i.e., the emergency diesel generators). This automatic transfer would occur only when the voltage on the safety-related buses feeding the Class 1E equipment falls below the setpoint values. The most likely occurrence of this event would be that instance when there would be a lower than nominal (i.e., degraded) voltage on the 120 kilovolt grid and the largest electrical load in the plant is connected to the safety-related buses. Table 3.3.3–2 of Specification 3/4.3.3 presently establishes the values of these setpoints at 89 percent of the nominal voltage on the buses. For example, trip setpoint for the 4160 volt buses is 3702 volts. The proposed change would raise the trip setpoints to 95 percent of the nominal voltage (i.e., 3952 volts). This change was necessitated by the discovery by the licensee in late May 1985, that it had made an error in its computation of the allowable setpoints. This error arose from an assumption by the licensee that the allowable lower limit for undervoltage at the safety-related motors was –20 percent of the nameplate voltage. However, this assumption was both undocumented and unverifiable. Additionally, the previous calculations to determine that allowable setpoints included a design margin of four percent which the licensee now concludes it cannot afford to incorporate into its calculations. Based on information provided by a vendor for specific Class 1E equipment, the licensee recalculated the required undervoltage relay setpoint for Division I to be 95 percent of nominal without the four percent margin cited above. The proposed changes to the undervoltage relay setpoints reflect the results of this recalculation.

In addition, the licensee has determined that the time delay in the Fermi-2 Technical Specifications associated with the undervoltage relay setpoint is too short to avoid unnecessary actuation of the Division I emergency diesel genertors in the event of an actuation of the emergency core cooling systems causing voltage transients in the plant. The purpose of this time delay is to prevent the undervoltage relay from tripping solely due to the worst case voltage dip at the safety-related buses caused by starting two residual heat removal pump motors and two core spray pump motors per division upon receipt of a loss-of-coolant accident signal. The licensee proposes to change this time delay from 19.7 seconds to 44.0 seconds. This revision to the Technical Specifications world be made in response to the licensee's application for amendment dated July 2, 1986.

Before issuance of the proposed license amendment, the Commission will have made findings required by the Atomic Energy Act of 1954, as amended (the Act) and the Commission's regulations.

The Commission has made a proposed determination that the amendment request involves no significant hazards consideration. Under the Commission's regulations in 10 CFR 50.92, this means that operation of the facility in accordance with the proposed amendment would not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated; or (2) create the possibility of a new or different kind of accident from any accident previously evaluated; or (3) involve a significant reduction in a margin of safety.

Accordingly, the licensee has determined, and the staff agrees, that the requested amendment does not: (1) Involve a significant increase in the probability or consequences of an accident previously evaluated because (a) the proposed undervoltage relay setpoints for Division I continue to provide assurance that, in the event of an accident, there will be a reliable source of power available for the Class 1E buses of this division to operate the required safety-related components and systems; (b) the emergency diesel generators will continue to be available in the event of any voltage instability on the 120 kilovolt grid; and (c) the lowest voltage at safety-related equipment permitted by the revised setpoints will continue to be at or above the lowest voltages at which the safety-related equipment can function satisfactorily; (2) create the possibility of a new or different kind of accident from an accident previously evaluated because the worst case (i.e., bounding) accidents, and the assumptions used in the analysis of these accidents, remain unchanged; and (3) involve a significant reduction in a margin of safety because even though there is a slightly higher probability of an automatic, unprelubricated start of the emergency diesel generators (EDG's), the probability of a reactor trip and an automatic start of the EDG's has been demonstrated to be relatively small based on the relative voltage stability of the 120 kilovolt grid at the Fermi-2 facility. Therefore, based on these considerations and the three criteria given above, the Commission has made a proposed determination that the amendment request involves no significant hazards consideration.

By letter dated July 15, 1986, the licensee provided and explanation of its exigent circumstances as required by § 50.91(a)(6)(iv) of 10 CFR Part 50. The potential undervoltage condition was first identified by the licensee on May 27, 1986. Further analysis by the licensee lead to a request for an Emergency Technical Specification change on July 11, 1986. The NRC staff denied this request on June 13, 1986, but found operation in the current mode and with current technical specifications was appropriate pending submittal of a more detailed, thorough proposal from the licensee. The staff further found that operation should be restricted to Modes 4 and 5. In developing this more thorough proposal, the licensee met with the staff on June 19, 1986, to determine what additional information would be needed to support the proposed tecnical specification change. Part of the information which the staff indicated was needed had to be obtained from an equipment vendor. This need for information from the vendor was a significant factor in the delay between the meeting with the staff on June 19, 1986, and the submittal of the exigent request. Once the information was available, the licensee prepared the amended technical specification request using its required review procedures and submitted the amended request on July 2, 1986. Assuming the fastest possible processing and publication by the staff of a normal public notice (i.e., a notice pursuant to 10 CFR 50.91(a)(2)), the latest date for a submittal by the licensee of its amended technical specification change request, without an impact on its estimated restart date of July 23, 1986, would have been June 17, 1986. This would been four days after the staff's rejection of the licensee's request for an emergency technical specification change and two days before meeting with the staff to determine the staff's requirements on this matter. Accordingly, we find that the licensee has made its best efforts to make a timely application for amendment, and the delay could not be avoided for the reasons cited above. Because a usual 30-day notice would extend significantly past the licensee's estimated readiness for restart, the

Commission has insufficient time to issue its usual 30-day notice of the proposed action for public comment.

If the proposed no significant hazards consideration determination becomes final, an opportunity for a hearing will be published in the Federal Register at a later date and any hearing request will not delay the effective date of the amendment.

If the Commission decides in its final determination that the amendment does involve a significant hazards consideration, a notice of opportunity for a prior hearing will be published in the Federal Register and, if a hearing is granted, it will be held before any amendment is issued.

The Commission is seeking public comments on this proposed determination of no significant hazards consideration. Comments on the proposed determination may be telephoned to Elinor G. Adensam, Director of BWR Project Directorate No. 3, by collect call to (301) 492–8180 or submitted in writing to the Rules and Procedures Branch Division of Rules and Records, Office of Administration, U.S. U.S. Nuclear Regulatory Commission, Washington, D.C. 20555, and should cite the publication date and page number of the Federal Register Notice. All comments received by August 6, 1986, will be considered in reaching a final determination. A copy of the application may be examined at the Commission's Public Document Room, 1717 H Street, NW., Washington, DC 20555, and at the Local Public Document Room, located at the Monroe County Library System, 3700 South Custer Road, Monroe, Michigan 48161.

Dated at Bethesda, Maryland, this 18th day of July 1986.

For the Nuclear Regulatory Commission.

Elinor G. Adensam,

Director, BWR Project Directorate No. 3 Division of BWR Licensing.

[FR Doc. 86–16595 Filed 7–21–86; 8:45 am]

BILLING CODE 7590–01–M

SECURITIES AND EXCHANGE COMMISSION

[Rel. No. IC–15202; File No. 811–3013]

Current Interest Second Fund, Inc.; Application for Investment Company Deregistration

July 15, 1986.

Notice is hereby given that Current Interest Second Fund, Inc. ("Applicant"), a Texas corporation registered under the Investment Company Act of 1940 ("Act") as an open-end, diversified, management investment company, filed an application on May 2, 1986, for an order of the Commission, pursuant to section 8(f) of the Act, declaring that Applicant has ceased to be an investment company. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act for the text of the applicable provisions thereof.

Applicant states that it registered under the Act and the Securities Act of 1933 on March 21, 1980. Applicant represents that, pursuant to a unanimous vote of its Board of Directors, an automatic exchange of all outstanding shares of Applicant was approved and occurred at the close of business on August 29, 1980, into Current Interest, Inc., another registered investment company. Applicant further represents that it does not have any securityholders, assets or liabilities, that it is not a party to any litigation or administrative proceeding, and that it does not intend to engage in any business activities other than those necessary for the winding up of its affairs. Finally, Applicant represents that it filed its Articles of Dissolution with the Secretary of the State of Texas on March 26, 1985.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than August 8, 1986, at 5:30 p.m., do so by submitting a written request setting forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commimssion, Washington, DC 20549. A copy of the request should be served personally or by mail upon Applicant at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86–16463 Filed 7–21–86; 8:45 am]

BILLING CODE 8010–01–M

[Release No. IC–15203; File No. 811–3494]

Liquid Investments Co.; Application for Investment Company Deregistration

July 15, 1986.

Notice is hereby given that Liquid Investments Co. ("Applicant"), Eleven Greenway Plaza, Suite 1919, Houston, Texas 70046, registered as an open-end, diversified management company under the Investment Company Act of 1940 ("Act"), filed an application on May 14, 1986, for an order, pursuant to section 8(f) of the Act, declaring that it has ceased to be an investment company as defined in the Act. All interested persons are referred to the application on file with the Commission for a statement of the representations contained therein, which are summarized below, and to the Act and the rules for the complete text of the relevant provisions.

Applicant states that it was incorporated under the laws of the State of Maryland and that its registration statement under the Act was filed on June 21, 1982. Applicant also states that its registration statement under the Securities Act of 1933 was declared effective on December 30, 1982, and that an initial public offering of its shares commenced immediately thereafter.

Applicant represents that it had one securityholder at the time of filing of the application. Applicant further represents that its board of directors resolved by written consent to approve the proposed Plan of Liquidation and Dissolution of Applicant, which was approved by its sole shareholder by written consent. Applicant states that a distribution will be made to the sole shareholder of the Applicant's remaining assets, if any, after payment of all costs or expenses associated with the winding-up of its business.

Applicant further states that it has no investment securities, no assets remaining other than for paying expenses and no debts, and that its not a party to any litigation or administrative proceeding. Applicant further states that within the last 18 months it has not transferred any of its assets to a separate trust, and that it is not now engaged, nor does it propose to engage, in any business activity other than that necessary to wind-up its affairs. Applicant further intends to file the papers necessary to dissolve itself under Marland State Law.

Notice is further given that any interested person wishing to request a hearing on the application may, not later than August 8, 1986, at 5:30 p.m., do so by submitting a written request setting

forth the nature of his interest, the reasons for his request, and the specific issues, if any, of fact or law that are disputed, to the Secretary, Securities and Exchange Commission, Washington, DC 20549. A copy of the request should be served personally or by mail upon Applicant(s) at the address stated above. Proof of service (by affidavit or, in the case of an attorney-at-law, by certificate) shall be filed with the request. After said date, an order disposing of the application will be issued unless the Commission orders a hearing upon request or upon its own motion.

For the Commission, by the Division of Investment Management, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-16464 Filed 7-21-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23437; File No. SR-CBOE-86-13]

Self-Regulatory Organizations; Proposed Rule Change by Chicago Board Options Exchange, Inc., Relating to Foreign Currency Options Permits and Incentives

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on May 15, 1986 the Chicago Board Options Exchange, Incorporated filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Text of the Proposed Rule Change

The Exchange deletes the text of Rule 22.13 and replaces it with the following language.

Foreign Currency Options Permits & Incentives

Rule 22.13. (a) Market Maker and Floor Broker Permits. The Exchange will issue at no cost 50 market maker and 20 floor broker permits. These nontransferable permits shall enable holders to trade currency options through August 31, 1987, during which period permit holders shall not be charged any dues or currency options transaction fees. Existing currency option permit or rights holders may convert from the original permit and the rights plans to these permits. If there are more than 50 market maker and 20 floor broker applicants, the Exchange's Membership Committee will select the most qualified.

All permit holders must accommodate if they are market makers and must execute if they are floor brokers at least 300 non-market-maker currency options contracts in every consecutive three month period, or the Exchange automatically shall recall and may reissue the permit for the remaining time. In addition, permit holders who are market makers must do 75 percent of their currency options transactions in person and must be able to carry currency options positions requiring a haircut of at least $100,000, or their permits shall be recalled. There shall be no appeal from these recall procedures because they are strictly numerical.

(b) Two Short Term Incentives. First, a permit holder can accumulate from June 1, 1986 through August 31, 1987, one credit per non-market-maker currency options contract accommodated or executed, toward the 50,000 credits necessary to convert his permit to a transferable, nonleasable currency option membership. Such a membership shall enable its owner to trade currency options as a market maker or floor broker and shall subject its owner to all of the obligations of regular members under the rules and policies of the Exchange, including the member death benefit, dues, fees, and other charges. Currency options membership owners shall have no interest in the property and assets of the Exchange and shall have no right to vote, to petition or to serve on any Exchange committee except a currency committee. Seventy additional currency options memberships and any memberships unearned by permit holders can be issued to permit holders or to regular members for at least 50,000 credits. If more credits are earned than memberships are available, the memberships will be allocated on a pro rata basis. No more than 100 such memberships can be obtained by market makers, and no more than 40 by floor brokers. Participants must notify the Exchange in writing. No other currency-only access program can be instituted without approval of 75 percent of currency options membership owners.

Second, for one year from September 1, 1986, for each market maker the Exchange will compute from trade match data in each currency options class the total number of in-person, non-market-maker contracts accommodated. Incentive payments will be allocated monthly among market makers. This allocation will be according to the ratio of each market maker's accommodation volume per currency options class to the total accommodation volume per currency options class. If a market maker handles 10 percent of the accommodation volume, he would receive 10 percent of the funds allocated to that class for that month. However, there is a $50 per contract cap, so that if a market maker trades only one contract, the maximum incentive payment is $50. The monthly total of incentive payments will not be more than $120,000 for all currency options classes. The Exchange may allocate this total any way it sees fit; allocations shall be announced in advance.

(c) Long Term Incentive. Starting September 1, 1987, market makers who are currency options or regular members may participate on a pro rata basis for a five-year period in a share of Exchange transaction fees according to the following schedule: 10,000 up to 20,000 contracts per day (cpd)—10 percent; 20,000 up to 30,000 cpd—20 percent; 30,000 up to 40,000 cpd—30 percent; 40,000 up to 50,000 cpd—40 percent and 50,000 to 100,000 cpd—50 percent. For example, if volume averaged 25,000 contracts per day in year one, the amount to be shared would be 10 percent of the tranaction fees related to the 10,000 contracts and 20 percent of the transaction fees related to the 5,000 contracts. There is no participation over 100,000 contracts per day. The election to participate must be made in writing to the Exchange before September 1, 1986. This share of Exchange transaction fees may be transferred to another market maker who must continue meeting the requirements and who is not already a participant in this long term incentive.

Participants also may receive double credits in connection with the currency options membership incentive described in the first paragraph of section (b) above. If participants elect in writing to receive double credits, they also must accommodate if they are market makers and must execute if they are floor brokers at least 300 non-market-maker currency options contracts in every consecutive three-month period; and market makers must do 75 percent of their currency options transactions in person.

Participants are required from the day following their election to share in Exchange fees, to the end of the five-year period (1) to maintain quotes and markets in one group of three currency options classes, (2) to be present continuously (nominees are interchangeable intraday) in the trading crowd during currency options trading hours on 90 percent of the business days in each year or partial year and (3) to maintain a minimum of $350,000 in currency trading capital. The Market Performance Committee shall determine whether these requirements have been met; review of a negative determinations shall be pursuant to Chapter 19 of the Exchange rules.

II Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the commission, the self-regulatory organization included statement concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and the Statutory Basis for, the Proposed Rule Change

The purpose of this proposed rule change is to encourage, by means of inexpensive access and short terms incentives, additional market makers and floor brokers to trade currency options. There will be no dues or fees charged to market makers or floor brokers by the Exchange in connection with currency options until September 1,

1987. (SR–DBOE–86–12) In addition, a long term incentive will reward those market makers who meet certain requirements and who make a commitment to trade currency options by September 1, 1986. Additional market makers and floor brokers in currency options will provide increased capacity to accommodate public customer and firm proprietary currency options orders (non-market-maker orders). With this increased capacity, the Exchange hopes to attract an increase number of non-market-maker orders and to build open interest in currency options contracts, so that this new product develops a deep and liquid market on the Exchange.

Up to 70 free currency options trading permits will be made available at the time the SEC approves this rule change. These permits will be effective through August 31, 1987. As a short term incentive, the 70 permit holders can convert their permits into currency options memberships by accommoding or executing 50,000 non-market-maker currency options contracts between June 1, 1986 and August 31, 1987. Regular members and permit holders can obtain at no cost on a pro rata basis up to 70 additional, and any unearned, currency options memberships by accommodating at least 50,000 such contracts by the same date. Through this currency membership incentive, the Exchange hopes to develop a committed currency options trading crowd.

The second short term incentive has the same goal. It amends and extends through August 31, 1987 the current six-month program of market maker incentives for accommodating non-market-maker orders, which ends August 31, 1986. (SR–CBOE–86–07) The monthly total of such credits will not be more than $120,000 for all currency options classes.

Finally, the Exchange will reward regular members and currency options permit holders who elect before September 1, 1986 to meet, and who do meet, the higher requirements listed in Part (c) of the proposed rule. This reward is a five-year pro rata sharing in Exchange currency options transaction fees and double credits for accommodating non-market-maker orders in connection with obtaining currency options memberships. By this longer term incentive, the Exchange is seeking to develop a longer term commitment to its currency options market.

This permit and incentive program is expected to have little, if any, impact on the number of market makers presently trading lower volume equity option classes because of the expertise and capital required to trade currency options. However, since new currency options traders can be current Exchange members, the Exchange will monitor which trading crowds such traders are coming from in order to insure that this program does not decrease liquidity in lower volume equity option classes.

The statutory basis for the proposed rule change is section 6(b)(5) of the Securities Exchange Act of 1934 (the Act), in that its primary objective is to increase the Exchange's capacity to accommodate non-market-maker orders.

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed program will impose a burden on competition. These permit and incentive programs are designed to foster competition by encouraging additional market makers and floor brokers to commit to trading currency options. Additional market makers will result in not only greater competition among market makers on the Exchange, but also increased competition among currency options markets.

To the extent market makers and floor brokers commit to trading in a new product like currency options, they forego the more predictable revenues in established markets for other options classes. The free access and the incentive programs are attempts to defray the costs of those market makers and floor brokers working to establish this new market.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

Comments were neither solicited nor received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the Federal Register or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such proposed rule change, or

(B) Institute procedings 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 submission should file six copies thereof with the Secretary, Securities and Exchange Commission, 450 Fifth Street, 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 at the Commission's Public Reference Section, 450 Fifth Street NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the CBOE. All submissions should refer to the file number in the caption above and should be submitted by August 12, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: July 14, 1986.

Jonathan G. Katz,

Secretary.

[FR Doc. 86–16547 Filed 7–21–86; 8:45 am]

BILLING CODE 8010–01–M

[Release No. 34–23428; File No. SR–CSE–86–4]

Self-Regulatory Organizations; Proposed Rule Change by the Cincinnati Stock Exchange Relating to an Increase in Authorized Memberships

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 ("Act"), 15 U.S.C. 78s(b)(1), notice is hereby given that on July 7, 1986, the Cincinnati Stock Exchange ("Exchange") filed with the Securities and Exchange Commission the Proposed Rule Change as described in Items I, II, and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the Proposed Rule Change from interested persons.

I. The Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Proposed Rule Change would amend Article II, section 5.2(b) of the Exchange's Code of Regulations to increase from 200 to 275 the maximum number of proprietary memberships authorized by the Exchange.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

A. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

The Exchange has issued all but three of the two hundred Certificates of Proprietary Membership currently authorized by its Code of Regulations. Interest in becoming a Proprietary Member has increased, and the Exchange expects such interest to be greater in the future. The authorization of more Certificates will enable the Exchange to satisfy this increased demand. In addition, such authorization will enhance the ability of the Exchange to raise capital.

The Proposed Rule Change is consistent with section 6(b)(5) of the Act in that it is designed to remove impediments to a free and open market. The Proposed Rule Change is also consistent with section 6(b)(2) of the Act because it creates greater opportunity for participation in the Exchange and the national market system.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the Proposed Rule Change will not impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has neither solicited nor received comments on the Proposed Rule Change.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the 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 person 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. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by August 12, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: July 14, 1986.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-16456 Filed 7-21-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 23444; File No. SR-DTC-86-06]

Self-Regulatory Organizations; Depository Trust Co.; Notice of Filing of Rule Change Instituting Book-Entry Procedures for Warrant Subscriptions

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934 (the "Act"), 15 U.S.C. 78(b)(1), notice is hereby given that on June 26, 1986, the Depository Trust Company ("DTC") filed with the Securities and Exchange Commission ("Commission") the proposed rule change described below. The Commission is publishing this notice to solicit comment. The proposal would allow DTC Participants to exercise warrant subscriptions by book-entry.

I. Description of the Proposal

The proposal provides procedures for book-entry exercise of warrant subscriptions by DTC participants.[1] Under the proposal, a DTC participant would be able to exercise qualifying warrant subscriptions on deposit in its account by authorizing DTC to surrender the warrants to the subscription agent. Upon receipt of the authorization, DTC would deduct the warrants from the participant's account, credit the underlying securities to the account and debit the participant's money settlement account and/or securities account for the cost of the subscription. The underlying securities would then be immediately available for the full range of DTC services, including book-entry delivery to other participants and book-entry pledge for collateral loans. A warrant ordinarily would qualify for application of the proposed rule change if DTC has on hand certificate inventory for the underlying securities sufficient to continue meeting expected processing requirements while awaiting delivery of additional physical certificates from the subscription agent.

[1] Currently, DTC participants must physically withdraw warrants and deliver them directly to the warrant subscription agent.

II. DTC's Rationale for the Proposal

DTC believes that the proposed rule change would provide DTC participants with an economic and orderly method for exercising warrant subscriptions. Participants would no longer have to withdraw warrants from their accounts to present physically to subscription agents for exercising. DTC also believes its participants would have much speedier access to the securities underlying the warrants and would not need to borrow securities or delay deliveries until the underlying securities were received. For those reasons, DTC believes the proposal is consistent with the Act.

II. Request for Comments

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will (A) by order approve such proposed change, or (B) institute proceedings to determine whether the proposed rule change should be disapproved.

Interested persons may submit written comments about the proposal by filing six copies of their comments with the Secretary, Securities and Exchange Commission, 450 Fifth Street, NW., Washington, DC 20549. Copies of the filing, 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 the filing also will be available for inspection and copying at DTC's principal office. All comments should refer to the file number in the caption above and should be submitted by August 12, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: July 16, 1986.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-16458 Filed 7-21-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23433; File No. SR-NYSE-86-18]

Self-Regulatory Organization; Proposed Rule Change by New York Stock Exchange, Inc., Relating to Amendments to Rule 134 of the NYSE Rules To Provide Procedures for Resolving "Questioned Trades" in Listed Bonds, Except United States Government Bonds

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 20, 1986, the New York Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II, and III below, which items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested parties.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The proposed rule change consists of an enactment to Rule 134 that provides a procedure for resolving "Questioned Trades" (uncompared trades) by members who execute orders on the floor of the Exchange in listed bonds except United States Government bonds. The proposed Rule also provides that if the "Questioned Trades" cannot be resolved (compared) by the fifth business day after the trade date, they must be closed out.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below and is set forth in sections (A), (B), and (C) below.

(A) Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

(1) Purpose

The proposed amendments to Exchange Rule 134 are to provide a formal procedure for resolving uncompared or "Questioned Trades" in listed corporate bonds, but will not apply to United States Government Bonds, since they are not compared and settled through a central clearing agency.

In its present form, Rule 134 does not distinguish between stocks and bonds, but it is recognized by the Exchange community as to only apply to listed stocks. This is because the clearance of trades in stocks has been handled by a central clearing agency since the turn of the century. A procedure for resolving uncompared trades in stocks has always been an integral part of the comparison process and is now embodied in Rule 134. In contrast, the clearance of bond transactions has been handled by a central clearing agency since only 1970. At that time, a separate procedure for resolving uncompared trades in bonds was developed but not adopted as a formal rule. In more recent years, the Exchange has implemented a number of computerized order processing systems that have greatly increased its ability to handle record-breaking volume. These systems also greatly improve the trade comparison process by accurately capturing trade details. The trade details can be inserted into the comparison process electronically, eliminating manual handling and the possibility of errors. One such system is the Automated Bonds System (ABS). About 85% of all listed bonds are traded in the ABS. Buy and sell orders are entered by members into terminals and when executions take place, the trade details are captured automatically. Thus, the uncompared rate in zero, and there are no "Questioned Trades" generated.

The remaining 15 percent of listed bonds are too active to be traded in the ABS, and are traded via the auction market process by open outcry, as are listed stocks. The details of each trade are reported by clearing firms to a central clearing agency for comparison and settlement. Because manual operations are involved, mistake can be and are made in recording and reporting trade details, resulting in uncompared trades that must be resolved.

While the informal operations procedures that have been in effect for resolving "Questioned Trades" in bonds have generally worked well, it is considered desirable to codify such procedures through the adoption of a formal rule. The proposed Rule provides for the timely resolution of uncompared trades by requiring them to be closed out if they cannot be resolved by the fifth business day after the trade date. As stated above, while present Rule 134 does not distinguish between listed stocks and listed bonds, the Rule, in its present form, is not suitable for bonds, because there are certain operational procedures that are unique to bond trading.

(2) Statutory Basis for the Proposed Rule Change

The statutory basis for the proposed rule change is section 6(b)(5) of the Securities Exchange Act of 1934 in that it will ". . . foster cooperation and coordination with persons engaged in regulating, clearing, settling, processing information with respect to, and facilitating transactions in securities . . ." and section 17(A)(a)(1) of the Act in that it will enhance "The prompt and accurate clearance and settlement of securities transactions, . . .".

(B) Self-Regulatory Organization's Statement on Burden on Competition

The Exchange does not believe that the proposed rule change will impose any burden on competition.

(C) Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants or Others

The Exchange has not solicited comments on the proposed rule change and no unsolicited comments have been received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days of such date if it finds such longer period to be appropriate and

publishes its reasons for so finding or (ii) as to which the self-regulatory organization consents, the Commission will:

(A) By order approve such rule change, or

(B) Institute proceedings to determine whether the proposed change should be disapproved.

IV. Solicitation of Comments

Interested persons are invited to submit 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. 522, will be available for inspection and copying in the Commission's Public Reference section, 450 Fifth Street, NW., Washington, DC. Copies of such filing will also be available for inspection and copying at the principal office of the above-mentioned self-regulatory organization. All submissions should refer to the file number in the caption above and should be submitted by August 12, 1986.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Dated: July 14, 1986.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-16459 Filed 7-21-86; 8:45 am]

BILLING CODE 8010-01-M

[Release No. 34-23436; File No. PHLX 86-16]

Self-Regulatory Organizations; Proposed Rule Change by the Philadelphia Stock Exchange, Inc., Relating to Narrowing of Options Spread Parameters

Pursuant to section 19(b)(1) of the Securities Exchange Act of 1934, 15 U.S.C. 78s(b)(1), notice is hereby given that on June 4, 1986 the Philadelphia Stock Exchange, Inc. filed with the Securities and Exchange Commission the proposed rule change as described in Items I, II and III below, which Items have been prepared by the self-regulatory organization. The Commission is publishing this notice to solicit comments on the proposed rule change from interested persons.

I. Self-Regulatory Organization's Statement of the Terms of Substance of the Proposed Rule Change

The Philadelphia Stock Exchange ("PHLX" or "Exchange") proposes to amend Exchange Rule 1014 (c)(ii) to narrow the bid-ask differential applicable to most foreign currency options traded on the Exchange. Italics indicate material proposed to be added; [brackets] indicate material proposed to be deleted.

Obligations and Restrictions Applicable to Specialists and Registered Option Traders

Rule 1014(a) through (c)(i)—No change.

(c)(ii) Options on Foreign Currencies—No change in the first five subparagraphs.

The Exchange may establish, however, differences other than the above for one or more series of classes of foreign currency options. The bid/ask differentials as stated above shall apply to all but the *two* longest term series of [foreign currency options] *European Currency Unit* options open for trading in each class. For *those* [these] series[,] *only*, the bid/ask differentials shall be twice those stated above.

(b) through (f) (iii)—unchanged.

II. Self-Regulatory Organization's Statement of the Purpose of, and Statutory Basis for, the Proposed Rule Change

In its filing with the Commission, the self-regulatory organization included statements concerning the purpose of and basis for the proposed rule change and discussed any comments it received on the proposed rule change. The text of these statements may be examined at the places specified in Item IV below. The self-regulatory organization has prepared summaries, set forth in sections (A), (B), and (C) below, of the most significant aspects of such statements.

A. Self-Regulatory Organization's Statements of the Purpose of, and Statutory Basis for the Proposed Rule Change

The purpose of the proposed rule change is to improve posted quotations in foreign currency options contracts by narrowing the maximum allowable bid-ask differential in the nine and twelve month term series of foreign currency option open for trading in each class except for those of the ECU.

Previously the maximum bid-ask differentials set forth in existing Rule 1014 applied to series of less than nine months. Under the proposed amendments to the rule, such provision is amended so as to make the maximum allowable bid-ask differentials applicable to all series of foreign currency options except the two longest term series open for trading in each class of ECU options. This amendment recognizes the volatility of the ECU as a special case and that the size of the ECU contract, about $60,000 is approximately twice as large as the option contracts on single currencies. Since the initiation of foreign currency option trading in ECU on PHLX on February 12, 1985 the spot price has increased in value versus the U.S. dollar 8.95 percent in ninety-nine days. This volatility and interest rate sensitivity is significant as compared with the Deutsche Mark and Swiss Franc options contracts which have the same bid/ask differentials as ECU except for the two longest term series outstanding in each class as proposed.

The proposed rule change is consistent with section 6(b)(5) of the 1934 Act in that it will facilitate transactions in securities and protect investors and the public interest.

B. Self-Regulatory Organization's Statement on Burden on Competition

The Exchange believes that the proposed rule change will not impose any burden on competition.

C. Self-Regulatory Organization's Statement on Comments on the Proposed Rule Change Received From Members, Participants, or Others

No written comments were solicited or received.

III. Date of Effectiveness of the Proposed Rule Change and Timing for Commission Action

Within 35 days of the date of publication of this notice in the **Federal Register** or within such longer period (i) as the Commission may designate up to 90 days or 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 office of the Philx. All submissions should refer to the file number in the caption above and should be submitted by August 12, 1986.

For the Commission by the Division of Market Regulation, pursuant to delegated authority.

Dated: July 14, 1986.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-1640 Filed 7-21-86; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Midwest Stock Exchange, Incorporated

July 15, 1966.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following stocks:

Allen Group Inc.
$1.75 Cumulative Convertible Exchangeable Preferred Stock (File No. 7-9050)
Atlanta /Sosnoff Capital Corporation
Common Stock, $.01 Par Value (File No. 7-9051)
Freeport-McMoran Resources Partners
Limited Partnership, Dep. Units, No Par Value (File No. 7-9052)
Lincoln National Convertible Securities Fund, Inc.
Common Stock, $.001 Par Value (File No. 7-9053)
Mai Basic Four, Inc.
Common Stock, $.25 Par Value (File No. 7-9054)
CRI Insured Mortgage Investment II, Inc.
Common Stock, $.01 Par Value (File No. 7-9055)
Newmont Gold Co.
Common Stock, $0.01 Par Value (File No. 7-9056)
Global Yield Fund, (The), Inc.
Common Stock, $.01 Par Value (File No. 7-9057)
Germany Fund, Inc., (The)
Common Stock, $.001 Par Value (File No. 7-9058)
Alberto-Culver Co.
Class A Common Stock, $.22 Par Value (File No. 7-9059)
Environmental Systems Co.
Common Stock, $.01 Par Value (File No. 7-9060)
Pall Corporation
Common Stock, $.25 Par Value (File No. 7-9061)
Alberto-Culver Company
Class B Common Stock, $.22 Par Value (File No. 7-9062)
IE Industries, Inc. (Holding Company)
Common Stock, $.25 Par Value (File No. 7-9063)
Lockheed Corporation (Delaware)
Common Stock, $1.00 Par Value (File No. 7-9064)
State Mutual Securities Trust
Common Stock, $1.00 Par Value (File No. 7-9065)
MESA Limited Partnership
Preference A Units, No Par Value (File No. 7-9066)
Southern New England Telecommunications Corporation
(Holding Company), Common Stock, $12.50 Par Value (File No. 7-9067)

These securities are listed and registered on one or more other national securities exchange and are reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before August 4, 1986, written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-16461 Filed 7-21-86; 8:45 am]

BILLING CODE 8010-01-M

Self-Regulatory Organizations; Applications for Unlisted Trading Privileges and of Opportunity for Hearing; Philadelphia Stock Exchange, Incorporated

July 15, 1986.

