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# federal register

Tuesday
April 22, 1980

## Highlights

27382 **Community Development** HUD/CPD revises policies and procedures for use of reallocated block grant funds; effective 5-22-80 (Part VII of this issue)

27363 **Cost Principles for Grants** OMB revises rules covering State and local governments; (Part III of this issue)

27388 **Biomedical Sciences Program** HEW/OE issues final regulations governing the awarding of direct discretionary grants (2 documents) (Part VIII of this issue)

26947 **Iranian Nationals** Justice/INS clarifies limited conditions under which they may seek adjustment of status; effective 4-11-80

26960 **Financial Assistance Programs** HEW/SSA issues coverage and conditions of eligibility for aid to families with dependent children; effective 4-22-80

26984 **Federal Acquisition Regulations** OMB/FPPO issues notice of availability and requests comments; comments by 6-20-80

26979 **Small Cities Community Development** HUD/CPD proposes to modify rules governing the block grant program; comments by 5-22-80

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# Highlights

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27400 **Federal Contracts** Labor/Sec'y proposes revisions for Administrative Procedings enforcing labor standards; comments by 5–27–80 (Part IX of this issue)

27410 **Board of Service Contract Appeals** Labor/Sec'y proposes establishment to hear matters related to Service Contracts, contract work hours, and Safety Standards Act; comments by 5–27–80 (Part X of this issue)

26943 **Rural Development** USDA/FmHA issues regulation to provide assistance to areas impacted by increased coal, uranium production; effective 4–22–80

27426 **Food Stamps** USDA/FNS provides for certification of households containing applicants for SSI and social security benefits; effective 8–1–80

27414, 27420 **AFDC Recipients** Labor/Sec'y and HEW/HDSO amends Work Incentive Program regulations; effetive 4–22–80 (2 documents) (Parts XI and XII of this issue)

26956 **Spirits** Treasury/ATF provides temporary optional method for determining proof; effective 4–22–80

26980 **Work Study Program** HUD/CPD proposes to convert present guidelines into regulations for Fiscal Year 1980; comments by 6–20–80

27204 **Microbiology or Immunology Devices** HEW/FDA proposes general rules applicable to classification; comments by 6–23–80 (161 documents) (Part II of this issue)

26959 **Mobile Homes** VA increases maximum permissible interest rate on guaranteed loans; effective 4–16–80

27018 **Privacy Act Documents** HUD/Sec'y

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This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.
The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each month.

## DEPARTMENT OF AGRICULTURE

### Agricultural Marketing Service

### 7 CFR Part 928

[Papaya Regulation 10, Amendment 3]

### Papayas Grown in Hawaii

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

**ACTION:** Amendment to final rule.

**SUMMARY:** This amendment suspends grade and size requirements for papayas handled within the production area and for export shipments during the period April 16 through April 30, 1980. Such action recognizes the current and prospective marketing situation for Hawaiian papayas and is consistent with the composition of the crop and would be in the interest of producers and consumers.

**EFFECTIVE DATE:** April 16, 1980.

**FOR FURTHER INFORMATION CONTACT:** Malvin E. McGaha, 202–447–5975.

**SUPPLEMENTARY INFORMATION:**

Findings.

This amendment is issued under the marketing agreement and Order No. 928 (7 CFR 928), regulating the handling of papayas grown in Hawaii. The agreement and order are effective under the Agricultural Marketing Agreement Act of 1937, as amended (7 U.S.C. 601–674). The action is based upon the recommendation and information submitted by the Papaya Administrative Committee and upon other information. This action would tend to effectuate the declared policy of the act.

The committee reports heavy rains and gale force winds in the production area have reduced available supplies of papayas. Therefore, the committee has recommended suspension of grade and size requirements for papayas handled to destinations within the production area and for export shipments during the period April 16 through April 30, 1980. This action would increase supplies available to meet current demand and would permit growers to market all the papayas that are suitable for shipment. Increased supplies of papayas are anticipated at the end of the period of suspension.

It is further found that it is impracticable and contrary to the public interest to give preliminary notice, engage in public rulemaking, and postpone the effective date of this amendment until May 22, 1980 (5 U.S.C. 553) in that the time intervening between the date when information upon which this amendment is based became available and the time when this amendment must become effective in order to effectuate the declared policy of the act is insufficient; and this amendment relieves restrictions on the handling of papayas grown in Hawaii.

Further, in accordance with procedures in Executive Order 12044, the emergency nature of this amendment warrants publication without opportunity for further public comment. The amendment has not been classified significant under USDA criteria for implementing the Executive Order. An Impact Analysis is available from Malvin E. McGaha, Chief, Fruit Branch, F&V, AMS, USDA, Washington, D.C. 20250, telephone 202–447–5975.

In § 928.310 (Papaya Regulation 10; 44 FR 77134, 45 FR 18370, 23638) paragraph (a) is amended by changing "April 16" to "May 1".

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

Dated: April 16, 1980, to become effective April 16, 1980.

D. S. Kuryloski,
*Deputy Director, Fruit and Vegetable Division, Agricultural Marketing Service.*

[FR Doc. 80-12208 Filed 4-21-80; 8:45 am]
BILLING CODE 3410-02-M

### Farmers Home Administration

### 7 CFR Part 1948

### Rural Development; Energy Impacted Area Development Assistance Program

**AGENCY:** Farmers Home Administration, USDA.

**ACTION:** Final rule.

**SUMMARY:** The Farmers Home Administration (FmHA) issues final regulations to provide assistance to areas impacted by increased coal or uranium production, processing or transportation. This action is taken to clarify previously issued regulations and is a result of an administrative action.

**EFFECTIVE DATE:** April 22, 1980.

**FOR FURTHER INFORMATION CONTACT:** Paul R. Kugler, Assistant Administrator, Farmers Home Administration, USDA, Room 5449 South Building, 14th & Independence Avenue, Washington, DC 20250, Phone: (202) 447–2573.

**SUPPLEMENTARY INFORMATION:** This final action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been determined to be exempt from those requirements. Paul Kugler made this determination because the change is made as clarification only, not involving additional burden on the public and is considered to be an agency management action. The Farmers Home Administration is amending § 1948.53 (t) of Subpart B, Part 1948, Chapter XVIII, Title 7 in the Code of Federal Regulations. This amendment will serve to clarify a portion of the regulation concerning deeds and leaseholds and other forms of land acquisition. The original intent of the law was not fullfilled by the original publication of § 1948.53 (t). The agency has determined that, in granting assistance to energy impacted areas, problems with interpretation of the existing regulation have caused difficulties for grantees. It is the policy of this Department that rules relating to public property, loans, grants, benefits, or contracts shall be published for comment notwithstanding the exemption in 5 U.S.C. 553 with respect to such rules. This clarification, however, is not published for proposed rulemaking since the purpose of the change is only to clarify the language in a previously published document and is strictly administrative in nature and publication is unnecessary.

Therefore, § 1948.53 (t) is amended to read as follows:

**§ 1948.53 Definitions.**

* * * * *

(t) *Site acquisition.* Obtaining legal title to a site (or sites) or obtaining

leaseholds or other interests in land, by an instrumentality of a state or local Government, or by FmHA, for housing, public facilities, or services.

* * * * *

**ENVIRONMENTAL IMPACT STATEMENT:** This document has been reviewed in accordance with FmHA Instruction 1901–G 'Environmental Impact Statements'. 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.

(Sec. 601 Pub. L. 95–620; delegation of authority by the Sec. of Agri., 7 CFR 2.23; delegation of authority by the Asst. Sec. for Rural Development, 7 CFR 2.70)

Dated: April 17, 1980.

**James E. Thornton,**

*Associate Administrator, Farmers Home Administration.*

[FR Doc. 80–12405 Filed 4–21–80; 8:45 am]

BILLING CODE 3410–07–M

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## Food Safety and Quality Service

## 7 CFR Part 2858

## Grading and Inspection, General Specifications for Approved Plants and Standards for Grades of Dairy Products; Dry Whey

**AGENCY:** Food Safety and Quality Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This document revises the U.S. Standards for Dry Whey to include whey of higher acidity made from certain types of Italian cheese and Cottage cheese. The Whey Products Institute requested the Department to revise the dry whey standard to include all dry wheys. The revision will aid in marketing of all dry wheys derived from cheesemaking.

**EFFECTIVE DATE:** June 22, 1980.

**FOR FURTHER INFORMATION CONTACT:** Richard W. Webber, Chief, Dairy Standardization Branch, Poultry and Dairy Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250, (202) 447–7473.

**SUPPLEMENTARY INFORMATION:**

### Background

This revision expands the quality criteria for existing U.S. Standards for Dry Whey to include dry whey resulting from the manufacture of Cottage and certain type Italian cheeses which have an acidity exceeding that of "sweet-type" whey. The present standard provides quality criteria only for "sweet-type" whey resulting mainly from the manufacture of Cheddar and Swiss cheese.

Whey is the liquid portion of milk remaining after the manufacture of cheese. Dry whey is the product resulting from the removal of most of the water from liquid whey. The amount of lactic acid (acidity) in the dry whey is dependent on the type of cheese from which the whey is derived. Cheese, such as Cheddar, Swiss, and Mozzarella, produces whey of relatively low acidity—0.12 to 0.16 percent titratable acidity. Whey produced from these cheeses is termed "sweet-type" whey. Conversely, Cottage cheese produces whey of high acidity—0.35 percent titratable acidity or above—and is called "acid-type" whey. Certain types of Italian cheeses will produce wheys that fall between 0.16 and 0.35 percent titratable acidity.

The 10-year period between 1969 and 1978 showed a 58.7 percent increase in total cheese production. Italian-type cheeses, particularly Mozzarella cheese, have increased 139.3 percent. Cottage cheese showed a smaller increase of 4.5 percent during this same period.

This rapid expansion in the production of cheese and particularly in the production of Italian-type cheese has resulted in a proportionately greater increase in the volume of whey produced annually. Whey production for 1978 was approximately 35.9 billion pounds. During 1978, dry "sweet-type" whey, potentially available and eligible for USDA grading service utilizing the existing U.S. Standards for Dry Whey, equaled approximately 1,433 million pounds. Potentially available dry whey, with acidity levels greater than that for "sweet-type" whey and therefore not eligible for USDA grading service, equaled approximately 720 million pounds.

In recent years, the utilization of whey has become increasingly important to the dairy industry. Although it is not a product purchased for household consumption, whey is utilized as an ingredient in many formulated foods, and technology is being developed to utilize whey in the manufacture of many new food products.

The substantial nutritional value of dry whey as a source of calcium, potassium, zinc, high quality protein, and other minerals and vitamins, as well as its natural acidity, is increasingly sought after by the food industry as an ingredient in other foods. Dry whey also contains all of the 10 essential amino acids necessary for proper nutrition.

In addition, whey that is not utilized as either a human or an animal food product must be disposed of in an environmentally safe manner. With the advent of successively more stingent environmental antipollution standards, the cost of proper antipollution disposal systems exceeds the resources of many smaller cooperative and family-owned cheese companies. One way to minimize the volume of pollutants that must be properly disposed of and resultant antipollution costs is to increase the utilization of cheese whey.

This revision was initiated by a request from the Whey Products Institute so that all human food dry whey might have the potential benefit of the USDA voluntary grading service. The Whey Products Institute, which represents a significant segment of the fluid and dry whey industry, has requested assistance from the Department to expand the U.S. grade standards to include all types of cheese whey produced.

Under the Agricultural Marketing Act of 1946 (§§ 202, 203(c), and 203(d)), Congress has directed the Department to promote the orderly marketing of agricultural products. One way of assisting in the orderly marketing process is the establishment of grade standards (standards of quality) which provide a common language for wholesale trading, a means of measuring value, and a basis for establishing prices.

USDA grade standards for dairy products are for voluntary use and identify the ranges of quality in the various products. Quality in general refers to the usefulness, desirability, and value of a product and its marketability. When dry whey is officially graded, the regulations governing the grading services of manufactured or processed dairy products require that all graded dairy products be produced in a USDA-approved plant. These regulations also require that charges be made for the grading services to cover the costs.

### Public Comments

On October 12, 1979, the Department published a proposed rule to revise the dry whey standards. The public comment period closed with three parties submitting comments. Two of the three, the Whey Products Institute and an individual industry member, supported the proposal and submitted suggested editorial changes. All of the suggested changes were evaluated and many were accepted. The third commenter, New Zealand Milk Products, Incorporated, was neither supportive nor nonsupportive of the revision, but submitted a comment

which was not accepted because of the intent of the Agricultural Marketing Act of 1946. The specific comments made are as follows:

1. One commenter requested that we clarify the implication that the Whey Products Institute represents all of the fluid and dry whey industry. The Whey Products Institute represents approximately 65 percent of the total whey industry and includes members producing or processing whey of all acidity levels.