The above named national securities exchange has filed applications with the Securities and Exchange Commission pursuant to section 12(f)(1)(B) of the Securities Exchange Act of 1934 and Rule 12f-1 thereunder, for unlisted trading privileges in the following stock:

The Pep Boys—Manny, Moe & Jack
Common Stock, $1.00 Par Value (File No. 7-9068)

This security is listed and registered on one or more other national securities exchange and is reported in the consolidated transaction reporting system.

Interested persons are invited to submit on or before August 4, 1986 written data, views and arguments concerning the above-referenced applications. Persons desiring to make written comments should file three copies thereof with the Secretary of the Securities and Exchange Commission, Washington, DC 20549. Following this opportunity for hearing, the Commission will approve the applications if it finds, based upon all the information available to it, that the extensions of unlisted trading privileges pursuant to such applications are consistent with the maintenance of fair and orderly markets and the protection of investors.

For the Commission, by the Division of Market Regulation, pursuant to delegated authority.

Jonathan G. Katz,

Secretary.

[FR Doc. 86-10462 Filed 7-21-86; 8:45 am]

BILLING CODE 8010-01-M

DEPARTMENT OF STATE

[Public Notice CM-8-983]

Subcommittee on Safety of Life at Sea; Working Group on Safety of Navigation and Working Group on Radio Communications; Meetings

Working Group on Safety of Navigation

The Working Group on Safety of Navigation of the Subcommittee on Safety of Life at Sea (SOLAS) will hold an open meeting on August 12, 1986 at 9:30 a.m. in Room 6600 of Department of Transportation Headquarters, 400 Seventh Street, SW., Washington, DC.

The purpose of the meeting will be to prepare the U.S. position relating to the agenda items listed below to be considered at the 33rd Session of the Subcommittee on Safety of Navigation of the International Maritime Organization (IMO) to be held in London, January 12-16, 1987.

—Decisons of other IMO bodies
—Routing of ships
—Problems related to deep-draft vessels

—Matters concerning search and rescue
—Amendment of regulations V/2(a) and V/3(b) of SOLAS
—Removal of disused offshore platforms
—Infringement of safety zones around offshore structures
—Method of supplying heading information at the emergency steering position
—World-wide navigation system
—Electronic chart display systems
—Navigational aids and related equipment
—Work program

For further information contact Mr. Edward J. LaRue, Jr., U.S. Coast Guard (G–WWM), Washington, DC 20593, Telephone: (202) 426–4958 (After July 14, 1986: (202) 267–0416).

Working Group on Radio Communications

The Working Group on Radio Communications of the Subcommittee on Safety of Life at Sea will conduct an open meeting on September 25, 1986 at 9:30 a.m. in Room 9230 of the Department of Transportation, 400 Seventh Street, SW., Washington, DC.

The purpose of the meeting is to prepare position documents for the 31st Session of the Subcommittee on Radiocommunications of the International Maritime Organization to be held in London during December 1986. In particular the working group will discuss the following topics:

—Maritime Distress System
—Digital Selective Calling
—Satellite Emergency Position Indicating Radio Beacons (EPIRBs)
—Preparations for the International Telecommunication Union (ITU) World Administrative Radio Conference (WARC) for Mobile Telecommunications
—Preparations for the International Radio Consultative Committee (CCIR) Study Group 8.

Members of the public may attend both meetings up to the seating capacity of the rooms.

For further information contact Mrs. Alice Cole, U.S. Coast Guard Headquarters (G–TTS–3/64), 2100 Second Street, SW., Washington, DC 20593. Telephone: (202) 426–1231.

Dated: July 8, 1986.

Richard C. Scissors,

Chairman, Shipping Coordinating Committee.

[FR Doc. 86–16361 Filed 7–21–86; 8:45 am]

BILLING CODE 4710–07–M

DEPARTMENT OF TRANSPORTATION

Office of the Secretary

[Notice 86–6]

Senior Executive Service Performance Review Boards (PRB); Membership

AGENCY: Department of Transportation (DOT).

ACTION: Notice.

SUMMARY: DOT publishes the names of the persons selected to serve on the various Departmental Performance Review Boards (PRB) established by DOT under the Civil Service Reform Act (CSRA).

FOR FURTHER INFORMATION CONTACT: Diana L. Zeidel, Director of Personnel, and Executive Secretary, DOT Executive Resources Board, (202) 426–4088.

SUPPLEMENTARY INFORMATION: The CSRA of 1978, which created the Senior Executive Service, requires that each agency implement a performance appraisal system making senior executives accountable for organizational and individual goal accomplishment. As part of this system, CSRA requires each agency to establish one or more PRBs, the function of which is to review and evaluate the initial appraisal of a senior executive's performance by the supervisor and to make recommendations to the final rating authority relative to the performance of the senior executive.

The persons named below have been selected to serve on one or more Departmental PRBs.

Issued in Washington, DC on July 15, 1986.

Jon H. Seymour,

Assistant Secretary for Administration.

Department of Transportation Senior Executive Service Performance Review Boards

Office of the Secretary

Barclay W. Webber
Assistant General Counsel for Environmental, Civil Rights and General Law
Diane R. Liff
Assistant General Counsel for Litigation
John J. Collins, Jr.
Assistant General Counsel for Legislation
John E. Turner
Director, Office of Information Resource Management
Joyce D. Shelton
Director, Office of Financial Management
Raymond A. Karam
Deputy Assistant Secretary for Budget and Programs
Philip W. Haseltine
Deputy Assistant Secretary for Planning and Policy Analysis
Richard F. Walsh
Director, Office of Economics
Paul L. Gretch
Director, Office of Aviation Operations
John V. Coleman
Director, Office of Essential Air Service
Patrick V. Murphy
Deputy Director, Office of Essential Air Service
Gregory S. Dole
Associate General Counsel
Amparo B. Bouchey
Director, Office of Small and Disadvantaged Business Utilization
Jeffrey R. Miller
Deputy Administrator, National Highway Traffic Safety Administration
Richard E. Bowman
Associate Administrator, Office of the Associate Administrator for Maritime Aids, Maritime Administration
John M. Mason
Chief Counsel, Federal Railroad Administration

Office of the Inspector General

Paul A. Adams
Inspector General, Department of Housing and Urban Development
John C. Layton
Inspector General, Department of Energy
Raymond A. Karam
Deputy Assistant Secretary for Budget and Programs, Office of the Secretary
Jack Kroll
Assistant Inspector General for Policy, Planning and Resources, Veterans Administration
Raymond F. Randolph
Assistant Inspector General for Audit, Small Business Administration
Richard D. Morgan
Executive Director, Federal Highway Administration
Don H. Clausen
Special Assistant to the Administrator, Federal Aviation Administration
Amparo B. Bouchey
Director, Office of Small and Disadvantaged Business Utilization, Office of the Secretary
Marshall Jacks, Jr.
Associate Administrator for Safety and Operations, Federal Highway Administration
Rosalind A. Knapp
Deputy General Counsel, Office of the Secretary

Urban Mass Transportation Administration

Kenneth W. Butler
Associate Administrator for Budget and Policy
Raymond A. Karam
Deputy Assistant Secretary for Budget and Programs, Office of the Secretary
Rosalind A. Knapp
Deputy General Counsel, Office of the Secretary
Carolina L. Mederos
Director, Office of Programs and Evaluation, Office of the Secretary
Jeffrey R. Miller
Deputy Administrator, National Highway Traffic Safety Administration

United States Coast Guard

RADM Henry H. Bell
Chief, Office of Personnel
RADM William P. Kozlovsky
Chief, Office of Acquisition
Rosalind A. Knapp
Deputy General Counsel, Office of the Secretary
Leon C. Watkins
Director, Office of Civil Rights, Federal Aviation Administration
Michael M. Finkelstein
Associate Administrator for Research and Development, National Highway Traffic Safety Administration
Rex C. Leathers
Associate Administrator for Engineering and Program Development, Federal Highway Administration
JoAnn C. Collins
Coordinator of Minority Affairs, Office of the Secretary
Erika Z. Jones
Chief Counsel, National Highway Traffic Safety Administration

Research and Special Programs Administration

Louis W. Roberts
Director, Transportation Systems Center
Melissa J. Allen
Deputy Assistant Secretary for Administration, Office of the Secretary
Michael M. Finkelstein
Associate Administrator for Research and Development, National Highway Traffic Safety Administration
Robert L. Krick
Director, Office of Research and Development, Federal Railroad Administration
Robert R. Collins
Special Assistant to the Administrator, Federal Railroad Administration

Maritime Administration

Reginald A. Bourdon
Associate Administrator for Policy and International Affairs
Richard E. Bowman
Associate Administrator for Maritime Aids
Earnest Hawkins
Associate Administrator for Administration
Gary S. Misch
Associate Administrator for Marketing and Domestic Enterprise
Robert J. Patton, Jr.
Deputy Chief Counsel
George Nesterczuk
Deputy Administrator, Research and Special Programs Administration

National Highway Traffic Safety Administration

Howard Smokin
Managing Director
Barry I. Belrice
Associate Administrator for Rulemaking
George L. Parker
Associate Administrator for Enforcement
Carolina L. Mederos
Director, Office of Programs and Evaluation, Office of the Secretary
Elaine L. Chao
Deputy Administrator, Maritime Administration
David P. Sloane
Deputy Assistant Secretary for Governmental Affairs, Office of the Secretary
Donald R. Trilling
Acting Manager of Industry Policy and Planning, Office of Commercial Space Transportation, Office of the Secretary
Earnest Hawkins
Associate Administrator for Administration, Maritime Administration

Federal Highway Administration

Daniel Markoff
Associate Administrator for Administration
Rex C. Leathers
Associate Administrator for Engineering and Program Development
R. Edward Quick
Director, Office of Civil Rights
John O. Hibbs
Regional Administrator, Region 5
Anthony J. McMahon
Chief Counsel
Joseph M. O'Connor
Associate Administrator for ROW and Environment
Wesley S. Mendenhall
Regional Administrator, Region 6
Shirley J. Ybarra
Special Assistant to the Secretary, Office of the Secretary
Robert R. Collins
Special Assistant to the Administrator, Federal Railroad Administration
Raymond A. Karam
Deputy Assistant Secretary for Budget and Programs, Office of the Secretary

Federal Aviation Administration

Wayne J. Barlow
Deputy Director, Northwest Mountain Region
Paul K. Bohr
Director, Great Lakes Region
Anthony J. Broderick, Jr.
Associate Administrator for Aviation Standards
Garland P. Castleberry
Director, Southern Region
Franklin L. Cunningham
Director, Alaskan Region
Joseph M. Del Balzo
Director, Eastern Region
Robert Donahue
Associate Administrator for Airports
E. Tazewell Ellett
Chief Counsel
Frank L. Frisbie
Deputy Associate Administrator for Development and Logistics
Brooks C. Goldman
Associate Administrator for Administration
Edwin S. Harris, Jr.
Director, Central Region
Walter S. Luffsey
Associate Administrator for Air Traffic
Homer C. McClure
Director, Western-Pacific Region
C.R. Melugin, Jr.
Director, Southwest Region
James E. Richardson, Jr.
Director, Mike Monroney Aeronautical Center
Leon C. Watkins
Director, Office of Civil Rights
Charles E. Weithoner
Associate Administrator for Human Resource Management
Robert E. Whittington
Director, New England Region
Arlene Feldman
Deputy Director, Federal Aviation Administration Technical Center
JoAnn C. Collins
Coordinator of Minority Affairs, Office of the Secretary
Shirley J. Ybarra
Special Assistant to the Secretary, Office of the Secretary
Robert R. Collins
Special Assistant to the Administrator, Federal Railroad Administration
Raymond J. Rogers
Associate Administrator for Administration, Federal Railroad Administration
S. Madeline Johnson

Director, Office of Commercial Space Transportation, Office of the Secretary

Federal Railroad Administration

Louis S. Thompson
Associate Administrator for Passenger and Freight Services
Raymond J. Rogers
Associate Administrator for Administration
John M. Mason
Chief Counsel
Rosalind A. Knapp
Deputy General Counsel, Office of the Secretary
Joseph W. Walsh
Associate Administrator for Safety
Earnest Hawkins
Associate Administrator for Administration, Maritime Administration

[FR Doc. 86-16378 Filed 7-21-86; 8:45 am]
BILLING CODE 4910-62-M

Federal Aviation Administration

Scottsdale Municipal Airport; Receipt of Noise Compatibility Program and Request for Review

AGENCY: Federal Aviation Administration, DOT.

ACTION: Notice.

SUMMARY: The Federal Aviation Administration (FAA) announces formal receipt of the proposed Scottsdale Municipal Airport noise compatibility program under the provisions of Title I of the Aviation Safety and Noise Abatement Act of 1979 (Public Law 96-193) and 14 CFR Part 150. The proposed noise compatibility program was submitted to the Western Pacific Regional Director on May 28, 1986, for review and approval under Part 150 in conjunction with noise exposure maps which were found acceptable by the FAA on February 7, 1986. The noise compatibility program will be approved or disapproved by the Administrator on or before December 22, 1986.

EFFECTIVE DATE: The effective date of the start of the formal 180-day review period for the Scottsdale Municipal Airport noise compatibility program is June 26, 1986.

FOR FURTHER INFORMATION CONTACT: L. Yvonne Gibson, Airport Planner, AWP-611.5, Federal Aviation Administration, Western-Pacific Region, P.O. Box 92007, World Way Postal Center, Los Angeles, California 90009, (213) 297-1621.

SUPPLEMENTARY INFORMATION: An airport operator who has submitted noise exposure maps that are accepted by FAA as meeting the criteria published in Part 150 may also submit a noise compatibility program for FAA approval. The program must set forth the measures the airport operator has taken or proposes to take for the reduction of existing noncompatible land uses and for the prevention of the introduction of additional noncompatible uses.

Scottsdale Municipal Airport (SDL) submitted to the FAA on May 28, 1986, a proposed noise compatibility program conducted at SDL. It was requested that the FAA approve the submittal to be implemented jointly by the airport, the airport users and the surrounding communities, as a noise compatibility program under Section 104(b) of the Aviation Safety and Noise Abatement Act of 1979.

Upon the February 7, 1986, acceptance of the SDL noise exposure maps and completion of the preliminary review of the submitted materials for a noise compatibility program, the FAA has formally received the noise compatibility program for SDL. Preliminary review indicates that the submittal conforms to the requirements of Part 150 for noise compatibility programs, but that further review will be necessary prior to approval or disapproval of the program by the Administrator. The formal review period, limited by law to a maximum of 180 days, will be completed on or before December 22, 1986.

The proposed program includes recommended measures relating to flight procedures for noise control purposes which are exempt from the 180-day review procedures. The FAA's detailed evaluation of these measures will be conducted under the provisions of Part 150, Section 150.33. The primary considerations in the evaluation process are whether the proposed measures may reduce the level of aviation safety, create an undue burden on interstate or foreign commerce, and are reasonably consistent with obtaining the goal of reducing existing noncompatible land uses and preventing the introduction of additional noncompatible land uses.

Interested persons are invited to comment on the proposed program with specific reference to these factors. All comments, other than those properly addressed to local land use authorities, will be considered by the FAA to the extent practicable. Because the FAA may approve the proposed noise compatibility program in less than 180 days, no formal comment period has been established. Comments received subsequent to FAA approval or disapproval, even if received beyond the 180-day limit, will be acknowledged and considered in evaluating project applications to implement elements of the program. Copies of the proposed noise compatibility program are available for examination at the following locations:

Federal Aviation Administration, 800 Independence Avenue, SW., Room 617, Washington, DC 20591

Federal Aviation Administration, Western-Pacific Region, Airports Division, 15000 Aviation Boulevard, Room 6E25, Hawthrone, California 90261

Mr. Peter Soderquist, Airport Director, 3939 Civic Center Plaza, Scottsdale, Arizona 85251.

Questions may be directed to the individual named above under the heading, "For further information contact."

Issued in Hawthorne, California, on June 26, 1986.

Wayne Newcomb,
Acting Director, Western Pacific Region.

[FR Doc. 86-16349 Filed 7-21-86; 8:45 am]
BILLING CODE 4910-13-M

Federal Railroad Administration

[RS&I-Ap-No 1021]

Metro-North Commuter Railroad Co.; Public Hearing

The Metro-North Commuter Railroad Company has petitioned the Federal Railroad Administration (FRA) seeking an exemption from the requirements of § 236.23 of the Rules, Standards and Instructions to the extent that a single flashing yellow light be used on roadway signals to indicate, "Proceed governed by the cab signal indications." This proceeding is identified as FRA Rules, Standards and Instructions Application No. 1021.

After examining the carrier's proposal and the available facts, the FRA has determined that a public hearing is necessary before a final decision is made on the proposal.

Accordingly, a public hearing is hereby set for 10 a.m. on September 4, 1986, in Room 305C, 26 Federal Plaza, New York, New York.

The hearing will be an informal one, and will be conducted in accordance with Rule 25 of the FRA Rules of Practice (49 CFR 211.25), by a representative designated by the FRA.

The hearing will be a nonadversary proceeding and, therefore, there will be no cross-examinations of persons presenting statements. The FRA representative will make an opening

statement outlining the scope of the hearing. After all initial statements have been completed, those persons who wish to make brief rebuttal statements will be given the opportunity to do so in the same order in which they made their initial statements. Additional procedures, if necessary for the conduct of the hearing, will be announced at the hearing.

Issued in Washington, DC, on July 17, 1986.

J. W. Walsh,

Associate Administrator for Safety.

[FR Doc. 86-16376 Filed 7-21-86; 8:45 am]

BILLING CODE 4910-06-M

Petitions for Exemption or Waiver of Compliance; Union Pacific Railroad Co. et al.

In accordance with 49 CFR 211.9 and 211.41, notice is hereby given that the Federal Railroad Administration (FRA) has received requests for an exemption from or waiver of compliance with certain requirements of its safety standards. The individual petitions are described below, including the party seeking relief, the regulatory provisions involved, and the nature of the relief being requested.

Interested parties are invited to participate in these proceedings by submitting written views, data, or comments. FRA does not anticipate scheduling a public hearing in connection with these proceedings since the facts do not appear to warrant a hearing. If any interested party desires an opportunity for oral comment, they should notify FRA, in writing, before the end of the comment period and specify the basis for their request.

All communications concerning these proceedings should identify the appropriate docket number (e.g., Waiver Petition Docket Number RST-84-21) and must be submitted in triplicate to the Docket Clerk, Office of Chief Counsel, Federal Railroad Administration, Nassif Building, 400 Seventh Street SW., Washington, DC 20590. Communications received before September 5, 1986, will be considered by FRA before final action is taken. Comments received after the date will be considered as far as practicable. All written communications concerning these proceedings are available for examination during regular business hours (9 a.m.-5 p.m.) in Room 8201, Nassif Building, 400 Seventh Street SW., Washington, DC 20590.

The individual petitions seeking an exemption or waiver of compliance are as follows:

Union Pacific Railroad Company

[Waiver Petition Docket Numbers SA-86-3 and PB-86-1]

The Union Pacific Railroad Company (UP) seeks a permanent waiver of compliance with certain provisions of the Railroad Safety Appliance Standards (49 CFR Part 231) and Railroad Power Brakes and Drawbars (49 CFR Part 232) for the operation of 175 trailers and 100 rail trucks to be used in intermodal freight service. The concept is designated Railmaster and uses modified highway trailers which are detachably connected with adapter/rail trucks. The petitioner states that all equipment requiring operator attention is accessible from ground level, that the coupling/uncoupling mechanism is operated from either side of the trucks, that personnel are precluded from going between vehicles and that the handbrake is operated from the ground on the side of truck. The petitioner requests a waiver for requirements for handholds, ladders, crossover platforms, and sill steps. In addition, the Railmaster coupler system is a slack-free pin connected tongue and pocket arrangement. For structural reasons and because the integral coupler tongue must pass over the highway tractor fifth wheel, the petitioner requests a waiver of coupler height from 34½ inches to a height of 55.4 inches above top of rail empty and 53.7 inches loaded. Proponent states that the coupler system is completely non-compatible with AAR couplers and that vehicles would not intercouple with interchange vehicles. The initial operations will be between Chicago, Illinois, and Mesquite, Texas, with crew changes at Salem, Illinois, Poplar Bluff, Missouri, and Texarkana.

Alcan Aluminum Corporation

[Waiver Petition Docket Number RSGM-86-10]

The Alcan Aluminum Corporation seeks a permanent waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR Part 223) for one Trackmobile, series 4500. The Alcan Aluminum Corporation states that the trackmobile is used on company owned track at its plant in Oswego, New York, and over an adjacent industrial track owned and operated by Consolidated Rail Corporation (Conrail) a distance of about ½ mile. The Alcan Aluminum Company trackmobile operates over this route about three times a week. There are no overhead bridges and the property on both sides of the Conrail track is owned and maintained by Alcan. The Alcan Aluminum Company indicates that the expense of retrofitting its equipment to comply with the safety glazing requirements would impose an undue burden on them to protect against situations which they do not encounter.

Dakota Southern Railway Company

[Waiver Petition Docket Number RSGM-86-11]

The Dakota Southern Railway Company seeks a waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR Part 223) for one SD-7 locomotive, number 512. The Dakota Southern operates over 82 miles of track owned by the State of South Dakota. Of that total trackage, about 5½ miles is through farming communities, each of less than 2,000 population. The remaining route mileage is through rural areas. The Dakota Southern Railway Company indicates that vandalism has not been a problem in their operations. Based on this history and the area of operation, the carrier contends that safety would not be adversely affected by the granting of a waiver.

Allegheny Railroad

[Waiver Petition Docket Number RSGM-86-12]

The Allegheny Railroad seeks a waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR Part 223) for four locomotives. The Allegheny Railroad indicates that the locomotives are operated over 150 miles of trackage between Erie and Emporium, Pennsylvania, at track speeds up to 40 miles per hour. The track route is primarily rural, passing through a number of small communities, with some trackage in Erie, Pennsylvania, and the communities of Warren and Emporium, Pennsylvania. The Allegheny Railroad indicates that vandalism has not been a problem on their property and feels that safety would not be adversely affected by the granting of a waiver.

Eureka Southern Railroad Company, Inc.

[Waiver Petition Docket Numbers RSGM-86-14 and SA-86-4]

The Eureka Southern Railroad Company, Inc. seeks a waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR Part 223) for three locomotives. Eureka Southern indicates that waivers for these provisions were granted for its predecessor rail line, the Arcata and Mad River Railroad Company (AMR). Eureka Southern is purchasing the former AMR trackage and its three locomotives and desires that a waiver be granted for the Eureka Southern operation in turn. Eureka Southern

states that its operating conditions will be much the same as its predecessor; but, indicates that the locomotive will also be used in track maintenance programs, a condition which expands the scope of the original waiver granted AMR.

The Eureka Southern also seeks a waiver of compliance with certain provisions of the Railroad Safety Appliance Standards (49 CFR Part 231) for three locomotives. These locomotives are 44-ton General Electric diesel electrics built between 1945 and 1951.

These locomotives were designed with a vertical ladder like step on all four corners that is fastened to the inside of the frame with the steps flush with the outside of the locomotive frame. Eureka Southern contends, as did its predecessor, Arcata and Mad River, that it is unable to build steps on the outside of the frame because of an impaired clearance condition existing on Eureka Southern's line. In addition, there is inadequate space to modify the current side ladder arrangements due to clearances between the locomotive frame and trucks. And modification of the corner steps would adversely restrict truck swing. Eureka Southern seeks continued operation of the locomotive without modification of the units.

Fremont and Elkhorn Valley Railroad

[Waiver Petition Docket Numbers RSGM–86–13, F–86–1, and PB–86–2]

The Fremont and Elkhorn Valley Railroad (FEVR) seeks a waiver of compliance with certain provisions of the Safety Glazing Standards (49 CFR Part 223) for thirteen passenger cars, one caboose, one steam locomotive and two diesel electric locomotives. The FEVR operates over 15.8 miles of trackage in a primarily rural area between Fremont and Hooper, Nebraska. About 1.8 miles of this trackage is owned by the Chicago and North Western Transportation Company. The FEVR states that they have had no problems with vandalism and, since their area of operation is rural territory, they contend that installation of FRA certified glazing would be an unnecessary financial burden.

The FEVR also seeks a waiver of compliance with certain provisions of the Railroad Freight Car Safety Standards (49 CFR Part 215) for one caboose that is more than 50 years old, measured from the date of original construction.

The FEVR also seeks a temporary waiver of compliance with certain provisions of Railroad Power Brakes and Drawbars (49 CFR Part 232) for three passenger cars and one caboose. The FEVR seeks a 60-day extension on the COT&S requirement for the brake equipment on these four pieces of equipment. The time is required to change the air brake equipment schedule on each car to a more modern complement of brake equipment.

Issued in Washington, DC, on July 16, 1986.

J. W. Walsh,

Associate Administrator for Safety.

[FR Doc. 86–16377 Filed 7–21–86; 8:45 am]

BILLING CODE 4910–06–M

National Highway Traffic Safety Administration

Petitions for Exemptions From the Vehicle Theft Prevention Standard; Austin Rover Group Ltd.

AGENCY: National Highway Traffic Safety Administration (NHTSA), DOT.

ACTION: Grant of petition for exemption.

SUMMARY: Austin Rover Group Limited petitioned the agency for an exemption from the marking requirements of the vehicle theft prevention standard for the Austin Rover Sterling passenger car line for model year 1987, pursuant to the provisions of section 605 of the Motor Vehicle Information and Cost Savings Act. The agency has determined that the antitheft device which the petitioner intends to install on this line as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts marking requirements of the standard. Therefore, the agency grants the petition.

DATE: The exemption granted by this notice will become effective beginning with the 1987 model year.

SUPPLEMENTARY INFORMATION: On March 14, 1986, Austin Rover Group Limited (ARG) petitioned the agency for an exemption from the parts marking requirements of the vehicle theft prevention standard (49 CFR Part 541), pursuant to the requirements of 49 CFR Part 543, *Petitions for Exemption from the Vehicle Theft Prevention Standard.* On January 7, 1986 (51 FR 706), NHTSA had published an interim final rule establishing the Part 543 requirements to be followed by manufacturers in preparing and submitting petitions for exemption during model year 1987. In its petition, ARG requested an exemption for the Austin Rover Sterling passenger car line. The agency reviewed the material submitted by ARG and concluded that ARG had met the requirements for petitions in § 543.5, as of March 17, the date on which the ARG petition was received by the agency. Accordingly, the 120-day period for processing ARG's petition began on that date since, as provided by § 543.7, the processing of a petition begins when the petition is complete.

In its petition, ARG described an antitheft device which is activated by removing the key from the ignition, ensuring that the doors, hood and trunk are closed, and then locking the front doors with the key. The device can also be activated by using a remote control infra-red system. These steps activate the starter interrupt function. They also arm an audible and visual alarm which is triggered by sensors in the front and rear doors, engine hood, and trunk lid.

The agency has determined that installation of ARG's device in the Austin Rover Sterling line is likely to be as effective as this line's compliance with the parts marking requirements of Part 541 in reducing and deterring vehicle theft. This determination is based on the information submitted by ARG with its petition and on other available information. The agency believes that the device will provide the types of performance listed in § 543.6(a)(2), i.e., promote activation, attract attention to unauthorized entries, prevent defeating or circumventing of the device by unauthorized persons, and prevent operation of the vehicle by unauthorized entrants.

As required by section 605(b) of the statute and § 543.6(b), the agency also finds that ARG has provided viable reasons for its belief that the antitheft device will reduce and deter theft. This conclusion is based on the information provided by ARG on its device. The agency noted the very similar methods of encouraging activation and preventing defeat in the ARG and Nissan antitheft devices. In the preamble to the January 7, 1986 interim final rule, NHTSA discussed its Preliminary Regulatory Evaluation analysis of National Crime Information Center theft data for the Nissan 280ZX/300ZX car lines. These data show that the theft rate for the 1984 Nissan 300ZX cars, which were equipped with the standard equipment antitheft device, is approximately 50 percent less than that of the 1983 280ZX models which lacked the antitheft device. Whether ARG's standard equipment antitheft device will reduce and deter theft to the same extent is not known at this time. However, NHTSA beleves the similarity between the ARG and Nissan devices indicates that the ARG device also will be effective in accomplishing this goal. ARG stated in its petition that its antitheft device contains additional protective features, which ARG believes

will result in its device reducing and deterring theft.

In addition, ARG submitted time trial results with its petition showing the effectiveness of its antitheft device against efforts of independent experts to enter a Sterling car and drive it away. Based on these results, ARG stated its belief that its antitheft device will be effective in reducing and deterring vehicle theft by increasing the time and degree of difficulty associated with entering and moving its vehicles. While experimental, NHTSA believes these results, as well as the other information on this antitheft device provided by ARG, demonstrate potential effectiveness.

As an aside, the agency notes that the limited and apparently conflicting data on the effectiveness of the pre-standard parts marking programs make it difficult in this first year of the theft legislation's implementation to compare the effectiveness of an antitheft device with the effectiveness of compliance with the theft prevention standard. The statute clearly requires such a comparison, which the agency has made on the basis of the limited data available.

For the reasons stated above, the agency grants ARG's petition for exemption from the parts marking requirements of Part 541 for the Austin Rover Sterling car line based on substantial evidence that this standard equipment antitheft device is likely to be as effective in reducing and deterring theft of this line as compliance with Part 541 would be. This exemption will become effective beginning with the 1987 model year.

NHTSA notes that if ARG wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.7(c) provides that an exemption granted under Part 543 applies only to vehicles which are equipped with the antitheft device on which the exemption of the line including those vehicles was based. Further, § 543.9(b)(2) provides for the submission of petitions "(t)o modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption."

The agency wishes to minimize the administrative burden which § 543.9(b)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change in the components or design of an antitheft device. The significance of many such changes could be *de minimis*. Therefore, NHTSA suggests that if ARG contemplates making any changes whose effects might be so characterized, it consult with the agency before undertaking to prepare and submit a modification petition.

(15 U.S.C. 2025, delegation of authority at 49 CFR 1.50)

Issued on July 16, 1986.

Jeffrey R. Miller,

Deputy Administrator.

[FR Doc. 86-16382 Filed 7-17-86; 1:13 pm]

BILLING CODE 4910-59-M

Petitions for Exemptions From the Vehicle Theft Prevention Standard; Mitsubishi Motors Corp.

AGENCY: National Highway Traffic Safety administration (NHTSA), DOT.

ACTION: Grant of petition for exemption.

SUMMARY: Mitsubishi Motor Corporation petitioned the agency for an exemption from the marking requirements of the vehicle theft prevention standard for the Mitsubishi Starion and Galant passenger car lines for model year 1987, pursuant to the provisions of section 605 of the Motor Vehicle Information and Cost Savings Act. The agency has determined that the antitheft device which the petitioner intends to install on these lines as standard equipment is likely to be as effective in reducing and deterring motor vehicle theft as would compliance with the parts marking requirements of the standard. Therefore, the agency grants the petition.

DATE: The exemption granted by this notice will become effective beginning with the 1987 model year.

SUPPLEMENTARY INFORMATION: On April 1, 1986, Mitsubishi Motors Corporation (MMC) petitioned the agency for an exemption from the parts marking requirements of the vehicle theft prevention standard (49 CFR Part 541), pursuant to the requirements of 49 CFR Part 543. *Petitions for Exemption from the Vehicle Theft Prevention Standard.* On January 7, 1986 (51 FR 706), NHTSA had published an interim final rule establishing the Part 543 requirements to be followed by manufacturers in preparing and submitting petitions for exemption during model year 1987. In its petition, MMC requested an exemption for the Starion and Galant passenger car lines. The agency reviewed the material submitted by MMC and concluded that MMC had met the requirements for petitions in Part 543.5, as of April 8, the date on which the MMC petition was received by the agency. Accordingly, the 120-day period for processing MMC's petition began on that date since, as provided by § 543.7, the processing of a petition begins when the petition is complete.