2. One commenter suggested that whey from Italian-type cheeses be classified as "sweet-type" whey with a slightly higher titratable acidity and be identified with a different nomenclature, such as modified sweet whey. This modification was suggested since the acidity, though higher than regular "sweet-type" whey, is achieved by the addition of acetic acid in the production of the cheese. The commenter further stated that acidity derived in this manner is not found naturally in "sweet-type" and "acid-type" whey; therefore, the use of acetic acid should be considered an additive. The Administrator has determined that the kind of acid is irrelevant for the purpose of classifying whey under this standard. The standard provides adequate differentiation between "sweet-type" whey, "acid-type" whey, and those cheese wheys with acidity levels falling in between.

The term "modified," when used in conjunction with whey, is generally recognized by the industry to represent cheese whey which has had its composition altered by processes, such as ultrafiltration, electrodailysis, gel fractionation, ion exchange, or chemical precipitation, which can remove one or more of the whey fractions. In view of this common usage, the use of the term "modified" in reference to acidity levels would be inappropriate.

The Food and Drug Administration's Standards of Identity for cheeses permit the process of direct acidification for the manufacture of some Italian-type cheese and Cottage cheese. Its use, however, is limited to a few regional marketing areas and is not widespread. It is the intent to permit all wheys derived from the legal manufacture of cheese to be eligible for grading under the revised standard.

3. One commenter suggested that the titratable acidity for dry "acid-type" whey should be a minimum of 0.40 percent on a reconstituted basis. The 0.35 percent titratable acidity minimum as stated in the revision has significant historical acceptance by the industry, the Department, the Whey Products Institute, and the Food and Drug Administration. This acidity is a minimum requirement; however, those wishing to market dry "acid-type" whey at higher acidity levels may do so.

4. One commenter suggested that the protein content should not be an optional test and should be tested according to the Kjeldahl method. The commenter stated this is necessary because of the lower protein content derived from such products as "co-precipitates" and Mozzarella cheese. The proposal very clearly states in the definition that whey is derived from the process of cheesemaking. Since "co-precipitates" are specifically identified products within the dairy industry, the whey derived from such a process would not be eligible for grading under the revised standard. The large volume of whey derived from the manufacture of Cottage and Italian-type cheeses is the primary motivating factor for the revision of the standard.

There is wide acceptance by the Food industry for wheys of all acidity levels and no indication that wheys are used solely for their protein content. Wheys are used for a variety of reasons, e.g., solubility, water binding, protein content, natural acidity, and their effects on finished product body and texture. Therefore, making the protein test optional is appropriate. Those users who wish to determine the protein content may optionally request the test to be performed. The Kjeldahl method is cited in the revision.

5. One commenter suggested that the scorched particle content should be part of the product specification rather than an optional test. The Department agrees that this test should be a grading criterion. However, with the present state of the art for this test, it cannot be successfully completed for all samples. Approximately 25 percent of the "acid-type" whey tested could not be successfully evaluated utilizing the current test procedures. Work is being conducted by the Science and Education Administration to develop a reliable test procedure. Until a reliable test can be developed, the Department maintains that the scorched particle content should remain an optional requirement.

6. One commenter made several editorial suggestions to alter terminologies used to describe the scorched particle content and physical appearance. The terminologies used are consistent with other USDA standards and are understood by the industry. However, certain editorial changes were made for clarity. To preserve consistency, the intent of the terms should remain as proposed.

7. One commenter suggested that the test methods used be the Official Methods of Analysis of the Association of Official Analytical Chemists (AOAC) or similar methods. The test methods utilized by the Department include the AOAC and the Standard Methods for Examination of Dairy Products when applicable tests have been established. Other test methods have been established by the USDA in cooperation with the dairy industry specifically to apply to U.S. grade standards. The procedures are published in a single document by the Department, titled "Methods of Laboratory Analysis," for the convenience of users and to simplify regulations. It is available from the Agency's Dairy Grading Branch.

8. One commenter recommended that the addition of the word "relative" be placed in the second sentence under § 2858.2602 Dry Whey so that it reads "It contains all constituents, except moisture, in the same *relative* proportions as in the whey." (Italics added only to indicate suggested rewording.) This change has been made and conforms to all other dry milk product grade standards.

9. One commenter recommended that the terms "sweet" and "acid" be designated as "sweet-type" and "acid-type." These changes have been made since these terms more accurately reflect terminologies currently used by the industry.

10. One commenter recommended that the optional test provisions for alkalinity of ash read as follows: *"Alkalinity of ash.* Not more than 225 ml. of 0.1 N HCl per 100 grams of 'sweet-type' whey; may exceed 225 ml. of 0.1 N HCl per 100 grams of 'acid-type' whey." It is not the Department's intention for the "Alkalinity of ash" test to be used for acid-type whey. The use of "safe and suitable pH adjusting ingredients permitted by § 2858.2601 is intended as processing aids within good manufacturing practices and not for substantial alteration of acidity levels. Therefore, the "Alkalinity of ash" optional test is appropriate only for "sweet-type" whey. The requirement for alkalinity of ash is being rewritten to clarify the Department's intent.

11. One commenter recommended that § 2858.2611 Explanation of Terms be deleted from the standard and put in a separate document. Many grade factors are determined subjectively and require written descriptions. These descriptive terms define specific quality factors and defects which determine grade. To assure uniform interpretation and use of the standards, the explanation of terms is included as a part of the standard and is subject to public comment under the rulemaking procedure. To remove these terms from the standard and place them

in a separate manual could permit changes in interpretation which would change the standard without public comment under rulemaking procedures. This is contrary to Department policy. Also, the inclusion of this section is consistent with the intent of Presidential and congressional directives to write Federal regulations so they can be understood by the average citizen. Therefore, the explanation of terms are included as a part of the standard.

12. One commenter recommended that the reference to cheesemaking be deleted from the definition of whey in order that whey produced by other processes, such as casein production, could be included. U.S. grade standards are established under the authority of the Agricultural Marketing Act of 1946 which sets forth criteria to assist in the orderly marketing of domestically produced agricultural products. There is no established casein industry operating within the United States which would require assistance through the revised Standards for Dry Whey. The definition was specifically worded so as to clearly identify that whey eligible for grading under this standard be from cheese.

*Options Considered*

The Department considered two options regarding this final rule:

1. Take no regulatory action at this time.

2. Amend the dry whey standards to allow grading of all food type wheys regardless of their acidities.

Option 2 was selected for reasons indicated herein.

In consideration of the foregoing, Subpart O—U.S. Standards for Dry Whey is revised by amending §§ 2858.2601 through 2858.2606 and by adding new §§ 2858.2607 through 2858.2611, and the Table of Contents is revised accordingly, to read as follows:

## PART 2858—GRADING AND INSPECTION, GENERAL SPECIFICATIONS FOR APPROVED PLANTS AND STANDARDS FOR GRADES OF DAIRY PRODUCTS

### Subpart O—United States Standards for Dry Whey [1]

**Definitions**

Sec.

2858.2601 Whey.
2858.2602 Dry Whey.

**U.S. Grade**

2858.2603 Nomenclature of U.S. grade.
2858.2604 Basis for determination of U.S. grade.
2858.2605 Requirements for U.S. grade.
2858.2606 Basis for acidity classification.
2858.2607 [Reserved]
2858.2608 Optional tests.
2858.2609 U.S. grade not assignable.
2858.2610 Test methods.

**Explanation of Terms**

2858.2611 Explanation of terms.

[1] Compliance with these standards does not excuse failure to comply with the provisions of the Federal Food, Drug, and Cosmetic Act.

### Subpart O—United States Standards for Dry Whey

**Definitions**

**§ 2858.2601 Whey.**

"Whey" is the fluid obtained by separating the coagulum from milk, cream, and/or skim milk in cheesemaking. The acidity of the whey may be adjusted by the addition of safe and suitable pH adjusting ingredients. Salt drippings (moisture removed from cheese curd as a result of salting) shall not be collected for further processing as whey.

**§ 2858.2602 Dry Whey.**

"Dry Whey" is the product resulting from drying fresh whey which has been pasteurized and to which nothing has been added as a preservative. It contains all constituents, except moisture, in the same relative proportions as in the whey.

**U.S. Grade**

**§ 2858.2603 Nomenclature of U.S. grade.**

The nomenclature of the U.S. grade is U.S. Extra.

**§ 2858.2604 Basis for determination of U.S. grade.**

The U.S. grade of dry whey is determined on the basis of flavor, physical appearance, bacterial estimate, coliform, milkfat content, and moisture.

**§ 2858.2605 Requirements for U.S. grade.**

(a) *U.S. Extra.* U.S. Extra Grade dry whey conforms to the following requirements:

(1) *Flavor* (applies to the reliquefied form). Shall have a normal whey flavor free from undesirable flavors, but may possess the following flavors to a slight degree: bitter, fermented, storage, and utensil; and the following to a definite degree: feed and weedy.

(2) *Physical appearance.* Has a uniform color, and is free flowing, free from lumps that do not break up under slight pressure, and is practically free from visible dark particles.

(3) *Bacterial estimate.* Not more than 50,000 per gram standard plate count.

(4) *Coliform.* Not more than 10 per gram.

(5) *Milkfat content.* Not more than 1.50 percent.

(6) *Moisture content.* Not more than 5.0 percent.

**§ 2858.2606 Basis for acidity classification.**

Acidity classification is not a U.S. grade requirement. Acidity classification will be made available only upon a U.S. graded product and the results will be shown on the grading certificate. The dry whey will be classified for acidity as follows:

(a) *Dry sweet-type whey.* Dry whey not over 0.16 percent titratable acidity on a reconstituted basis.

(b) *Dry whey ——% titratable acidity.* Dry whey over 0.16 percent, but below 0.35 percent titratable acidity on a reconstituted basis. The blank being filled with the actual acidity.

(c) *Dry acid-type whey.* Dry whey with 0.35 percent or higher titratable acidity on a reconstituted basis.

**Note:** Because of an error in printing, §§ 2858.2607 through 2858.2610 were inadvertantly omitted. They will appear in the **Federal Register** issue of April 23, 1980.

**Explanation of Terms**

**§ 2858.2611 Explanation of terms.**

(a) *With respect to flavor.*

(1) *Slight.* An attribute barely identifiable and present only to a small degree.

(2) *Definite.* An attribute readily identifiable and present to a substantial degree.

(3) *Undesirable.* Identifiable flavors in excess of the intensity permitted, or those flavors not otherwise listed.

(4) *Bitter.* Distasteful, similar to taste of quinine.

(5) *Feed.* Feed flavors such as alfalfa, sweet clover, silage, or similar feed.

(6) *Fermented.* Flavors, such as fruity or yeasty, produced through unwanted chemical changes brought about by microorganisms or their enzyme systems.

(7) *Storage.* Lacking in freshness and imparting a "rough" or "harsh" aftertaste.

(8) *Utensil.* A flavor that is suggestive of improper or inadequate washing and sterilization of utensils or factory equipment.

(9) *Weedy.* Aromatic flavor characteristic of the weeds eaten by cows carried through into the dry whey.

(b) *With respect to physical appearance.*

(1) *Slight pressure.* Only sufficient pressure to readily disintegrate the lumps.

(2) *Practically free.* Present only upon very critical examination.

(3) *Free flowing.* Capable of being poured continuously without interruption.

(4) *Lumps.* Loss of powdery consistency but not caked into hard chunks.

(5) *Uniform color.* Free from variation in shades or intensity of color.

(6) *Visible dark particles.* The presence of scorched or discolored specks capable of being seen by the eye.

(Agricultural Marketing Act of 1946; Secs. 203, 205, 60 Stat. 1087, as amended, 1090 as amended; 7 U.S.C. 1622, 1624)

This final rule has been reviewed under the USDA criteria established to implement Executive Order 12044, "Improving Government Regulations." A determination has been made that this action should not be classified "significant" under those criteria. A Final Impact Statement has been prepared and is available from Richard W. Webber, Chief, Dairy Standardization Branch, Poultry and Dairy Quality Division, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, DC 20250.

Done at Washington, DC, on: April 16, 1980.

**Donald L. Houston,**

*Administrator Food Safety and Quality Service.*

[FR Doc. 80-12140 Filed 4-21-80; 8:45 am]

BILLING CODE 3410-DM-M

## DEPARTMENT OF JUSTICE

### Immigration and Naturalization Service

### 8 CFR Part 245

### Adjustment of Status to That of Persons Admitted for Permanent Residence; Amendment To Clarify Asylum Cases

**AGENCY:** Immigration and Naturalization Service, Justice.

**ACTION:** Final rule.

**SUMMARY:** This is an additional amendment to the regulations of the Immigration and Naturalization Service dealing with limitations and restrictions imposed upon Iranian nationals. The amendment further clarifies the limited conditions under which an Iranian national may seek adjustment of status under section 245 of the Act.

**EFFECTIVE DATE:** April 11, 1980.

**FOR FURTHER INFORMATION CONTACT:**

*For general information:* Stanley J. Keiszkiel, Acting Instructions Officer, Immigration and Naturalization Service, 425 Eye Street, N.W., Washington, DC 20536. Telephone; (202) 633-3048.

*For specific information:* Andrew J. Carmichael, Jr., Acting Associate Commissioner, Examinations, Immigration and Naturalization Service, 425 Eye Street, N.W. Washington, DC 20536. Telephone; (202) 633-2982.

**SUPPLEMENTARY INFORMATION:** Because of the Iranian Government's failure to resolve the international crisis it created by the unlawful detention of American citizens in the United States Embassy in Tehran, the President of the United States announced the break in diplomatic relations with that country on April 7, 1980. Consistent with the President's proclamation, it is in the national interest to place appropriate limitations and restrictions upon those Iranian nationals who are presently in the United States as nonimmigrants. The Immigration and Naturalization Service has published amendments to its regulations to place appropriate limitations and restrictions upon Iranian nationals presently in the United States. These amendments were published in the **Federal Register** on April 16, 1980. However, we believe further amendatory language is required regarding those Iranian nationals who seek adjustment of status in asylum cases; therefore, 8 CFR 245.1(d) will be further amended to include those nonimmigrant aliens who have applied for asylum as well as those who have been granted asylum. Applicants for asylum were not included in the original amendments to the regulations.

Compliance with the provisions of 5 U.S.C. 553 as to notice of proposed rule making and delayed effective date is unnecessary because the amendment confers a benefit upon the parties affected and delay in implementing the amendment is unnecessary and contrary to the public interest.

Accordingly, the following amendment is made to Chapter I of Title 8 of the Code of Federal Regulations:

## PART 245—ADJUSTMENT OF STATUS TO THAT OF PERSONS ADMITTED FOR PERMANENT RESIDENCE

**§ 245.1 [Amended]**

8 CFR 245.1(d) is amended by deleting the last clause of the last sentence at the end of the existing subparagraph which reads, "(2) he/she has been granted asylum in the United States." and substituting in its place, "(2) he/she has applied for or has been granted asylum in the United States."

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(Secs. 103 and 245; (8 U.S.C. 1103 and 1255))

*Effective date:* This amendment is effective as of April 11, 1980.

Dated: April 17, 1980.

**David Crosland,**

*Acting Commissioner of Immigration and Naturalization.*

[FR Doc. 80-12406 Filed 4-21-80; 8:45 am]

BILLING CODE 4410-10-M

## DEPARTMENT OF AGRICULTURE

### Food Safety and Quality Service

### 9 CFR Part 309

### Ante-Mortem Inspection; DES in Cattle—Certification of Reconditioning

**AGENCY:** Food Safety and Quality Service, USDA.

**ACTION:** Final interim rule.

**SUMMARY:** On June 29, 1979, the Food and Drug Administration (FDA) withdrew the approval for, and thereby banned the manufacture, distribution, and use of, diethylstilbestrol (DES) in animal feed and implants in cattle and sheep. The ban was effective as to the use of the drug on November 1, 1979. A recent investigation by FDA revealed a widespread disregard of the ban by some feedlots. This document amends the Federal Meat Inspection regulations to require that cattle offered for slaughter from such feedlots identified by FDA be accompanied by sworn statements regarding the use of DES in those cattle, and that the statements made therein be supported by personal knowledge and records. This emergency action is necessary in order to protect the public health from animals exposed to DES.

**EFFECTIVE DATE:** April 22, 1980.

**FOR FURTHER INFORMATION CONTACT:**

Dr. W. H. Irvin, Assistant Deputy Administrator, Field Operations, Meat and Poultry Inspection Program, Food Safety and Quality Service, Room 4869, South Agriculture Building, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-3697.

**SUPPLEMENTARY INFORMATION:**

Significance

This final action has been reviewed under procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044, and has been classified as not significant. The emergency nature of this action warrants publication of this final action without completion of a Final Impact

Statement. A Final Impact Statement will be developed after public comments have been received.

**Comments and Immediate Review**

This amendment to the Federal Meat Inspection regulations is scheduled for immediate review under provisions of Executive Order 12044 and Secretary's Memorandum 1955. Such review will include the possible establishment of a date for terminating this rule or a requirement that the rule be reviewed to determine the continued need for it.

Comments concerning this amendment are presently being sought as part of the immediate review and must be received on or before May 22, 1980.

Interested persons are invited to submit written comments concerning this amendment. Comments must be sent in duplicate to the Executive Secretariat, Attn: Annie Johnson, Food Safety and Quality Service, Room 3807, South Building, U.S. Department of Agriculture, Washington, D.C. 20250. Comments should bear a reference to the date and page number of this issue of the **Federal Register** All comments made pursuant to this document will be made available for public inspection in the office of the Executive Secretariat during regular business hours.

The review will include preparation of an impact analysis statement which will be available from Dr. W. H. Irvin, Assistant Deputy Administrator, Field Operations, Meat and Poultry Inspection Program, Food Safety and Quality Service, U.S. Department of Agriculture, Washington, D.C. 20250, (202) 447-3697.

**Background**

The Food Safety and Quality Service (FSQS) and the Food and Drug Administration (FDA) are currently undertaking a number of emergency actions in response to the illegal distribution and use of diethylstilbestrol (DES) implants in cattle.

On June 29, 1979, the Commissioner of the FDA announced his decision to ban the use of DES in cattle after a lengthy administrative proceeding.[1] DES had been used to increase the rate and efficiency of weight gain for animals. The chemical had been administered to such animals in feed or in subcutaneous implants. Implanting, typically in the animal's ear, permitted the drug to be released slowly into the animal's system. FDA concluded, based upon scientific evidence, that the chemical is a carcinogen in both humans and animals. Additionally, FDA found that residues of DES were present in animals intended for human food after administration of DES in feed or subcutaneous implants on such animals.

The ban imposed by FDA prohibited the use of DES in animal feed as well as the implanting of DES pellets in animals. That FDA action became effective with respect to the manufacture and shipment of DES animal drugs on July 13, 1979, and with respect to the use of DES animal drugs and the manufacture, shipment, and use of feed containing DES on November 1, 1979.[2] A recent FDA onsite investigation has revealed, however, widespread disregard for the ban of the drug as a subcutaneous implant, with approximately 115 feedlots identified as of April 16, 1980, where DES was implanted in cattle on or after November 1, 1979.[3]

Based upon the FDA findings that DES is a carcinogen, the FDA ban on the manufacture and shipment of DES for animal drug use, and on the use of DES in cattle as a subcutaneous implant, and the FDA conclusion that DES residues are unsafe in animal tissue, FSQS has concluded that amendment of the Federal meat inspection regulations is required to protect the public health from animals implanted with DES on or after November 1, 1979. This final interim rule is a necessary emergency measure. FSQS considers animals treated with DES to have been treated with or exposed to a substance that may impart a biological residue which would make the edible tissues of the animals unfit for human food or otherwise adulterated under the Federal Meat Inspection Act (21 U.S.C. 601(m)).

This rule amending section 309.16 of the Federal meat inspection regulations (9 CFR 309.16) requires that certain steps be taken with regard to those animals suspected of having received DES.

**The Program**

FDA and FSQS are working closely together at the headquarters and regional office levels to eliminate the illegal use of DES and to require the reconditioning of animals, to which DES has been administered at feedlots, to make them fit for use as food. FDA regional offices are identifying these feedlots. Once confirmed by onsite investigation, the feedlot will be designated by FDA for control, and FSQS regional officials notified.

Once a feedlot is identified for control, FDA will communicate directly with the chief official or other person responsible for the feedlot operation (the "official").[4] The official will be notified that the feedlot has been found to have implanted cattle with DES or is suspected of having implanted cattle with DES on or after November 1, 1979. Thereafter, that official must elect to divert the adulterated animals to nonfood use, or to attempt to recondition the animals. FSQS bases its action on FDA's determinations that removal of a DES implant followed by a withdrawal period of 41 days if the animal's liver and kidneys are discarded (or 61 days if they are not) is necessary to recondition the animals to make them fit for use as food. Any distribution for food use of cattle that have received DES illegally, without reconditioning, could subject the responsible individuals or companies to the full range of legal remedies available under the Federal Food, Drug and Cosmetic Act and the Federal Meat Inspection Act.

Cattle offered for slaughter at an official establishment that have been held on or after November 1, 1979, at any FDA-identified feedlot, must be certified as specified below before they can be accepted for slaughter.

A. *Cattle That Have Not Received DES on or After November 1, 1979.* Cattle that had been held on or after November 1, 1979, at any such FDA-identified feedlot which were not implanted with DES on or after November 1, 1979, may be slaughtered if the following assurances are provided:

The official must sign a sworn statement that establishes that DES has

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[1] On June 29, 1979, the Commissioner of the FDA affirmed a prior decision of an Administrative Law Judge of that Agency that withdrew FDA's approval of the new animal drug DES (FDA Docket No. 76N-0002). In the July 6, 1979, **Federal Register**, FDA published three final rules implementing this decision. These rules provided for the:

1. Revocation of the animal drug regulations providing for the use of DES in cattle and sheep as an additive to animal feed and as a subcutaneous implant (44 FR 39387);

2. Revocation of the animal drug regulation providing for the methods of analysis approved for the detection of DES in the edible tissues of cattle and sheep treated with DES (44 FR 39388); and

3. Revocation of the new animal drug applications for the use of DES in cattle and sheep as an additive to animal feed and as a subcutaneous implant (44 FR 39618).

[2] On October 16, 1979, FSQS amended the Federal meat inspection regulations by deleting the requirement of DES certification and eliminating related constraints on the slaughter of uncertified cattle and sheep (44 FR 59498-59499). That action was necessary to reflect the order by the FDA prohibiting the manufacture, shipment, and use of animal drugs and feed containing DES. The FSQS amendment was effective on November 21, 1979.

[3] A list of these feedlots as identified by FDA may be obtained from the local regional office, Meat and Poultry Inspection Program, Food Safety and Quality Service, or from FDA district offices.

[4] If a person other than a feedlot official or person responsible at the feedlot presents for slaughter at an official establishment animals identified as suspected of having received DES on or after November 1, 1979, the obligations of officials under the regulation will apply to such person.

not been implanted in the animals in question on or after November 1, 1979. In addition, he/she must have personal knowledge and written records that establish this fact. The sworn statement must be presented to the Inspector-in-Charge of the official establishment to which the animals are brought for slaughter. Before accepting the sworn statement, the Inspector-in-Charge will verify the statement with the appropriate MPI regional office if previous verification from FDA has not been received.[5] The appropriate form for the sworn statement may be obtained from local FSQS or FDA personnel.

B. *Cattle Which Have Received DES on or After November 1, 1979.* If the official chooses to recondition, for further distribution as food, cattle which have received DES implants on or after November 1, 1979, the regulations herein require that the following conditions be met prior to slaughter:

1. All cattle implanted with DES on or after November 1, 1979, must have the implants or what remains of the implants removed. This shall be done by or under the direct supervision of a USDA accredited veterinarian who in turn must provide a sworn statement, which will be presented to FSQS, that all such cattle presented for slaughter have had this act accomplished. All DES implant sites must be surgically explored. In the event that the implant site cannot be located, the sites customarily used by that feedlot must be surgically explored. All possible traces of the DES implant are to be removed. Unless the implant or residual material from the implant is removed, reconditioning is unacceptable. If the implant site cannot be determined and there is no customary implant site to be explored, cattle identified by the feedlot's records as having been implanted on or after November 1, 1979, cannot be reconditioned under this program.

2. After the implant and/or residual material from the implant is successfully removed, each animal is to receive a serially numbered ear tag. Records are required to show the date the implant was removed and the ear tag number for that animal.

3. After removal of the implant, the animal may be slaughtered after 41 days following the removal of the implant if the liver and kidneys of the animal are discarded; or after 61 days if they are not.

In order for the cattle to be accepted for slaughter, the regulations herein require that the official execute a sworn statement, based upon his/her personal knowledge and written records, verifying that all the requirements discussed above have been accomplished for all cattle that are intended for slaughter for food purposes.[5] This statement, along with a copy of the accredited veterinarian's sworn statement, must be submitted to the Inspector-in-Charge of the official establishment to which the animals are brought for slaughter. The appropriate forms for the sworn statements may be obtained from local FSQS or FDA personnel.

## Other Actions

To assure that cattle that have received DES on or after November 1, 1979, and that have not been reconditioned are not marketed, FSQS is reinstituting its national sampling program in which animal tissues will be selected at random and tested for DES. This program had been suspended to deal more effectively with recent PCB emergencies. Further, the animal tissues and excretory product of animals from which DES implants have been removed will also be sampled by the Agency.

Accordingly, § 309.16 of the Federal meat inspection regulations (9 CFR 309.16) is revised by amending paragraph (a) by adding a phrase at the beginning thereof and adding the new paragraph (c) as follows:

**§ 309.16 Livestock suspected of having biological residues.**

(a) Except as provided by paragraph (c) below, * * *

* * * * *

(c) Cattle that have been held on or after November 1, 1979, at any feedlot identified by FDA as having, or suspected as having, implanted cattle with DES on or after November 1, 1979,[6] shall not be slaughtered in any official establishment except as provided below.

(1) *Cattle Which Have Not Received DES on or After November 1, 1979.* Cattle that have been held on or after November 1, 1979, at any FDA-identified feedlot which were not implanted with DES on or after November 1, 1979, may be slaughtered at an official establishment provided that the official[7] presenting the animals for slaughter executes and presents, to the Inspector-in-Charge of the official establishment, a sworn statement certifying, based upon his/her personal knowledge and written records, that the animals covered by the sworn statement have received no DES in any form on or after November 1, 1979.