In its petition, MMC described an antitheft device which is activated by removing the key from the ignition, ensuring that the doors, hood and trunk are closed, and then locking the driver's door by depressing the door lock knob. These steps activate the starter interrupt function. They also arm an audible and visual alarm which is triggered by sensor in the doors, engine hood, and trunk/hatch.

The agency has determined that installation of MMC's device in the Starion and Galant lines is likely to be as effective as these lines' compliance with the parts marking requirements of Part 541 in reducing and deterring vehicle theft. This determination is based on the information. The agency believes that the device will provide the types of performance listed in § 543.6(a)(2), i.e., promote activation, attract attention to unathorized entries, prevent defeating or circumventing of the device by unauthorized persons, prevent operation of the vehicle by unauthorized entrants, and ensure the reliability and durability of the device.

As required by section 605(b) of the statute and § 543.6(b), the agency also finds that MMC has provided adequate reasons for its belief that the antitheft device will reduce and deter theft. This conclusion is based on the information provided by MMC on its device. The agency noted the very similar methods of encouraging activation and preventing defeat in the MMC and Nissan antitheft devices. In the preamble to the January 7, 1986 interim final rule, NHTSA discussed its Preliminary Regulatory Evaluation analysis of National Crime Information Center theft data for the Nissan 280ZX/300ZX car lines. These data show that the theft rate for the 1984 Nissan 300ZX cars, which were equipped with the standard equipment antitheft device, is approximately 50 percent less than that of the 1983 280ZX models which lacked the antitheft device. Whether MMC's standard equipment antitheft device will reduce and deter theft to the same extent is not known at this time. However, NHTSA believes the similarity between the MMC and Nissan devices indicates that the MCC device also will be effective in accomplishing this goal.

As an aside, the agency notes that the limited and apparently conflicting data on the effectiveness of the pre-standard parts marking programs make it difficult in this first year of the theft legislation's implementation to compare the effectiveness of an antitheft device with

the effectiveness of compliance with the theft prevention standard. The statute clearly requires such a comparison, which the agency has made on the basis of the limited data available.

For the reasons stated above, the agency grants MMC's petition for exemption from the parts marking requirements of Part 541 for the Starion and Galant car lines based on substantial evidence that this standard equipment antitheft device is likely to be as effective in reducing and deterring theft of this line as compliance with Part 541 would be. This exemption will become effective beginning with the 1987 model year.

NHTSA notes that if MMC wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.7(c) provides that an exemption granted under Part 543 applies only to vehicles which are equipped with the antitheft device on which the exemption of the line including those vehicles was based. Further, § 543.9(b)(2) provides for the submission of petitions "(t)o modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption."

The agency wishes to minimize the administrative burden which § 543.9(b)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change in the components or design of an antitheft device. The significance of many such changes could be *de minimis*. Therefore, NHTSA suggests that if MMC contemplates making any changes whose effects might be so characterized, it consult with the agency before undertaking to prepare and submit a modification petition.

(15 U.S.C. 2025, delegation of authority at 49 CFR 1.50)

Issued on July 16, 1986.

Jeffrey R. Miller,

Deputy Administrator.

[FR Doc. 86-16381 Filed 7-17-86; 1:13 pm]

BILLING CODE 4910-59-M

Petitions for Exemption From the Vehicle Theft Prevention Standard; Toyota Motors Ltd.

AGENCY: National Highway Traffic Administration (NHTSA), DOT.

ACTION: Grant of petition for exemption.

SUMMARY: Toyota Motors Limited petitioned the agency for an exemption from the marking requirements of the vehicle theft prevention standard for the Toyota Supra and Cressida passenger car lines, pursuant to the provisions of section 605 of the Motor Vehicle Information and Cost Savings Act. The agency has determined that the antitheft devices which the petitioner intends to install on these lines as standard equipment are likely to be as effective in deterring and reducing vehicle thefts as would compliance with the parts marking requirements of the standard. Therefore, the agency grants the petition.

DATE: The exemption granted by this notice will become effective beginning with the 1987 model year.

SUPPLEMENTARY INFORMATION: On January 7, 1986 (51 FR 706), NHTSA published an interim final rule establishing requirements to be followed by manufacturers in preparing and submitting petitions for exemption from the parts marking requirements of the vehicle theft prevention standard during model year 1987 (49 CFR Part 543). These requirements were issued pursuant to section 605 of the Motor Vehicle Information and Cost Savings Act. On March 11, 1986, Toyota Motor Corporation (Toyota) petitioned the agency for an exemption from these parts marking requirements of the vehicle theft prevention standard for the Toyota Supra and Cressida passenger car lines. The agency reviewed the material submitted by Toyota with its letter and concluded that Toyota had met the requirements for petitions in Part 543.5, as of March 17, the date on which the Toyota letter was received by the agency. Accordingly, the 120-day period for processing Toyota's petition began on that date since, as provided by § 543.7, the processing of a petition begins when the petition is complete.

In its petition, Toyota described an antitheft device that is activated by removing the key from the ignition, ensuring that the hood and truck/hatch are closed and that the passenger door is locked, and then locking the driver's door without using the key. These steps engage the starter interruption relay. They also arm an audible and visual alarm which is triggered by sensors in the doors, truck/hatch, and engine hood. Toyota pointed out several mechanical differences between the device installed as standard equipment in the Supra and Cressida lines. The agency has concluded that these minor engineering differences should not affect the overall effectiveness of this antitheft device.

The agency has determined that installations of Toyota's device in the Supra and Cressida car lines is likely to be as effective as these lines's compliance with the parts marking requirements of Part 541 in reducing and deterring vehicle theft. This determination is based on the information submitted by Toyota with its petition and on other available information. The agency believes that the device will provide the types of performance listed in § 543.6(a)(2), i.e., promote activation, attract attention to unauthorized entries, prevent defeating or circumventing of the device by unauthorized persons, prevent operation of the vehicle by authorized entrants, and ensure the reliability and durability of the device.

As required by section 605(b) of the statute and §543.6(b), Toyota has provided viable reasons for its belief that these antitheft devices will reduce and deter theft. The agency's conclusion on this matter is based on the information provided by Toyota with its petition and on other available information. Toyota submitted time trial results with its petition showing the differences in the length of time Toyota examiners needed to defeat the antitheft devices offered in Model Year 1985 compared with the time needed to defeat its improved Model Year 1987 standard equipment antitheft device. Based on these results, Toyota stated its belief that the improved antitheft device will be effective in reducing and deterring vehicle theft by increasing the time and degree of difficulty associated with entering and moving its vehicles. While experimental, NHTSA believes these results, as well as the other information on this antitheft device provided by Toyota, demonstrate potential effectiveness.

In addition, the agency notes that very similar methods of encouraging activation and preventing defeat in the Toyota and Nissan antitheft devices. In the preamble to the January 7, 1986 interim final rule, NHTSA discussed its Preliminary Regulatory Evaluation analysis of National Crime Information Center theft data for the Nissan 280ZX/300ZX car lines. These data show that the theft rate for the 1984 Nissan 300ZX cars, which were equipped with the standard equipment antitheft device, is approximately 50 percent less than that of the 1983 280ZX models which lacked the antitheft device. Whether Toyota's standard equipment antitheft device will reduce and deter theft to the same extent is not known at this time. However, NHTSA believes the similarity between the Toyota and Nissan devices indicates that the Toyota device also will be effective in accomplishing this goal.

As an aside, the agency notes that the limited and apparently conflicting data on the effectiveness of the pre-standard parts marking programs make it difficult in this first year of the theft legislation's implementation to compare the effectiveness of an antitheft device with the effectiveness of compliance with the theft prevention standard. The statute clearly requires such a comparison, which the agency has made on the basis of the limitation data available.

For the reasons stated above, the agency grants Toyota's petition for exemption from the parts marking requirements of Part 541 for the Supra and Cressida car lines based on substantial evidence that this standard equipment antitheft device is likely to be as effective in reducing and deterring theft of this line as compliance with Part 541 would be. This exemption will become effective beginning with the 1987 model year.

NHTSA notes that if Toyota wishes in the future to modify the device on which this exemption is based, the company may have to submit a petition to modify the exemption. Section 543.7(c) provides that an exemption granted under Part 543 applies only to vehicles which are equipped with the antitheft device on which the exemption of the line including those vehicles was based. Further, §543.9(b)(2) provides for the submission of petitions "(t)o modify an exemption to permit the use of an antitheft device similar to but differing from the one specified in that exemption."

The agency wishes to minimize the administrative burden which §543.9(b)(2) could place on exempted vehicle manufacturers and itself. The agency did not intend in drafting Part 543 to require the submission of a modification petition for every change in the components or design of an antitheft device. The significance of many such changes could be *de minimis*. Therefore, NHTSA suggests that if Toyota contemplates making any changes whose effects might be so characterized, it consult with the agency before undertaking to prepare and submit a modification petition.

(15 U.S.C. 2025, delegation of authority at 49 CFR 1.50)

Issued on July 16, 1986.

Jeffrey R. Miller,

Deputy Administrator.

[FR Doc. 86-16380 Filed 7-17-86; 12:02 pm]

BILLING CODE 4910-59-M

[Docket No. IP-86-08; Notice 1]

Wayne Corp.; Receipt of Petition for Determination of Inconsequential Noncompliance

Wayne Corporation, of Richmond, Indiana, has petitioned to be exempted from the notification and remedy requirements of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1381 *et seq.*) for apparent noncompliance with 49 CFR 571.217, Motor Vehicle Safety Standard No. 217, *Bus Window Retention and Release*, on the basis that it is inconsequential as it relates to motor vehicle safety.

This Notice of receipt of a petition is published under section 157 of the National Traffic and Motor Vehicle Safety Act (15 U.S.C. 1417) and does not represent any agency decision or other exercise of judgment concerning the merits of the petition.

Paragraph S5.2.2 of Federal Motor Vehicle Safety Standard No. 217, *Bus Window Retention and Release*, specifies the requirements for a manually opened window in a bus with a gross vehicle weight rating of 10,000 pounds or less. These windows must provide "an opening large enough to admit unobstructed passage, keeping a major axis horizontal at all time, of an ellipsoid generated by rotating about its minor axis an ellipse having a major axis of 20 inches and a minor axis of 13 inches."

Wayne indicates that not more than 10 non-school buses that it manufactured between September 1, 1978 and March 14, 1986, do not meet the ellipsoid opening requirements of paragraph S5.2.2. These buses consist of three models: Chaperones, Transettes and Busettes.

Wayne stated that the windows received from its supplier have variances in window opening from 19.875 inches to 20.25 inches. Since the standard requires a major axis to be 20 inches the Wayne windows that are 19.875 inches fall below the requirement. Because of this noncompliance, the major axis must be rotated approximately 6 degrees from the horizontal in order to meet the test requirements of Standard No. 217.

Wayne contends that the overall window opening in their non-complying vehicles is large enough to provide space for a larger than average person to egress, although the passenger may need to rotate his hips or shoulders 6 degrees.

The presence of numerous emergency exits is believed by Wayne to improve emergency egress. The worst case situation in Wayne buses, maximum number of passengers with minimum number of exits, provides better than one exit for every three passengers.

Interested persons are invited to submit written data, views and arguments on the petition of Wayne Corporation described above. Comments should refer to the docket number and be submitted to: Docket Section, National Highway Traffic Safety Administration, Room 5109, 400 Seventh Street SW., Washington, DC 20590. It is requested but not required that five copies be submitted.

All comments received before the close of business on the closing date indicated below will be considered. The application and supporting materials, and all comments received after the closing date will also be filed and will be considered to the extent possible. When the petition is granted or denied, the Notice will be published in the **Federal Register** pursuant to the authority indicated below.

Comment closing date: August 21, 1986.

(Sec. 102, Pub. L. 93-492, 88 Stat. 1470 (15 U.S.C. 1417); delegations of authority at 49 CFR 1.50 and 49 CFR 501.8)

Issued on July 16, 1986.

Barry Felrice,

Associate Administrator for Rulemaking.

[FR Doc. 86-16379 Filed 7-21-86; 8:45 am]

BILLING CODE 4910-59-M

DEPARTMENT OF THE TREASURY

Office of the Secretary

[Department Circular—Public Debt Series—No. 24-86]

Treasury Notes of July 31, 1988, Series AC-1988

Washington, July 17, 1986.

1. Invitation for Tendors

1.1. The Secretary of the Treasury, under the authority of Chapter 31 of Title 31, United States Code, invites tenders for approximately $10,000,000,000 of United States securities, designated Treasury Notes of July 31, 1988, Series AC-1988 (CUSIP No. 912827 TW 2), hereafter referred to as Notes. The Notes will be sold at auction, with bidding on the basis of yield. Payment will be required at the price equivalent of the yield of each accepted bid. The interest rate on the Notes and the price equivalent of each accepted bid will be determined in the manner described below. Additional amounts of the Notes may be issued to Government accounts and Federal Reserve Banks for

their own account in exchange for maturing Treasury securities.

2. Description of Securities

2.1. The Notes will be dated July 31, 1986, and will accrue interest from that date, payable on a semiannual basis on January 31, 1987, and each subsequent 6 months on July 31 and January 31 through the date that the principal becomes payable. They will mature July 31, 1988, and will not be subject to call for redemption prior to maturity. In the event any payment date is a Saturday, Sunday, or other non-business day, the amount due be payable (without additional interest) on the next-succeeding business day.

2.2. The Notes are subject to all taxes imposed under the Internal Revenue Code of 1954. The Notes are exempt from all taxation now or hereafter imposed on the obligation or interest thereof by any State, any possession of the United States, or any local taxing authority, except as provided in 31 U.S.C. 3124.

2.3. The Notes will be acceptable to secure deposits of Federal public monies. They will not be acceptable in payment of Federal taxes.

2.4. Notes in registered definitive form will be issued in denominations of $5,000, $10,000, $100,000, and $1,000,000. Notes in book-entry form will be issued in multiples of those amounts. Notes will not be issued in bearer form.

2.5. Denominational exchanges of registered definitive Notes, exchanges of Notes between registered definitive and book-entry forms, and transfers will be permitted.

2.6. The Department of the Treasury's general regulations governing United States securities apply to the Notes offered in this circular. These general regulations include those currently in effect, as well as those that may be issued at a later date.

3. Sale Procedures

3.1. Tenders will be received at Federal Reserve Banks and Branches and at the Bureau of the Public Debt, Washington, DC 20239, prior to 1:00 p.m., Eastern Daylight Saving time, Wednesday, July 23, 1986. Noncompetitive tenders as defined below will be considered timely if postmarked no later than Tuesday, July 22, 1986, and received no later than Thursday, July 31, 1986.

3.2. The par amount of Notes bid for must be stated on each tender. The minimum bid is $5,000, and larger bids must be in multiples of that amount. Competitive tenders must also show the yield desired, expressed in terms of an annual yield with two decimals, e.g., 7.10%. Fractions may not be used. Noncompetitive tenders must show the term "noncompetitive" on the tender form in lieu of a specified yield.

3.3. A single bidder, as defined in Treasury's single bidder guidelines, shall not submit noncompetitive tenders totaling more than $1,000,000. A noncompetitive bidder may not have entered into an agreement, nor make an agreement to purchase or sell or otherwise dispose of any noncompetitive awards of this issue prior to the deadline for receipt of tenders.

3.4. Commercial banks, which for this purpose are defined as banks accepting demand deposits, and primary dealers, which for this purpose are defined as dealers who make primary markets in Government securities and are on the list of reporting dealers publishes by the Federal Reserve Bank of New York, may submit tenders for accounts of customers if the names of the customers and the amount for each customer are furnished. Others are permitted to submit tenders only for their own account.

3.5. Tenders for their own account will be received without deposit from commercial banks and other banking institutions; primary dealers, as defined above; Federally-insured savings and loan associations; States, and their political subdivisions or instrumentalities; public pension and retirement and other public funds; international organizations in which the United States holds membership; foreign central banks and foreign states; Federal Reserve Banks; and Government accounts. Tenders from all others must be accompanied by full payment for the amount of Notes applied for, or by a guarantee from a commercial bank or a primary dealer of 5 percent of the par amount applied for.

3.6. Immediately after the deadline for receipt of tenders, tenders will be opened, followed by a public announcement of the amount and yield range of accepted bids. Subject to the reservations expressed in section 4, noncompetitive tenders will be accepted in full, and then competitive tenders will be accepted, starting with those at the lowest yields, through successively higher yields to the extent required to attain the amount offered. Tenders at the highest accepted yield will be prorated if necessary. After the determination is made as to which tenders are accepted, an interest rate will be established, at a ⅛ of one percent increment, which results in an equivalent average accepted price close to 100.000 and a lowest accepted price above the original issue discount limit of 99.500. That stated rate of interest will be paid on all of the Notes. Based on such interest rate, the price on each competitive tender allotted will be determined and each successful competitive bidder will be required to pay the price equivalent to the yield bid. Those submitting noncompetitive tenders will pay the price equivalent to the weighted average yield of accepted competitive tenders. Price calculations will be carried to three decimal places on the basis of price per hundred, e.g., 99.923, and the determinations of the Secretary of the Treasury shall be final. If the amount of noncompetitive tenders received would absorb all or most of the offering, competitive tenders will be accepted in an amount sufficient to provide a fair determination of the yield. Tenders received from Government accounts and Federal Reserve Banks will be accepted at the price equivalent to the weighted average yield of accepted competitive tenders.

3.7. Competitive bidders will be advised of the acceptance of their bids. Those submitting noncompetitive tenders will be notified only if the tender is not accepted in full, or when the price at the average yield is over par.

4. Reservations

4.1. The Secretary of the Treasury expressly reserves the right to accept or reject any or all tenders in whole or in part, to allot more or less than the amount of Notes specified in section 1, and to make different percentage allotments to various classes of applicants when the Secretary considers it in the public interest. The Secretary's action under this Section is final.

5. Payment and Delivery

5.1. Settlement for the Notes allotted must be made at the Federal Reserve Bank or Branch or at the Bureau of the Public Debt, wherever the tender was submitted. Settlement on Notes allotted to institutional investors and to others whose tenders are accompanied by a guarantee as provided in section 3.5. must be made or completed on or before Thursday, July 31, 1986. Payment in full must accompany tenders submitted by all other investors. Payment must be in cash; in other funds immediately available to the Treasury; in Treasury bills, notes, or bonds maturing on or before the settlement date but which are not overdue as defined in the general regulations governing United States securities; or by check drawn to the order of the institution to which the tender was submitted, which must be received from institutional investors no

later than Tuesday, July 29, 1986. In addition, Treasury Tax and Loan Note Option Depositaries may make payment for the Notes allotted for their own accounts and for accounts of customers by credit to their Treasury Tax and Loan Note Accounts on or before Thursday, July 31, 1986. When payment has been submitted with the tender and the purchase price of the Notes allotted is over par, settlement for the premium must be completed timely, as specified above. When payment has been submitted with the tender and the purchase price is under par, the discount will be remitted to the bidder.

5.2. In every case where full payment has not been completed on time, an amount of up to 5 percent of the par amount of Notes allotted shall, at the discretion of the Secretary of the Treasury, be forfeited to the United States.

5.3. Registered definitive securities tendered in payment for the Notes allotted are not required to be assigned if the new Notes are to be registered in the same names and forms as appear in the registrations or assignments of the securities surrendered. When the new Notes are to be registered in names and forms different from those in the inscriptions or assignments of the securities presented, the assignment should be to "The Secretary of the Treasury for (Notes offered by this circular) in the name of (name and taxpayer identifying number)". Specific instructions for the issuance and delivery of the new Notes, signed by the owner or authorized representative, must accompany the securities presented. Securities tendered in payment must be delivered at the expense and risk of the holder.

5.4 Registered definitive Notes will not be issued if the appropriate identifying number as required on tax returns and other documents submitted to the Internal Revenue Service (e.g., an individual's social security number or an employer identification number) is not furnished. Delivery of the Notes in registered definitive form will be made after the requested form of registration has been validated, the registered interest account has been established, and the Notes have been inscribed.

6. General Provisions

6.1. As fiscal agents of the United States, Federal Reserve Banks are authorized, as directed by the Secretary of the Treasury, to receive tenders, to make allotments, to issue such notices as may be necessary, to receive payment for, to issue and deliver the Notes on full-paid allotments, and to maintain, service, and make payment on the Notes.

6.2. The Secretary of the Treasury may at any time supplement or amend provisions of this circular if such supplements or amendments do not adversely affect existing rights of holders of the Notes. Public announcement of such changes will be promptly provided.

6.3. The Notes issued under this circular shall be obligations of the United States, and therefore, the faith of the United States Government is pledged to pay, in legal tender, principal and interest on the Notes.

Gerald Murphy,

Fiscal Assistant Secretary.

[FR Doc. 86-16608 Filed 7-21-86; 10:22 am]

BILLING CODE 4810-40-M

Sunshine Act Meetings

Federal Register
Vol. 51, No. 140
Tuesday, July 22, 1986

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).

CONTENTS

1

EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

DATE AND TIME: Monday, July 28, 1986, 2:00 PM (Eastern Time)

PLACE: Clarence M. Mitchell, Jr., Conference Room No. 200–C on the 2nd Floor of the Columbia Plaza Office Building, 2401 "E" Street, NW., Washington, DC 20507.

STATUS: Closed to the public.

MATTERS TO BE CONSIDERED:

CLOSED

Litigation Authorization; General Counsel Recommendations.

NOTE.—Any matter not discussed or concluded may be carried over to a later meeting. (In addition to publishing notices on EEOC Commission meetings in the Federal Register, the Commission also provides a recorded announcement a full week in advance on future Commission sessions. Please telephone (202) 634–6748 at all times for information on these meetings.) **CONTACT PERSON FOR MORE INFORMATION:** Cynthia C. Matthews, Executive Officer at (202) 634–6748.

Dated: July 17, 1986.

Cynthia C. Matthews,

Executive Officer, Executive Secretariat.

This Notice Issued July 17, 1986.

[FR Doc. 86–16544 Filed 7–18–86; 2:49 pm]

BILLING CODE 6750-06-M

2

FEDERAL DEPOSIT INSURANCE CORPORATION

Pursuant to the provisions of the "Government in the Sunshine Act" (5 U.S.C. 552b), notice is hereby given that at 5:07 p.m. on Monday, July 14, 1986, the Board of Directors of the Federal Deposit Insurance Corporation met in closed session to discuss matters pertaining to the anticipated closing of First National Bank and Trust Company of Oklahoma City, Oklahoma City, Oklahoma.

In calling the meeting, the Board determined, on motion of Chairman L. William Seidman, seconded by Director C.C. Hope, Jr. (Appointive), concurred in by Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was recessed at 5:25 p.m. and at 7:19 p.m. that same day the meeting was reconvened, at which time the Board of Directors: (1) Received bids for the purchase of certain assets of and the assumption of the liability to pay deposits made in The First National Bank and Trust Company of Oklahoma City, Oklahoma City, Oklahoma, which was closed by the Comptroller of the Currency on Monday, July 14, 1986; (2) accepted the bid for the transaction submitted by First Interstate Bank of Oklahoma City, National Association, Oklahoma City, Oklahoma, a newly-chartered national bank subsidiary of First Interstate Bancorp, Los Angeles, California; and (3) provided such financial assistance, pursuant to section 13(c)(2) of the Federal Deposit Insurance Act (12 U.S.C. 1823(c)(2)), as was necessary to facilitate the purchase and assumption transaction.

In reconvening the meeting, the Board determined, on motion of Chairman L. William Seidman, seconded by Director C.C. Hope, Jr. (Appointive), concurred in by Director Robert L. Clarke (Comptroller of the Currency), that Corporation business required its consideration of the matters on less than seven days' notice to the public; that no earlier notice of the meeting was practicable; that the public interest did not require consideration of the matters in a meeting open to public observation; and that the matters could be considered in a closed meeting pursuant to subsections (c)(8), (c)(9)(A)(ii), and (c)(9)(B) of the "Government in the Sunshine Act" (5 U.S.C. 552b(c)(8), (c)(9)(A)(ii), and (c)(9)(B)).

The meeting was held in Room 6020 of the FDIC Building located at 550 17th Street, NW., Washington, DC.

Dated: July 17, 1986.

Federal Deposit Insurance Corporation.

Hoyle L. Robinson,

Executive Secretary.

[FR Doc. 86–16512 Filed 7–18–86; 8:45 am]

BILLING CODE 6714-01-M

3

SECURITIES AND EXCHANGE COMMISSION

Notice is hereby given pursuant to the provisions of the Government in the Sunshine Act, Pub. L. 94–409, that the Securities and Exchange Commission will hold the following meeting during the week of July 21, 1986:

A closed meeting will be held on Tuesday, July 22, 1986, at 2:30 p.m. An open meeting will be held on Thursday, July 24, 1986, at 2:30 p.m., in Room IC30.

The Commissioners, Counsel to the Commissioners, the Secretary of the Commission, and recording secretaries will attend the closed meeting. Certain staff members who are responsible for the calendared matters may also be present.

The General Counsel of the Commission, or his designee, has certified that, in his opinion, one or more of the exemptions set forth in 5 U.S.C. 552b(c)(4), (8), (9)(A) and (10) and 17 CFR 200.402(a) (4), (8), (9)(i) and (10), permit consideration of the scheduled matters at a closed meeting.

Commissioner Fleischman, as duty officer, voted to consider the items listed for the closed meeting in closed session.

The subject matter of the closed meeting scheduled for Tuesday, July 22, 1986, at 2:30 p.m., will be:

Litigation matter.
Institution of injunctive actions.
Formal orders of investigation.
Regulatory matter regarding financial institution.
Settlement of injunctive action.
Chapter 11 proceeding.

The subject matter of the open meeting scheduled for Thursday, July 24, 1986, at 2:30 p.m., will be:

Consideration of whether to authorize publication of a release requesting comments on the rulemaking petition submitted by the Securities Industry Association. The petition, as supplemented, proposes that the

Commission adopt a rule that would allow a written confirmation of a securities purchase to be sent to investors in registered public offerings prior to the time a prospectus that meets the statutory requirements of the Securities Act of 1933 is delivered to them. Currently, a confirmation must be preceded or accompanied by a statutory prospectus. For further information, please contact Brent H. Taylor at (202) 272-2434.

At times changes in Comomission priorities require alterations in the schelduling of meeting items. For further information and to ascertain what, if any, matters have been added, deleted or postponed, please contact: David C. Mahaffey at (202) 272-2091.

Jonathan G. Katz,

Secretary.

July 17, 1986.

[FR Doc. 86-16526 Filed 7-18-86; 1:36 pm]

BILLING CODE 8010-01-M

4

TENNESSEE VALLEY AUTHORITY

"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT: 51 FR 136 (July 16, 1986).

PREVIOUSLY ANNOUNCED TIME AND DATE OF MEETING: 10:15 a.m. (EDT), Friday, July 18, 1986.

PREVIOUSLY ANNOUNCED PLACE OF MEETING: TVA West Tower Auditorium, 400 West Summit Hill Drive, Knoxville, Tennesse.

STATUS: Open.

ADDITIONAL MATTERS: The following items are added to the previously announced agenda:

Old Business Items

2. Consulting contract with Charles F. Reeves of Belmont, Massachusetts, for consulting services in the broad areas of civil, mechanical and construction engineering with emphasis on structures, piping, and equipment response to earthquake ground motion, requested by Office of Nuclear Power.

New Business Items

D. Personnel Items

12. Supplement to personal services Contract No. TV-65375A with Bechtel North American Power Corporation, Gaithersburg, Maryland, for performance of general engineering, design, and architectural services, requested by Office of Nuclear Power.

13. Supplement to personal services Contract No. TV-66821A with General Electric Company, Atlanta, Georgia, for engineering and related support to the Browns Ferry Nuclear Plant's Site Services Group, requested by Office of Nuclear Power.

F. Unclassified

4. Contract No. TV-70230A for outside services between Columbia State Community College and TVA under the Job Training Partnership Act to provide operating engineer training to unemployed residents of Hickman, Perry, Lewis, Maury, Marshall, Giles, Lawrence, and Wayne Counties, Tennesse.

CONTACT PERSON FOR MORE INFORMATION: Graven H. Crowell, Jr., Director of Information, or a member of his staff can respond to requests for information about this meeting. Call 615-632-8000, Knoxville, Tennessee. Information is also available at TVA's Washington, Office, 202-245-0101.

SUPPLEMENTARY INFORMATION:

TVA Board Action

The TVA Board of Directors has found, the public interest not requiring otherwise, that TVA business requires the subject matter of this meeting be changed to include the additional items shown above and that no earlier announcement of this change was possible.

The members of the TVA Board voted to approve the above findings and their approvals are recorded below.

Dated: July 17, 1986.

Approved.

C.H. Dean, Jr.,

Director and Chairman.

John B. Waters,

Director.

[FR Doc. 86-16481 Filed 7-18-86; 9:09 am]

BILLING CODE 8120-01-M

federal register

Tuesday
July 22, 1986

Part II

Department of Health and Human Services

Food and Drug Administration

21 CFR Parts 16 and 814

Premarket Approval of Medical Devices; Final Rule

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 16 and 814

[Docket No. 79N-0009]

Premarket Approval of Medical Devices

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to prescribe the contents of a premarket approval application (PMA) for a medical device and the criteria FDA will employ in approving, disapproving, or withdrawing approval of a PMA. This action is based on a proposed rule that was published in the Federal Register of December 12, 1980.

The purpose of the final rule is to establish clear and uniform procedures for FDA's review of PMA's for class III (premarket approval) medical devices.

EFFECTIVE DATE: November 19, 1986. For additional information concerning this effective date, see paragraph 101 in the preamble of this document.

FOR FURTHER INFORMATION CONTACT: Charles H. Kyper, Center for Devices and Radiological Health (HFZ-402), Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7445.

SUPPLEMENTARY INFORMATION:

Introduction

The purpose of the final rule is to establish clear and uniform procedures for FDA's review of PMA's for class III (premarket approval) medical devices. FDA's objective in reviewing such applications is twofold. First, FDA's objective is to facilitate the approval of PMA's for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval. Second, FDA's objective is to ensure the disapproval of PMA's for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval. Thus, consumers will benefit from both the "health promotion" and "health protection" aspects of the final rule. A new section (§ 814.2) has been added to the final rule to codify its purpose.

Highlights of the final rule may be summarized as follows:

1. The rule sets out clear and uniform procedures to increase the efficiency of the agency's review of PMA's. The rule contains sufficient flexibility to accommodate the wide variety of medical devices that are subject to its provisions.

2. The rule requires applicants to submit a comprehensive scientific summary of the safety and effectiveness data upon which the applicant bases its request for approval. These summaries should promote greater efficiency in reviewing applications as well as aid the agency in complying with the statutory requirement to make available to the public a detailed summary of information respecting the safety and effectiveness of a device and which was the basis for FDA's action on an application.

3. The rule requires updating of safety and effectiveness data while applications are being reviewed within the agency. This requirement will ensure that product approvals are based upon the most up-to-date information available to the applicant and to FDA.

4. The rule sets forth criteria for acceptance of foreign studies consistent with the need to supply valid scientific evidence as well as the need to comply with standards protecting human subjects. The standards used are based on those that the agency applies to biomedical research involving human exposure to any test article subject to FDA regulations.

5. The rule requires a PMA supplement for any change in a device affecting the safety or effectiveness of the device for which there is an approved PMA.

6. The rule implements those sections of the statute permitting FDA to impose postapproval restrictions on the sale, distribution, or use of a device that are necessary to ensure the continued safety and effectiveness of the device.

7. The rule cross references the final rule (49 FR 36326; September 14, 1984) requiring medical device reporting (MDR) (21 CFR Part 803) to ensure that holders of approved PMA's are aware that MDR applies to devices covered by approved applications. Any reporting requirement in an order approving a PMA which is in addition to the reporting requirements under MDR remains in effect.

In preparing this final rule, the agency has taken into account changes made in the final regulations governing approval of new drugs and antibiotics for human use (50 FR 7452; February 22, 1985). Although the statutory scheme differs somewhat for drugs and devices, the agency has attempted to provide consistency in its standards for premarket review of these products, where appropriate. This effort is most evident, for example, in the provisions of each rule concerning the use of summaries, update reports, and foreign data. FDA believes that the resulting consistency will benefit consumers by providing the same high level of protection across product lines, and also will aid applicants that seek approval for marketing of human drugs and medical devices.