(2) *Cattle Which Have Received DES on or After November 1, 1979.* Cattle that have been held on or after November 1, 1979, at any FDA identified feedlot that were implanted with DES on or after November 1, 1979, may be slaughtered at an official establishment provided that:

(i) The implant, or its remains, are surgically removed by or under the direct supervision of a USDA accredited veterinarian. In the event that the implant or its remains cannot be located after careful physical examination of any animal identified by the feedlot's records as having been implanted with DES on or after November 1, 1979, the holder's customary implant site or sites must be surgically removed or opened, examined, and scraped free of any implant material and contaminated tissue. If the implant site cannot be determined and there is no customary implant site to be explored, cattle identified by the feedlot's records as having been implanted on or after November 1, 1979, cannot be reconditioned under this program;

(ii) Each animal subject to paragraph (c) of this section is individually identified by a serially numbered metal ear tag;

(iii) The USDA accredited veterinarian executes a sworn statement certifying that the appropriate procedure required by paragraph (c) has been performed;

(iv) The official presenting the animal for slaughter executes and presents to the Inspector in Charge at the official establishment a sworn statement based upon his/her personal knowledge and written records. In the sworn statement, the certifying official must acknowledge that the animals covered by the statement (A) have been implanted with DES on or after November 1, 1979; (B) have been explanted (identifying the USDA accredited veterinarian performing the explanting and the date on which it occurred); and (C) have been withheld under his/her personal supervision from any additional

[5] If a person presenting animals for slaughter at an official establishment did not have custody of the animals for the entire time period for which the treatment of the animals must be verified, additional affidavits sworn by the person(s) having custody for the remainder of the appropriate period must be submitted.

[6] A list of these feedlots as identified by FDA may be obtained from the local regional office, Meat and Poultry Inspection Program, Food Safety and Quality Service, or from FDA district offices.

[7] The "official" means the chief official or other person responsible for the FDA identified feedlot's operation. If a person other than a feedlot official or person responsible at the feedlot presents for slaughter at an official establishment animals identified as suspected of having received DES at an FDA identified feedlot, the obligations of officials under the regulation will apply to such person.

implants of DES for a period of at least 41 days[8] [9] immediately prior to slaughter since explanting; and

(v) A copy of the USDA accreditied veterinarian's sworn statement is attached to the sworn statement of the official presenting the animal for slaughter.

(34 Stat. 1264, 21 U.S.C. 621 as amended by 81 Stat. 584, 588, 592, 593; 42 FR 35625, 35626, 35631)

Dr. Donald L. Houston, Administrator, Food Safety and Quality Service, has determined that an emergency situation exists which warrants the publication without opportunity for a public comment on this final action because of the necessity of prompt action to prevent the introduction of adulterated meat into food channels.

Therefore, pursuant to authority in 5 U.S.C. 553, it is found upon good cause tha notice and other public procedures with respect to this amendment at this time are impracticable and contrary to the public interest and good cause is found for making this amendment effective less than 30 days after publication of this document in the **Federal Register.**

Done at Washington, D.C., on April 16, 1980.

**Donald L. Houston,**

*Administrator, Food Safety and Quality Service.*

[FR Doc. 12382 Filed 4-21-80; 8:45 am]

BILLING CODE 3410-DM-M

## DEPARTMENT OF ENERGY

### 10 CFR Part 782

### Claims of Patent and Copyright Infringement

**AGENCY:** Department of Energy.

**ACTION:** Final rule.

**SUMMARY:** The Department of Energy is publishing a final regulation which sets forth the requirements for the filing of claims against the Department where a potential claimant believes that the Department is infringing privately owned rights in patented inventions or copyrighted works. These regulations tell potential claimants what information they must supply to the Department regarding alleged infringement before the Department will consider a claim to have been filed.

**EFFECTIVE DATE:** May 1, 1980.

**FOR FURTHER INFORMATION CONTACT:** Jack Q. Lever, Jr., Office of the Assistant General Counsel for Patents, U.S. Department of Energy, Washington, D.C. 20545 (301) 353-5093

**SUPPLEMENTARY INFORMATION:** Proposed regulation relating to claims of patent and copyright infringement (10 CFR 782) filed against DOE were published at (44 FR 40521, July 11, 1979). No written comments were received by the deadline of August 15, 1979. The proposed regulations are therefore being issued as a final rule.

Section 651 of the Department of Energy Organization Act (42 U.S.C. 7261) authorizes the Secretary of Energy to acquire releases before suit is brought for past infringement of patents or copyrights by the Department of Energy. In addition to that settlement authority, the head of the Department has authority to settle claims of patent and copyright infringement pursuant to 42 U.S.C. 2223; 22 U.S.C. 2356; 35 U.S.C. 183; and 28 U.S.C. 1498(b).

The Department is issuing regulations setting forth requirements for the filing of claims against DOE where a potential claimant belives DOE is infringing privately-owned rights in patented inventions or copyrighted works. The regulations are designed to tell potential claimants what information they must supply to DOE regarding alleged infringement before the Department will consider a claim to have been filed. The regulations identify certain commonly received communications that are concerned with rights in patents and copyrights but that will not be considered sufficient to constitute the formal filing of a claim.

The requirements for filing of an administrative claim are important because filing a claim carries with it rights relating to the statute of limitations for filing suit against the Government. In the case of patent infringement claims, Title 35 United States Code § 286 provides that, in the case of claims against the Government, the six year statute of limitations for filing suits for patent infringement may be tolled up to six years between the date of receipt of a written claim for compensation by the Government and the date of mailing by the Government of a notice that the claim has been denied. Copyright infringement claims can be tolled indefinitely under 28 U.S.C. 1498(b) between the date of receipt of a written claim for compensation and the date of mailing by the Government of a notice that the claim has been denied. The regulations set forth guidelines as to what the Department considers necessary to file a claim for patent or copyright infringement.

(Department of Energy Organization Act; Section 651, 91 Stat. 601, 42 U.S.C. 7261; Atomic Energy Act of 1954; Section 107(d), 88 Stat. 1241, 42 U.S.C. 5817(d); Section 161(g), 80 Stat. 443, 42 U.S.C. 2201(g); Section 172, 62 Stat. 933, 42 U.S.C. 2223; Foreign Assistance Act of 1961, Section 2356, 75 Stat. 440, 22 U.S.C. 2356; Patents, Invention Secrecy Act; Section 183, 66 Stat. 4, 35 U.S.C. 183; Judiciary and Judicial Procedure Act, Section 1498, 62 Stat. 601, 28 U.S.C. 1498)

In consideration of the foregoing, the Department of Energy hereby establishes a new Part 782 of Title 10 of the Code of Federal Regulations, as set forth below.

Issued in Washington, D.C., April 5, 1980.

**Lynn R. Coleman,**

*General Counsel, U.S. Department of Energy.*

Part 782 is added to read as set forth below:

## PART 782—CLAIMS FOR PATENT AND COPYRIGHT INFRINGEMENT

### Subpart A—General

Sec.

782.1 Purpose.
782.2 Objectives.
782.3 Authority.

### Subpart B—Requirements and Procedures

782.5 Contents of communication initiating claim.
782.6 Processing of administrative claims.
782.7 Incomplete notice of infringement.
782.8 Indirect notice of infringement.

**Authority:** Department of Energy Organization Act; Section 651, 91 Stat. 601, 42 U.S.C. 7261; Atomic Energy Act of 1954; Section 107(d), 88 Stat. 1241, 42 U.S.C. 5817(d); Section 161(g), 80 Stat. 443, 42 U.S.C. 2201(g); Section 172, 62 Stat. 933, 42 U.S.C. 2223; Foreign Assistance Act of 1961, Section 2356, 75 Stat. 440, 22 U.S.C. 2356; Patents, Invention Secrecy Act; Section 183, 66 Stat. 4, 35 U.S.C. 183; Judiciary and Judical Procedure Act, Section 1498, 62 Stat. 601, 28 U.S.C. 1498.

### Subpart A—General

#### § 782.1 Purpose.

The purpose of this regulation is to set forth policies and procedures for the filing and disposition of claims asserted against the Department of Energy of infringement of privately owned rights in patented inventions or copyrighted works.

#### § 782.2 Objectives.

Whenever a claim of infringement of privately owned rights in patented inventions or copyrighted works is asserted against the Department of Energy, all necessary steps shall be taken to investigate and to settle administratively, to deny, or otherwise

[8] Except for the liver and kidneys, all parts of the cattle that have been withheld from DES implants for at least 41 days prior to slaughter may be used for food. If the liver and kidneys are also to be used for food, the animals must be withheld from DES implants for at least 61 days immediately prior to slaughter.

[9] If a person presenting animals for slaughter at an official establishment did not have custody of the animals for the entire time period for which the treatment of the animals must be verified, additional affidavits sworn by the person(s) having custody for the remainder of the appropriate period must be submitted.

to dispose of such claim prior to suit against the United States.

**§ 782.3 Authority.**

The General Counsel or the General Counsel's delegate is authorized to investigate, settle, deny, or otherwise dispose of all claims of patent and copyright infringement pursuant to 42 U.S.C. §§ 2201(g), 2223, 5817(d) and 7261; the Foreign Assistance Act of 1961, 22 U.S.C. § 2356 (formerly the Mutual Security Acts of 1951 and 1954); the Invention Secrecy Act, 35 U.S.C. § 183; and 28 U.S.C. § 1498.

## Subpart B—Requirements and Procedures

**§ 782.5 Contents of communication initiating claim.**

(a) *Requirements for Claim.* A patent or copyright infringement claim for compensation, asserted against the United States as represented by the Department of Energy under any of the applicable statutes cited in § 782.3, must be actually communicated to and received by an agency, organization, office, or field establishment within the Department of Energy. Claims must be in writing and must include the following:

(1) An allegation of infringement;

(2) A request, either expressed or implied, for compensation;

(3) A citation of the patents or copyrighted items alleged to be infringed;

(4) In the case of a patent infringement claim, a sufficiently specific designation to permit identification of the items or processes alleged to infringe the patents, giving the commercial designation if known to the claimant, or, in the case of a copyright infringement claim, the acts alleged to infringe the copyright;

(5) In the case of a patent infringement claim, a designation of at least one claim of each patent alleged to be infringed or, in the case of a copyright infringement claim, a copy of each work alleged to be infringed;

(6) As an alternative to paragraphs (a)(4) and (5) of this section, certification that the claimant has made a bona fide attempt to determine the items or processes which are alleged to infringe the patents, or the acts alleged to infringe the copyrights, but was unable to do so, giving reasons, and stating a reasonable basis for the claimant's belief that the patents or copyrighted items are being infringed.

(b) *Additional Information for Patent Infringement Claims.* In addition to the information listed in paragraph (a) of this section the following material and information generally is necessary in the course of processing a claim of patent infringement. Claimants are encouraged to furnish this information at the time of filing a claim to permit rapid processing and resolution of the claim.

(1) A copy of the asserted patents and identification of all claims of the patents alleged to be infringed.

(2) Identification of all procurements known to claimant that involve the accused items or processes, including the identity of the vendors or contractors and the Government acquisition activity or activities.

(3) A detailed identification and description of the accused articles or processes, particularly where the articles or processes relate to components or subcomponents of the item acquired, and an element-by-element comparison of representative claims with the accused articles or processes. If available, the identification and description should include documentation and drawings to illustrate the accused articles or processes in sufficient detail to enable verification that the claims of the asserted patents read on the accused articles or processes.

(4) Names and addresses of all past and present licensees under the patents and copies of all license agreements and releases involving the patents.

(5) A brief description of all litigation in which the patents have been or are now involved, and their present status.

(6) A list of all persons to whom notices of infringement have been sent, including all departments and agencies of the Government, and a statement of the status or ultimate disposition of each.

(7) A description of Government employment or military service, if any, by the inventors or patent owner.

(8) A list of all contracts between the Government and inventors, patent owner, or anyone in privity with them that were in effect at the time of conception or actual reduction to practice of the inventions covered by the patents.

(9) Evidence of title to the asserted patents or other right to make the claim.

(10) If it is available to claimant, a copy of the Patent Office file of each patent.

(11) Pertinent prior art of which the claimant has become aware after issuance of the asserted patents.

In addition to the foregoing, if claimant can provide a statement that the investigation may be limited to the specifically identified accused articles or processes, or to a specific acquisition (e.g. identified contracts), it may speed disposition of the claim.

(c) *Denial for Refusal to Provide Information.* In the course of investigating a claim, it may become necessary for the Department of Energy to request information in the control and custody of claimant that is relevant to the disposition of the claim. Failure of the claimant to respond to a request for such information may be sufficient reason alone for denying a claim.

**§ 782.6 Processing of administrative claims.**

(a) *Filing and Forwarding of Claims.* All communications regarding claims should be addressed to:

General Counsel, ATTN: Assistant General Counsel for Patents, Office of the General Counsel, U.S. Department of Energy, Washington, D.C. 20545.