Background

In the Federal Register of December 12, 1980 (45 FR 81769), FDA published proposed regulations to establish procedures for the premarket approval of medical devices. Interested persons were given until February 10, 1981, to comment. The comment period was extended to April 13, 1981, by a notice published in the Federal Register of February 17, 1981 (46 FR 12502). FDA received 43 comments on the proposal. Comments were received from device manufacturers, industry trade associations, public interest groups, health professional associations, the Office of Management and Budget (OMB), and members of the public. The following is a summary of the significant comments received on the proposal, including comments received from OMB (see paragraph 101 of this preamble) and the agency's response to them.

Subpart A—General

Scope (§ 814.1)

1. Several comments disagreed with the agency's statement in the preamble to the proposed regulations (45 FR 81769) that it may initiate the recall of any preamendments class III device for which the agency has issued a final regulation under section 515(b) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360e(b)) requiring the filing of an application for approval of a PMA or a notice of completion of a product development protocol (PDP), and for which a PMA or notice of completion of a PDP has not been filed within the requisite period of time. Some comments argued that a manufacturer that fails to file a PMA or a notice of completion of a PDP within the period set forth in section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)) and specified in the preamble to the proposal should not be required to recall a device from the marketplace. Other comments noted the difficulty in recalling devices implanted in patients.

A preamendments class III device is one that was commercially distributed before May 28, 1976, the date the Medical Device Amendments of 1976 (Pub. L. 94-295) (the amendments) were signed into law, or one that, although not distributed until on or after that date, is substantially equivalent to such

a device. A preamendments class III device is required to have an approved PMA or a declared completed PDP after FDA so requires under a regulation promulgated under section 515(b) of the act.

Section 515(b)(2)(A) of the act provides that a proceeding for the promulgation of a regulation to require premarket approval of a preamendments device shall be initiated by publication of a notice of proposed rulemaking. Section 501(f)(1)(A) of the act provides that within 90 days after the date of promulgation of a regulation under section 515(b) of the act or 30 months after classification, whichever is later, any person who commercially distributes the device shall file a PMA or a notice of completion of a PDP or cease commercial distribution of the device. As an alternative to filing a PMA or notice of completion of a PDP, however, the person may obtain an investigational device exemption (IDE) under section 520(g) of the act (21 U.S.C. 360j(g)) and Part 812 of FDA's regulations (21 CFR Part 812) and continue limited distribution of the device to obtain safety and effectiveness data from clinical trials. If the person fails to file a PMA or a notice of completion of a PDP for the device and an IDE is not in effect for the device, the device is adulterated under section 501(f)(1)(A) of the act. Interstate commerce in an adulterated device is prohibited under section 301 of the act (21 U.S.C. 331) and an adulterated device is subject to seizure and condemnation under section 304 of the act (21 U.S.C. 334). Violations of section 301 also may be enjoined under section 302 of the act (21 U.S.C. 332) and persons responsible for such violations are subject to prosecution under section 303 of the act (21 U.S.C. 333). In lieu of seizure or injunction actions, FDA may request that the manufacturer or distributor of an adulterated device recall the device. FDA's policy concerning recalls is at 21 CFR Part 7.

FDA will not request recall, or recommend seizure, of an implanted device under circumstances that would necessitate explanation of the device to effect recall or seizure unless such action is necessary to protect the health of the patient. If an implanted device is adulterated under section 501(f)(1)(A) of the act because of the manufacturer's failure to submit a PMA and explanation of the device is not necessary to protect the health of the patient, FDA will require only that commercial distribution of the device cease. FDA also may invoke its authorities under section 518 of the act (21 U.S.C. 360h) to require notification, repair, replacement, or refund when a device in commercial distribution presents an unreasonable risk of substantial harm to the public health.

2. On its own initiative, FDA has added a new § 814.1(d) to the final rule to explain the effect of these regulations on PMA's that were approved before the effective date of these regulations. The new paragraph provides that all requirements imposed on such PMA's as a condition to approval for marketing which are inconsistent with these regulations are revoked. FDA intends that holders of PMA's approved before the effective date of these regulations shall comply with the requirements of these regulations. For example, holders of approved PMA's who were required to comply with the requirements for new drugs, set forth in 21 CFR Part 310, are no longer required to comply with Part 310 but rather are to comply with the requirements of these regulations. All previously imposed conditions to approval that are consistent with these regulations remain in effect. Holders of approved PMA's who are uncertain whether a specific requirement imposed as a condition to approval remains in effect may request clarification from FDA's Center for Devices and Radiological Health (CDRH).

3. Comments suggested that FDA delete the word "immediately" that precedes the phrase "before May 28, 1976" in proposed § 814.1(c)(1). These comments stated that a preamendments device is any device marketed at any time before May 28, 1976, even if it was not in commercial distribution on May 27, 1976.

FDA agrees with these comments and has deleted the word "immediately" from § 814.1(c)(1) of the final regulations. FDA also has revised final § 814.1(c)(1) to make clear that Part 814 does not apply to a device that is substantially equivalent to a device first marketed on, or after May 28, 1976, which has been reclassified into class I or class II.

Definitions (§ 814.3)

4. One comment said that FDA should limit the definition of "amended PMA" in proposed § 814.3(b) to substantive changes in pending PMA's.

The term "amended PMA" has been changed in § 814.3(f) of the final rule to "PMA amendment." In paragraph 45 of this preamble, FDA discusses distinctions in treatment between major and minor PMA amendments. No such distinction is necessary in the definition. For clarity, FDA also has added to the final rule definitions of "PMA" and "PMA supplement."

5. Four comments stated that the definition of "statement of material fact" in proposed § 814.3(g) (final § 814.3(i)) should be deleted from the regulations and that FDA should use a case-by-case approach to determine whether statements of fact are material. Another comment said that the proposed definition is not workable, especially the provision that "silence" or "omission" of information may constitute a statement of material fact. Another comment suggested that FDA qualify the proposed definition by adding the phrase "if the statement or omission is intended by the person making it to be misleading or to have a probative effect."

FDA disagrees with these comments and has retained the definition as proposed. Under section 515(e)(1)(C) of the act, an untrue statement of material fact is a ground for withdrawing approval of a PMA. FDA has concluded that a false statement of material fact also should be a ground for FDA to refuse to accept a PMA for filing or to deny approval of a PMA. Therefore, it is appropriate to define the term "statement of material fact." The definition used in these regulations is adopted from the definition of relevant evidence in Rule 401 of the Federal Rules of Evidence. A silence or omission can be as misleading as a false statement. For example, the failure to include in an application data tending to show that the device in question is not safe or effective could mislead FDA in making a determination whether the application should be approved. Moreover, a false statement, whether it is made intentionally to mislead, may mislead FDA as to the safety or effectiveness of a device. FDA concludes, therefore, that it is inappropriate to limit the definition to cases in which the person making the statement intends it to be misleading or to have a probative effect.

6. Several comments stated that the 2-year retention period for inactive master files, described in the preamble to the proposed rule (see 45 FR 81774), was too short a time. Some comments suggested that FDA retain any master file indefinitely. Other comments suggested extending the retention period to 4 or 5 years. Comments also suggested that FDA notify the person who submitted the master file before destroying it.

FDA agrees, in part, with the comments. If a master file, as defined in final § 814.3(d), is referenced within 5 years after its submission, FDA will retain the master file indefinitely. FDA will not destroy any master file submitted to the agency. Rather, it will return to the person who submitted it

any master file not referenced within 5 years after submission (see § 814.20(c)).

Confidentiality (§ 814.9)

7. FDA has reorganized § 814.9 to identify more clearly the data, information, and other materials that comprise a PMA file and the events that cause such data, information, and other materials to become publicly available.

8. Because of the concern expressed in many comments regarding the disclosability of the existence of and the information contained in a PMA, this paragraph discusses the general rules governing disclosure of information in, or pertaining to, a PMA. Specific issues raised by the comments concerning disclosure are discussed in paragraphs 9 to 16 of this preamble.

The Freedom of Information Act (FOIA) (5 U.S.C. 552) and sections 301(j) and 520 (c) and (h) of the act (21 U.S.C. 331(j), 360j (c) and (h)) govern disclosure of the existence of a pending PMA and information contained in a PMA file. FOIA generally governs access by the public to government records. Under FOIA, the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1)–(9)). One such provision, 5 U.S.C. 552(b)(4), exempts records that are "trade secrets and commercial or financial information obtained from a person and privileged or confidential" from the requirement of mandatory public disclosure. In addition, section 301(j) of the act prohibits using to one's own advantage or revealing to anyone other than the Secretary or officers or employees of the Department of Health and Human Services or to a court when relevant in a judicial proceeding under the act any information acquired under, *inter alia*, section 515 concerning any method or process which, as a trade secret, is entitled to protection. Section 520(c) of the act prohibits FDA from disclosing any information exempted from public disclosure under 5 U.S.C. 552(b)(4) or using any such information as the basis for reclassifying a class III device or as the basis for the establishment of a performance standard for a device that has been reclassified from class III into class II. Part 20 of FDA's regulations (21 CFR Part 20) sets forth FDA's general regulations concerning public availability of FDA records.

Under section 520(h)(1) of the act, FDA is required to make publicly available a detailed summary of the safety and effectiveness information that is contained in a PMA and that is the basis of an order approving, denying approval of, or withdrawing approval of, a PMA. In addition, under section 520(h)(2) of the act, FDA is required to make publicly available a detailed summary of the safety and effectiveness information upon which basis an advisory committee makes a recommendation to FDA as a result of a petition for administrative review of FDA's decision to approve, deny approval, or withdraw approval of a PMA. Section 520(h)(3) of the act provides that any information made publicly available under section 520(h)(1) or (2) may not be used to establish the safety or effectiveness of a device by any person other than the person who submitted the information.

In the preamble to the proposal, FDA stated that it was considering revising its policy on disclosing the existence of PMA submissions (see 45 FR 81770). In the **Federal Register** of March 28, 1978 (43 FR 12869, as corrected at 43 FR 13857; March 31, 1978), FDA proposed to disclose to the public, upon request, the fact of the existence of a submitted but not yet approved PMA. FDA's proposal regarding the disclosability of the existence of PMA's was part of a general proposal governing the confidentiality of applications for investigation and approval of new drugs, new animal drugs, and medical devices, as well as premarket notifications for medical devices. As a result, in the December 12, 1980 proposal, FDA reserved § 814.9(a) until such time as the March 28, 1978 proposal was made final. Because FDA has not yet acted on the March 28, 1978 proposal, FDA is no longer reserving § 814.9(a). If the agency issues any final rule based on the March 28, 1978 proposal, the agency will amend these regulations to make any necessary conforming changes. Regarding disclosability of the existence of a PMA, § 814.9(b) of this final rule provides that the existence of a PMA file may not be disclosed by FDA before an approval order is issued to the applicant unless it previously has been publicly disclosed or acknowledged.

9. Many comments stated that, under section 520(h)(1) of the act, FDA is required to issue an order approving, denying approval, or withdrawing approval of a PMA before releasing any data contained in the PMA.

FDA disagrees. As discussed in paragraph 8 of this preamble, section 520(h) of the act requires that a detailed summary of the safety and effectiveness information that is contained in a PMA and that is the basis of the agency's decision be made publicly available upon the approval, denial, or withdrawal of approval of a PMA. This section does not govern the public availability of information requested under FOIA. See *Public Citizen Health Research Group* v. *FDA*, No. 82–1745 (D.C. Cir., April 15, 1983).

10. Several comments stated that FDA should not disclose the existence or contents of a PMA if the PMA is abandoned or determined to be unnecessary or the device that is the subject of the PMA is reclassified. These comments suggested that FDA notify the applicant 30 days before disclosure of the existence or contents of a PMA to enable the applicant to contest the decision to disclose.

At the time that a PMA is abandoned or the device that is the subject of the PMA is reclassified or determined to be substantially equivalent to a class I or class II device, the confidential commercial nature or trade secret status of information about or contained in the PMA becomes problematic. The regulations provide that the existence of a PMA, and safety and effectiveness data and other information in a PMA not previously disclosed and that are not trade secret or confidential commercial or financial information, may be disclosed when a PMA is abandoned or the device is reclassified or determined to be substantially equivalent to a class I or class II device. As noted in paragraph 8 of this preamble, however, certain information contained in the PMA may retain its exempt status. For example, if a PMA is abandoned, any information in the PMA that continues to be trade secret or confidential commercial or financial information does not become publicly available.

FDA's practice regarding notification to an applicant prior to disclosure is set forth in § 20.45, which provides that in situations in which the confidentiality of data or information is uncertain and there is a request for public disclosure, FDA will consult with the person who has submitted the data or information before determining whether such data or information are available for public disclosure.

FDA has revised proposed § 814.9(c)(1) (final § 814.9(g)(1)) governing abandonment of a PMA and has added § 814.9(g)(6) governing voluntary withdrawal of a PMA. The proposal stated that a PMA would be considered to be abandoned if the applicant failed to communicate with FDA within 90 days after the date on which FDA notified the applicant that the PMA appeared to have been abandoned. Under final § 814.9(g)(1), FDA will consider a PMA abandoned if: (1) (a) The applicant fails to respond to a request for additional information, other

than a request for an amendment, within 180 days after the date FDA issues the request or (b) other circumstances indicate that further work is not being undertaken with respect to the PMA, and (2) the applicant fails to communicate with FDA within 7 days after the date on which FDA notifies the applicant that the PMA appears to have been abandoned. A response to such a notification which states that the PMA has not been abandoned must show that the application remains viable. If the applicant fails to respond in writing to a request for an amendment within 180 days, but the PMA is not considered to be abandoned under the criteria set out above, it is considered to be voluntarily withdrawn under § 814.44(g). An applicant may also voluntarily withdraw a PMA by so requesting in writing to FDA. If a PMA is considered to be voluntarily withdrawn or abandoned, all safety and effectiveness data and other information not previously disclosed to the public are available for public disclosure provided the data and information do not constitute trade secret or confidential commercial or financial material under § 20.61. In addition, if a PMA is considered to be abandoned (1) manufacturing methods or processes, (2) production, sales, distribution, and similar data and (3) quantitative or semiquantitative formulas will be available for public disclosure provided the data and information do not constitute trade secret or confidential commercial or financial material.

FOIA requires, in 5 U.S.C. 552(a)(3), that agencies make specified information "promptly available to any person." Under FOIA and § 20.41, FDA is required to respond to any FOIA request within 10 days after filing of the request. The 90-day response period in the proposal has been revised to provide a 7-day response period because the proposal would have extended the time for FDA to respond to requests under FOIA for release of information in an abandoned PMA beyond the 10-day response time specified in FOIA and § 20.41.

11. One comment suggested that proposed § 814.9(b) (final § 814.9(d)) be revised to make clear that public disclosure or acknowledgement refers only to disclosure or acknowledgement by the applicant. The comment suggested adding the words "by the applicant" at the end of the first sentence of the proposed provision.

FDA disagrees with the comment. FDA is not required to determine from what source the information became public. The agency's intent, as reflected by the proposed regulation, is that any lawful public disclosure triggers acknowledgement by the agency of the existence of a PMA or any information in the PMA that has been so disclosed. This intent is consistent with the agency's policies and procedures under the general FOIA regulations at Part 20.

12. Two comments stated that the phrase "if disclosure is relevant to public consideration of a specific pending issue" in proposed § 814.9(b) (final § 814.9(d)) respecting disclosure of a summary of portions of the safety and effectiveness data before an approval order issues is vague and should be clarified or deleted.

FDA believes the phrase is as clear as the subject matter permits and does not require change. The summaries referred to in final § 814.9(d) may be released, e.g., for consideration of an issue at an open session of an FDA advisory committee meeting.

13. One comment on proposed § 814.9(b) (final § 814.9(d)) stated that the existence of a pending PMA should be disclosed immediately after its submission because such preapproval disclosure is relevant to public consideration of a specific pending issue, e.g., the subject PMA.

FDA disagrees with the comment. Disclosure of the existence of a PMA that had not been publicly disclosed or acknowledged immediately after the submission of the PMA would have limited benefit to the general public at such time and could adversely affect the commercial interests of the applicant. If FDA issues a final order approving, denying, or withdrawing approval of the PMA, or if it is abandoned or determined to be unnecessary, or the device that is the subject of the PMA is reclassified, the existence of the pending PMA and all the nonexempt data or other information submitted with the PMA or incorporated in it by reference become available for public disclosure. FDA believes that the information necessary to enable public review of the propriety of FDA's decision to approve or disapprove a PMA is available in a timely manner under the current regulatory scheme.

14. One comment stated that the final rule should make clear that FDA will release detailed summaries of safety and effectiveness data for a device immediately upon issuance of an approval order for the device and that judicial or administrative review will not delay release of the summaries.

FDA agrees with the comment. Judicial or administrative review will not delay the public availability of the summary. The summary will be publicly available upon issuance of an approval order.

15. One comment stated that information in the summary of safety and effectiveness data issued by FDA should include a factual statement of the basis for the determination as to whether any foreign research submitted as part of the PMA accords with applicable standards for the protection of human subjects.

FDA will disclose such information in the summary of safety and effectiveness data if the information is relevant to a specific pending issue, e.g., the validity of particular foreign studies. Safety and effectiveness data from foreign studies will be discussed in the summary in the same manner as data from domestic studies. FDA does not believe that any change in the final rule is necessary.

16. FDA has deleted from the final rule proposed § 814.9(d) concerning the confidentiality of data in master files. Final § 814.9(a) provides that when a master file is incorporated into a PMA, the confidentiality of the information in the master file will be governed by the same rules as the other information in the PMA.

Research Conducted Outside the United States (§ 814.15)

17. Many comments addressed the proposed standards governing the protection of human research subjects who participate in foreign clinical studies. Several comments stated that FDA should accept foreign studies if they are performed in accordance with the applicable foreign law. Some comments suggested that informed consent should be required. One comment suggested that FDA require adherence to foreign law, U.S. law, and World Medical Assembly standards and, in addition, that the final rule should specifically refer to the Declaration of Helsinki. Finally, several comments stated that studies begun after, as well as before, the effective date of the regulations should be subject to the general standard that "the rights, safety, or welfare of human subjects have not been violated."

FDA believes that, for research conducted outside the United States to be accepted as part of a PMA, it is necessary that the research be conducted in accordance with ethical principles acceptable to the world community. The Declaration of Helsinki, first adopted by the 18th World Medical Assembly in Helsinki, Finland, in 1964, describes these ethical principles, including informed consent. In addition, some foreign countries have adopted ethical standards that are different from

those contained in the Declaration of Helsinki but that offer greater protection to the individual. Accordingly, FDA has concluded that data from foreign research submitted as part of a PMA should be required to meet the ethical principles contained in either the Declaration of Helsinki or the laws of the country where the research is conducted, whichever affords greater protection to the individual. This standard has been applied to clinical investigations involving human subjects with drugs since 1975 (40 FR 16056; April 9, 1975). Extending the standard to the device research area should promote greater consistency in the standards of international research.

The standard described above will apply to all foreign research submitted in support of a PMA begun after the effective date of these regulations and final § 814.15(b) so provides. For foreign research begun before the effective date, FDA retains the standard described in proposed § 814.15(c) that "the rights, safety, or welfare of human subjects have not been violated" and final § 814.15(c) so provides. FDA believes that this general standard provides sufficient guidance for evaluating foreign research for adherence to ethical principles. FDA will, however, use the Declaration of Helsinki and foreign laws as reference points in determining whether foreign research begun before the effective date meets this general standard.

18. Many comments on proposed § 814.15(b) stated that compliance with all the provisions of Part 812 (IDE regulations) is not appropriate for all foreign studies and should not be required, e.g., some foreign countries may not have institutional review boards.

FDA agrees in part with the comments and has revised final § 814.15(a). The threshold question for determining the applicability of Part 812 to foreign studies is whether the foreign research is conducted under the auspices of a U.S. IDE. Foreign studies conducted under an approved IDE are required to comply with Part 812 (although, under § 812.10, the sponsor of an IDE may request a waiver of certain requirements, such as the IRB requirement). For foreign studies not conducted under an approved IDE, FDA will accept them in support of a PMA if the studies are well conducted, well designed, and performed by qualified investigators, and if the data are scientifically valid. In assessing the validity of the data, FDA will use the principles set forth at 21 CFR 860.7. As noted in paragraph 17 of this preamble, if begun after the effective date of these regulations, such studies are required to comply with the Declaration of Helsinki or the laws of the country in which the study is conducted, whichever affords greater protection to human subjects. If begun before the effective date of these regulations, such studies will be acceptable if the rights, safety, or welfare of human subjects were not violated.

19. One comment on proposed § 814.15(c) stated that FDA should delete the phrase "and that the rights, safety, or welfare of human subjects have not been violated." The comment said that this requirement imposes a subjective philosophical concept on the peoples of other countries.

FDA has substituted the word "and" for the word "or" in final § 814.15(c) to make clear that FDA will not accept studies in which the rights, or the safety, or the welfare of human subjects have been violated. FDA is not imposing a subjective philosophical concept on the peoples of other nations but rather is attempting to ensure that research submitted as part of a PMA is conducted in accordance with ethical principles generally acceptable to the world community.

20. FDA is adding a new section to clarify its policy on approval of PMA's based solely on foreign clinical data (final § 814.15(d)). FDA's policy is to consider all clinical studies on their merits regardless of the country in which they were conducted. Under this section, a PMA containing clinical data only from studies conducted outside the United States that otherwise meet the criteria in Part 814 for approval may be approved if: (a) The foreign data are applicable to the U.S. population and U.S. medical practice; (b) the studies have been performed by clinical investigators of recognized competence; and (c) the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the study through an on-site inspection or other appropriate means. This provision is modeled on a similar provision in FDA's final regulations governing approval for marketing of new drugs and antibiotic drugs for human use (50 FR 7505).

The purpose of this provision is to facilitate the availability of devices as soon as scientifically valid data are available that show the devices to be safe and effective. The agency is committed to relying on those studies, foreign or domestic, that meet contemporary scientific standards for demonstrating the safety and effectiveness of medical devices. The criteria set forth in § 814.15(d) (1), (2), and (3) are designed to ensure that foreign data supporting a PMA are as credible and reliable, and as applicable to the U.S. population, as are domestic data.

21. One comment on proposed § 814.15 stated that, because section 515(c)(1)(A) of the act requires the "submission" of all data bearing on safety or effectiveness of the device, all such data, including all foreign data, must be "accepted" by FDA as support for PMA approval to the extent they are scientifically valid. The comment said that FDA's foreign data policy unfairly discriminates against data from studies conducted in foreign countries.

FDA disagrees with the contention that the agency's policy on use of foreign data is inconsistent with the statute or discriminates unfairly against such data. Section 515(c)(1)(A) of the act requires the applicant to submit full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations bearing on the safety or effectiveness of the device for which premarket approval is sought. Data from a study, however, prove the safety and effectiveness of a device only if the study is conducted in accordance with accepted standards for clinical studies. If such standards are not followed, FDA considers the data from the study to be questionable. Further, as stated in final § 814.15(d), FDA may approve an application based solely on foreign data if the data are applicable to the U.S. population and U.S. medical practice; the studies are performed by investigators of recognized competence; and the data may be considered valid without the need for an on-site inspection or if such an inspection is necessary, FDA can validate the data by such inspection or other appropriate means. By this policy, FDA does not discriminate against foreign studies because the same standard is used to evaluate domestic studies.

Although data from an improperly conducted clinical study may not be used to prove the safety and effectiveness of a device, such data may indicate to FDA that a valid study may prove that a device is unsafe or ineffective. An applicant that conducts or has knowledge of a clinical study that provides data indicating that the device may be unsafe or ineffective may not withhold such data because the applicant determines that the clinical study may not be valid. Although the applicant may include in the PMA a statement that a study does not contain

valid scientific data, FDA will make the final determination as to the validity of the data. Failure to submit data from such a study constitutes a ground for refusing to accept for filing a PMA or for denying or withdrawing approval of a PMA because the application fails to contain full reports of all investigations in accordance with section 515(c)(1)(A) of the act.

22. Three comments on proposed § 814.15 stated that advisory panel concurrence is necessary for FDA to conduct on-site inspections of foreign studies and to require additional information from foreign manufacturers regarding adherence to ethical principles.

FDA disagrees. Section 515(c)(1)(A)–(F) of the act lists the required contents of a PMA, including, for example, full reports on safety and effectiveness studies, a full description of manufacturing methods, and specimens of proposed labeling. Section 515(c)(1)(G) of the act provides that "other information relevant to the subject matter of the application" may be required to be submitted only with the concurrence of the appropriate FDA advisory committee. An FDA on-site inspection, foreign or domestic, is not part of the contents of a PMA and, therefore, falls outside the scope of section 515(c)(1)(A)–(F) of the act. On-site inspections are not requirements that applicants submit information to the agency. Rather, such inspections are part of the agency's review procedure, and are similar to the reviews of data that are conducted by FDA in its own offices. Section 515(c)(1)(G), therefore, does not apply. An explanation of adherence to ethical principles is part of the "full reports" requirement of section 515(c)(1)(A), not "other information" as the term is used in section 515(c)(1)(G) and, therefore, does not require advisory panel concurrence.

23. One comment stated that on-site inspections impinge unnecessarily on the legitimate needs of foreign producers for confidentiality of trade secrets. The comment also said that only the authorities of the producing country can verify whether research conforms to the requirements of their own legislation.

FDA disagrees with the comment. Section 301(j) of the act prohibits the disclosure of all foreign or domestic trade secrets obtained by FDA. The act and implementing regulations governing the public availability of government records offer adequate protection for trade secret information. Further, the purpose of a foreign on-site inspection is to validate the authenticity and accuracy of the data and other information submitted in the PMA, not to verify conformity with foreign laws. The on-site inspection, which involves comparing the data in the PMA with the medical records maintained by the on-site clinical investigators, falls squarely within FDA's capabilities.

Abbreviated Applications

24. One comment suggested that FDA should add to the regulations a provision providing for abbreviated applications for preamendments devices and other special situations. The comment said that the provision for authorization of omissions from a PMA is insufficient.

FDA believes that it is neither necessary nor appropriate to include such a provision in the regulations at this time. FDA will provide guidance on the kind and amount of data or information necessary to support PMA approval. Such guidance may be given, for example, through guidelines or at the time that proposed regulations calling for premarket approval applications for preamendments devices issue under section 515(b) of the act. This will enable FDA to tailor the requirements to particular devices and particular circumstances. See, e.g., the proposed rule to require the filing of a PMA or a notice of completion of a PDP for the implanted cerebellar stimulator, especially Section IV (48 FR 40273; September 6, 1983).

Subpart B—Premarket Approval Application (PMA)

Application (§ 814.20)

25. Several comments said that the requirement in proposed § 814.20(b)(2) that the applicant submit 12 copies of the PMA is excessive. One comment suggested that only a detailed summary of the PMA should be provided to each member of the FDA advisory committee to which FDA refers a PMA for review and that a full copy of the PMA could be provided if the committee member requests one.

FDA has reviewed its needs in light of the comments and has determined that six copies will generally be sufficient for an efficient review of a PMA. Therefore, FDA has revised the regulation accordingly.

26. Two comments stated that it was unclear in proposed § 814.20(b)(2) whether confidential information is to be included in only one copy or included in all copies but identified as confidential in only one copy. These comments and others suggested that confidential information should be included in only one copy. Other comments suggested that such information should be identified in all copies because FDA may lose the one copy.

FDA agrees that proposed § 814.20(b)(2) was unclear in this regard, and, therefore, has revised the final rule to make clear that any trade secret or confidential commercial or financial information in the PMA is to be contained in all copies and identified in at least one copy. Such information needs to be included in all copies to allow for efficient concurrent review. Trade secret or confidential commercial or financial information may be identified in all copies, if the applicant desires.

27. FDA, on its own initiative, has substantially revised § 814.20(b)(3), which requires that the PMA include a summary, to describe in greater detail the required contents of the summary to assist applicants in preparing a PMA. The information required by revised § 814.20(b)(3) is substantially the same as that included in the "Guideline for the Arrangement and Content of a Premarket Approval Application," which was issued in November 1980 and referenced in the preamble to the proposed rule. FDA notes that the summary required to be provided by an applicant under § 814.20(b)(3) may be used by the agency to prepare the detailed summary of information respecting the safety and effectiveness of the device for public disclosure when the application is approved (§ 814.44(d)), or when approval of the application is denied (§ 814.45(d)), or when approval of the application is withdrawn (§ 814.46(e)).

One significant addition to the final rule is the requirement that the summary include information on the marketing history of the device. This information is necessary to evaluate the safety and effectiveness of any preamendments device that has a long marketing history, and of any postamendments device that has a significant foreign marketing history.

28. Several comments suggested deleting the word "complete" in proposed § 814.20(b)(4) before the word "description" because it is overly broad. These comments suggested that, especially in the case of electronic equipment, FDA require that an application contain only sufficient information to describe adequately how the device functions.

FDA disagrees with this suggestion and is retaining the word "complete" in the introductory phrase of final § 814.20(b)(4). The word "complete" is necessary and appropriate in this context and not overly broad. FDA does not expect an excessively detailed

description but only enough detail to describe the aspects of the device that could affect safety or effectiveness.

29. Two comments suggested that the photographs, drawings, or other pictorial depictions required under proposed § 814.20(b)(4)(i) be required only if necessary to provide a complete description of the device. A comment noted, for example, that a picture of an in vitro diagnostic product probably would not be necessary while a drawing of a computed tomography x-ray (CT) system could require 4,000 to 6,000 pages.

A photograph, drawing, or other pictorial depiction of the device generally is necessary to provide a complete description of the device. For example, a picture of an in vitro diagnostic device may assist the reviewer in visualizing the process described in the instructions for use. Although FDA may not need 6,000 pages of drawings of a CT system in an initial submission, a schematic drawing is usually necessary to permit FDA to determine whether the device has been shown to be safe and effective. An applicant who does not believe that a photograph, drawing, or other pictorial depiction of a particular device is necessary to provide a complete description may omit such a depiction if the applicant adequately justifies the omission under § 814.20(d). For these reasons, FDA has not revised § 814.20(b)(4)(i).

30. One comment suggested that the word "properties" in proposed § 814.20(b)(4)(iii) is confusing.

A "property" is a quality or trait of a device that contributes to the ability of the device to function safely and effectively. The word "properties" is used in section 515(c)(1)(B) of the act. FDA believes that the word "properties" has a common and accepted meaning in the medical device industry and, therefore, is retaining it in § 814.20(b)(4)(iii). However, the agency has substituted the phrase "relevant to" for the proposed phrase "used in" to clarify the provision further.

31. Two comments pointed out in reference to proposed § 814.20(b)(4)(v) that the methods used in, and the facilities and controls used for, manufacturing and processing an expensive prototype device are not established until marketing approval is certain. In such circumstances, it would not be possible to include a complete description of this information with a PMA, according to the comments. These comments suggested that the applicant should only be required to state in the PMA that, if the PMA is approved, the manufacturer will comply with current good manufacturing practice (CGMP) regulations for devices (21 CFR Part 820).

FDA agrees that, in some cases, complete manufacturing information may not be available at the time the PMA is submitted. In these cases, § 814.20(d) provides that the applicant may attempt to justify the omission of this information from the PMA for the purpose of meeting the threshold filing requirement. If FDA accepts the justification for the omission of manufacturing information from the PMA, FDA will file the PMA and determine whether the PMA is otherwise approvable. FDA cannot determine whether the methods used in, or facilities or controls used for, the manufacture, processing, packing, storage, or installation of the device conform to the CGMP regulations, as required by section 515(d)(2)(C) of the act, based solely on a claim by an applicant that it will comply with the CGMP regulations if its PMA is approved. Manufacturing information will, therefore, be required at such time as FDA informs the applicant that its PMA is approvable subject to FDA's determination that methods, facilities, and controls used for manufacturing the device conform to the requirements of section 520(f) of the act and Part 820 of the regulations. FDA will require that the applicant submit the manufacturing information and will verify the information before the agency will issue an order under § 814.44(d) approving the applicant's PMA.