If any communication relating to a claim or possible claim of patent or copyright infringement is received by an agency, organization, office, or field establishment within the Department of Energy, it should be forwarded to the Assistant General Counsel for Patents.

(b) *Disposition and Notification.* The General Counsel shall investigate and administratively settle, deny, or otherwise dispose of each claim by denial or settlement. When a claim is denied, the Department shall so notify the claimant or his authorized representative and provide the claimant with the reasons for denying the claim. Disclosure of information shall be subject to applicable statutes, regulations, and directives pertaining to security, access to official records, and the rights of others.

**§ 782.7 Incomplete notice of infringement.**

(a) If a communication alleging patent or copyright infringement is received that does not meet the requirements set forth above in § 782.5, the sender shall be advised in writing by the General Counsel:

(1) That the claim for infringement has not been satisfactorily presented; and

(2) Of the elements considered necessary to establish a claim.

(b) A communication, such as a mere offer of a license, in which an infringement is not alleged in accordance with § 782.5(a) above shall not be considered a claim for infringement.

**§ 782.8 Indirect notice of infringement.**

If a patent or copyright owner communicates an allegation of infringement in the performance of a Government contract, grant, or other arrangement to addressees other than those specified in § 782.5(a), such as Department of Energy contractors including contractors operating government-owned facilities, the communication shall not be considered a claim within the meaning of § 782.5 until it meets the requirements of that section.

[FR Doc. 80-12213 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-01-M

**COMMODITY FUTURES TRADING COMMISSION**

**17 CFR Parts 145, 146 and 147**

## Assignment of FOI, Privacy and Sunshine Acts Compliance Staff; Amendment of Commission Rules Under the Freedom of Information Act, the Privacy Act and the Government in the Sunshine Act

**AGENCY:** Commodity Futures Trading Commission.

**ACTION:** Final rules.

**SUMMARY:** The Commodity Futures Trading Commission ("Commission") has determined to centralize staff responsibility for compliance with the Freedom of Information Act ("FOIA"), 5 U.S.C. 552, the Privacy Act of 1974, 5 U.S.C. 552a, and the Government in the Sunshine Act ("Sunshine Act"), 5 U.S.C. 552b. This FOI, Privacy and Sunshine Acts compliance staff will be part of the Office of the Secretariat located in the Commission's principal office in Washington, D.C. The Commission is amending its rules under the FOIA, the Privacy Act and the Sunshine Act to reflect the added responsibilities of the new compliance staff. This staff will be primarily responsible for responding to requests for access to Commission records, making certain Commission records available to the public and handling various other matters under the three statutes. The Commission is taking this action to improve the efficiency of its administration of these statutes. In addition, the Commission has determined to substitute offices and telephone numbers which the public can contact for assistance in obtaining access to available Commission records in place of the public reference facilities which heretofore have been provided for by rule. Other charges reflect the 1978 amendments to Section 8 of the Commodity Exchange Act and specify payment of fees to the Commission.

**EFFECTIVE DATE:** April 28, 1980

**FOR FURTHER INFORMATION CONTACT:** Jane K. Stuckey, Secretary of the Commission, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581, (202) 254–6126, or William E. Gressman, Special Counsel, Office of the General Counsel, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581, (202) 254–5529.

**SUPPLEMENTARY INFORMATION:** Effective April 28, 1980, the Commission will assign an FOI, Privacy and Sunshine Acts compliance staff in its Office of the Secretariat to handle requests and various other matters under the FOIA, the Privacy Act and the Sunshine Act. The Commission's rules under the foregoing statutes are contained, respectively, in Parts 145 (Commission Records and Information), 146 (Records Maintained on Individuals) and 147 (Open Commission Meetings) of Title 17 of the Code of Federal Regulations. Up to this time, FOIA and Privacy Act requests for access to Commission records have been handled by the Commission's Office of Public Information.[1] Because of the increasing volume of requests,[2] some of which are quite complex,[3] the Commission has determined to assign the new compliance staff, which with increased authority and greater responsibility under the three statutes will help assure efficient and timely administration of the FOIA, the Privacy Act and the Sunshine Act. Accordingly, Parts 145, 146 and 147 of the Commission's regulations are being amended to reflect the newly-centralized duties of the FOI, Privacy and Sunshine Acts compliance staff.

The FOI, Privacy and Sunshine Acts compliance staff will be part of the Commission's Office of the Secretariat in the Washington, D.C. headquarters. The head of the new staff will be the Assistant Secretary of the Commission for FOI, Privacy and Sunshine Acts compliance; the Deputy to the Assistant Secretary of the Commission for FOI, Privacy and Sunshine Acts compliance will be the other professional on the new staff. The primary responsibilities of the new staff will be: to respond initially to requests by members of the public under the FOIA, the Privacy Act and the Sunshine Act to inspect and copy Commission records; to make certain Commission records, recordings and transcripts available for public inspection and copying; and to make initial determinations with respect to petitions for confidential treatment. Generally, requests to inspect or copy Commission records are to be directed to the FOI, Privacy and Sunshine Acts compliance staff.[4] Inquiries concerning the nature and extent of available Commission records may be directed to the regional offices as well as the compliance staff. See § 145.7(a) and footnote 5 below. The compliance staff will also assume various other administrative responsibilities under the FOIA, the Privacy Act and the Sunshine Act, such as assistance in compiling the Commission's annual Privacy Act notice of systems of records and the annual reports of the Commission under all three statutes.

### Particular Amendments

As noted above, all FOIA and Privacy Act functions presently performed by the Commission's Office of Public Information, as well as various Sunshine Act functions, are being transferred to the FOI, Privacy and Sunshine Acts compliance staff. Thus, the Commission is amending its FOIA, Privacy Act and Sunshine Act rules in Parts 145, 146 and 147 to delete all references to Office of Public Information (except for that in § 147.4(d)(1), see footnote 1 above) and to insert in place thereof references to the new compliance staff.

Furthermore, FOIA Rule 145.7(f) presently requires the Director of the Office of Public Information to consult

[1] In addition to processing FOIA and Privacy Act requests for Commission records, the Office of Public Information ("OPI") is responsible for disseminating Commission news to the media and the general public and circulating news reports to members and staff of the Commission. All of OPI's FOIA and Privacy Act functions will be transferred to the compliance staff. This staff will also acquire certain functions under the Sunshine Act, see §§ 147.2(g), 147.5, 147.6, 147.8(a) & (b)(1) and 147.9(b), although OPI will continue to distribute and make available public calendars announcing Commission meetings pursuant to § 147.4(d)(1).

[2] In 1979, 418 FOIA requests and 4 Privacy Act requests were filed with the Commission which represents a 200% increase over the number of requests filed in 1977. Several requests for Commission transcripts and recordings under the Sunshine Act were also received.

[3] Complex requests include those for voluminous records, as well as those seeking access to sensitive Commission records, such as open investigatory records. In addition, the Commission has a procedure whereby a person submitting information to the Commission may petition for confidential treatment of it (§ 145.9). When an FOIA request is received for such information, it is necessary to decide both the petition and the request, and both the petitioner and the requester have notice and appeal rights.

[4] See FOIA Rules 145.7(a), (b) & (c) and 145.9b(b); Privacy Act Rule 146.3(a) and paragraph b. of Appendix A to Part 146 (which also permits requests for copies to be made to the Commission staff member through whom arrangements for access were made, in conjunction with the compliance staff); and Sunshine Act Rules 147.8(a) and 147.9(b).

However, requests to inspect or copy certain publicly-available records described in FOIA Rule 145.2 may be made with the new staff or in person or by telephone at the appropriate Commission regional office. See §§ 145.7(b) & (c). Likewise, oral requests for access to the publicly-available portions of registration forms may be made to the Commission's Chicago regional office where all the registration forms are maintained, see § 145.6(b), as well as to the compliance staff. See § 145.7(j)(1) for certain limitations on oral requests.

But under FOIA Rules 145.7(b) & (c), as amended, written requests to inspect or copy such publicly-available records should be directed to the FOI, Privacy and Sunshine Acts compliance staff, which will expeditiously coordinate with a particular regional office when appropriate. In order to centralize FOIA administration in the new staff, the Commission is deleting the provision in Rule 145.7(c) which currently allows written requests for certain records located in a regional office to be directed to that office. Once the new rule becomes effective, members of the public are urged to address written requests for records located in regional offices to the FOI, Privacy and Sunshine Acts compliance staff. If a request is addressed to a regional office, it will be responded to in coordination with the compliance staff. In this regard, note should be made of § 145.7(j)(2).

with the Commission's Office of the General Counsel prior to denying a request for records. The Commission is amending that provision so that the Assistant Secretary of the Commission for FOI, Privacy and Sunshine Acts compliance may, but need not, consult with the Office of the General Counsel prior to denial of an FOIA request. This amendment reflects the Commission's intent that the compliance staff, composed of trained professionals, will have the requisite expertise to handle routine initial responses to requests independently.

The Commission is amending FOIA Rule 145.2 to provide that the publicly-available records described in that rule will be available for public inspection and copying in the offices of the FOI, Privacy and Sunshine Acts compliance staff as well as at the regional offices of the Commission.

When it initially adopted its Freedom of Information Act rules in 1976 (41 FR 16288, *et seq.*), the Commission provided for public reference facilities in Rule 145.6. At that time, the Commission believed that the costs associated with these facilities would be justified in view of the anticipated public demand for them at its Washington, D.C. headquarters and various regional offices. Since then, however, the Commission has not experienced any significant public demand for public reference facilities either at its Washington headquarters or in the regional offices. In light of these considerations, the Commission has now determined to amend Rule 145.6 by deleting the provision for public reference facilities and inserting instead a provision for offices and telephone numbers that members of the public may contact for assistance in obtaining access to Commission records at the Commission's Washington headquarters as well as at each regional office.[5] The primary contact point will be the FOI, Privacy and Sunshine Act compliance staff. It is felt that this modification will properly serve the public interest as well as aid in conserving the Commission's limited resources.

In addition, the Commission is amending the wording of FOIA Rule 145.5(c) and Sunshine Act Rule 147.3(b)(3) to parallel the 1978 Congressional amendment of Section 8(a) of the Commodity Exchange Act, 7 U.S.C. § 12(a), as amended by § 16 of the Futures Trading Act of 1978, Pub. L. 95-405, 92 Stat. 873. Congress, in addition to recodifying Section 8, made explicit that "market positions" are among the particular types of business information which are generally required to be kept nonpublic.

Further amendments provide that, where applicable, checks and money orders for fees imposed under the three statutes should be made payable to the Commodity Futures Trading Commission. See FOIA Rule 145.9b(d) and Privacy Act Rule 146.5(f) and paragraph c. of Appendix A to Part 146 (§ 147.9(a) of the Commission's Sunshine Act rules incorporates the FOIA fee schedule in Rule 145.9b). Previously, the Commission's rules provided that checks and money orders should be made payable to the Treasury of the United States. These amendments merely reflect the fact that the Commission is now to be named as payee. The fees collected will continue to be deposited to the account of the United States Treasury.

The Commission finds that these amendments relate solely to agency orgnization, procedure and practice. Therefore, the provisions of the Administrative Procedure Act as codified, 5 U.S.C. 553, generally requiring notice of proposed rulemaking and other opportunity for public participation, are not applicable. In order to allow time for the FOI, Privacy and Sunshine Acts compliance staff to be assigned and for the public to adjust thereto and to the other amendments being affected, these amendments will become effective on April 28, 1980.

In consideration of the foregoing and pursuant to the authority in 5 U.S.C. 552, 5 U.S.C. 552a, 5 U.S.C. 552b and Section 2(a)(11) of the Commodity Exchange Act, 7 U.S.C. 4a(j), the Commission hereby amends Parts 145, 146 and 147 of Chapter I of Title 17 of the Code of Federal Regulations as follows:

## PART 145—COMMISSION RECORDS AND INFORMATION

1. The table of sections in Part 145 is amended as follows:

Sec.
145.0 Definition.
* * * * *
§ 145.6 Commission offices to contact for assistance; registration records available at Chicago regional office.
* * * * *

2. Part 145 is amended by adding a new § 145.0 as follows:

**§ 145.0 Definition.**

For purposes of this Part 145, the term "FOI, Privacy and Sunshine Acts compliance staff" refers to the staff in the Office of the Secretariat in the Commission's principal office in Washington, D.C. who are assigned to respond to requests and handle various other matters under the Freedom of Information Act, the Privacy Act of 1974 and the Government in the Sunshine Act.

3. Part 145 is amended by deleting the words "Office of Public Information" wherever they appear and inserting the words "FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat" in their place, by deleting the words "Director of the Office of Public Information" wherever they appear and inserting the words "Assistant Secretary of the Commission for FOI, Privacy and Sunshine Acts compliance" in their place, and by deleting the word "Director" wherever it appears and inserting the words "Assistant Secretary of the Commission" in its place.