32. Numerous comments objected to the requirement in proposed § 814.20(b)(5) that the applicant refer to any relevant performance standard, mandatory or voluntary, proposed or final, and provide adequate information to demonstrate how the device meets the performance standard or justify any deviation. Most of these comments suggested that this requirement should apply only to performance standards promulgated under section 514 of the act because section 515(c)(1)(D) of the act requires reference only to section 514 standards. One comment said that this provision should be limited to standards known to the applicant. Several comments said that this provision amounts to an endorsement of a voluntary standard contrary to law and FDA policy. One comment, which supported the proposed provision, stated that FDA has authority for this requirement under sections 515(c)(1)(A) and 701(a) of the act and that, in the past, the medical device industry has argued that whenever possible voluntary standards should be used in lieu of section 514 standards.

FDA has revised § 814.20(b)(5) to require that the applicant justify any deviation from either a section 514 standard or a standard issued under the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b et seq.) and explain any deviations from a voluntary standard. FDA also has revised the final rule to limit the provision on voluntary standards to those that are known, or that should reasonably be known, to the applicant. FDA believes that the requirement as revised is reasonable and will provide useful information for more efficient review of PMA's. Voluntary standards are part of the manufacturing environment and, when these standards are adequate, may help improve the safety and effectiveness of any device that conforms to them. For this reason, whether a device conforms to a voluntary standard is relevant to FDA's evaluation of the safety and effectiveness of the device. Section 515(c)(1)(D) refers only to standards under section 514 of the act. FDA believes, however, that it has the authority under section 515(c)(1) (B) and (C) of the act to require information on the existence of voluntary and proposed standards that are known, or that should reasonably be known, to the applicant, as well as information regarding compliance with such standards. Such information is relevant to FDA's review of aspects of the device such as its components, ingredients and properties, and the methods used in its manufacture and processing. For example, whether a device complies with Underwriter's Laboratories standards on electrical safety may be relevant in determining if the device presents risk of electric shock to the user or patient. Section 515(c)(1)(A) of the act refers to investigations of the device and is not relevant to standards. FDA does not endorse standards by the requirements in § 814.20(b)(5) but will use the information provided under that section to evaluate certain aspects of the safety or effectiveness of the device. Deviations from a standard which do not affect the safety or effectiveness of the device will not result in denial of approval of the PMA. Moreover, in simply requiring that an applicant include information concerning a voluntary standard, FDA makes no representation that FDA considers the standard adequate. If FDA knows of a standard not addressed by the applicant, the agency may ask the applicant to address relevant aspects of this standard. A list of voluntary standards known to FDA is available from CDRH upon request to the Office of

Standards and Regulations (HFZ–84), 5600 Fishers Lane, Rockville, MD 20857.

33. FDA, on its own initiative, has expanded final § 814.20(b)(6) (i) and (ii) (proposed § 814.20(b) (7) and (8) respectively), concerning nonclinical laboratory studies and clinical investigations to specify the type of information to be submitted by applicants to describe such studies and to be consistent with similar provisions in FDA's final regulations governing approval for marketing of new drugs and antibiotic drugs for human use (50 FR 7495-7496).

34. Several comments said that the reference to Parts 52, 54, and 56, FDA's regulations on bioresearch monitoring, in proposed § 814.20(b)(8) (final § 814.20(b)(6)(ii)) should be deleted because these regulations were not yet final. One comment suggested that this section should refer to the act rather than to the proposed rules. Two comments suggested that the applicant be required only to show compliance with "applicable requirements of" Parts 52, 54, and 56. Another comment said that FDA should not attempt to enforce other regulations through the PMA regulations.

Reference to Part 56 is appropriate because these regulations now are final. The final regulations establishing Parts 52 and 54 are in the final stages of development. Until these regulations become effective, Parts 812 and 813 state the requirements concerning sponsors of clinical investigations and clinical investigators. When FDA issues Parts 52 and 54 as final rules, FDA will amend the PMA regulations as well as Parts 812 and 813 to conform them to the provisions of Parts 52 and 54. FDA, on its own initiative, has added to § 814.20(b)(6)(ii)(*a*) provisions requiring compliance with the requirements of Part 50, concerning informed consent for human subjects. This change is clearly within the scope of the notice of proposed rulemaking on those regulations. FDA believes that adding the phrase "applicable requirements of" as suggested by the comments would be redundant. FDA will use the information regarding compliance with the bioresearch regulations to the extent that this information is necessary to evaluate the data submitted. Variations from the bioresearch regulations, if adequately justified, should not adversely affect the review of the PMA. FDA believes that it is appropriate to require adherence to regulations promulgated under other sections of the act in considering PMA approval, particularly where, as here, those regulations are intended to ensure the validity of the data submitted in support of the PMA and to provide protection of the rights, safety, and welfare of subjects in the clinical investigations during which the data are gathered. FDA has emphasized this point in final §§ 814.45(a) and 814.46(a) by stating that failure to comply with these requirements and failure to justify noncompliance may result in denial, or withdrawal of approval, of the PMA.

35. Several comments objected to the requirement in proposed § 814.20(b)(13) (final § 814.20(b)(7)) that the applicant include a justification when only one investigator is used. One comment said that the number of investigators needed to determine safety and effectiveness of a device should be left to the applicant to determine. Another comment said that this requirement should be deleted because it is more properly the subject of the IDE regulations. Two comments said that it should be made clear that one investigator means one individual and not one institution. One comment said that the word "justification" should be clarified. Two comments suggested that "justification" should be changed to "explanation."

FDA believes that to demonstrate the reproducibility of results, clinical investigations of a device should normally involve more than one investigator. Therefore, FDA has concluded that if a PMA is supported by only one investigation, it is appropriate to require that the applicant justify why data collected by only one clinical investigator provide reasonable assurance of safety and effectiveness of the device. FDA disagrees with the comment suggesting that this requirement is more properly a part of the IDE regulations (21 CFR Parts 812 and 813). This requirement concerns the reproducibility of data submitted to obtain premarket approval rather than the conduct of a clinical investigation. The agency advises that the term "investigator" is defined in §§ 812.3(i) and 813.3(e) as an individual who actually conducts an investigation. FDA does not believe that it is necessary to define the term again in these regulations. FDA believes that use of the word "justification" in § 814.20(b)(7) is appropriate because more than an explanation is needed. The applicant is required to provide sufficient reasons why the application should not be denied under section 515(d)(2) of the act because, for example, there is a lack of showing of reasonable assurance that the device is safe or effective due to potential bias or a lack of reproducibility of the test results obtained by a single investigator.

36. Numerous comments objected to proposed § 814.20(b)(6) as overly broad. Most of these comments suggested that the applicant should be required to submit only a bibliography of all publications, whether adverse or supportive, known to or reasonably obtainable by the applicant that are relevant to an evaluation of the safety or effectiveness of the device. Comments said that copies of such publications should not be required. Several comments suggested that FDA delete the reference to Institutional Review Boards (IRB's) in this section because it is not relevant to PMA's; other comments suggested that a reference to advisory committees should be inserted instead.

FDA agrees that proposed § 814.20(b)(6) (§ 814.20(b)(8) in the final rule) was overly broad. FDA has revised final § 814.20(b)(8) to delete the requirement that the applicant submit copies of all published adverse information and copies of unpublished adverse information in the possession of, or reasonably obtainable by, the applicant. Final § 814.20(b)(8)(i) requires that the applicant submit a bibliography of all adverse or supportive publications, other than those submitted in greater detail in the body of the PMA, that are known to or should reasonably be known to the applicant. Final § 814.20(b)(8)(ii) requires a description and analysis of all supportive and adverse information, other than published studies, known to or that should reasonably be known to the applicant. FDA may request the applicant to provide actual publications or documents, if necessary. FDA advises that if the applicant knows of unpublished information concerning its device but is unable to obtain copies of such information, then, in lieu of the description and analysis of such information otherwise required to be submitted, the applicant may inform FDA of the location of the information, e.g., the name and address of the person that the applicant believes has such information. FDA also agrees that the reference to an IRB in proposed § 814.20(b)(6) was inappropriate and in the final rule has substituted the words "FDA advisory committee."

37. Several comments said that samples submitted to FDA under proposed § 814.20(b)(9) (final § 814.20(b)(9)) should be returned to the applicant or the applicant should be reimbursed for them.

Under section 515(c)(1)(E) of the act, FDA may require the submission of samples of the device or, if such submission is impractical or unduly burdensome, the identification of the

location of one or more of the devices that is readily available for examination and testing. Because submission of samples is required by statute and is a reasonable cost to be borne by the applicant, the agency is not providing for return of, or reimbursement for, the samples. The agency may have future regulatory use for the samples.

38. Several comments said that proposed § 814.20(b)(10) (final § 814.20(b)(10)), requiring submission of proposed information, installation instructions, literature, and labeling, exceeds the requirements of section 515(c)(1)(F) of the act in that the act requires that only proposed labeling be submitted. One comment said that the word "information" in this section is unclear. Another comment said that installation instructions may be irrelevant to the safety or effectiveness of a device. One comment said that this section should specify that the labeling to be submitted is labeling as defined in section 201(m) of the act (21 U.S.C. 321(m)) and includes advertising.

FDA regulations (21 CFR 1.1(b)) provide that the definitions in section 201 of the act apply to those terms when used in regulations issued under the act. Therefore, "labeling" as used in § 814.20(b)(10) means labeling as defined in section 201(m) of the act (which includes all labels and other written, printed, or graphic matter (1) upon the device, its container or wrapper, or (2) accompanying the device). Labeling includes general information and literature, as well as advertising, if they accompany the device. In all cases, labeling includes instructions for installation. FDA believes that installation instructions are relevant to the safety or effectiveness of a device. FDA agrees, however, that the section as proposed was unclear and has revised final § 814.20(b)(10) to make clear that only proposed labeling is required to be submitted. FDA notes, however, that all labeling for a device subject to premarket approval is "proposed labeling" until FDA approves the PMA for the device.

39. One comment objected to proposed § 814.20(b)(11). The comment said that FDA does not have any authority to require patient labeling. Another comment said that FDA may require patient labeling only under section 520(e) of the act. One comment said that patient labeling should be the subject of another regulation but that, if it is not, the requirement should be limited to cases in which patient labeling is necessary for the safe and effective use of the device. Many comments said that the reference to restricted devices in proposed § 814.20(b)(11) is inappropriate because the agency withdrew its proposed restricted device regulations.

FDA has deleted proposed § 814.20(b)(11) because the provision was not appropriately included in § 814.20. Patient labeling and labeling for restricted devices are discussed elsewhere in this document (see paragraphs 84 and 85 of this preamble and final § 814.82(a)(3)).

40. One comment suggested that FDA combine proposed § 814.20(b) (12) and (14) because both requirements are governed by 21 CFR Part 25. Another comment said that the reference in proposed § 814.20(b)(12) should be to 21 CFR 25.1 not to 25.22. One comment said 21 CFR 25.1 should be revised to provide that environmental impact statements are not required for PMA's.

FDA agrees that proposed § 814.20(b) (12) and (14) should be combined and has done so in § 814.20(b)(11) of the final rule. The reference to 21 CFR 25.22 was to the proposed revisions to Part 25 published in the **Federal Register** of December 11, 1979 (44 FR 71742). The proposed revisions to Part 25 were issued to comply with regulations issued by the Council on Environmental Quality (40 CFR Parts 1500 to 1506). The final regulations revising Part 25 were published in the **Federal Register** of April 26, 1985 (50 FR 16636) and became effective on July 25, 1985. In accordance with final Part 25, FDA concludes that, in general, an environmental assessment is required in applications seeking premarket approval of medical devices, just as the agency requires EA's in similar applications for other new products it regulates. A PMA for a device is excluded under § 25.24(e)(4), however, if the device is of the same type and for the same use as a previously approved device and if approval of the device does not result in the release of substances that could cause toxic effects on organisms in the environment. Devices that are excluded by this provision compete for the same market with already approved devices of the same type and use and therefore do not result in increased environmental introduction of the device (see 50 FR 16646).

Also, changes that require prior approval under § 814.39(e) may be made without submitting a supplement so long as the changes are reported in a periodic report (see paragraphs 51a and 51b of this preamble) are excluded under § 25.24(e)(5) from the requirement to submit an EA (see 50 FR 16646). Proposed §§ 814.20(b) (12) and (14) have been deleted from the final rule. Final § 814.20(b)(11) requires the applicant to comply with the applicable provisions of Part 25.

41. Several comments argued, in reference to proposed § 814.20(b)(15) (final § 814.20(b)(12)), that FDA may request additional information only when the request is approved by the appropriate FDA advisory committee. One comment said that this section should be deleted. Another comment suggested that this section specify that FDA may request only additional safety and effectiveness data.

FDA disagrees with these comments. Section 515(c)(1)(G) of the act provides that FDA may require "other information" relevant to the subject matter of the application with the concurrence of the appropriate FDA advisory committee. Section 515(c)(1)(G) refers only to types of information not included in section 515(c)(1) (A) through (F) of the act. The phrase "other information" in final § 814.20(b)(12) refers to types of information not listed elsewhere in § 814.20(b) and may include types of information listed in section 515(c)(1)(A)–(F) of the act as well as other types. If FDA needs to obtain information of a type not specified in section 515(c)(1)(A)–(F) of the act, FDA will obtain the concurrence of the appropriate advisory committee as required by section 515(c)(1)(G) of the act. The final rule has been revised to clarify this point.

42. FDA, on its own initiative, has made the following additional changes in § 814.20 in the final rule:

FDA has added § 814.20(d) to the final rule to require that an applicant identify and justify omission of any information otherwise required by § 814.20(b) to be included in the PMA (proposed § 814.20(d) is renumbered as § 814.20(h) in the final rule). The statement of omission and the justification for the omission should be submitted as a separate section in the PMA and identified in the table of contents. Under proposed § 814.20(b), FDA would have provided that the agency must authorize an omission. Under the final rule, FDA will correspond with the applicant regarding an omission if FDA determines that the omitted information is necessary to enable the agency to accept the PMA for filing or to determine whether to approve the PMA.

FDA has added new § 814.20(e) to the final rule to require that during the period of FDA review of an application, the applicant update its PMA with any new information concerning the safety or effectiveness of the device from ongoing or completed studies. These update reports are due 3 months after

the filing date, following receipt of an approvable letter, and at other times as requested by FDA. These update reports are necessary to ensure that the decision to permit marketing approval of a new device is based on the most up-to-date information available. FDA considers the additional information submitted in the update to be a PMA amendment. However, unless the information included in an update report is a major amendment (see paragraph 45 of this preamble) under § 814.37, FDA will not extend the 180-day review period for the PMA because of the submission of an update report. Before submitting the first such report, applicants are encouraged to consult with the contact person who will be identified in the notice of filing provided to the applicant under § 814.42(a) regarding further details on the update report's form and content.

FDA also has added new § 814.20(f) to the final rule to allow an applicant whose device contains a color additive subject to section 706 of the act (21 U.S.C. 376) to submit the information specified in 21 CFR 71.1 as part of the PMA rather than in a separate color additive petition. An applicant may submit a separate color additive petition if it prefers to do so. Under section 706(a) of the act, any color additive used in or on a device is required to be listed under section 706(b) of the act, i.e., approved, if the color additive comes in direct contact with the body for a significant period of time. Parts 70 and 71 of FDA's regulations on color additives specify the form, content, disclosability, review, and processing of color additive petitions, as well as standards for approval or denial of petitions, and fees for processing. At present, Parts 70 and 71 refer expressly only to the use of color additives in foods, drugs, and cosmetics. In the near future, FDA will propose amendments to Parts 70 and 71 to make the procedures specified in those regulations expressly applicable to color additives used in medical devices, and to add provisions specifically applicable to such color additives. Until Parts 70 and 71 are amended, however, all petitions for the use of color additives in devices, whether submitted as part of a PMA or separately, are subject to the existing procedures in Parts 70 and 71. A PMA for a device containing a color additive that is subject to section 706 of the act will not be approved until the color additive is "listed" (approved) for use in that device pursuant to section 706(b) of the act. Review of color additive petitions for colors used in devices undergoing PMA review will proceed simultaneously with PMA review.

Insufficient Information in a PMA (§ 814.31)

43. One comment suggested that proposed § 814.31 (a) and (b), which would have provided that FDA would consider a PMA insufficient to permit a determination of safety and effectiveness if it did not include all the information required by § 814.20 or if it contained a false statement of material fact and § 814.40(b) which would have provided for the filing of a PMA if it complied with the requirements of Subpart B describing a PMA, are redundant and that § 814.31 (a) and (b) should be deleted. Another comment suggested that not all the information required in § 814.20 is applicable to all devices and that § 814.31(a) should be modified to reflect this.

FDA agrees that proposed § 814.31(a) is unnecessary and has deleted it from the final rule. If FDA determines that a PMA does not include all the information required by § 814.20 (or § 814.39 if the submission is a PMA supplement) and FDA has not accepted any justification provided under § 814.20(d) for omission of the information, FDA will refuse to file the application.

Proposed § 814.31(b) sets forth a ground for denial of approval of a PMA. FDA disagrees with the comment that this section is redundant of proposed § 814.40(b), which concerns grounds for refusing to file a PMA. In the final rule, proposed § 814.31(b) has been combined with § 814.45(a), which sets forth the grounds for denial of a PMA. FDA agrees that due to the wide variety of devices subject to premarket approval, not all the information required under § 814.20 is necessary for each device. Under § 814.20(d), however, the applicant may attempt to justify the omission of any allegedly inapplicable category of information.

44. Several comments objected to proposed § 814.31(c) providing for FDA inspection of records "pertinent" to a PMA. Several of these comments stated that FDA was creating a new inspection authority in this provision. Two comments argued that FDA has authority to inspect records only of facilities manufacturing restricted devices. Two other comments argued that FDA has authority only to inspect records required to be kept under the act.

FDA disagrees with the comments. Under section 515(d)(2)(A)–(C) of the act, FDA is required to deny approval of an application if there is a lack of showing of reasonable assurance that the device is safe and effective, or if the methods used in and the facilities and controls used for the manufacture, or processing, or packing, or installation of the device do not conform to current good manufacturing practice in accordance with section 520(f) of the act. Inspection of facilities and records pertinent to a PMA is necessary to carry out this statutory mandate. Additional authority to conduct inspections is discussed in paragraph 94 of this preamble. FDA has concluded that an approvable letter issued by FDA may state that allowing inspection is a condition to approval. Thus, proposed § 814.31(c) has been redesignated § 814.44(e)(1)(ii) in the final rule. Section 814.44(e) describes the contents of an approvable letter.

Amended and Resubmitted PMA's (§ 814.37)

45. Many comments objected to proposed § 814.37(a) (final § 814.37(c)) which provides for an extension of the 180-day review period for up to another 180 days if an amendment to a PMA is submitted. Comments suggested that a distinction be made between minor amendments and major amendments and that the former should not result in an extension of the review period. Other comments suggested a distinction between amendments requested by FDA and those voluntarily submitted by the applicant, and that FDA-requested amendments should not result in an extension of the review period. Many comments argued that the extension of the review period should run from the date FDA receives the amendment and not from the end of the original review period. Other comments suggested that the review period not be extended to a period greater than the time remaining in the original 180-day period measured from the date of the request, such period to begin again on the date the amendment is received by FDA. One comment suggested that an extension should never exceed 90 days from the end of the initial 180-day review period.

FDA agrees that only major amendments (i.e., those requiring substantial FDA review time) warrant an extension of the 180-day review period. Major amendments would generally involve one of the following:

An amendment that contains new data from a previously unreported study, significant updated data from a previously reported study, detailed new analyses of previously submitted data, or required information previousiy omitted. When a major PMA amendment is submitted, the applicant

will be deemed by FDA to have withdrawn the original submission and resubmitted the PMA. Under § 814.37(c), FDA has 180 days to approve or deny approval of the resubmitted PMA. Section 814.37(c) is consistent with section 515(d)(1) of the act, which provides that FDA is to approve or deny approval of a PMA within 180 days after the receipt of an application that meets the requirements of section 515(c)(1) of the act. (H. Rept. 94–853, 94th Cong., 2d Sess., pp. 31–32, 1976.) A PMA for which a major amendment is submitted failed to meet the requirements of section 515(c)(1) of the act, and the PMA is, as amended and resubmitted, considered to be a new application "received" by FDA.

FDA is aware that Congress intended that requests for amendments should not delay unnecessarily the review of a PMA. (H. Rept. 94–853, *supra*, at p. 32.) FDA agrees with the comments stating that if a PMA amendment is not major, FDA should be able to complete its review within a period of less than 180 days from the date the amendment is received. Therefore, FDA has revised the final rule (§ 814.37(c)) to provide that the review period may be extended for up to 180 days only if the applicant on its own initiative, or at FDA's request, submits a major PMA amendment.

Suggestions that FDA request amendments to provide additional necessary information occur when deficiencies in the PMA are noted during its review by FDA or an FDA advisory committee. FDA advises that it may communicate with the applicant orally or in writing about such deficiencies in the application or about the agency's need for more data or information or for changes in the application to facilitate the review. Because FDA-initiated amendments are due to deficiencies or omissions in the original application or to changes intended to facilitate review, it would be unreasonable to deny the agency the additional time needed to review them. Moreover, providing FDA inadequate time to review new "needed" additional information could result in a disincentive for agency reviewers even to ask for the information, something clearly not in the public interest. For these reasons, FDA has not changed the regulation to make the time period for review of a PMA depend on whether FDA requested the amendment or the applicant submitted the amendment on its own initiative.

Final § 814.37(a) provides that an applicant on its own initiative may submit a PMA amendment. Final § 814.37(b) provides that FDA may request an applicant to amend its PMA. New § 814.37(c)(2) has been added to the final rule to make clear that if an applicant refuses to submit additional information requested by FDA under circumstances in which the submission would constitute a major PMA amendment, the review time for the PMA will be extended only for the number of days between FDA's request for an amendment and the date FDA receives the applicant's written refusal to submit additional information.

46. One comment suggested that FDA notify the applicant within 30 days of any deficiencies that may prevent filing of a PMA amendment.

If the PMA or the PMA supplement has been filed, FDA will accept the amended PMA, i.e., the prior PMA plus the PMA amendment, as being filed on the date the PMA amendment is received. FDA does not believe notification is necessary.

47. Several comments stated that the 30 days allowed for submitting a PMA amendment requested by FDA in proposed § 814.37(b) would be inadequate in many instances, for example, when an additional clinical study is needed. One comment suggested that the applicant be given a "reasonable time" in which to file a requested PMA amendment rather than a uniform 30 days. Another comment suggested that an applicant be given 90 days. Another comment suggested that FDA and the applicant agree on the due date for submission of a PMA amendment.

Proposed § 814.37(b) (final § 814.37(d)) was intended to inform applicants that FDA would stop the review of a PMA, i.e., consider the PMA inactive, if a response to any request for an amendment was not received within 30 days of the request. FDA agrees, however, that the applicant may not be able in all cases to submit the requested information within 30 days. Because of the changes in § 814.37(c) of the final rule, discussed in paragraph 45 of this preamble, FDA believes that a time period for a response to a PMA amendment requested by FDA is not necessary, and, therefore, in the final rule has deleted the proposed 30-day time frame for a response to such request. However, if FDA does not receive any response to a written request for a PMA amendment within 180 days of the date of the request, FDA will consider the PMA to be voluntarily withdrawn by the applicant.

48. Several comments requested clarification of the term "withdrawn" in proposed § 814.37(b) (final § 814.37(d)). One comment suggested adding the word "voluntarily" before "withdrawn" to avoid confusion with the withdrawal of approval under section 515(e) of the act and to protect the confidentiality of the PMA. Another comment suggested that FDA specify that the period after which FDA will consider a PMA withdrawn begins on the date the applicant receives the request to amend the PMA. One comment suggested that FDA notify the applicant 30 days before the PMA would be considered to be withdrawn.

FDA has modified proposed § 814.37(b) (final § 814.37(d)) to clarify that FDA will consider a PMA to be voluntarily withdrawn by the applicant if a response to a request for amendment is not received by FDA within 180 days of the request. The confidentiality of a withdrawn PMA is subject to § 814.9 and Part 20. The 180-day period provided in § 814.37(d) begins on the date that FDA mails the request for an amendment. FDA believes that 180 days from this date is sufficient time for the applicant to respond to FDA's request. Because the applicant will be notified in any request for an amendment that the PMA will be considered withdrawn if a written response is not received within 180 days, FDA believes that any subsequent notification to the same effect is not necessary.

49. One comment stated that FDA should not request amendments later than 30 days after the date the PMA is received.

FDA disagrees. A PMA cannot be reviewed thoroughly enough within 30 days of receipt to determine the need for an amendment. The additional information provided in an amendment may permit FDA to approve a PMA that FDA otherwise would deny.

50. Several comments stated that additional information may be required by FDA only with the concurrence of the appropriate FDA advisory committee established under section 513 of the act.

A request for additional information included in section 515(c)(1)(A)–(F) of the act does not require the concurrence of an advisory committee established under section 513 of the act. FDA will obtain the concurrence of the appropriate advisory committee if the agency requests information other than that provided for in section 515(c)(1)(A)–(F) of the act. (See paragraph 41 of this preamble for a related comment.)

PMA Supplements (§ 814.39)

51a. Many comments requested clarification of the requirement in proposed § 814.39 that PMA

supplements be submitted for "changes that significantly affect the safety or effectiveness of a device." Comments suggested that:

(i) FDA eliminate the list of examples of significant changes and allow the applicant to determine if any change is significant.

(ii) FDA clarify whether all of the listed examples are always significant and if they are not, change "include" to "may include." For example, according to the comments, not all changes in packaging are significant.

(iii) Manufacturers do not have discretion to determine whether a change is significant. All changes should be submitted. FDA can quickly rule on insignificant changes.

(iv) FDA specify that a change in suppliers is not a significant change affecting safety or effectiveness.

(v) FDA specify that packaging changes do not significantly affect safety or effectiveness.

(vi) FDA list a broad range of changes that do not require a PMA supplement.

FDA has thoroughly reviewed the proposed requirements for submission of supplements to approved PMA's. Based on this review, FDA has concluded that agency preclearance is needed for those changes to an approved device that affect its safety or effectiveness. However, FDA is taking several actions to facilitate the development of device modifications. For example, in instances where the applicant has prepared a protocol (approved by the agency) for shelf-life extension, FDA has determined that submission of a supplement is not necessary for changes affecting shelf-life of the device so long as the protocol is followed. Such changes are to be reported in the required periodic reports.

FDA acknowledges that certain types of changes made in accordance with FDA approved protocols need to be submitted in a PMA supplement but do not require a lengthy, detailed review by the agency. Therefore, as described in paragraph 51b. of this preamble, FDA has established a procedure for channeling certain other types of changes into a more abbreviated procedure of 30 days or less. Examples include additional lens finishing laboratories for rigid gas permeable contact lenses and new suppliers of magnets for magnetic resonance imaging devices. This procedure will allow FDA to focus the majority of its resources on reviewing those important types of device changes or modifications that truly warrant agency review because of their impact on safety or effectiveness.

FDA also acknowledges that the agency does not need to review in advance every change made in a device for which an application previously has been submitted. In addition, FDA does not need to approve in advance every such change. FDA, however, does need to review in advance a change affecting the safety or effectiveness of such device.

While it is not possible to describe every change, FDA has concluded that is appropriate to list types of changes that would require approval of a PMA supplement and to allow the applicant some discretion in determining when a supplement is necessary (also, see paragraph 57 of this preamble for a related comment). FDA has deleted the term "significant" from final § 814.39(a). FDA believes this term could be confusing and that it is clearer to state simply that the agency will review a change affecting the safety or effectiveness of the device. The revised rule conforms more closely to the statutory standards for deciding whether to approve an application. As noted above, FDA agrees that not all changes of the type listed in proposed or final § 814.39(a) always will affect the safety or effectiveness of a device. For example, packaging or labeling changes could be cosmetic. Similarly changes in manufacturing or sterilization procedures could be minor in nature, depending upon the scope of the change. The burden is primarily on the PMA holder to use good science and common sense in determining whether a supplement is required. FDA has retained "labeling changes" and "changes in packaging" in the final rule (§ 814.39(a) (2) and (6)), however, because some changes in labeling or packaging do affect the safety or effectiveness of the device, e.g., changes in the packaging for a sterile device or changes in claimed intended use of a device.

FDA advises that information about any change that is not required to be submitted in a PMA supplement under § 814.39(a) is required to be provided to FDA in the periodic reports to be submitted under § 814.39(b). Therefore, FDA believes that changing § 814.39(a) to read "Such changes may include" as suggested by the comments may be misleading.

FDA agrees in part with the request to delete changes in suppliers from the list. Only changes caused by these persons affecting safety or effectiveness of the device require FDA approval of a PMA supplement under § 814.39(a). FDA has deleted from the final rule the phrase "or involvement of subcontractors, suppliers, or distributors" (proposed § 814.39(a)(3)) but advises that any involvement by such persons that could affect the safety or effectiveness of a device requires FDA review and approval.

51b. FDA has added new § 814.39(e), under which FDA may identify changes that the holder of an approved PMA may make to a device without submitting a PMA supplement under § 814.39(a). Under this provision, FDA may identify such a change in an advisory opinion under § 10.85 of the agency's practices and procedures regulations, if the change applies to a generic type of device, or in correspondence with the applicant, if the change applies only to the applicant's device. FDA will require that such a change be reported to FDA in (1) a periodic report under § 814.84 or (2) a "30-day PMA supplement" under § 814.39(e). FDA will identify in the advisory opinion or the letter the type of information that is to be included in the report or 30-day PMA supplement. If the change is required to be reported in a periodic report, the change may be made before it is reported to FDA. If the change is required to be reported in a 30-day PMA supplement, the change may be made 30 days after FDA files the supplement, unlesss FDA advises the applicant that the supplement is not approvable or is disapproved or that additional information is required.

The supplement should be clearly identified in accordance with the instructions in the letter or advisory opinion. This will ensure proper identification of the supplement when received by FDA and prompt preparation and issuance by FDA of an acknowledgment letter that will indicate the date that the supplement will be deemed approved.

The supplement contents must precisely follow the instructions in the letter or advisory opinion. Any supplement that is not administratively complete will not be filed and, therefore, will not be deemed approved 30 days after receipt.

Whether FDA will dispense with the requirement for a PMA supplement for a change to a generic type of device, including a change in labeling will depend on the nature of the change and of the information available to support the conclusion that a PMA supplement is not required to provide reasonable assurance of the safety and effectiveness of the device, as changed. For example, to dispense with the requirement of a PMA supplement to add a new indication for use of a generic type of device, FDA must be able to conclude, based on publicly available, valid scientific evidence, that the device is safe and effective for the new use. In

contrast, to dispense with the requirement of a PMA supplement for a change in commonly used quality control procedures, e.g., a change in written procedures describing processing controls, FDA need only conclude that the new procedures comply with the CGMP regulations. To dispense with the requirement of a PMA supplement for other changes to a generic type of device, e.g., a change in materials used in the device, FDA must be able to conclude, through a scientifically sound rationale based on publicly available, valid scientific evidence that may include but need not be limited to clinical experience, that the device, as changed, will remain safe and effective for its intended use under the conditions of use specified in the labeling.

Whether FDA will dispense with the requirement for a PMA supplement for a change to a device product, including a change in labeling, will also depend on the nature of the change and on the information available to support the conclusion that a PMA supplement is not required to provide reasonable assurance of the safety and effectiveness of the device product, as changed. For two reasons, however, FDA anticipates that it will be more likely to dispense with the requirement of a PMA supplement in this circumstance than in the case of a generic type of device. First, the change will apply only to a device product and to an individual PMA holder and therefore will not require a determination of safety and effectiveness on a generic basis. Second, once the product has been marketed under the PMA for a substantial period of time, FDA will have obtained significant information about the performance of the product and the PMA holder and will better be able to determine whether the device, as changed, will remain safe and effective for its intended use under the conditions specified in the labeling.

52. On its own initiative, FDA has made the following additional changes in § 814.39(a) of the final rule. Proposed § 814.39(a) (3) through (6) have been redesignated § 814.39(a) (4) through (7) in the final rule. For clarity, new § 814.39(a)(3) requiring a PMA supplement if a different facility or establishment is used to manufacture, process, or package the device has been added to the final rule. Also, § 814.39(a)(8) has been added to the final rule to specify when a change in the expiration date of the device requires a PMA supplement.

FDA also has modified § 814.39(b) in the final rule. The phrase "does not significantly affect" has been changed to "does not affect" to be consistent with the change in § 814.39(a) discussed in paragraph 51a. of this preamble.

53. One comment argued that to require submission of a PMA "supplement" is without legislative authority.

The final rule provides that a PMA supplement is to be submitted to the agency when a change affecting the safety or effectiveness of the device is made in a device for which there is an approved PMA. If the change affects the safety or effectiveness of the device, then the device, as changed, is a "new" device and under section 513(f) of the act is automatically classified into class III and subject to premarket approval. FDA could require that a new PMA be submitted for the device. In such circumstance, the new PMA would include information about the basic device, unnecessarily duplicating the original PMA, as well as new information about the effect of the change. FDA believes, however, that a PMA supplement will inform FDA of all safety and effectiveness issues attributable to the changes to the device. Moreover, FDA considers a PMA supplement and all the information in the PMA to be "before" the agency at the time the supplement is reviewed. Thus, when an applicant submits a PMA supplement for a change in an approved device, the applicant has, in effect, submitted a new PMA for the "new" (changed) device. For these reasons, FDA concludes that it has the authority to require applicants to submit PMA supplements to the agency for its approval before the changed device is marketed. As discussed in paragraph 57 of this preamble, however, certain changes that enhance the safety of the device or the safety in use of the device may be placed into effect before FDA approves the PMA supplement.

54. Several comments suggested inclusion of administrative requirements applicable to PMA supplements, e.g., establishing a 180-day time limit for FDA to review PMA supplements, a format for supplements, and specifying the number of copies required to be provided.

FDA agrees and has revised § 814.39(c) in the final rule to include provisions concerning PMA supplements. A PMA supplement will be required to comply with the requirements in § 814.20 for an original PMA except that the information required in the supplement is limited to that needed to support the change and that only three copies of a supplement need be submitted; the time limits for FDA review of a supplement will be the same as that provided for an original PMA (see paragraphs 42, 45, and 58 of this preamble). The supplement also is required to explain the reason for the change. If FDA determines that advisory committee review of the PMA supplement is required or appropriate, the agency will request necessary additional copies of the PMA supplement.

55. One comment stated that only periodic reporting rather than PMA supplements should be required for changes in devices that are not implantable, life-supporting, or life-sustaining. Another comment suggested that reports of changes that enhance safety should be required only under the periodic reporting procedure. Several comments suggested that a record of changes should be maintained in the device master file for FDA inspection rather than requiring each change to be submitted to FDA.

FDA generally disagrees with the comments. Section 515 of the act requires premarket approval of class III devices to ensure their safety and effectiveness. Any change in such a device that affects safety or effectiveness, including a change that the applicant believes enhances its safety, is subject to the requirement. It is the responsibility of FDA to determine whether the device, as changed, remains safe and effective. FDA, however, will identify on a case by case basis changes that may be made via a "30-day supplement" or a periodic report (see paragraph 51(b) of this preamble).

FDA notes that not all PMA's will refer to a master file under Part 814 and presumes that the comments meant the device master record provided for in § 820.181 of the CGMP regulations. A record of changes in a device that could affect safety and effectiveness also would be maintained by the manufacturer in its device master record. In the case of a class III device, however, a PMA is required to be submitted to FDA for premarket approval. The availability of records to FDA investigators cannot substitute for the premarket approval requirements of section 515 of the act. FDA's inspections generally occur only once every 2 years, a frequency that is insufficient to allow FDA to learn in a timely manner of changes that affect the safety or effectiveness of devices subject to approved PMA's. Therefore, any such changes are to be the subject of a PMA supplement.

56. One comment stated that the final rule should clarify that a change in a device that might adversely affect its safety or effectiveness will cause it to be a new device requiring a separate PMA.

As discussed in paragraph 53 of this preamble, FDA believes that a change in an approved device generally should be the subject of a PMA supplement, not a new original PMA. FDA emphasizes that such PMA supplement is required to provide reasonable assurance that the device as changed is safe and effective. If the PMA supplement fails to provide reasonable assurance of safety and effectiveness, FDA will deny approval of the supplement, thereby making the marketing of the device in other than its approved form illegal.

57. One comment suggested that proposed § 814.39(d)(3) be deleted and that guidelines listing specific changes that do not require FDA approval prior to implementation be issued at a future date only if necessary. Another comment inquired as to how guidelines would be communicated to future applicants.

FDA agrees that proposed § 814.39(d)(3) which would have provided for the agency to issue guidelines under Part 814 be deleted from the final rule. Section 10.90(b) (21 CFR 10.90(b)) of FDA's administrative practices and procedures regulations provides that FDA may issue guidelines to assist the affected industry in complying with the agency's regulations. Special provisions to do so under Part 814 would be redundant and § 814.39(d)(3) is not included in this final rule. To give applicants guidance as to what types of changes that require a PMA supplement may be implemented before receiving approval from FDA, FDA has specified in final § 814.39(d)(2) changes that will not require such prior approval. These changes are limited to certain changes that enhance the safety of the device or the safety in the use of the device. FDA advises that the availability of agency guidelines routinely are announced in the **Federal Register** and may also be announced in other appropriate FDA publications.

Subpart C—FDA Action on a PMA

58. On its own initiative FDA has reorganized subpart C and added a new section describing time frames for reviewing a premarket approval application (final § 814.40).

Filing a PMA (§ 814.42)

59. Several comments suggested that proposed § 814.40(a) be modified by adding the word "shall" in place of the word "will" and stating that notification from FDA shall occur within 30 days and include the assigned PMA reference number. Another comment suggested that FDA establish a time limit for the agency to notify an applicant after the determination to refuse to file a PMA has been made. The comment suggested adding the words "within 10 working days of the determination not to exceed 30 days after receipt of the PMA."

FDA disagrees in part with these comments. Proposed § 814.40(a) (final § 814.42) stated only that FDA would notify an applicant that the PMA had been received. At such time, a determination on filing the PMA would not have been made. The proposed rule did not specify a time limit for notification that FDA had filed or refused to file a PMA. However, FDA has revised the final rule (§ 814.42(a)) to state that within 45 days of receipt of a PMA the agency will determine whether to file the application and will notify the applicant in writing of such determination. This notification will include the PMA reference number and the date the PMA was received (§ 814.42(b)). FDA has deleted the proposed statement concerning notification to the applicant of receipt of the PMA within 30 days. This statement is unnecessary because the final rule has been revised to provide that FDA will notify the applicant of its decision whether to file the PMA. FDA believes that the use of the word "shall" may mislead the applicant into believing that if a notification on filing is not sent within 45 days, the PMA is automatically filed. FDA agrees with the comment that FDA should notify the applicant of the refusal to file, but believes the 45-day time frame for such notification to be more reasonable than that suggested by the comment.

60. One comment stated that the applicant should be entitled to a conference with the Director of the Bureau of Medical Devices (now the Director of CDRH) if a resubmitted PMA is refused for filing to ensure that seriatim refusals to file do not become a mechanism for extending the 180-day review period.

FDA agrees that an opportunity for an informal conference should be provided to an applicant in the event FDA refuses to file the applicant's PMA. The agency did not propose to provide for such a conference because the proposal would have permitted the applicant to file the PMA over protest. However, FDA has reconsidered its proposal to allow filing a PMA over protest and has concluded that its original proposal is inappropriate because FDA may not file a PMA that does not include all the information required under section 515(c)(1) (A)–(G) of the act.

Section 515(d)(1)(A) of the act provides that action on a PMA (approval or denial) shall be taken "no * * * later than one hundred and eighty days after the *receipt* of an application under [section 515(c)]." (Emphasis added.) The legislative history is clear that "receipt" means receipt of an application containing all the information required by section 515 and regulations issued thereunder (H.R. Rep. No. 94–853, 94 Cong., 2d Sess, p. 31–32 (1976)). Furthermore, under section 515(c)(2) of the act, FDA is required to accept a PMA for filing and to refer such PMA to an advisory committee only if the application includes all the information described in section 515(c)(1) (A)–(G) of the act.

FDA believes that granting an applicant an informal conference to discuss the reasons for the agency's refusal to file the application, in addition to being allowed by the statute, will better utilize FDA resources. Therefore, FDA has revised the final rule to permit the applicant to request an informal conference with the Director of the Office of Device Evaluation, CDRH, to discuss the agency's refusal to file a PMA (§ 814.42(d)(2)) and has deleted proposed § 814.42(c), which provided for filing over protest. Under § 814.42(d)(2) of the final rule, following the informal conference an applicant may appeal a refusal to file to the Director of CDRH. The decision of the Director represents final agency action on whether to file a PMA.

61. Many comments stated that the period within which FDA is required to act on a PMA should be 180 days from the date of receipt of the PMA. According to the comments, calculating the review period from 30 days after receipt extends the period for review to 210 days, in violation of the statute. One comment suggested that the 30-day time frame be reduced to 14 days. These comments misinterpreted proposed § 814.40(d). Proposed § 814.40(d) and the final rule (final § 814.42(b)) state that if a PMA is accepted for filing, the date of filing is the date the PMA was first received. Because the date of filing is the date of receipt of a PMA meeting the requirements of section 515(c) of the act and § 814.20, the suggested change in the time frame for determining if the PMA is adequate for filing is unnecessary.

Grounds for Acceptance or Refusal to File (§ 814.42)

62. Several comments suggested that proposed § 814.42(a) (stating that a PMA accepted for filing would be reviewed if it contained sufficient information for review) be deleted because if a PMA is

filed, sufficient information for review is included in the PMA.

FDA agrees with the comment and has deleted proposed § 814.42(a). A PMA accepted for filing contains sufficient information to enable FDA to review the PMA (see paragraphs 60 and 61 of this preamble). During the review of the PMA, however, FDA or the advisory committee to which the PMA is referred for review and recommendation respecting approval may request that the applicant submit additional information whenever such information is necessary for FDA to determine whether to approve the application.

63. Many comments objected to provisions of proposed § 814.42(b) which provided that FDA would delay the review of a PMA if another manufacturer submits (i) a premarket notification under section 510(k) of the act requesting FDA to determine that the same device is substantially equivalent to a device for which premarket approval is not required or for which premarket approval has been postponed until promulgation of a regulation under section 515(b) of the act, or (ii) a reclassification petition under section 5!3 of the act for the same device. Several comments stated that review of a PMA should not be delayed even if the same manufacturer submits a PMA, a premarket notification requesting a determination of substantial equivalence, or a reclassification petition for the same device. The comments suggested that such delay violates the 180-day statutory review period. Several comments suggested that a delay may occur only if the PMA applicant concurs.

FDA agrees in part with the comments. FDA will not refuse to accept a PMA for filing on the ground that there is pending a petition for reclassification of the same device, whether the PMA is submitted by the same or another manufacturer. Therefore, FDA has deleted proposed § 814.42(b)(1) (i) and (2) from the final rule.

FDA disagrees, however, with the comments stating that review of a PMA should not be delayed if the same manufacturer submits a PMA and a premarket notification for the same device. FDA also disagrees with comments suggesting that any delay occur only with the concurrence of the PMA applicant.

A premarket notification submission, by definition, is inappropriate for a device for which a final regulation under section 515(b) of the act has established a date by which a PMA or notice of completion of a PDP is required to be filed with FDA, or for a transitional device (which includes any device substantially equivalent to a transitional device) under section 520(1) of the act. Nor is a premarket notification submission appropriate for a new device, as is discussed below. If the PMA applicant or a different person inappropriately submits a premarket notification submission, FDA will not delay its review of a PMA for any such device. FDA will instead notify the person making the submission that the device in question requires a PMA rather than a premarket notification.

A premarket notification submission may be appropriate, however, under the following circumstances: The device is not subject to a final regulation under section 515(b) of the act, the device is not a transitional device, and the device is not a new device. Whether a device is a new device, i.e., one not substantially equivalent to a device in commercial distribution before May 28, 1976, is determined during FDA review of a premarket notification submission. If a PMA is submitted concurrently with a premarket notification by the same applicant in either of these circumstances, FDA will consider the PMA voluntarily withdrawn by the applicant until FDA determines that the device is a new device and therefore subject to the requirement of a PMA. FDA believes that this procedure is in accord with the act, is consistent with efficient administration of the act, and will eliminate potential duplication of effort for both the applicant and FDA. FDA, however, will continue to review a PMA if a different person submits a premarket notification for the same device. If before FDA completes review of the PMA, the agency determines that the device is substantially equivalent to another device that does not require premarket approval before commercial distribution, FDA will terminate review of the PMA because the PMA will then no longer be necessary. In this event, FDA will notify the PMA applicant and provide the applicant an opportunity to voluntarily withdraw its PMA. FDA recommends that any applicant who contemplates concurrent submission of a PMA and premarket notification for the same device should consult with FDA on the appropriate procedure before making such a submission.

64. One comment suggested that the information that a PMA was filed over protest be withheld from the reviewing advisory committee. The comment also stated that the FDA employee who determined that the PMA would not be filed should be prohibited from further participation in the review process of the PMA.

As discussed in paragraph 60 of this preamble, FDA has deleted from the final rule proposed § 814.42(c), which provided for filing over protest. Therefore, further response to this comment is unnecessary.

Procedures for Review (§ 814.44)

65. Many comments discussed proposed § 814.44(a) regarding FDA's consultation with the appropriate advisory committee. The comments suggested the following modifications to the proposal:

(i) FDA should clarify the phrase "relevant portions" in proposed § 814.44(a). Proprietary information should be deleted before sending the PMA to committee members unless such information is required for the determination of the safety and effectiveness of the device.

(ii) FDA should not deny approval of any PMA unless FDA contacts all committee members, not merely a majority.

(iii) Advisory committee meetings should be the rule because they allow exchange between committee members and an opportunity for the nonvoting consumer and industry representatives to influence the voting committee members. Telephone and mail communication should be used only rarely and when used, FDA should obtain from the applicant a waiver of the right to a full advisory committee hearing. All telephone conversations should be recorded.

(iv) The applicant should have an opportunity to be present and to comment on the deliberations of the committee to avoid recommendations based on misunderstandings. The general public should be barred from committee meetings to protect trade secrets.

FDA advises that it will distribute a copy of, or relevant portions of, the PMA to each member of the appropriate advisory committee as required under 21 CFR 14.35(d)(1). Relevant portions of any PMA include all data necessary for the committee members to determine whether to recommend approval or denial of approval of the PMA. For example, FDA will distribute to all committee members clinical data contained in the PMA but may decide not to distribute to each member information concerning the manufacturing process for the device. This information may be outside the expertise of one or more members and, therefore, unnecessary for those members' review of the PMA. Proprietary information is adequately protected under § 20.80(c) of FDA's regulations governing conduct of special government employees and, thus, it is

not necessary to delete proprietary information from committee members' copies of the PMA.

Although FDA will attempt to include all members of the appropriate advisory committee in the committee's review of a PMA, under § 14.22(d) only a majority of current voting members is necessary to allow a committee to act. FDA is not required to obtain a waiver of the right to a full committee hearing from the applicant, because such right does not exist. FDA agrees with the comments that advisory committee meetings are required to be held. Under § 14.22(g), however, such meetings may be held by telephone conference if time and circumstances require; FDA will announce in the **Federal Register** any advisory committee meetings, including those held by conference call. Under § 14.35(e), advisory committee meetings may not be held by mail. A transcript or recording of each portion of a committee meeting, including meetings by telephone, will be made in accordance with § 14.61. Part 14 governs attendance at any advisory committee meeting of any interested person, including an applicant. Under § 14.27(b)(3), portions of meetings that concern trade secret or confidential commercial or financial information will be closed to the public.

To clarify the agency's intent, final § 814.44(a) provides for concurrent review of the PMA by FDA and the appropriate advisory committee upon the filing of the PMA. During this review, FDA may communicate with the applicant and with the advisory committee. Final § 814.44(b) provides that a report that includes the committee's recommendation on the PMA will be submitted to FDA and that a committee meeting subject to 21 CFR Part 14 will be held prior to the committee's issuance of its report and recommendation.

66. One comment suggested that FDA state in § 814.44(a) that, except in unusual circumstances, PMA's will be reviewed in chronological order of receipt by the agency.

PMA's are reviewed within FDA by offices specializing in certain medical areas, e.g., cardiovascular devices, dental devices, and are in turn reviewed by FDA advisory committees specializing in these areas. As a general rule, FDA begins the review of PMA's in each area in the order in which they are received. Numerous factors, however, such as the need for additional data and the types of reviews to be performed, may affect the order in which the reviews are completed. A large workload in one specialty area or difficulty in arranging a committee meeting, for example, will affect the order in which two or more PMA's may be reviewed within the agency or by its advisory committees. Therefore, FDA has not adopted the comment's suggestion.

67. One comment suggested that proposed § 814.44(b) (final § 814.44(c)) be changed from "FDA will review the report and the recommendations of the panel" to "FDA will review the PMA and the report and the recommendations of the panel," to clarify the time period within which the agency is required to act on any PMA.

FDA advises that it did not intend to imply that the time for acting on a PMA would not begin until it received a report and recommendation from the reviewing advisory committee. Therefore, the agency has revised § 814.44(c) in the final rule to make clear that the 180 days for its review and action on an application accepted for filing includes the time for review of the PMA, not just the advisory committee report and recommendation on the PMA.

68. Several comments expressed concern about the public disclosure of information in an approved PMA provided for in proposed § 814.44(c) (final § 814.44(d)). The comments stated that, under section 520(h) of the act, only a detailed summary of safety and effectiveness may be released.

FDA may withhold from public disclosure only those types of information that are exempt from public disclosure under FOIA. Section 520(h) of the act requires FDA to provide a detailed summary of safety and effectiveness information but does not limit FDA to disclosing only that information. The confidentiality of information in PMA's is discussed in paragraphs 8–16 of this preamble. Section 814.9 of the final rule sets forth the provisions concerning disclosure.

69a. One comment urged the agency to add the word "simultaneously" before the word "publish" in proposed § 814.44(c) (final § 814.44(d)) to ensure that the public is informed on a timely basis of an approved PMA.

FDA believes that publishing a notice of approval simultaneously with issuance of an approval order may not always be practical. FDA, however, intends to provide notice of approval of a PMA as soon as possible after issuance of the approval order.

69b. On its own initiative, FDA is providing in final § 814.44(d) for approval of a PMA on the basis of submission of draft final labeling if the agency determines that only editorial or similar minor deficiencies exist in the draft final labeling provided with the PMA. This change is consistent with the practice FDA has followed in its review and approval process for class III devices and with changes made in the final regulations governing approval of new drugs and antibiotics for human use (50 FR 7483, 7504). The approval letter will require applicants to submit to FDA a copy of the final printed labeling prior to marketing. Although applicants will not have to wait for prior approval of the final printed labeling, this procedure will enable FDA to ensure that the final labeling conforms to the provisions of the approval order.

70. On its own initiative, FDA is providing in final § 814.44(e) for approvable letters. An "approvable letter" reflects the agency's conclusion that important but easily resolved deficiencies exist in a PMA, and that FDA will approve the PMA if the applicant submits, and FDA finds acceptable, specific additional information or material identified in the letter or if the applicant agrees to other specific conditions identified in the letter. An approvable letter may provide, for example, for submission of revised draft final labeling, an FDA inspection to determine compliance with the current good manufacturing practice requirements of Part 820 or to verify all records pertinent to the PMA, a restriction imposed under section 515(d)(1)(B)(ii) of the act, or postmarketing conditions described in Subpart E. The applicant may amend the PMA as requested, the course of action that most applicants probably will elect to follow. An applicant that is dissatisfied with the conditions stated in the "approvable" letter may, however, elect to treat the "approvable" letter as a denial of the PMA and seek administrative review under section 515 (d)(3) and (g) by filing a petition in the form of a petition for reconsideration under 21 CFR 10.33. If the applicant does not file such a petition by the thirtieth day after the date of receipt of the approvable letter, FDA will regard the letter to be a request to the applicant for a PMA amendment. If FDA does not receive a response to the approvable letter within 180 days, FDA will consider the PMA to be voluntarily withdrawn (final § 814.44(g)(2)).

71. On its own initiative, FDA has revised proposed § 814.44(d) (final § 814.44(e)(1)(iv)) to provide that a PMA approval may impose postapproval conditions in accordance with Subpart E and has moved the list of types of postapproval conditions to § 814.82 because FDA believes that they are more appropriately listed where postapproval requirements are set forth. In addition, FDA has provided in final

§ 814.44(e)(1)(iii) that conditions to approval of a PMA may restrict a device under section 515(d)(1)(B)(ii) of the act. The added provisions merely describe FDA's statutory authority and current practice in approving for marketing class III devices.

72. Several comments argued that FDA lacks legal authority to issue "not approvable" letters (proposed § 814.44(b)(2) (final § 814.44(f)) because "not approvable" status is not authorized by the act. The comments further argued that the failure of the agency to deny approval of a PMA prevents an applicant from obtaining administrative or judicial review of the action. One comment said that FDA states, in the preamble to the proposal, that a not approvable PMA is considered voluntarily withdrawn (with preservation of the confidentiality of the PMA) but that proposed §§ 814.44(b) and 814.45(c) contradict this statement.

FDA advises that a "not approvable" letter reflects the agency's conclusion that major deficiencies exist in the PMA or that the information contained in the PMA cannot support approval of the PMA. Although the term "not approvable" is not mentioned in section 515 of the act, FDA believes that the use of not approvable letters is appropriate and within FDA's discretion. A "not approvable" letter will permit the applicant to submit additional information to correct deficiencies in a PMA. The letter also will provide that the applicant may treat a "not approvable" letter as a denial and request administrative review under section 515 (d)(3) and (g) of the act. Thus, administrative review and, subsequently, judicial review, are available. Final § 814.44(f) has been revised to make clear these provisions. If the applicant does not file a petition requesting administrative review by the thirtieth day after the date of receipt of the not approvable letter, FDA will regard its not approvable letter to be a request to the applicant for a PMA amendment. If FDA does not receive a response to the not approvable letter within 180 days, FDA will consider the PMA to be voluntarily withdrawn (final § 814.44(g)(2)).

73. One comment requested modification of proposed § 814.44(b)(2) to comply with section 515(d)(2) of the act by changing the second sentence to read "FDA shall inform the applicant of the deficiencies in the PMA and, if practical, the measures required to place it in approvable form: * * *".

FDA agrees with the comment's intent and has changed the final rule to make clear that a not approvable letter will describe any deficiencies in an application that preclude approval of the PMA, and, where practical, will identify measures required to place the PMA in approvable form (final § 814.44(f)).

74. One comment suggested that proposed § 814.44(e) be included under § 814.45. Another comment suggested that, under proposed § 814.44(e)(2), FDA may not withdraw approval of a PMA unless the agency determines that the inadequate methods, facilities, or controls cannot or will not be corrected.

FDA intended that proposed § 814.44(e) (final § 814.44(g)) set forth conditions under which FDA might suggest that the applicant voluntarily withdraw a pending PMA. The comments on proposed § 814.44(e) appear to assume, incorrectly, that the section refers to FDA withdrawal of approval of an approved PMA. Section 814.44(g) of the final rule lists those situations in which FDA will consider a pending PMA voluntarily withdrawn. The circumstances identified in proposed § 814.44(e) (i.e., that additional evidence is needed to support a finding that the device is safe and effective, or the methods, facilities, and controls used in manufacturing, processing, and packing the device are inadequate) would result in FDA requesting that the PMA be amended. At such time, as alternatives to amending the PMA or treating the request to be a denial of approval and petitioning for administrative review, the applicant could voluntarily withdraw the PMA (final § 814.44(g)(3)) or not respond to the request within 180 days, thereby resulting in the PMA being considered voluntarily withdrawn (final §§ 814.37(d) and 814.44(g)).

Denial/withdrawal of approval of a PMA (§§ 814.45, 814.46)

75. Many comments stated that the standard in proposed § 814.45(a) for denying approval or withdrawing approval of a PMA, i.e., "if other information available to FDA creates doubts about the safety or effectiveness of the device," is ambiguous and exceeds FDA's authority. The comments suggested that the statutory language be used, i.e., "there is a lack of showing of reasonable assurance of safety or effectiveness" or "that the device is unsafe or ineffective under the conditions of use prescribed, recommended, or suggested in the labeling of the device." One comment suggested that proposed § 814.45(a) be revised to meet statutory differences regarding the denial of approval of a PMA (section 515(d)(2) of the act) and the withdrawal of approval of a PMA (section 515(e) of the act).

In the final rule, FDA has established separate sections to provide procedures for denial of approval of a PMA (final § 814.45), and procedures for withdrawal of approval of a PMA (final § 814.46). The statement in proposed § 814.45(a) to which the comments objected was intended to provide that FDA may use information other than that submitted in the PMA to determine if a pending PMA should be denied approval as well as, if approval of any PMA should be withdrawn. The statement was not intended to broaden FDA's authority beyond that granted by the act. FDA has revised final §§ 814.45(c) and 814.46(a)(2) to make clear that information not included in a PMA may be the basis for the denial or withdrawal of approval of the PMA. Furthermore, the "new information" justifying withdrawal of approval under section 515(e)(1) of the act may be based upon a reevaluation of the data and information upon which approval was based (H.R. Rep. No. 94–853, *supra*, at 32). Final §§ 814.45 and 814.46 incorporate the differences between the statutory grounds for denial of approval and withdrawal of approval.

76. One comment argued that FDA should be required to state in any order denying approval of a PMA all reasons for the agency's action.

FDA agrees with the comment. Final § 814.45(b) states that FDA will inform the applicant of the deficiencies in the PMA including each of the grounds under section 515(d)(2) of the act and Part 814 upon which approval of the PMA is being denied.

77. One comment suggested that proposed § 814.45(a) refer to FDA's guideline for the arrangement and content of a PMA, which sets out the elements of a well-controlled investigation.

FDA agrees that it may be helpful to include a reference to the PMA guideline and has referred to this guideline in § 814.20 of the final rule, in which the contents of a PMA are discussed. FDA notes that § 860.7(e) describes the principles of a well-controlled investigation. A change in § 814.45 is not necessary to accommodate the comment's suggestion.

78. Many comments discussed public disclosure of the existence and contents of a PMA that is denied approval or for which approval is withdrawn. Several comments suggested that disclosure should not occur when a PMA is denied approval because a manufacturer's production plans are confidential. Other comments stated that disclosure should not occur until such time as the

applicant has exhausted all administrative remedies.

Public disclosure of the existence of a PMA may occur when the applicant or the agency takes a procedural step that is public, e.g., the applicant files a petition for reconsideration to obtain administrative review, or the agency issues a notice of opportunity for hearing on a proposed withdrawal of approval of a PMA. Public disclosure of PMA's and the information contained in them is discussed generally in paragraphs 8–16 of this preamble.

79. One comment requested that the regulations make clear that material submitted in a PMA supplement cannot cause withdrawal of the approved original PMA unless information in the PMA supplement removes the assurance of the safety and effectiveness of the device, as established in the original PMA.

The grounds for withdrawing approval of a PMA are set forth in section 515(e)(1) (A)–(G) of the act and referred to in § 814.46(a) of the final rule. If FDA obtains information from any source, including a PMA supplement, that any of the grounds in section 515(e)(1) (A)–(G) or § 814.46(a) of the final rule applies to the device, FDA may initiate proceedings to withdraw approval of the PMA. FDA does not believe any change in the final rule is required.

Subpart E—Postapproval Requirements

Postapproval requirements (§ 814.82)

80. Section 814.82(a) has been revised to combine proposed §§ 814.44(d) and 814.82(a) to list in one section of the final rule all postapproval requirements that FDA may impose.

81. Several comments objected generally to postapproval requirements stating that such requirements are outside the scope of FDA's authority. Many of the comments argued that FDA has authority under section 515(d)(1)(B)(ii) of the act only to restrict the sale and distribution of the device to the extent provided under section 520(e) of the act. One comment alleged further that the restrictions authorized by section 520(e) of the act on the sale and distribution of a device are an unnecessary interference with the practice of medicine. In contrast, one comment supported the proposed postapproval requirements arguing that they are consistent with sections 515(d)(1)(B)(ii) and 701(a) of the act and are necessary to determine the long-term safety and effectiveness of devices and to obtain patient information on the risks, benefits, and uses of devices. This comment also argued that postapproval surveillance is essential to ensure the continued safety and effectiveness of devices with an approved PMA.

Sections 515, 519, 520, and 701(a) of the act authorize FDA to impose postapproval requirements to provide reasonable assurance of the safety and effectiveness of a device under the conditions of use prescribed, recommended, or suggested in its labeling. Although section 515(d)(1)(B)(ii) of the act provides that FDA may restrict the sale and distribution of the device only to the extent provided under section 520(e) of the act, this section does not limit FDA's authority to impose other postapproval requirements under its authority in section 515 and other sections of the act. FDA interprets section 515 of the act as authorizing imposition of postapproval requirements and has imposed such requirements in PMA approval orders since the enactment of the amendments. The most common types of postapproval requirements imposed by FDA are to require periodic reporting of patient experience with the device to assess long-term safety and effectiveness, reporting of device defects or adverse reactions, and submission of annual reports of published and unpublished studies involving the device. Postapproval requirements enable FDA to determine whether reasonable assurance of safety and effectiveness of a device continues and whether other action, such as withdrawal of approval, is necessary.

Postapproval requirements included as conditions to approval of a device are directed to the PMA applicant and, therefore, generally should not interfere in any way with the practice of medicine. Although some restrictions on the sale and distribution of a device by the applicant may affect physicians and other health professionals, FDA will impose such restrictions only when, because of the device's potential for harmful effect or the collateral measures necessary to its use, reasonable assurance of the safety and effectiveness of the device cannot be assured in any other way. By enacting section 515(d)(1)(B)(ii), Congress must be assumed to have made a policy decision that some restriction in the range of choices available to physicians is necessary to protect the public health.

FDA's authority for specific postapproval requirements is discussed in more detail in paragraphs 82 through 95 of this preamble.

82. Comments objected to proposed § 814.44(d)(2) (final § 814.82(a)(2)), which provided for FDA to require continuing or special studies of the safety or effectiveness of the device as a condition to approval. The comments said that requiring such studies would be outside the scope of FDA's authority. Comments stated that FDA had not demonstrated any need for such a requirement and that such studies should be required only for new "high technology" devices.

FDA did not intend to suggest in proposed § 814.44(d)(2) that, as a condition to premarket approval, the agency would require that new clinical studies be performed on a device after a PMA is approved. FDA intended that for certain devices a PMA applicant would be required to followup and report to FDA on a specified number of patients and devices after device approval. To make clear its intent, FDA has revised final § 814.82(a)(2) to provide that, when required by FDA in the approval order, the applicant shall continue to report on the safety, effectiveness, or reliability of a device for its intended use. The PMA approval order will state the reason or purpose for these reports and will identify the recordkeeping or reporting requirements involved. FDA may require that the reports include information on, among other things, patient demographics, safety and effectiveness data, adverse reactions and complications, patient discontinuation data, patient complaints, device failures and replacements, and statistical analyses of the data.

FDA has authority under sections 515 and 519 of the act to require that applicants conduct postapproval evaluations and submit reports of such evaluations. Under section 515 of the act, FDA has authority to require the submission of valid scientific evidence to provide reasonable assurance of a device's long-term safe and effective use. Under section 519 of the act, FDA is authorized to require the maintenance of records and the submission of reports and such information as is necessary to ensure, among other things, a device's safety and effectiveness. The primary purpose of these reports is to obtain information on the long-term safety, effectiveness, or reliability of certain devices when, for example, long-term data are unavailable when the PMA is submitted. FDA will review the information submitted by an applicant to determine whether any safety or effectiveness concerns arising during long-term use of an approved device need to be addressed. The alternative to providing for submission of postapproval reports is to deny approval of the PMA. This alternative could delay unnecessarily the benefits to be derived from a device for which FDA review of information from short-term studies or limited patient population studies has

led the agency to conclude that the information provides reasonable assurance of the device's safety and effectiveness for the short term.