4. In § 145.2, the introductory paragraph is amended to read as follows:

**§ 145.2 Records available for public inspection and copying; documents published and indexed.**

Except as provided in § 145.5, pertaining to nonpublic matters, the following materials shall be available for public inspection and copying during normal business hours at the offices of the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, located in the principal office of the Commission in Washington, D.C. and at the regional offices of the Commission:

* * * * *

5. In § 145.5, paragraph (c) is amended to read as follows:

**§ 145.5 Nonpublic matters.**

* * * * *

(c) Specifically exempted from disclosure by statute, including data and information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers that have been obtained by the Commission in an investigation conducted pursuant to section 8 or section 16 of the Commodity Exchange Act, as amended, 7 U.S.C. 12 and 20, for the efficient execution of the provisions of the Act or in order to provide information for the use of Congress;

* * * * *

6. § 145.6 is amended to read as follows:

**§ 145.6 Commission offices to contact for assistance; registration records available at Chicago regional office.**

(a) Whenever this Part 145 directs that

[5] Persons inquiring as to the nature or extent of available Commission records (see § 145.7(a)) may do so by contacting in person or by telephone the regional offices listed in § 145.6(a) or by making an inquiry in person, by telephone or by mail directed to the FOI, Privacy and Sunshine Acts compliance staff. In amending Rule 145.7(a), the Commission has determined to require all written inquiries to be directed to the new compliance staff. Any written inquiries directed to the regional offices will be responded to in coordination with the compliance staff.

a request be directed to the FOI, Privacy and Sunshine Acts compliance staff at the principal office of the Commission in Washington, D.C., it shall be addressed or otherwise directed to the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581. The telephone number of the compliance staff is (202) 254–6314. Whenever this Part 145 permits an inquiry or request to be directed to a regional office of the Commission (see §§ 145.2, 145.6(b) (Chicago regional office only) and 145.7 (a), (b) & (c)), it may be directed to the FOI, Privacy and Sunshine Acts compliance staff for direct response or referral or to the appropriate regional office (or Minneapolis sub-office) of the Commission at the following locations and telephone numbers:

Division of Economics and Education, Commodity Futures Trading Commission, One World Trade Center, Suite 4747, New York, New York 10048, Telephone: (212) 466–2071.

Division of Trading and Markets, Commodity Futures Trading Commission, Sears Tower, Suite 4600, 233 South Wacker Drive, Chicago, Illinois 60606, Telephone: (312) 353–9499.

Division of Trading and Markets, Commodity Futures Trading Commission, 510 Grain Exchange Building, Minneapolis, Minnesota 55415, Telephone: (612) 725–2025.

Division of Trading and Markets, Commodity Futures Trading Commission, 4901 Main Street, Room 208, Kansas City, Missouri 64112, Telephone: (816) 374–2994.

Division of Enforcement, Commodity Futures Trading Commission, Two Embarcadero Center, Suite 1660, San Francisco, California 94111, Telephone: (415) 556–7503.

(b) The Chicago regional office of the Commission shall have available for public inspection and copying the publicly-available portions of applications for registration as a futures commission merchant, commodity trading advisor or commodity pool operator (Form 7–R) and applications for registration as an associated person or floor broker (Form 8–R), which also serve as supplemental forms for principals and branch office managers of those filing the Form 7–R. Unless disclosure is required under the Freedom of Information Act, the supplementary attachments, if any, to items 3, 4 and 12 of Form 8–R generally will not be available for public inspection and copying. When such supplementary statements are on file or when an application for registration is subject to a petition for confidential treatment filed under § 145.9, the FOI, Privacy and Sunshine Acts compliance staff will decide any request for access in accordance with the procedures set forth in §§ 145.7 and 145.9.

7. In § 145.7, paragraphs (a), (b) and (c) and the third sentence of paragraph (f) are amended to read as follows:

**§ 145.7 Requests for Commission records and copies thereof.**

(a) *Public inquiries.* Inquiries concerning the nature and extent of available Commission records may be made in person or by telephone to the FOI, Privacy and Sunshine Acts compliance staff and the regional offices of the Commission at the addresses and telephone numbers set forth in § 145.6(a). All written inquiries shall be addressed to the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581.

(b) *Time and place of request for inspection of documents.* Requests for inspection of Commission records shall be made in person or by telephone during normal business hours to the FOI, Privacy and Sunshine Acts compliance staff located at the principal office of the Commission in Washington, D.C. or by mail addressed to the FOI, privacy and Sunshine Acts compliance staff, Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581. However, with respect to records described in §§ 145.2 and 145.6(b), requests for inspection may be made in person or by telephone during normal business hours at the appropriate regional office.

(c) *Requests for copies of records.* Requests for copies of Commission records shall be made either in person or by telephone during normal business hours to the FOI, Privacy and Sunshine Acts compliance staff located at the principal office of the Commission in Washington, D.C. or by mail addressed to the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581. However, with respect to records described in §§ 145.2 and 145.6(b), requests for copies may be made in person or by telephone during normal business hours at the appropriate regional office.

* * * * *

(f) *Initial determinations, denials.* * * * The Assistant Secretary of the Commission may consult with the Office of the General Counsel of the Commission as to any determination under this section or any other matter arising under the Freedom of Information Act and the Commission's rules thereunder.

* * * * *

8. In § 145.9b, paragraph (b) and the first sentence of paragraph (d) are amended to read as follows:

**§ 145.9b Appendix B—Schedule of fees.**

* * * * *

(b) Requests for copies of documents shall be made either in person, by telephone or by mail addressed to the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, Commodity Futures Trading Commission, 2033 K Street, N.W., Washington, D.C. 20581, except that in person or telephone requests for copies of publicly-available records described in §§ 145.2 and 145.6(b) may also be made to the appropriate regional office.

* * * * *

(d) Payment must be made by check or money order payable to the Commodity Futures Trading Commission. * * *

* * * * * *

## PART 146—RECORDS MAINTAINED ON INDIVIDUALS

9. In § 146.2, paragraph (c) is amended to read as follows:

**§ 146.2 Definitions.**

* * * * *

(c) The term "FOI, Privacy and Sunshine Acts compliance staff" refers to the staff in the Office of the Secretariat in the Commission's principal office in Washington, D.C. who are assigned to respond to requests and handle various other matters under the Freedom of Information Act, the Privacy Act of 1974 and the Government in the Sunshine Act;

* * * * *

10. Part 146 is amended by deleting the words "Privacy Unit" wherever they appear and inserting the words "FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat" in their place.

11. In § 146.5, the third sentence of paragraph (f) is amended to read as follows:

**§ 146.5 Disclosure of requested information to individuals; fee for copies of records.**

* * * * *

(f) * * * Payment should be made by check or money order payable to the Commodity Futures Trading Commission. * * *

* * * * *

12. In § 146.9, paragraph (c) is amended to read as follows:

**§ 146.9 Appeals to the Commission.**

* * * * *

(c) The petition shall be directed to
* * *
* * * * *

13. In § 146.11, the third sentence of paragraph (b) is amended to read as follows:

**§ 146.11 Public notice of records systems.**
* * * * *

(b) * * * Mail requests shall be directed to * * *

14. The first sentence of paragraph c. of Appendix A to Part 146 is amended to read as follows:

**Appendix A—Fees for Copies of Records Requested Under the Privacy Act of 1974**
* * * * *

c. Payment must be made by check or money order payable to the Commodity Futures Trading Commission * * *
* * * * *

## PART 147—OPEN COMMISSION MEETINGS

15. § 147.2 is amended by deleting the "." at the end of paragraph (f) and inserting a ";" in its place, and by adding a new paragraph (g) as follows:

**§ 147.2 Definitions.**
* * * * *

(g) The term "FOI, Privacy and Sunshine Acts compliance staff" refers to the staff in the Office of the Secretariat in the Commission's principal office in Washington, D.C. who are assigned to respond to requests and handle various other matters under the Freedom of Information Act, the Privacy Act of 1974 and the Government in the Sunshine Act.

16. In § 147.3, the second sentence of paragraph (b)(3) is amended to read as follows:

**§ 147.3 General requirement of open meetings; grounds upon which meetings may be closed.**
* * * * *

(b) * * *

(3) * * * This includes, but is not limited to, data and information that would separately disclose the business transactions or market positions of any person and trade secrets or names of customers that have been obtained by the Commission in an investigation conducted pursuant to section 8 or section 16 of the Commodity Exchange Act, as amended, 7 U.S.C. 12 and 20, for the efficient execution of the provisions of the Act or in order to provide information for the use of Congress;
* * * * *

**§§ 147.5 and 147.6 [Amended]**

17. §§ 147.5 and 147.6 are amended by deleting the words "Commission's Public Reference Room" wherever they appear and inserting the words "offices of the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat" in their place.

18. In § 147.8, paragraphs (a) and (b)(1) are amended to read as follows:

**§ 147.8 Public availability of transcripts, recordings and minutes of closed meetings.**

(a) The Commission shall make promptly available to the public, in the offices of the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, * * *

(b)(1) * * * shall be made by the Assistant Secretary of the Commission for FOI, Privacy and Sunshine Acts compliance * * *
* * * * *

19. In § 147.9, paragraph (b) is amended to read as follows:

**§ 147.9 Requests for copies of transcripts, recordings or minutes of closed meetings.**
* * * * *

(b) Requests for copies of transcripts, transcriptions of electronic recordings or sets of minutes as described in paragraph (a) of this section shall be made either in person, by telephone, or by mail addressed to the FOI, Privacy and Sunshine Acts compliance staff, Office of the Secretariat, * * *

Issued in Washington, D.C. on April 17, 1980 by the Commission.

**Jane K. Stuckey**

*Secretary of the Commission.*

[FR Doc. 80-12323 Filed 4-21-80; 8:45 am]

BILLING CODE 6351-01-M

## DEPARTMENT OF ENERGY

### Federal Energy Regulatory Commission

### 18 CFR Part 292

**[Docket No. RM79-54]**

### Small Power Production and Cogeneration Facilities, Qualifying Status

April 14, 1980.

**AGENCY:** Federal Energy Regulatory Commission, DOE.

**ACTION:** Notice denying extension of time.

**SUMMARY:** On April 7, 1980, Consolidated Edison Company of New York filed a motion for extension of time to apply for rehearing of Order No. 70, issued March 13, 1980. (45 FR 17959, March 20, 1980) The motion states that issues in Order No. 70 relate to the Staff's Notice of Finding of No Significant Impact, issued March 31, 1980, which may be appealed to the Commission within 30 days; additional time is requested to coordinate the rehearing application and possible appeal.

Because the period for applying for rehearing is a statutory deadline which may not be extended, the motion is denied.

**FOR FURTHER INFORMATION CONTACT:** Kenneth F. Plumb (202) 357-8400.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12212 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Food and Drug Administration

### 21 CFR Ch. 1

### DES in Cattle—Certification of Reconditioning; Cross Reference

**Cross Reference.** For a final interim rule developed jointly by the Department of Agriculture, Food Safety and Quality Service (FSQS) and the Food and Drug Administration, and issued by FSQS concerning the disregard of an FDA ban on the use of diethylstilbestrol (DES) as a chemical implant or in animal feed in cattle by certain FDA identified feedlots and the imposition of a requirement that such cattle, when presented for slaughter, be accompanied by sworn statements regarding the use of DES with those cattle, see FR Doc. 80-12382, published elsewhere in this issue. Refer to the Table of Contents at the front of this issue for the page number of this FSQS document.

BILLING CODE 3410-DM-M

### 21 CFR Part 522

### Implantation or Injectable Dosage Form New Animal Drugs not Subject to Certification; Triamcinolone

**AGENCY:** Food and Drug Administration.

**ACTION:** Final rule.

**SUMMARY:** This document amends the animal drug regulations for triamcinolone injection to indicate those conditions of use for which applications for approval of identical products need not include certain types of effectiveness data. These conditions of use were classified as effective as a result of a National Academy of Sciences/National Research Council (NAS/NRC), Drug Efficacy Study Group evaluation of the product. In lieu of certain effectiveness data, approval may

require submissions of bioequivalence or similar data. An earlier Federal Register publication has reflected that this product is in compliance with the conclusions of the review.

**EFFECTIVE DATE:** April 22, 1980.

**FOR FURTHER INFORMATION CONTACT:** Henry C. Hewitt, Bureau of Veterinary Medicine (HFV-110), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301-443-3430.

**SUPPLEMENTARY INFORMATION:** The NAS/NRC review of this product was published in the Federal Register of April 12, 1969 (34 FR 6447). In that document, the Academy concluded, and the Food and Drug Administration concurred, that the product was effective as an anti-inflammatory agent for use in certain animals.

That announcement was issued to inform holders of new animal drug applications (NADA's) of the findings of the Academy and the agency, and to inform all interested persons that such articles could be marketed if they were the subject of approved NADA's and otherwise complied with the requirements of the Federal Food, Drug, and Cosmetic Act.

The American Cyanamid Co., P.O. Box 400, Princeton, NJ 08540, responded to the notice by submitting a supplemental NADA (12-392V) providing current information covering manufacturing and controls and revising the labeling for the safe and effective use of the product as an anti-inflammatory agent in dogs and cats. The supplemental application was approved by a regulation published in the Federal Register of March 25, 1971 (36 FR 5602). The regulation reflecting this approval established a new section for the drug in 21 CFR 135b.29, recodified at 21 CFR 522.2480. The new section did not specify those conditions of use that were NAS/NRC approved.

This document amends the regulations to indicate those conditions of use for which applications for approval of identical products need not include certain types of effectiveness data required for approval by § 514.111(a)(5)(vi) of the new animal drug regulations. In lieu of those data, approval of applications for such products may be obtained if bioequivalency or similar data are submitted as suggested in the guideline for submitting NADA's for generic drugs reviewed by the NAS/NRC. The guideline is available from the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.1) and redelegated to the Director of the Bureau of Veterinary Medicine (21 CFR 5.83), Part 522 is amended in § 522.2480 by adding after paragraph (d) (1), (2) (i), (ii), and (iii), and (3) the footnote reference "[100]" and by adding at the end of the section the footnote to read as follows:

**§ 522.2480 Triamcinolone injection.**

* * * * *

(d) *Conditions of use.* (1) * * * [1]

(2)(i) * * * [1]

(ii) * * * [1]

(iii) * * [1]

(3) * * * [1]

*Effective date.* This regulation shall be effective April 22, 1980.

(Sec. 512(i), 82 Stat. 347 (21 U.S.C. 360b(i)).)

Dated: April 14, 1980.

**Lester M. Crawford,**

*Director, Bureau of Veterinary Medicine.*

[FR Doc. 80-12064 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

## DEPARTMENT OF THE TREASURY

### Bureau of Alcohol, Tobacco and Firearms

### 27 CFR Part 13

**[T.D. ATF-68]**

### Optional Method for Determination of Proof for Spirits

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms, Department of the Treasury.

**ACTION:** Temporary rule (Treasury decision).

**SUMMARY:** This temporary rule relates to the Distilled Spirits Tax Revision Act of 1979, Subtitle A of Title VIII of the Trade Agreements Act of 1979 (Pub. L. 96-39). This temporary rule provides an optional method for determination of proof for spirits containing solids of 400 milligrams or less per 100 milliliters.

**EFFECTIVE DATE:** The effective date of the temporary regulations is April 22, 1980.

**FOR FURTHER INFORMATION CONTACT:** Edward J. Sheehan, Coordinator, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms, Washington, DC 20226, Telephone: 202-566-7626.

**SUPPLEMENTARY INFORMATION:** This temporary rule adds temporary regulations in 27 CFR Part 13 to provide for an optional method for determination of proof for spirits containing solids of 400 milligrams or less per 100 milliliters. The temporary regulations as added by this document will remain in effect until superseded by final regulations. In addition, Notice No. 329, 44 FR 71612 (1979), a notice of proposed rulemaking for final regulations providing for submission of written comments, applies to this temporary regulation.

#### Background

Prior to the implementation of the Distilled Spirits Tax Revision Act of 1979 on January 1, 1980, 27 CFR Part 186, Gauging Manual, governed the gauging of spirits. Section 186.31 provided methods for determination of proof based on the solids content of spirits. The methods for determination of proof based on solids content were generally divided between: (1) Those spirits on which the proof was determined in bond; and (2) Those spirits on which the proof was determined after removal from bond on tax determination.

With the passage of the Distilled Spirits Tax Revision Act of 1979, an all-in-bond system was established. Spirits were no longer processed and bottled after tax determination. Under the all-in-bond system, all spirits are processed and bottled in bond. As a result, the provisions in 27 CFR Part 186 relating to the methods for determination of proof after tax determination were obsolete. Therefore, the Bureau's temporary regulations, T.D. ATF-62 (44 FR 71612), eliminated this method for determination of proof after tax determination.

Under the temporary regulations issued in T.D. ATF-62, the Gauging Manual was recodified as 27 CFR Part 13. Under 27 CFR 13.31, the proof of spirits is determined by a standard method, adopted from recodified Part 186, depending upon the solids content of the spirits. If spirits contain solids of 400 milligrams or less per 100 milliliters at gauge proof, the proof of spirits is determined by the use of a hydrometer and thermometer. This gauging method determines the apparent proof of the spirits. If spirits contain solids in excess of 400 milligrams but not in excess of 600 milligrams per 100 milliliters at gauge proof, there is added to the apparent proof the proof obscuration. This establishes the true proof of the spirits. If spirits contain solids in excess

[1] These conditions are NAS/NRC reviewed and deemed effective. Applications for these uses need not include effectiveness data as specified by § 514.111 of this chapter, but may require bioequivalency and safety information.

of 600 milligrams per 100 milliliters at gauge proof, the proof is determined on the basis of true proof by: (1) The use of a hydrometer and thermometer after the spirits have been distilled in a small laboratory still and restored to the original volume and temperature by the addition of water; or (2) A recognized laboratory method which is equal or superior in accuracy to the distillation method.

**New Provisions**

This temporary rule adds a new Subpart F—Transitional Gauging Procedures, to provide an optional method for determination of proof for spirits containing solids of 400 milligrams or less per 100 milliliters. Under 27 CFR 13.71 in Subpart F, the apparent proof of spirits containing solids of 400 milligrams or less per 100 milliliters shall be determined by the use of a hydrometer and thermometer as presently required in 27 CFR 13.31. However, 27 CFR 13.71 allows proprietors at their option to add to the proof so determined on such spirits the obscuration as determined in 27 CFR 13.32. This allows proprietors to determine the true proof of such spirits, if they so desire. Additionally, under 27 CFR 13.72 in Subpart F, any proprietor exercising this option in proofing spirits containing solids of 400 milligrams or less per 100 milliliters, shall record the obscuration so determined on the record of gauge required by 27 CFR Part 19.

Section 13.71 incorporates some of the provisions in the previous regulations in 27 CFR Part 186 for proofing of spirits after tax determination. Previous requirements allowed certain rectified spirits to use obscuration. However, this privilege was not extended to spirits to which had not been added materials containing solids, in a process of rectification. Section 13.71 allows proprietors to use an obscuration for all spirits containing solids of 400 milligrams or less per 100 milliliters including spirits such as bourbon whiskey, rum, brandy, blended whiskey, etc.

**Proposed Revisions**

The new Subpart F—Transitional Gauging Procedures, is a temporary measure until final rules are issued. The Bureau was petitioned to consider modification of gauging procedures prescribed in 27 CFR Part 13 in order to relieve the burden of added operating expenses which accrued as a result of the inability to take into account obscuration on certain products. In changing to the all-in-bond method of operation and making all gauges of distilled spirits in bond, proprietors could no longer take into account obscuration of certain products which necessitated the use of additional spirits in these products. Although the temporary regulations, 27 CFR Part 13, simplified and made consistent the gauges for all products, inequities may have resulted which require additional, unexpected costs for certain products. The Bureau will study the gauging of spirits and use of obscuration to determine the most cost efficient method of gauging spirits which will at the same time protect the revenue. Factors to be considered are the times when true proof gauges must be made, whether true proof should be determined on all products or whether cut-off points should be established for solids content below which true proof would not be determined. During the interim this temporary rule gives proprietors the option to use obscuration to determine the true proof of spirits containing solids of 400 milligrams or less per 100 milliliters.

**Drafting Information**

The principal author of this document is Edward J. Sheehan of the Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms. However, personnel from other offices of the Bureau and from the Treasury Department participated in developing this document, both on matters of substance and style.

**Effective Date**

Issuance of this Treasury decision as a temporary rule with notice and public procedure under 5 U.S.C. 553(b) and in compliance with the effective date limitation in 5 U.S.C. 553(d) is impracticable and not in the public interest because revisions in the gauging manual, 27 CFR Part 13, have created inequities which have imposed additional, unexpected costs upon certain products and immediate action is necessary to rectify the situation while the Bureau studies the appropriate gauging methods.

Accordingly, this Treasury decision becomes effective on April 22, 1980.

**Authority and Issuance**

These regulations are issued under the authority contained in 26 U.S.C. 7805 (68A Stat. 917, as amended).

Accordingly, Title 27 Code of Federal Regulations is amended as follows:

**Paragraph 1.** The table of sections for Part 13 is amended to reflect the addition of Subpart F—Transitional Gauging Procedures, immediately following Subpart E—Prescribed Tables. As amended, the table of sections reads as follows:

## PART 13—GAUGING MANUAL

* * * * *

**Subpart F—Transitional Gauging Procedures**

Sec.
13.71 Optional method for determination of proof for spirits containing solids of 400 milligrams or less per 100 milliliters.
13.72 Recording obscuration by proprietors using the optional method for determination of proof.

**Authority:** 26 U.S.C. 7805 (68A Stat. 917, as amended).

**Par. 2.** Subpart F—Transitional Gauging Procedures, is added immediately following the regulations in Subpart E—Prescribed Tables. As added, Subpart F reads as follows:

### Subpart F—Transitional Gauging Procedures

**§ 13.71 Optional method for determination of proof for spirits containing solids of 400 milligrams or less per 100 milliliters.**

The proof of spirits shall be determined to the nearest tenth degree which shall be the proof used in determining the proof gallons and all fractional parts thereof to the nearest tenth proof gallon. The proof of spirits containing solids of 400 milligrams or less per 100 milliliters shall be determined by the use of a hydrometer and thermometer in accordance with the provisions of § 13.23. However, notwithstanding, the provisions of § 13.31, the proprietor may, at his option, add to the proof so determined the obscuration determined as prescribed in § 13.32.

(Sec. 201, Pub. L. 85–859, 72 Stat. 1358, as amended, 1362, as amended (26 U.S.C. 5204, 5211))

**§ 13.72 Recording obscuration by proprietors using the optional method for determination of proof.**

Any proprietor using the optional method for determination of proof for spirits containing solids of 400 milligrams or less per 100 milliliters as provided in § 13.71 shall record the obscuration so determined on the record of gauge required by 27 CFR Part 19.

(Sec. 201, Pub. L. 96–39, 93 Stat. 284 (26 U.S.C. 5207))

Signed March 26, 1980.

**Miles N. Keathley,**

*Acting Director.*

Approved: April 14, 1980.

**Richard J. Davis,**

*Assistant Secretary (Enforcement and Operations).*

[FR Doc. 80-12300 Filed 4-17-80; 4:40 pm]

BILLING CODE 4810-31-M

## DEPARTMENT OF DEFENSE

### Department of the Army

### 32 CFR Part 655

### Use of Radiation Sources by Non-Army Entities on Army Land (AR 385-11)

**AGENCY:** Department of the Army.

**ACTION:** Final rule.

**SUMMARY:** This amendment publishes existing procedures for non-Army agencies, including civilian contractors, to obtain permits to use radioactive materials or radiation sources on Army installations. It also describes the circumstances and forms to be used by requestors in applying for a Department of the Army (DA) permit.

**EFFECTIVE DATE:** May 1, 1980.

**FOR FURTHER INFORMATION CONTACT:** Mr. Darwin Taras, Headquarters, US Army Materiel Development and Readiness Command, ATTN: DRCSF-P, 5001 Eisenhower Avenue, Alexandria, VA 22333 (202) 274-9340.

**SUPPLEMENTARY INFORMATION:** The purpose of the requirement for a permit is to assure that the Department of the Army has complete information regarding non-Army uses of radiation sources on Army lands so that persons, property, or Army missions are not adversely affected by any non-Army radiation sources. The Army's regulations on radiation safety have been revised and consolidated into one regulation on ionizing radiation protection. The consolidated regulation continues the requirement for a permit and the established forms and procedures without substantial change. This requirement, and the implementing forms and procedures, is being published in the **Federal Register**, under 5 U.S.C. 552(a), to provide interested persons and non-Army agencies with the information to deal effectively with the Department of the Army when radiation sources are desired to be used on Army lands. Since this regulation continues, without substantive change, a pre-existing rule which is not considered to have a substantial and direct impact on the public or any significant portion thereof, notice of proposed rulemaking and the procedures applicable thereto are considered unnecessary.

(10 U.S.C. 3012)

By Authority of the Secretary of the Army.

Dated: April 14, 1980.

**George A. Bailey,**

*Colonel, U.S. Army, Director, Administrative Management, TAGO.*

Accordingly, 32 CFR is amended by adding a new Part 655 to read as follows:

## PART 655—RADIATION SOURCES ON ARMY LAND

**Authority:** 10 U.S.C. 3012.

**§ 655.10 Use of radiation sources by non-Army entities on Army land (AR 385-11).**

(a) Department of the Army permits are required for use, storage, possession, and disposal of radiation sources by non-Army agencies (including civilian contractors) on an Army installation. Concurrence of the installation commander and approval by Headquarters, Department of the Army is required to obtain a Department of the Army (DA) permit.

(1) If a Nuclear Regulatory Commission (NRC) license already permits use or storage of radioactive sources at unspecified Army installations, the non-Army agency still needs a DA permit. The non-Army requestor will send six (6) copies of DA Form 3337 to the installation commander. The commander will then send four (4) copies of DA Form 3337 to Commander, US Army Materiel Development and Readiness Command, ATTN: DRCSF-P, 5001 Eisenhower Avenue, Alexandria, VA 22333. The non-Army requestor may obtain DA Form 3337 from the local Army installation or by written request to Commander, US Army Materiel Development and Readiness Command, ATTN: DRCSF-P, Alexandria, VA 22333.