FDA has found that continued evaluation and periodic postapproval reporting is necessary for other than "high technology" devices. PMA approval orders for intraocular lenses, extended wear contact lenses, artificial heart valves, pulse generators, external muscle stimulators for treatment of scoliosis, and artificial hip prostheses routinely have included, as a condition to approval, the requirement that the PMA applicant evaluate the long-term safety, effectiveness, and reliability of the device by submitting to FDA information on the device's use by a specified number of patients for a specified period of time. For these devices there was, at the time of the PMA approvals, insufficient valid scientific evidence of long-term safety, effectiveness, or reliability of the devices for their intended use.

FDA believes that requiring postapproval reporting is not unduly burdensome in light of the protection it will provide for the public health and in light of the alternative to requiring such reporting.

83. Comments objected to proposed § 814.44(d)(3) (final § 814.82(a)(3)), which provides that an approval order may require prominent display in the labeling of a device of warnings, hazards, or precautions. These comments argued that labeling is already subject to adequate control under other sections of the act and regulations.

FDA disagrees with these comments. Section 515(d) of the act provides that FDA shall deny approval of a PMA if there is a lack of showing of reasonable assurance that the device is safe or effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling, or if based upon a fair evaluation of all material facts, the proposed labeling is false or misleading in any particular. Under section 515 of the act, FDA has the authority to ensure that the labeling of a class III device is, among other things, accurate and not misleading. To achieve that objective, FDA may conclude in a given case that certain parts of a device's labeling should be displayed prominently. Although other sections of the act, and other regulations, contain provisions relating to labeling, certain class III devices present unique labeling concerns that need to be addressed individually in the approval order.

84. Comments on proposed § 814.82(a)(1) (final § 814.82(a)(3)) said that FDA is authorized to require prior approval of advertising only in extraordinary circumstances as described in section 502(r) of the act and that FDA should delete this section until a final rule for restricted devices is published.

Section 515(d)(1)(B)(ii) of the act provides that an approval order may require, as a condition to approval, that the sale and distribution of a device be restricted, but only to the extent that they may be restricted under section 520(e) of the act. FDA may designate a device as restricted if, because of the device's potential for harmful effect or the collateral measures necessary to its use, FDA determines that there cannot be reasonable assurance of the device's safety and effectiveness other than by restricting it. Section 502(q)(1) of the act provides that a restricted device is misbranded if its advertising is false or misleading in any particular. Section 502(r) of the act provides, among other things, that a restricted device is misbranded unless all advertisements for the device include (1) a true statement of the device's established name, and (2) a brief statement of the intended uses of the device and relevant warnings, precautions, side effects, and contraindications. Section 502(r) of the act further provides that, except in extraordinary circumstances, a regulation issued under section 502(r) may not require prior approval by FDA of the content of any advertisement. FDA has the authority under sections 515(d)(1)(B)(ii) and 520(e) of the act to restrict the sale or distribution of a device. FDA may regulate, in accordance with section 502 (q)(1) and (r) of the act, advertisements for devices restricted in an approval order. Therefore, FDA concludes that the comments have not provided any reasons to delete proposed § 814.82(a)(1) (final 814.82(a)(3)).

FDA has revised final § 814.82(a)(3) to clarify that the advertising restrictions apply only to restricted devices, including devices restricted under a PMA approval order. Final § 814.82(a)(3) provides that FDA may impose in the approval order a requirement that warnings, hazards, and precautions important for the safe and effective use of the device be prominently displayed on all labeling and advertising for a restricted device. As the statute provides, however, FDA will not routinely require prior approval of advertisements. Indeed, prior approval of advertisements will be required only in extraordinary circumstances, in accordance with section 502(r) of the act.

85. Comments said that FDA's authority to require patient labeling for prescription devices has not been established and that patient labeling should be the subject of a separate regulation. Several comments said that physicians should be able to withhold patient labeling when it is in the best interest of the patient to do so.

FDA's authority to require patient labeling exists under sections 201(n), 502, and 515(d)(2) (A), (B), and (D) and (e)(1)(F) of the act. FDA's authority to require patient labeling for prescription drugs has been upheld. *Pharmaceutical Manufacturer's Ass'n* v. *FDA*, 634 F.2d 106 (3d Cir. 1980). The comments did not provide any reason why patient labeling to be required by way of a PMA approval order should be the subject of a separate regulation. Because a PMA approval order will require that patient labeling be provided only when it is necessary to reasonably assure the safety and effectiveness of the device, FDA generally will not provide that the physician may withhold patient labeling but may do so in appropriate cases.

86. Several comments objected to the provision in proposed § 814.44(d)(4) (final § 814.82(a)(4)) that provides that an approval order may require that the approved device bear an identification code or, if the device is an implant, that a card with the identification code be given to the patient. These comments said that there is not any demonstrated need for such a requirement and that the provision violates section 520(j) of the act. One comment said that traceability is dealt with in the device CGMP regulations.

FDA believes that in certain cases there may be a need for an identification code to facilitate the swift distribution of information to patients or physicians or the swift recall of a device. Section 520(j) of the act provides that FDA may impose traceability requirements when necessary to assure the protection of the public health. FDA concludes that final § 814.82(a)(4) does not violate section 520(j) of the act because the agency will impose traceability requirements only when necessary to protect the public health. Contrary to the assertion in the comments, the device CGMP regulations do not contain a similar requirement for traceability.

87. Several comments objected to proposed § 814.44(d)(5) which would allow for the automatic termination of the approval of a PMA on a specified expiration date or upon occurrence of a specified event. These comments said that automatic termination violates due process and that it circumvents the procedures described in the act that must be followed when FDA proposes the withdrawal of an approval. Comments also stated that the proposed

regulation was unclear as to the devices it would cover.

FDA agrees with these comments and has deleted this provision from the final rule. If it is necessary to withdraw approval of a device, FDA will follow the procedures in § 814.45.

88. Comments on proposed § 814.82(a)(4) (final § 814.82(a)(6)) said that patient identification information is not available to the applicant and that FDA will have to obtain this information from physicians and other health professionals. Comments also said that the requirement that applicants maintain records enabling them to trace patients violates sections 519(a)(4) and 520(j) of the act because FDA has failed to establish that the requirement "is necessary to assure the protection of the public health." Comments suggested that direct contact with a patient should not be permitted without consultation with the physician and pointed out that section 519 of the act requires "due regard for the professional ethics of the medical profession and the interests of patients."

Section 519(a)(4) of the act provides that FDA may not require that the identity of a patient be disclosed in records, reports, or information unless required for the medical welfare of an individual, to determine the safety or effectiveness of a device, or to verify a record, report, or information submitted under the act. Section 520(j) of the act provides that FDA may not impose requirements for the traceability of a device unless the requirements are necessary to assure the protection of the public health. As discussed in paragraph 86 of this preamble, FDA may impose in the approval order a requirement that the manufacturer place an identification code on the device or on a card given to patients. Such a system would enable a patient to determine whether his or her device was involved in, for example, a recall. At times, however, this system may not be sufficient, and information on the patient's identity may be necessary to protect the health of the individual patient. FDA will describe more specifically in the individual approval order for the particular device the public health reasons for requiring patient identification information. FDA has revised § 814.82(a)(5) in the final rule to make clear that the agency will impose the requirement of identification of individual patients only in accordance with the criteria of section 519(a)(4) of the act. FDA generally will notify patients through their physicians whenever patient notification is necessary. In cases where a device presents a serious threat to health, e.g., when a notification under section 518(a) of the act (21 U.S.C. 360h(a)), is required, it may be necessary for FDA to notify the patient directly to eliminate or reduce the risk to health. Decisions concerning direct patient notification can only be made on a case-by-case basis. In making decisions on notification directly to patients, FDA will maintain due regard for the professional ethics of the medical profession and the interest of patients.

89. Comments on proposed § 814.82(a) (final § 814.82(a)(6)) said that the proposal violates section 519 of the act because FDA failed to state the reason or purpose for the recordkeeping requirements. Comments also stated that the proposed requirements are unduly burdensome because FDA may impose a recordkeeping format incompatible with existing formats used by the manufacturer, e.g., a particular computer software system. The comments argued that the public interest would be better served if manufacturers were permitted to design their own methods for organizing and indexing files. Comments also said that the relationship between proposed § 814.82(a) and the device CGMP recordkeeping requirements is unclear.

FDA disagrees in part and agrees in part with the comments. FDA believes that requiring manufacturers to record and maintain records of safety and effectiveness data for a class III device falls within the agency's authority under sections 515 and 519 of the act. FDA will impose a recordkeeping requirement in the approval order when the requirement, for example, records of postapproval studies or specific batch testing requirements and information concerning experience with the use of the device, is necessary to provide reasonable assurance of the continued safety and effectiveness of the device. When FDA imposes a recordkeeping requirement in an approval order, the agency will describe the specific reason for or purpose of the requirement and the specific records to be kept. FDA agrees that applicants should be permitted to devise their own recordkeeping formats, indexing, and organization systems so long as the records are "accessible" to FDA employees for copying and verification under § 814.82(b) of the final rule. Such requirements are in addition to CGMP recordkeeping requirements and will be imposed only when CGMP requirements are not adequate to enable FDA to determine whether there is reasonable assurance of the safety and effectiveness of the device.

90. Several comments objected to the provision in proposed § 814.44(d)(6) (final § 814.82(a)(8)) that provides that FDA may impose a postapproval requirement of batch testing. These comments said that batch testing is authorized only for devices subject to a standard under section 514(a)(2)(B)(ii) of the act. One comment said that batch testing is covered by the device CGMP regulations.

FDA disagrees with these comments. Although section 514(a)(2)(B)(ii) of the act provides that batch testing may be included as a provision of a performance standard, this section does not limit FDA's authority to require batch testing as a postapproval requirement under section 515 of the act. FDA may require such testing as a postapproval requirement when necessary to provide reasonable assurance that the device, including its components, will continue to meet the specifications submitted in the PMA and on the basis of which the PMA was approved. Under § 820.160 of the CGMP regulations, testing of a production run, lot, or batch is required "where practical." The PMA approval order, however, may establish more specific batch testing requirements for the device than the general requirements in the CGMP regulations.

91. Comments on proposed § 814.82(a)(3) (final § 814.82(a)(7)) said that the proposed requirement would violate section 519 of the act because FDA failed to state the reason or purpose for requiring periodic reporting and, further, that requests for periodic reports should be supported with reasons why the reports are necessary. Comments further stated that periodic reporting should be limited to annual reporting.

FDA believes that periodic reporting of the kind of information described in § 814.84(b) of the final rule is necessary to monitor the safety and effectiveness of a device. Initial approval of a PMA is based on information of the type required by § 814.84(b) to be provided in periodic postapproval reports. FDA needs to know of any change in this information to determine whether there continues to be reasonable assurance of safety and effectiveness. Final § 814.82(a)(7) is consistent with section 519 of the act and FDA's responsibilities under section 515(e) of the act concerning withdrawal of approval of a PMA. If reports or information in addition to that listed in § 814.84(b) are required, FDA will specify the reason or purpose for the submission of such reports or information and will identify to the fullest extent practical such report

or information. The frequency of periodic reports will be decided on a case-by-case basis depending on many factors such as the risk to health associated with the device, the extent of past experience with the device, and the population that will use the device.

92. Comments on proposed § 814.82(a)(5) (final § 814.82(a)(9)) argued that the section is vague and overly broad and that it is arbitrary to imply that any information may be required by FDA at its will or option. One comment suggested that FDA modify proposed § 814.82(a)(5) to read "such other requirements as FDA may impose as a result of new evidence or factual information related to the safety or efficacy of an approved medical device." Comments also said that the imposition of postapproval requirements must have the concurrence of the advisory committee.

FDA agrees in part with these comments and has revised final § 814.82(a)(9) to provide that FDA will impose only such requirements as are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of a device. FDA has not adopted the wording suggested by the comment because the comment appears to assume that FDA will impose these requirements in an additional or subsequent order after the approval order issues. As discussed in paragraph 93 of this preamble, after an approval order issues, FDA will impose additional requirements only through notice and comment rulemaking. Section 515 of the act does not require that an advisory committee concur with FDA's decision to impose postapproval requirements as conditions to approval for marketing of any class III device.

93. Comments on proposed § 814.82(a)(5) said that applicants should be notified if FDA plans to impose additional postapproval requirements after the agency approves a PMA. The comments said that such notice should set forth the reasons the postapproval requirements are needed and permit the applicants an opportunity to discuss the additional requirements with FDA before their imposition. The comments argued that proposed § 814.82(a)(5) constitutes a de facto withdrawal of approval without the protection of notice and comment rulemaking, and sections 515(d)(1)(B)(ii) and 520(e) of the act specify that postapproval requirements may only be imposed at the time of PMA approval or by regulation. Other comments suggested that a reasonable period of time be allowed before postapproval requirements become effective and that an opportunity for administrative review be provided.

FDA agrees with the comments and has revised § 814.82 (a) and (a)(9) in the final rule to make clear its intent to impose postapproval requirements by order or regulation at the time of approval or by regulation subsequent to approval.

94. Several comments said that proposed § 814.82(c) (final § 814.82(b)) concerning access by the agency to records and reports should apply only to restricted devices. Other comments stated that this section conflicts with section 519 of the act and is redundant of sections 520(f) and 704 of the act and the device CGMP regulations.

FDA disagrees with these comments. In proposing § 814.82(c), FDA cited its authority under section 519 as well as section 515 of the act. FDA's compliance with section 519 in imposing recordkeeping requirements is discussed in paragraph 89 of this preamble. The first sentence of section 704(a) of the act applies to all devices, and section 704(e) of the act authorizes FDA to have access to and to copy and verify records required to be kept under sections 519 and 520(g) of the act. Thus, authority under section 704 of the act is not limited to restricted devices. The only authority in section 704 of the act that is limited to restricted devices is the second sentence of section 704(a). In light of FDA's authority under these sections of the act, there is no reason to limit § 814.82(b) of this final rule to restricted devices. Although § 814.82(b), to some extent, restates FDA's authority under sections 520(f) and 704 of the act, as well as the device CGMP regulations, FDA believes that this reference will be useful to the PMA applicant and should remain in the final rule.

FDA advises that it will impose postapproval recordkeeping requirements in an approval order only when necessary to provide reasonable assurance of a device's safety and effectiveness. Further, FDA will follow the criteria of section 519 of the act in imposing these requirements. FDA will not seek access to records under § 814.82(a)(6) that are outside the scope of its authority under the act.

95. Comments on proposed § 814.82(d) (final § 814.82(c)) stated that failure to comply with a postapproval requirement is not a statutory ground for withdrawal of a PMA and that proposed § 814.82(d) therefore should be deleted.

FDA disagrees with the comments. FDA imposes postapproval requirements when necessary to provide reasonable assurance, or the continued reasonable assurance, of the safety and effectiveness of the device under the conditions of use prescribed, recommended, or suggested in the labeling of the device. Under section 515(e)(1)(B) of the act, a lack of showing of reasonable assurance of safety or effectiveness each is a ground for withdrawing a PMA. Thus, FDA may initiate withdrawal proceedings under § 814.46 when a postapproval requirement is not met.

96. Many comments objected to the provisions of proposed § 814.82(e) which would have provided that postapproval requirements imposed after approval of a PMA may be treated by an applicant as withdrawal of approval and that failure to request a hearing constitutes a waiver of the applicants' rights to review of the requirements. The comments stated that the holder of an approved PMA should not be considered to have waived all rights to administrative and judicial review because of the imposition of postapproval requirements after the approval order issues. The comments stated that § 814.82(e) was confusing as well as objectionable.

Proposed § 814.82(e) has been deleted from the final rule. The comments, accordingly, are moot.

Reports (§ 814.84)

97. Several comments suggested that proposed § 814.84(a) be deleted because 21 CFR Part 803 (medical device reporting) that FDA published in the **Federal Register** of November 18, 1980 (45 FR 76183) was not a final rule. One comment stated that a reference in these regulations to Part 803 would be unnecessary even if proposed Part 803 were made final, because it would be redundant.

Section 814.84, like the proposal, requires compliance with Part 803. In the **Federal Register** of May 27, 1983 (48 FR 24014), FDA issued a reproposed rule to require the reporting of device-related deaths and serious injuries and of device malfunctions that are likely to cause or contribute to a death or serious injury. In the preamble to the May 27, 1983 reproposal (48 FR 24021), FDA stated that the agency would consider the need for reporting of adverse device experiences for devices subject to premarket approval when the agency develops final PMA regulations.

In the interest of uniformity of reporting requirements for all medical devices, FDA is providing in § 814.84 that holders of approved PMA's shall comply with Part 803, the final rule on medical device reporting (49 FR 36326; September 14, 1984). In addition, a few

devices are subject to additional regulations requiring reporting, such as devices that emit radiation that are subject to reporting under 21 CFR 1002.20 or Part 1003. As is also noted in § 814.84 and discussed in paragraphs 92 and 93 of this preamble, special reporting requirements may be imposed by the order approving the device when necessary to assure its continued safety and effectiveness.

98. One comment said that the information required under proposed § 814.84(b) (1) and (2) has no bearing on the safety or effectiveness of the device and also that the information is available through field inspections. Several other comments noted that significant changes would be reported in PMA supplements and argued that insignificant changes need not be reported on the theory that under section 519 of the act FDA cannot require the reporting of insignificant changes.

FDA disagrees with the comments. Changes in the physical or chemical characteristics of a device or changes in the manufacturing process often affect the safety or effectiveness of the device. Submission of the periodic reports required by final § 814.84(b) (1) and (2) will enable FDA to monitor changes not required to be reported in PMA supplements. Although this information may be available through establishment inspections, inspections of manufacturers of class III devices are generally made only every 2 years. For this reason, FDA believes that more up-to-date information, and, therefore, more frequent periodic reporting, is necessary. FDA believes that the reporting of all changes in a device required to have premarket approval is within FDA's authority under sections 515 and 519 of the act. FDA has modified § 814.84(b) by replacing proposed § 814.84(b) (1) and (2) with a cross-reference to § 814.39(b) in final § 814.84(b)(1) because these sections were duplicative. Also, additional changes have been made in proposed § 814.84(b)(3) (final § 814.84(b)(2)) to conform the language to § 814.20(b)(6). The applicant will be required to submit only reports that are known to or reasonably should be known to the applicant. This change was made to establish requirements for postapproval submission of published and unpublished reports of studies involving the device consistent with requirements applicable to the device when approval first was requested (see paragraph 33 of this preamble).

99. One comment suggested that the proposed restricted device regulations published in the **Federal Register** of October 3, 1980 (45 FR 65619), or designation of a device as a critical device under § 820.3(f) of the CGMP regulations, not the PMA approval process, should govern reporting requirements. Another comment said that there is no need for any additional records or reports beyond those already required under the device CGMP regulations. One other comment said that proposed § 814.84 would violate section 519(a) of the act because no reasons are stated for requesting any reports.

FDA disagrees with these comments. Reporting requirements are needed to provide reasonable assurance of and the continued reasonable assurance of the safety and effectiveness of individual devices. Most class III devices are life-sustaining, life-supporting, or of substantial importance in preventing the impairment of health. FDA imposes reporting requirements only when necessary to obtain such reasonable assurance. FDA will describe in detail in the approval order the specific reasons or purposes for requiring a periodic report when a requirement is imposed and will identify such a report to the fullest extent practicable.

Economic Impact

100. The agency has assessed the economic impact of the final rule in accordance with Executive Order 12291 and concludes that the final rule is not a major rule under the criteria included in the Executive Order. These regulations are exempt from the requirement for a regulatory flexibility analysis because they were originally proposed prior to January 1, 1981.

FDA estimates that the costs of the requirements for premarket approval of medical devices are approximately $22 million per year. Included in this estimate are the costs of device development, clinical testing, and administrative activities associated with preparing PMA's and PMA supplements for submission to the agency. This estimate reflects costs that applicants for approval of recently approved PMA's considered to be in excess of what the applicants, in the absence of any premarket approval requirements, would have spent to satisfy themselves that the devices they sponsored were suitable for marketing. Thus, the estimate includes any costs attributable to provisions of the amendments as well as any incremental regulatory cost of the agency's implementation of the amendments. Because, for the most part, this final rule codifies current agency policies and practices respecting procedures for the premarket approval of medical devices, little, if any, of this cost is an increase over the existing burden.

This estimate is based upon a projection of 100 PMA's being submitted each year to FDA. In 1982 and 1983, an average of 84 PMA's were received annually and the agency believes that only a modest increase in this number is likely in the next few years. A detailed analysis of all PMA's submitted to the agency was used as the basis for extrapolating the cost experience data obtained from 20 applicants for approval of class III medical devices recently approved for marketing through the PMA process. Details of the analysis are discussed in a threshold assessment which is on file under Docket No. 79N-0009 for public review in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

About two-thirds of the cost estimate is attributed to increased emphasis on clinical investigations. The contacted applicants reported that to meet FDA requirements, clinical investigations are longer and involve more patients or more investigators than the applicants otherwise would regard as necessary to ensure the safety and effectiveness of the device under investigation. Providing additional data or other information to FDA during the agency review of a PMA accounts for another 12 percent of the cost estimate. Another 10 percent of the cost estimate reflects additional device development costs, e.g., in vitro tests. Other minor cost factors include the preparation of a PMA for submission, development of manufacturing and controls data, and preparation of PMA supplements.

Most applicants that supplied cost data also emphasized the lost revenues due to the delayed marketing of their devices while awaiting agency review of PMA's. The portion of these prospective revenues in excess of variable costs could indeed be perceived as a loss by an individual applicant. However, this loss will not usually be a loss to industry as a whole. The majority of recent PMA's involve devices that are largely substitutable with already marketed devices, e.g., contact lenses, contact lens accessories, and pacemakers. In these instances, most of the expected sales to a new market entrant simply replace the market share of sponsors of already marketed devices. Net industry losses could occur when a delayed device embodies real therapeutic or promotional advantages over existing products. Such products are comparatively rare, and even after allowing for marginal improvements in other products, the agency concludes

that not more than an equivalent of five such devices are approved each year. On this basis, the delays in revenues would approximate $4 million per year. Consideration of these revenue effects does not change the outcome of the threshold assessment.

Paperwork Reduction Act of 1980

101. On May 13, 1981, OMB provided its comments on the recordkeeping and periodic reporting requirements contained in the proposal. OMB stated that FDA should review and evaluate the public comments received in response to the proposed rule and "make any indicated changes to the application procedure."

As discussed throughout this preamble and particularly in paragraphs 25 through 57 and 80 through 99, FDA has carefully considered the public comments received on the proposed application procedure, including comments on the recordkeeping and periodic reporting requirements. The final rule provides that an applicant is required to provide only such information, keep only such records, and make only such reports to the agency as may be reasonably necessary to show that a class III device for which an applicant seeks premarket approval or for which an application has been approved by FDA is safe and effective for human use and otherwise to protect the public health.

In accordance with the Paperwork Reduction Act of 1980 and 5 CFR 1320.13(g) of OMB's regulations implementing the provisions of that act, FDA has submitted the final rule to OMB for approval of the collection of information requirements contained in §§ 814.15(b), 814.20, 814.39, 814.82, and 814.84 of the rule. These requirements will not be effective until FDA obtains OMB approval. In accordance with 5 CFR 1320.13(j), prior to November 19, 1986, FDA will publish in the **Federal Register** a notice of OMB's decision to approve, modify, or disapprove these requirements. Interested persons desiring to submit comments on the collection of information requirements pursuant to the Paperwork Reduction Act and its implementing regulations (5 CFR Part 1320) should direct them by September 22, 1986, to the Office of Information and Regulatory Affairs, OMB, Rm. 30002, New Executive Office Bldg., Washington, DC 20503, Attn: Desk Officer for FDA.

List of Subjects

21 CFR Part 16

Administrative practice and procedure.

21 CFR Part 814

Administrative practice and procedure, Medical devices, Premarket approval, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and the Freedom of Information Act and under authority delegated to the Commissioner of Food and Drugs, Parts 16 and 814 are amended as follows:

PART 16—REGULATORY HEARING BEFORE THE FOOD AND DRUG ADMINISTRATION

1. The authority citation for 21 CFR Part 16 is revised to read as follows:

Authority: Sec. 201 et seq., Pub. L. 717, 52 Stat. 1040 as amended (21 U.S.C. 321 et seq.); sec. 1 et seq., Pub. L. 410, 58 Stat. 682 as amended (42 U.S.C. 201 et seq.); sec. 4, Pub. L. 91–513, 84 Stat. 1241 (42 U.S.C. 257a); sec. 301 et seq., Pub. L. 91–513, 84 Stat. 1253 (21 U.S.C. 821 et seq.); sec. 409(b), Pub. L. 242, 81 Stat. 600 (21 U.S.C. 679(b)); sec. 24(b), Pub. L. 85–172, 82 Stat. 807 (21 U.S.C. 467f(b)); sec. 2 et seq., Pub. L. 91–597, 84 Stat. 1620 (21 U.S.C. 1031 et seq.); secs. 1–9, Pub. L. 625, 44 Stat. 1101–1103 as amended (21 U.S.C. 141–149); secs. 1–10, Chap. 358, 29 Stat. 604–607 as amended (21 U.S.C. 41–50); sec. 2 et seq., Pub. L. 783, 44 Stat. 1406 as amended (15 U.S.C. 401 et seq.); sec. 1 et seq., Pub. L. 89–755, 80 Stat. 1296 as amended (15 U.S.C. 1451 et seq.); 21 CFR 5.11.

2. In § 16.1 by adding in numerical sequence a new entry in paragraph (b)(2) to read as follows:

§ 16.1 Scope.

* * * * *

(b) * * *

(2) * * *

* * * * *

Section 814.46(c) relating to withdrawal of approval of a device premarket approval application.

* * * * *

3. Part 814 is added to read as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

Subpart A—General

Sec.

Subpart B—Premarket Approval Application (PMA)

Subpart C—FDA Action on a PMA

Subpart D—Administrative Review [Reserved]

Subpart E—Postapproval Requirements

Authority: Secs. 501–503, 510, 513–520, 701(a), 702, 703, 704, 705, 706, 708, and 801, 52 Stat. 1049–1058 as amended, 67 Stat. 477 as amended, 74 Stat. 399–407 as amended, 76 Stat. 794–795 as amended, 90 Stat. 540–574, 582–583 (21 U.S.C. 351, 352, 353, 360, 360c–360j, 371(a), 373, 374, 375, 379, 381); Pub. L. 90–23, 81 Stat. 54–56 as amended by 88 Stat. 1561–1565 (5 U.S.C. 552); 21 CFR 5.11.

Subpart A—General

§ 814.1 Scope.

(a) This part implements section 515 of the act by providing procedures for the premarket approval of medical devices intended for human use.

(b) References in this part to regulatory sections of the Code of Federal Regulations are to Chapter I of Title 21, unless otherwise noted.

(c) This part applies to any class III medical device, unless exempt under section 520(g) of the act, that:

(1) Was not on the market (introduced or delivered for introduction into commerce for commercial distribution) before May 28, 1976, and is not substantially equivalent to a device on the market before May 28, 1976, or to a device first marketed on, or after that date, which has been classified into class I or class II; or

(2) Is required to have an approved premarket approval application (PMA) or a declared completed product development protocol under a regulation issued under section 515(b) of the act; or

(3) Was regulated by FDA as a new drug or antibiotic drug before May 28, 1976, and therefore is governed by section 520(1) of the act.

(d) This part amends the conditions to approval for any PMA approved before the effective date of this part. Any condition to approval for an approved PMA that is inconsistent with this part is revoked. Any condition to approval for an approved PMA that is consistent with this part remains in effect.

§ 814.2 Purpose.

The purpose of this part is to establish an efficient and thorough device review process—

(a) To facilitate the approval of PMA's for devices that have been shown to be safe and effective and that otherwise meet the statutory criteria for approval; and

(b) To ensure the disapproval of PMA's for devices that have not been shown to be safe and effective or that do not otherwise meet the statutory criteria for approval. This part shall be construed in light of these objectives.

§ 814.3 Definitions.

For the purposes of this part:

(a) "Act" means the Federal Food, Drug, and Cosmetic Act (sections 201–902, 52 Stat. 1040 et seq., as amended (21 U.S.C. 321–392)).

(b) "FDA" means the Food and Drug Administration.

(c) "IDE" means an approved or considered approved investigational device exemption under section 520(g) of the act and Parts 812 and 813.

(d) "Master file" means a reference source that a person submits to FDA. A master file may contain detailed information on a specific manufacturing facility, process, methodology, or component used in the manufacture, processing, or packaging of a medical device.

(e) "PMA" means any premarket approval application for a class III medical device, including all information submitted with or incorporated by reference therein. "PMA" includes a new drug application for a device under section 520(1) of the act.

(f) "PMA amendment" means information an applicant submits to FDA to modify a pending PMA or a pending PMA supplement.

(g) "PMA supplement" means a supplemental application to an approved PMA for approval of a change or modification in a class III medical device, including all information submitted with or incorporated by reference therein.

(h) "Person" includes any individual, partnership, corporation, association, scientific or academic establishment, Government agency, or organizational unit thereof, or any other legal entity.

(i) "Statement of material fact" means a representation that tends to show that the safety or effectiveness of a device is more probable than it would be in the absence of such a representation. A false affirmation or silence or an omission that would lead a reasonable person to draw a particular conclusion as to the safety or effectiveness of a device also may be a false statement of material fact, even if the statement was not intended by the person making it to be misleading or to have any probative effect.

(j) "30-day PMA supplement" means a supplemental application to an approved PMA in accordance with § 814.39(e).

§ 814.9 Confidentiality of data and information in a premarket approval application (PMA) file.

(a) A "PMA file" includes all data and information submitted with or incorporated by reference in the PMA, any IDE incorporated into the PMA, any PMA supplement, any report under § 814.82, any master file, or any other related submission. Any record in the PMA file will be available for public disclosure in accordance with the provisions of this section and Part 20. The confidentiality of information in a color additive petition submitted as part of a PMA is governed by § 71.15.

(b) The existence of a PMA file may not be disclosed by FDA before an approval order is issued to the applicant unless it previously has been publicly disclosed or acknowledged.

(c) If the existence of a PMA file has not been publicly disclosed or acknowledged, data or information in the PMA file are not available for public disclosure.

(d) If the existence of a PMA file has been publicly disclosed or acknowledged before an order approving, or an order denying approval of the PMA is issued, data or information contained in the file are not available for public disclosure before such order issues. FDA may, however, disclose a summary of portions of the safety and effectiveness data before an approval order or an order denying approval of the PMA issues if disclosure is relevant to public consideration of a specific pending issue.

(e) Upon issuance of an order approving, or an order denying approval of any PMA, FDA will make available to the public the fact of the existence of the PMA and a detailed summary of information submitted to FDA respecting the safety and effectiveness of the device that is the subject of the PMA and that is the basis for the order.

(f) After FDA issues an order approving, or an order denying approval of any PMA, the following data and information in the PMA file are immediately available for public disclosure:

(1) All safety and effectiveness data and information previously disclosed to the public, as such disclosure is defined in § 20.81.

(2) Any protocol for a test or study unless the protocol is shown to constitute trade secret or confidential commercial or financial information under § 20.61.

(3) Any adverse reaction report, product experience report, consumer complaint, and other similar data and information, after deletion of:

(i) Any information that constitutes trade secret or confidential commercial or financial information under § 20.61; and

(ii) Any personnel, medical, and similar information disclosure of which would constitute a clearly unwarranted invasion of personal privacy under § 20.63; provided, however, that except for the information that constitutes trade secret or confidential commercial or financial information under § 20.61, FDA will disclose to a patient who requests a report all the information in the report concerning that patient.

(4) A list of components previously disclosed to the public, as such disclosure is defined in § 20.81.

(5) An assay method or other analytical method, unless it does not serve any regulatory purpose and is shown to fall within the exemption in § 20.61 for trade secret or confidential commercial or financial information.

(6) All correspondence and written summaries of oral discussions relating to the PMA file, in accordance with the provisions of §§ 20.103 and 20.104.

(g) All safety and effectiveness data and other information not previously disclosed to the public are available for public disclosure if any one of the following events occurs and the data and information do not constitute trade secret or confidential commercial or financial information under § 20.61:

(1) The PMA has been abandoned. FDA will consider a PMA abandoned if:

(i)(A) The applicant fails to respond to a request for additional information within 180 days after the date FDA issues the request or

(B) Other circumstances indicate that further work is not being undertaken with respect to it, and

(ii) The applicant fails to communicate with FDA within 7 days after the date on which FDA notifies the applicant that the PMA appears to have been abandoned.

(2) An order denying approval of the PMA has issued, and all legal appeals have been exhausted.

(3) An order withdrawing approval of the PMA has issued, and all legal appeals have been exhausted.

(4) The device has been reclassified.

(5) The device has been found to be substantially equivalent to a class I or class II device.

(6) The PMA is considered voluntarily withdrawn under § 814.44(g).

(h) The following data and information in a PMA file are not available for public disclosure unless they have been previously disclosed to the public, as such disclosure is defined in § 20.81, or they relate to a device for which a PMA has been abandoned and they no longer represent a trade secret or confidential commercial or financial information as defined in § 20.61:

(1) Manufacturing methods or processes, including quality control procedures.

(2) Production, sales, distribution, and similar data and information, except that any compilation of such data and information aggregated and prepared in a way that does not reveal data or information which are not available for public disclosure under this provision is available for public disclosure.

(3) Quantitative or semiquantitative formulas.

§ 814.15 Research conducted outside the United States.

(a) A study conducted outside the United States submitted in support of a PMA and conducted under an IDE shall comply with Part 812. A study conducted outside the United States submitted in support of a PMA and not conducted under an IDE shall comply with the provisions in paragraph (b) or (c) of this section, as applicable.

(b) *Research begun after effective date.* FDA will accept studies submitted in support of a PMA which have been conducted outside the United States and begun on or after November 19, 1986, if the data are valid and the investigator has conducted the studies in conformance with the "Declaration of Helsinki" or the laws and regulations of the country in which the research is conducted, whichever accords greater protection to the human subjects. If the standards of the country are used, the applicant shall state in detail any differences between those standards and the "Declaration of Helsinki" and explain why they offer greater protection to the human subjects.

(c) Research begun before effective date. FDA will accept studies submitted in support of a PMA which have been conducted outside the United States and begun before November 19, 1986, if FDA is satisfied that the data are scientifically valid and that the rights, safety, and welfare of human subjects have not been violated.

(d) *As sole basis for marketing approval.* A PMA based solely on foreign clinical data and otherwise meeting the criteria for approval under this part may be approved if:

(1) The foreign data are applicable to the U:S. population and U.S. medical practice;

(2) The studies have been performed by clinical investigators of recognized competence; and

(3) The data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA can validate the data through an on-site inspection or other appropriate means.

(e) *Consultation between FDA and applicants.* Applicants are encouraged to meet with FDA officials in a "presubmission" meeting when approval based solely on foreign data will be sought.

§ 814.17 Service of orders.

Orders issued under this part will be served in person by a designated officer or employee of FDA on, or by registered mail to, the applicant or the designated agent at the applicant's or designated agent's last known address in FDA's records.

§ 814.19 Product development protocol (PDP).

A class III device for which a product development protocol has been declared completed by FDA under this chapter will be considered to have an approved PMA.

Subpart B—Premarket Approval Application (PMA)

§ 814.20 Application.

(a) The applicant or an authorized representative shall sign the PMA. If the applicant does not reside or have a place of business within the United States, the PMA shall be countersigned by an authorized representative residing or maintaining a place of business in the United States and shall identify the representative's name and address.

(b) Unless the applicant justifies an omission in accordance with paragraph (d) of this section, a PMA shall include:

(1) The name and address of the applicant.

(2) A table of contents that specifies the volume and page number for each item referred to in the table. A PMA shall include separate sections on nonclinical laboratory studies and on clinical investigations involving human subjects. A PMA shall be submitted in six copies each bound in one or more numbered volumes of reasonable size. The applicant shall include information that it believes to be trade secret or confidential commercial or financial information in all copies of the PMA and identify in at least one copy the information that it believes to be trade secret or confidential commercial or financial information.

(3) A summary in sufficient detail that the reader may gain a general understanding of the data and information in the application. The summary shall contain the following information:

(i) *Indications for use.* A general description of the disease or condition the device will diagnose, treat, prevent, cure, or mitigate, including a description of the patient population for which the device is intended.

(ii) *Device description.* An explanation of how the device functions, the basic scientific concepts that form the basis for the device, and the significant physical and performance characteristics of the device. A brief description of the manufacturing process should be included if it will significantly enhance the reader's understanding of the device. The generic name of the device as well as any proprietary name or trade name should be included.

(iii) *Alternative practices and procedures.* A description of existing alternative practices or procedures for diagnosing, treating, preventing, curing, or mitigating the disease or condition for which the device is intended.

(iv) *Marketing history.* A brief description of the foreign and U.S. marketing history, if any, of the device, including a list of all countries in which the device has been marketed and a list of all countries in which the device has been withdrawn from marketing for any reason related to the safety or effectiveness of the device. The description shall include the history of the marketing of the device by the applicant and, if known, the history of the marketing of the device by any other person.

(v) *Summary of studies.* An abstract of each significant published and unpublished clinical investigation and each nonclinical laboratory study described in the PMA under paragraph (b)(6) of this section and a summary of the results of tests submitted under paragraph (b)(7) of this section. Such summary shall include a description of the objective of the study, a description of the experimental design of the study, a brief description of how the data were collected and analyzed, and a brief description of the results, whether positive, negative, or inconclusive. This section shall include the following:

(A) A summary of the nonclinical laboratory studies submitted in the application;

(B) A summary of the clinical investigations involving human subjects submitted in the application including a discussion of subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, results of statistical analyses of the clinical investigations, contraindications and precautions for use of the device, and other information from the clinical investigations as appropriate (any investigation conducted under an IDE shall be identified as such).

(vi) *Conclusions drawn from the studies.* A discussion demonstrating that the data and information in the application constitute valid scientific evidence within the meaning of § 860.7 and provide reasonable assurance that the device is safe and effective for its intended use. A concluding discussion shall present benefit and risk considerations related to the device including a discussion of any adverse effects of the device on health and any proposed additional studies or surveillance the applicant intends to conduct following approval of the PMA.

(4) A complete description of:

(i) The device, including pictorial representations;

(ii) Each of the functional components or ingredients of the device if the device consists of more than one physical component or ingredient;

(iii) The properties of the device relevant to the diagnosis, treatment, prevention, cure, or mitigation of a disease or condition;

(iv) The principles of operation of the device; and

(v) The methods used in, and the facilities and controls used for, the manufacture, processing, packing, storage, and, where appropriate, installation of the device, in sufficient detail so that a person generally familiar with current good manufacturing practice can make a knowledgeable judgment about the quality control used in the manufacture of the device.

(5) Reference to any performance standard under section 514 of the act or the Radiation Control for Health and Safety Act of 1968 (42 U.S.C. 263b et seq.) in effect or proposed at the time of the submission and to any voluntary standard that is relevant to any aspect of the safety or effectiveness of the device and that is known to or that should reasonably be known to the applicant. The applicant shall—

(i) Provide adequate information to demonstrate how the device meets, or justify any deviation from, any performance standard established under section 514 of the act or under the Radiation Control for Health and Safety Act, and

(ii) Explain any deviation from a voluntary standard.

(6) The following technical sections which shall contain data and information in sufficient detail to permit FDA to determine whether to approve or deny approval of the application:

(i) A section containing results of the nonclinical laboratory studies with the device including microbiological, toxicological, immunological, biocompatibility, stress, wear, shelf life, and other laboratory or animal tests as appropriate. Information on nonclinical laboratory studies shall include a statement that each such study was conducted in compliance with Part 58, or, if the study was not conducted in compliance with such regulations, a brief statement of the reason for the noncompliance.

(ii) A section containing results of the clinical investigations involving human subjects with the device including clinical protocols, number of investigators and subjects per investigator, subject selection and exclusion criteria, study population, study period, safety and effectiveness data, adverse reactions and complications, patient discontinuation, patient complaints, device failures and replacements, tabulations of data from all individual subject report forms and copies of such forms for each subject who died during a clinical investigation or who did not complete the investigation, results of statistical analyses of the clinical investigations, device failures and replacements, contraindications and precautions for use of the device, and any other appropriate information from the clinical investigations. Any investigation conducted under an IDE shall be identified as such. Information on clinical investigations involving human subjects shall include the following:

(A) A statement with respect to each study that it either was conducted in compliance with the institutional review board regulations in Part 56, or was not subject to the regulations under § 56.104 or § 56.105, and that it was conducted in compliance with the informed consent regulations in Part 50; or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(B) A statement that each study was conducted in compliance with Part 812 or Part 813 concerning sponsors of clinical investigations and clinical investigators, or if the study was not conducted in compliance with those regulations, a brief statement of the reason for the noncompliance.

(7) For a PMA supported solely by data from one investigation, a justification showing that data and other information from a single investigator are sufficient to demonstrate the safety and effectiveness of the device and to ensure reproducibility of test results.

(8)(i) A bibliography of all published reports not submitted under paragraph (b)(6) of this section, whether adverse or supportive, known to or that should reasonably be known to the applicant and that concern the safety or effectiveness of the device.

(ii) An identification, discussion, and analysis of any other data, information, or report relevant to an evaluation of the safety and effectiveness of the device known to or that should reasonably be known to the applicant from any source, foreign or domestic, including information derived from investigations other than those proposed in the application and from commercial marketing experience.

(iii) Copies of such published reports or unpublished information in the possession of or reasonably obtainable by the applicant if an FDA advisory committee or FDA requests.

(9) One or more samples of the device and its components, if requested by FDA. If it is impractical to submit a requested sample of the device, the applicant shall name the location at which FDA may examine and test one or more devices.

(10) Copies of all proposed labeling for the device. Such labeling may include, e.g., instructions for installation and any information, literature, or advertising that constitutes labeling under section 201(m) of the act.

(11) An environmental assessment under § 25.22(a)(18) prepared in the applicable format in § 25.31, unless the action qualifies for exclusion under § 25.24(e) (4) or (5). If the applicant believes that the action qualifies for exclusion, the PMA shall under § 25.23(c) provide information that establishes to FDA's satisfaction that the action requested is included within the excluded category and meets the criteria for the applicable exclusion.

(12) Such other information as FDA may request. If necessary, FDA will obtain the concurrence of the appropriate FDA advisory committee before requesting additional information.

(c) Pertinent information in FDA files specifically referred to by an applicant

may be incorporated into a PMA by reference. Information in a master file or other information submitted to FDA by a person other than the applicant will not be considered part of a PMA unless such reference is authorized in writing by the person who submitted the information or the master file. If a master file is not referenced within 5 years after the date that it is submitted to FDA, FDA will return the master file to the person who submitted it.

(d) If the applicant believes that certain information required under paragraph (b) of this section to be in a PMA is not applicable to the device that is the subject of the PMA, and omits any such information from its PMA, the applicant shall submit a statement that identifies the omitted information and justifies the omission. The statement shall be submitted as a separate section in the PMA and identified in the table of contents. If the justification for the omission is not accepted by the agency, FDA will so notify the applicant.

(e) The applicant shall periodically update its pending application with new safety and effectiveness information learned about the device from ongoing or completed studies that may reasonably affect an evaluation of the safety or effectiveness of the device or that may reasonably affect the statement of contraindications, warnings, precautions, and adverse reactions in the draft labeling. The update report shall be consistent with the data reporting provisions of the protocol. The applicant shall submit three copies of any update report and shall include in the report the number assigned by FDA to the PMA. These updates are considered to be amendments to the PMA. The time frame for review of a PMA will not be extended due to the submission of an update report unless the update is a major amendment under § 814.37(c)(1). The applicant shall submit these reports—

(1) 3 months after the filing date,

(2) Following receipt of an approvable letter, and

(3) At any other time as requested by FDA.

(f) If a color additive subject to section 706 of the act is used in or on the device and has not previously been listed for such use, then, in lieu of submitting a color additive petition under Part 71, at the option of the applicant, the information required to be submitted under Part 71 may be submitted as part of the PMA. When submitted as part of the PMA, the information shall be submitted in three copies each bound in one or more numbered volumes of reasonable size. A PMA for a device that contains a color additive that is subject to section 706 of the act will not be approved until the color additive is listed for use in or on the device.

(g) FDA has issued a PMA guideline to assist the applicant in the arrangement and content of a PMA. This guideline is available from the Center for Devices and Radiological Health, Office of Standards and Regulations (HFZ–80), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857.

(h) A PMA, PMA amendment, PMA supplement, or correspondence with respect to a PMA shall be sent to the PMA Document Mail Center (HFZ–401), Center for Devices and Radiological Health, Food and Drug Administration, 8757 Georgia Ave., Silver Spring, MD 20910.

§ 814.37 PMA amendments and resubmitted PMA's.

(a) An applicant may amend a pending PMA or PMA supplement to revise existing information or provide additional information.

(b) FDA may request the applicant to amend a PMA or PMA supplement with any information regarding the device that is necessary for FDA or the appropriate advisory committee to complete the review of the PMA or PMA supplement.

(c) A PMA amendment submitted to FDA shall include the PMA or PMA supplement number assigned to the original submission and, if submitted on the applicant's own initiative, the reason for submitting the amendment. FDA may extend the time required for its review of the PMA, or PMA supplement, as follows:

(1) If the applicant on its own initiative or at FDA's request submits a major PMA amendment (e.g., an amendment that contains significant new data from a previously unreported study, significant updated data from a previously reported study, detailed new analyses of previously submitted data, or significant required information previously omitted), the review period may be extended up to 180 days.

(2) If an applicant declines to submit a major amendment requested by FDA, the review period may be extended for the number of days that elapse between the date of such request and the date that FDA receives the written response declining to submit the requested amendment.

(d) An applicant may on its own initiative withdraw a PMA or PMA supplement. If FDA requests an applicant to submit a PMA amendment and a written response to FDA's request is not received within 180 days of the date of the request, FDA will consider the pending PMA or PMA supplement to be withdrawn voluntarily by the applicant.

(e) An applicant may resubmit a PMA or PMA supplement after withdrawing it or after it is considered withdrawn under paragraph (d) of this section, or after FDA has refused to accept it for filing, or has denied approval of the PMA or PMA supplement. A resubmitted PMA or PMA supplement shall comply with the requirements of § 814.20 or § 814.39, respectively, and shall include the PMA number assigned to the original submission and the applicant's reasons for resubmission of the PMA or PMA supplement.

§ 814.39 PMA supplements.

(a) After FDA approval of a PMA, an applicant shall submit a PMA supplement for review and approval by FDA before making a change affecting the safety or effectiveness of the device for which the applicant has an approved PMA, unless the change is of a type for which FDA, under paragraph (e) of this section, has advised that an alternate submission is permitted. While the burden for determining whether a supplement is required is primarily on the PMA holder, changes for which an applicant shall submit a PMA supplement include but are not limited to the following types of changes if they affect the safety or effectiveness of the device:

(1) New indications for use of the device.

(2) Labeling changes.

(3) The use of a different facility or establishment to manufacture, process, or package the device.

(4) Changes in manufacturing facilities, methods, or quality control procedures.

(5) Changes in sterilization procedures.

(6) Changes in packaging.

(7) Changes in the performance or design specifications, circuits, components, ingredients, principle of operation, or physical layout of the device.

(8) Extension of the expiration date of the device based on data obtained under a new or revised stability or sterility testing protocol that has not been approved by FDA. If the protocol has been approved, the change shall be reported to FDA under paragraph (b) of this section.

(b) An applicant may make a change in a device after FDA's approval of a PMA for the device without submitting a PMA supplement if the change does not affect the device's safety or

effectiveness and the change is reported to FDA in postapproval periodic reports required as a condition to approval of the device, e.g., an editorial change in labeling which does not affect the safety or effectiveness of the device.

(c) All procedures and actions that apply to an application under § 814.20 also apply to PMA supplements except that the information required in a supplement is limited to that needed to support the change. A summary under § 814.20(b)(3) is required for only a supplement submitted for new indications for use of the device, significant changes in the performance or design specifications, circuits, components, ingredients, principles of operation, or physical layout of the device, or when otherwise required by FDA. The applicant shall submit three copies of a PMA supplement and shall include information relevant to the proposed changes in the device. A PMA supplement shall include a separate section that identifies each change for which approval is being requested and explains the reason for each such change. The applicant shall submit additional copies and additional information if requested by FDA. The time frames for review of, and FDA action on, a PMA supplement are the same as those provided in § 814.40 for a PMA.

(d)(1) After FDA approves a PMA, any change described in paragraph (d)(2) of this section that enhances the safety of the device or the safety in the use of the device may be placed into effect by the applicant prior to the receipt under § 814.17 of a written FDA order approving the PMA supplement provided that:

(i) The PMA supplement and its mailing cover are plainly marked "Special PMA Supplement—Changes Being Effected";

(ii) The PMA supplement provides a full explanation of the basis for the changes;

(iii) The applicant has received acknowledgement from FDA of receipt of the supplement; and

(iv) The PMA supplement specifically identifies the date that such changes are being effected.

(2) The following changes are permitted by paragraph (d)(1) of this section:

(i) Labeling changes that add or strengthen a contraindication, warning, precaution, or information about an adverse reaction.

(ii) Labeling changes that add or strengthen an instruction that is intended to enhance the safe use of the device.

(iii) Labeling changes that delete misleading, false, or unsupported indications.

(iv) Changes in quality controls or manufacturing process that add a new specification or test method, or otherwise provide additional assurance of purity, identity, strength, or reliability of the device.

(e) FDA will identify a change to a device for which an applicant has an approved PMA and for which a PMA supplement under paragraph (a) is not required. FDA will identify such a change in an advisory opinion under § 10.85, if the change applies to a generic type of device, or in correspondence to the applicant, if the change applies only to the applicant's device. FDA will require that a change for which a PMA supplement under paragraph (a) is not required be reported to FDA in—

(1) A periodic report under § 814.84 or

(2) A 30-day PMA supplement under this paragraph.

FDA will identify, in the advisory opinion or correspondence, the type of information that is to be included in the report or 30-day PMA supplement. If the change is required to be reported to FDA in a periodic report, the change may be made before it is reported to FDA. If the change is required to be reported in a 30-day PMA supplement, the change may be made 30 days after FDA files the 30-day PMA supplement unless FDA requires the PMA holder to provide additional information, informs the PMA holder that the supplement is not approvable, or disapproves the supplement. The 30-day PMA supplement shall follow the instructions in the correspondence or advisory opinion. Any 30-day PMA supplement that does not meet the requirements of the correspondence or advisory opinion will not be filed and, therefore, will not be deemed approved 30 days after receipt.

Subpart C—FDA Action on a PMA

§ 814.40 Time frames for reviewing a PMA.

Within 180 days after receipt of an application that is accepted for filing and to which the applicant does not submit a major amendment, FDA will review the PMA and, after receiving the report and recommendation of the appropriate FDA advisory committee, send the applicant an approval order under § 814.44(d), an approvable letter under § 814.44(e), a not approvable letter under § 814.44(f), or an order denying approval under § 814.45. The approvable letter and the not approvable letter will provide an opportunity for the applicant to amend or withdraw the application, or to consider the letter to be a denial of approval of the PMA under § 814.45 and to request administrative review under section 515 (d)(3) and (g) of the act.

§ 814.42 Filing a PMA.

(a) The filing of an application means that FDA has made a threshold determination that the application is sufficiently complete to permit a substantive review. Within 45 days after a PMA is received by FDA, the agency will notify the applicant whether the application has been filed.

(b) If FDA does not find that any of the reasons in paragraph (e) of this section for refusing to file the PMA applies, the agency will file the PMA and will notify the applicant in writing of the filing. The notice will include the PMA reference number and the date FDA filed the PMA. The date of filing is the date that a PMA accepted for filing was received by the agency. The 180-day period for review of a PMA starts on the date of filing.

(c) If FDA refuses to file a PMA, the agency will notify the applicant of the reasons for the refusal. This notice will identify the deficiencies in the application that prevent filing and will include the PMA reference number.

(d) If FDA refuses to file the PMA, the applicant may:

(1) Resubmit the PMA with additional information necessary to comply with the requirements of section 515(c)(1)(A)–(G) of the act and § 814.20. A resubmitted PMA shall include the PMA reference number of the original submission. If the resubmitted PMA is accepted for filing, the date of filing is the date FDA receives the resubmission;

(2) Request in writing within 10 working days of the date of receipt of the notice refusing to file the PMA, an informal conference with the Director of the Office of Device Evaluation to review FDA's decision not to file the PMA. FDA will hold the informal conference within 10 working days of its receipt of the request and will render its decision on filing within 5 working days after the informal conference. If, after the informal conference, FDA accepts the PMA for filing, the date of filing will be the date of the decision to accept the PMA for filing. If FDA does not reverse its decision not to file the PMA, the applicant may request reconsideration of the decision from the Director of the Center for Devices and Radiological Health. The Director's decision will constitute final administrative action for the purpose of judicial review.

(e) FDA may refuse to file a PMA if any of the following applies:

(1) The application is incomplete because it does not on its face contain

all the information required under section 515(c)(1) (A)–(G) of the act;

(2) The PMA does not contain each of the items required under § 814.20 and justification for omission of any item is inadequate;

(3) The applicant has a pending premarket notification under section 510(k) of the act with respect to the same device, and FDA has not determined whether the device falls within the scope of § 814.1(c).

(4) The PMA contains a false statement of material fact.

§ 814.44 Procedures for review of a PMA.

(a) FDA will begin substantive review of a PMA after the PMA is accepted for filing under § 814.42. FDA will forward the PMA, or relevant portions thereof, to each member of the appropriate FDA advisory committee for review. During the review process, FDA may communicate with the applicant as set forth under § 814.37(b), or with the advisory committee to respond to questions that may be posed by committee members or to provide additional information to the committee. FDA will maintain a record of all communications with the applicant and with the advisory committee.

(b) The advisory committee shall submit a report to FDA which includes the committee's recommendation and the basis for such recommendation on the PMA. Before submission of this report, the committee shall hold a public meeting to review the PMA in accordance with Part 14. This meeting may be held by a telephone conference under § 14.22(g). The advisory committee report and recommendation may be in the form of a meeting transcript signed by the chairperson of the committee.

(c) FDA will complete its review of the PMA and the advisory committee report and recommendation and, within the later of 180 days from the date of filing of the PMA under § 814.42 or the number of days after the date of filing as determined under § 814.37(c), issue an approval order under paragraph (d) of this section, an approvable letter under paragraph (e) of this section, a not approvable letter under paragraph (f) of this section, or an order denying approval of the application under § 814.45(a).

(d) FDA will issue to the applicant an order approving a PMA if none of the reasons in § 814.45 for denying approval of the application applies. FDA will approve an application on the basis of draft final labeling if the only deficiencies in the application concern editorial or similar minor deficiencies in the draft final labeling. Such approval will be conditioned upon the applicant incorporating the specified labeling changes exactly as directed and upon the applicant submitting to FDA a copy of the final printed labeling before marketing. FDA also will give the public notice of the order, including notice of an opportunity for any interested person to request review under section 515(d)(3) of the act. The notice of approval will be published in the **Federal Register** and will state that a detailed summary of information respecting the safety and effectiveness of the device which was the basis for the order approving the PMA, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of approval is published, data and information in the PMA file will be available for public disclosure in accordance with § 814.9.

(e) FDA will send the applicant an approvable letter if the application substantially meets the requirements of this part and the agency believes it can approve the application if specific additional information is submitted or specific conditions are agreed to by the applicant.

(1) The approvable letter will describe the information FDA requires to be provided by the applicant or the conditions the applicant is required to meet to obtain approval. For example, FDA may require, as a condition to approval:

(i) The submission of certain information identified in the approvable letter, e.g., final labeling;

(ii) An FDA inspection that finds the manufacturing facilities, methods, and controls in compliance with Part 820 and, if applicable, that verifies records pertinent to the PMA;

(iii) Restrictions imposed on the device under section 515(d)(1)(B)(ii) or 520(e) of the act;

(iv) Postapproval requirements as described in Subpart E of this part.

(2) In response to an approvable letter the applicant may:

(i) Amend the PMA as requested in the approvable letter; or

(ii) Consider the approvable letter to be a denial of approval of the PMA under § 814.45 and request administrative review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under § 10.33; or

(iii) Withdraw the PMA.

(f) FDA will send the applicant a not approvable letter if the agency believes that the application may not be approved for one or more of the reasons given in § 814.45(a). The not approvable letter will describe the deficiencies in the application, including each applicable ground for denial under section 515(d)(2) (A)–(E) of the act, and, where practical, will identify measures required to place the PMA in approvable form. In response to a not approvable letter, the applicant may:

(1) Amend the PMA as requested in the not approvable letter (such an amendment will be considered a major amendment under § 814.37(c)(1)); or

(2) Consider the not approvable letter to be a denial of approval of the PMA under § 814.45 and request administrative review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under § 10.33; or

(3) Withdraw the PMA.

(g) FDA will consider a PMA to have been withdrawn voluntarily if:

(1) The applicant fails to respond in writing to a written request for an amendment within 180 days after the date FDA issues such request;

(2) The applicant fails to respond in writing to an approvable or not approvable letter within 180 days after the date FDA issues such letter; or

(3) The applicant submits a written notice to FDA that the PMA has been withdrawn.

§ 814.45 Denial of approval of a PMA.

(a) FDA may issue an order denying approval of a PMA if the applicant fails to follow the requirements of this part or if, upon the basis of the information submitted in the PMA or any other information before the agency, FDA determines that any of the grounds for denying approval of a PMA specified in section 515(d)(2) (A)–(E) of the act applies. In addition, FDA may deny approval of a PMA for any of the following reasons:

(1) The PMA contains a false statement of material fact;

(2) The device's proposed labeling does not comply with the requirements in Part 801 or Part 809;

(3) The applicant does not permit an authorized FDA employee an opportunity to inspect at a reasonable time and in a reasonable manner the facilities, controls, and to have access to and to copy and verify all records pertinent to the application;

(4) A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations in Part 58 and no reason for the noncompliance is provided or, if it is, the differences

between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study; or

(5) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in Part 56 or informed consent regulations in Part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(b) FDA will issue any order denying approval of the PMA in accordance with § 814.17. The order will inform the applicant of the deficiencies in the PMA, including each applicable ground for denial under section 515(d)(2) of the act and the regulations under this part, and, where practical, will identify measures required to place the PMA in approvable form. The order will include a notice of an opportunity to request review under section 515(d)(3) of the act.

(c) FDA will use the criteria specified in § 860.7 to determine the safety and effectiveness of a device in deciding whether to approve or deny approval of a PMA. FDA may use information other than that submitted by the applicant in making such determination.

(d) FDA will give the public notice of an order denying approval of the PMA. The notice will be published in the **Federal Register** and will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of denial of approval is made publicly available, data and information in the PMA file will be available for public disclosure in accordance with § 814.9.

(e) FDA will issue an order denying approval of a PMA after an approvable or not approvable letter has been sent and the applicant:

(1) Submits a requested amendment but any ground for denying approval of the application under section 515(d)(2) of the act still applies; or

(2) Notifies FDA in writing that the requested amendment will not be submitted; or

(3) Petitions for review under section 515(d)(3) of the act by filing a petition in the form of a petition for reconsideration under § 10.33.

§ 814.46 Withdrawal of approval of a PMA.

(a) FDA may issue an order withdrawing approval of a PMA if, from any information available to the agency, FDA determines that:

(1) Any of the grounds under section 515(e)(1) (A)–(G) of the act applies.

(2) Any postapproval requirement imposed by the PMA approval order or by regulation has not been met.

(3) A nonclinical laboratory study that is described in the PMA and that is essential to show that the device is safe for use under the conditions prescribed, recommended, or suggested in its proposed labeling, was not conducted in compliance with the good laboratory practice regulations in Part 58 and no reason for the noncompliance is provided or, if it is, the differences between the practices used in conducting the study and the good laboratory practice regulations do not support the validity of the study.

(4) Any clinical investigation involving human subjects described in the PMA, subject to the institutional review board regulations in Part 56 or informed consent regulations in Part 50, was not conducted in compliance with those regulations such that the rights or safety of human subjects were not adequately protected.

(b)(1) FDA may seek advice on scientific matters from any appropriate FDA advisory committee in deciding whether to withdraw approval of a PMA.

(2) FDA may use information other than that submitted by the applicant in deciding whether to withdraw approval of a PMA.

(c) Before issuing an order withdrawing approval of a PMA, FDA will issue the holder of the approved application a notice of opportunity for an informal hearing under Part 16.

(d) If the applicant does not request a hearing or if after the Part 16 hearing is held the agency decides to proceed with the withdrawal, FDA will issue to the holder of the approved application an order withdrawing approval of the application. The order will be issued under § 814.17, will state each ground for withdrawing approval, and will include a notice of an opportunity for administrative review under section 515(e)(2) of the act.

(e) FDA will give the public notice of an order withdrawing approval of a PMA. The notice will be published in the **Federal Register** and will state that a detailed summary of information respecting the safety and effectiveness of the device, including information about any adverse effects of the device on health, has been placed on public display and that copies are available upon request. When a notice of withdrawal of approval is published, data and information in the PMA file will be available for public disclosure in accordance with § 814.9.

Subpart D—Administrative Review [Reserved]

Subpart E—Postapproval Requirements

§ 814.80 General.

A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.

§ 814.82 Postapproval requirements.

(a) FDA may impose postapproval requirements in a PMA approval order or by regulation at the time of approval of the PMA or by regulation subsequent to approval. Postapproval requirements may include as a condition to approval of the device:

(1) Restriction of the sale, distribution, or use of the device as provided by section 515(d)(1)(B)(ii) or 520(e) of the act.

(2) Continuing evaluation and periodic reporting on the safety, effectiveness, and reliability of the device for its intended use. FDA will state in the PMA approval order the reason or purpose for such requirement and the number of patients to be evaluated and the reports required to be submitted.

(3) Prominent display in the labeling of a device and in the advertising of any restricted device of warnings, hazards, or precautions important for the device's safe and effective use, including patient information, e.g., information provided to the patient on alternative modes of therapy and on risks and benefits associated with the use of the device.

(4) Inclusion of identification codes on the device or its labeling, or in the case of an implant, on cards given to patients if necessary to protect the public health.

(5) Maintenance of records that will enable the applicant to submit to FDA information needed to trace patients if such information is necessary to protect the public health. Under section 519(a)(4) of the act, FDA will require that the identity of any patient be disclosed in records maintained under this paragraph only to the extent required for the medical welfare of the individual, to determine the safety or effectiveness of the device, or to verify a record, report, or information submitted to the agency.

(6) Maintenance of records for specified periods of time and organization and indexing of records into identifiable files to enable FDA to determine whether there is reasonable assurance of the continued safety and effectiveness of the device.

(7) Submission to FDA at intervals specified in the approval order of

periodic reports containing the information required by § 814.84(b).

(8) Batch testing of the device.

(9) Such other requirements as FDA determines are necessary to provide reasonable assurance, or continued reasonable assurance, of the safety and effectiveness of the device.

(b) An applicant shall grant to FDA access to any records and reports required under the provisions of this part, and shall permit authorized FDA employees to copy and verify such records and reports and to inspect at a reasonable time and in a reasonable manner all manufacturing facilities to verify that the device is being manufactured, stored, labeled, and shipped under approved conditions.

(c) Failure to comply with any postapproval requirement constitutes a ground for withdrawal of approval of a PMA.

§ 814.84 Reports.

(a) The holder of an approved PMA shall comply with the requirements of Part 803 and with any other requirements applicable to the device by other regulations in this subchapter or by order approving the device.

(b) Unless FDA specifies otherwise, any periodic report shall:

(1) Identify changes described in § 814.39(a) and changes required to be reported to FDA under § 814.39(b).

(2) Contain a summary and bibliography of the following information not previously submitted as part of the PMA:

(i) Unpublished reports of data from any clinical investigations or nonclinical laboratory studies involving the device or related devices and known to or that reasonably should be known to the applicant.

(ii) Reports in the scientific literature concerning the device and known to or that reasonably should be known to the applicant. If, after reviewing the summary and bibliography, FDA concludes that the agency needs a copy of the unpublished or published reports, FDA will notify the applicant that copies of such reports shall be submitted.

Frank E. Young,

Commissioner of Food and Drugs.

Otis R. Bowen,

Secretary of Health and Human Services.

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