(2) A DA permit is not required for temporary one-time use or storage (less than 15 consecutive calendar days) of sealed radioactive sources by users with a proper NRC license or agreement state license, if the local commander determines that adequate safety exists. The request for temporary use or storage authority will be submitted on DA Form 3337 in triplicate to the installation commander. A copy of the user's request and local commander's approval will be sent through command channels to CDR, DARCOM within 3 days of the approval.

(b) In all cases approvals will require users to restore the property to its previous condition.

[FR Doc. 80-12249 Filed 4-21-80; 8:45 am]

BILLING CODE 3710-08-M

### Department of the Air Force

### 32 CFR Part 953

### Violations of Public Trust in Contract, Procurement, and Other Matters; Correction

**AGENCY:** Department of the Air Force, DoD.

**ACTION:** Correction to final rule.

**SUMMARY:** In FR Doc. 80-10412, appearing on page 23423, in the issue for Monday, April 7, 1980, make the following correction:

Change the word "CONTACT " to "CONTRACT" in the second line of the Part title below the Supplementary Information.

**FOR FURTHER INFORMATION CONTACT:** Carol Rose, 697-1861.

**Carol M. Rose,**

*Air Force Federal Register Liaison Officer.*

[FR Doc. 80-12252 Filed 4-21-80; 8:45 pm]

BILLING CODE 3910-01-M

## COPYRIGHT ROYALTY TRIBUNAL

### 37 CFR Part 302

### Final Rule With Respect to 1980 Filing of Claims To Cable Royalty Fees

**AGENCY:** Copyright Royalty Tribunal (Tribunal).

**ACTION:** Final rule.

**SUMMARY:** This document amends the Copyright Royalty Tribunal's rule concerning the content of claims to cable royalty fees for secondary transmissions by cable systems by establishing the requirements for claims to be filed in July 1980 as authorized by 17 USC 111(d)(5)(A).

**EFFECTIVE DATE:** The rule is effective May 1, 1980.

**FOR FURTHER INFORMATION CONTACT:** Mary Lou Burg, Chairman, Copyright Royalty Tribunal, 202-653-5175.

**SUPPLEMENTARY INFORMATION:**

**Background**

In the **Federal Register** of March 7, 1980 (45 FR 14884) the Tribunal published a notice of proposed rulemaking concerning the content of claims to cable royalty fees for secondary transmissions by cable systems by establishing the requirements for claims to be filed in July 1980.

**The Proposed Rule**

17 USC 111(d)(5)(A) requires that during July of each year every person claiming royalty fees for secondary

transmissions by cable systems shall file a claim with the Tribunal. The Tribunal has adopted in 37 CFR Part 302 a rule concerning the filing and content of such claims. Section 302.7 regulates the filing of claims for secondary transmissions "during calendar years 1979 and subsequent calendar years." It states that "such filing shall include such information as the Copyright Royalty Tribunal may require." The purpose of the proposed rule is to establish the requirements for the July 1980 filing.

The proposed rule only requires claims to cable royalties to include (1) the name of the person claiming cable fees, (2) the address of such person, (3) a general statement of the nature of the works providing the basis of the claim and (4) identification of at least one secondary transmission establishing a basis for the claim.

### Comments on the Proposal

The Tribunal received four comments on the proposed rule. The American Society of Composers, Authors and Publishers, the Motion Picture Association of America, Inc., and the National Association of Broadcasters supported the proposed rule without amendment. The Joint Sports Claimants proposed two amendments. One amendment would add the following language: "a joint claim shall include a concise statement of the authorization for the filing of the joint claim." The purpose of the proposed amendment is to preclude unauthorized filing of joint claims. Another amendment proposed that "Section 302.7 be amended to require a complete listing of every program claimed for, including date of telecast and station." The purpose of the proposed amendment is described as to assist the Tribunal and claimants in identifying "the true scope" of claims filed by parties.

### Tribunal's Response

The Tribunal accepts the proposed amendment requiring that a joint claim shall include a concise statement of the authorization for the joint claim. Similar language has been included in the rules of the Tribunal pertaining to previous filings of joint claims.

The Tribunal has not accepted the proposal of the Joint Sports Claimants that the 1980 cable filings shall include a complete listing of every copyrighted program claimed. During the pending proceeding for the distribution of royalty fees for 1978 cable performances, the Tribunal rejected a similar proposal of the Joint Sports Claimants.

Accordingly, 37 CFR Part 302 is amended by revising § 302.7 to read as follows:

**§ 302.7 Filing of claims to cable royalty fees for secondary transmissions during calendar year 1979 and subsequent calendar years.**

(a) During the month of July 1980 and in July of each succeeding year, every person claiming to be entitled to compulsory license fees for secondary transmissions during the preceding calendar year shall file a claim to such fees in the office of the Copyright Royalty Tribunal. No royalty fees shall be distributed to copyright owners for secondary transmissions during the specified period unless such owner has filed a claim to such fees during the following calendar month of July. For purposes of this clause claimants may file claims jointly or as a single claim. Such filing shall include such information as the Copyright Royalty Tribunal may require. A joint claim shall include a concise statement of the authorization for the filing of the joint claim.

(b) Claims filed during the month of July 1980 shall include the following information:

(1) The full legal name of the person or entity claiming compulsory license fees.

(2) The full address, including a specific number and street name or rural route, of the place of business of the person or entity.

(3) A general statement of the nature of the copyrighted works, whose secondary transmission provides the basis of the claim.

(4) Identification of at least one secondary transmission establishing a basis for the claim.

**Mary Lou Burg,**

*Chairman, Copyright Royalty Tribunal.*

[FR Doc. 80-12248 Filed 4-21-80; 8:45 am]

BILLING CODE 1410-01-M

## VETERANS ADMINISTRATION

### 38 CFR Part 36

### Increase in Maximum Permissible Interest Rate on Guaranteed Mobile Home Loans

**AGENCY:** Veterans Administration.

**ACTION:** Final regulations.

**SUMMARY:** The VA [Veterans Administration) is increasing the maximum interest rates on guaranteed mobile home loans. These increases in interest rates apply to mobile home unit loans, lot only loans, and combination mobile home unit and lot loans. The maximum mobile home interest rates are increased because the former interest rates were not sufficiently competitive to induce private sector lenders to make VA guaranteed mobile home loans. The increase in the interest rates will assure a continuing supply of funds for mobile home loans; thereby allowing veterans to purchase a mobile home unit, a lot on which to place a previously purchased mobile home or a combination mobile home unit and lot with the assistance of a no downpayment VA loan.

**EFFECTIVE DATE:** April 16, 1980.

**FOR FURTHER INFORMATION CONTACT:** Mr. George D. Moerman, Loan Guaranty Service (264), Department of Veterans Benefits, Veterans Administration, 810 Vermont Avenue, N.W., Washington, D.C. 20420, 202-389-3042.

**SUPPLEMENTARY INFORMATION:** The Administrator is required by title 38, United States Code, section 1819(f) to establish maximum interest rates for mobile home loans guaranteed by the Veterans Administration as he finds the mobile home loan capital markets demand. Recent market indicators—including the prime interest rate, the general increase in interest rates charged on conventional and Federal Housing Administration mobile home loans, and the rate of discount charged on VA mobile home loans—have shown that the mobile home capital markets have become more restrictive. The maximum rates in effect for VA guaranteed mobile home loans have not been sufficiently competitive to induce private lenders and investors to make VA guaranteed mobile home loans. To assure a continuing supply of funds to enable veterans to purchase either a mobile home unit, lot, or a combination unit and lot with the assistance of VA guaranteed loan financing, it has been determined that an increase in the maximum mobile home interest rates is necessary. These increased rates will assure an acceptable return to the lender or investor which will make VA loans competitive with other available investments and assure a continuing supply of funds for VA guaranteed mobile home loans.

The three separate maximum interest rates for loans to purchase a mobile home unit, or to purchase a lot on which to place a previously acquired unit, or to acquire a combination mobile home unit with a lot are being increased. The increase in the maximum rates is accomplished by amending § 36.4212(a)(1), (2) and (3), title 38, Code of Federal Regulations. Compliance with the procedure for publication of proposed regulations prior to final adoption is waived because compliance would create an acute shortage of loan funds pending the final date which

would necessarily be more than 30 days after publication in proposed form.

These amendments are adopted under authority of sections 210(c), 1819(f) and (g) of title 38, United States Code.

Approved: April 15, 1980.

By direction of the Administrator.

**Rufus H. Wilson,**

*Deputy Administrator.*

In § 36.4212, paragraph (a) is revised to read as follows:

**§ 36.4212 Interest rates and late charges.**

(a) The interest rate charged the borrower on a loan guaranteed or insured pursuant to 38 U.S.C. 1819 may not exceed the following maxima except on loans guaranteed or insured pursuant to guaranty or insurance commitments issued by the Veterans Administration prior to the respective effective date: (38 U.S.C. 1819(f))

(1) Effective April 16, 1980, 17½ percent simple interest per annum for a loan which finances the purchase of a mobile home unit only.

(2) Effective April 16, 1980, 15 percent simple interest per annum for a loan which finances the purchase of a lot only and the cost of necessary site preparation, if any.

(3) Effective April 16, 1980, 17 percent simple interest per annum for a loan which will finance the simultaneous acquisition of a mobile home and a lot and/or the site preparation necessary to make a lot acceptable as the site for the mobile home.

* * * * *

(38 U.S.C. 210(c), 1819(g))

[FR Doc. 80-12336 Filed 4-21-80; 8:45 am]

BILLING CODE 8320-01-M

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Center for Disease Control

### 42 CFR Part 74

### Clinical Laboratories—Deletion of Requirement for License Fees

**AGENCY:** Center for Disease Control, Public Health Service, HEW.

**ACTION:** Final rule (with subsequent comment period).

**SUMMARY:** This rule amends the regulation which requires payment of license fees for laboratories licensed under the Clinical Laboratories Improvement Act of 1967. It eliminates the requirement for payment of license fees since the fees collected do not offset administrative costs for collecting the fees.

**DATES:** This regulation is effective April 22, 1980. Comments must be received on or before May 22, 1980.

**ADDRESS:** Comments or inquiries may be submitted to: Dr. Louis C. LaMotte, Director, Licensure and Proficiency Testing Division, Bureau of Laboratories, Center for Disease Control, 1600 Clifton Road, N.E., Atlanta, Georgia 30333.

Comments will be available for public inspection between 8 a.m. and 4:30 p.m. in Building 6, Room 154, at the same address.

**FOR FURTHER INFORMATION CONTACT:** Dr. Louis C. LaMotte, (404) 329-3824 or FTS: 236-3824.

**SUPPLEMENTARY INFORMATION:** Under an Interagency Agreement between the Health Care Financing Administration (HCFA) and the Public Health Service (PHS), HCFA has responsibility for the survey of laboratories, their licensure under the Clinical Laboratories Improvement Act of 1967, and their approval for Medicare reimbursement purposes. The Public Health Service, through the Center for Disease Control (CDC), has responsibility for the development of standards and for all technical and scientific matters arising under both programs. In addition, CDC has responsibility for monitoring the effectiveness and uniformity of the survey activities of States and approved national accreditation bodies.

HCFA currently issues licenses to approximately 1,000 laboratories. License fee revenues were approximately $63,000 in fiscal year 1978. Thus, the average fee collected per laboratory is less than $65 per year. License fee revenues collected do not offset the administrative costs of collection. It appears that administrative costs for license fee collection will be increased somewhat with the decentralization of licensing activities to the HCFA Regional Offices.

Accordingly, an advantage would accrue to both the Government and the public with the elimination of the license fee provisions. Clinical laboratories will, of course, avoid license fee costs, and their administrative and financial management costs also should be appreciably lessened. It is noted that increasing the license fee is not an option since the statutory limit is already being collected.

We propose to issue a Final Rule without a Notice of Proposed Rulemaking since it is considered to be in the best interest of the public. However, comments received during the comment period will be evaluated and acted upon in the same manner as if this document were a proposal.

**§ 74.10 [Amended]**

Part 74 of Title 42, Code of Federal Regulations, is amended by deleting and reserving paragraph (d) of § 74.10.

Dated: February 27, 1980.

**Julius E. Richmond,**

*Assistant Secretary for Health.*

Approved: April 16, 1980.

**Patricia Roberts Harris,**

*Secretary.*

[FR Doc. 80-12335 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-86-M

## Office of Education

### 45 CFR Part 134

### Grants to State Educational Agencies for Educational Improvement, Resources, and Support

*Correction*

In FR Doc. 80-10559, published at page 23602, on Monday, April 7, 1980, on page 23602, in the third column, under 2. Part B, in the last line of paragraph (c), "indirect" should be corrected to read "direct".

BILLING CODE 1505-01-M

## Social Security Administration

### 45 CFR Part 233

### Coverage and Conditions of Eligibility in Financial Assistance Programs; Aid to Families With Dependent Children, Residence

**AGENCY:** Social Security Administration, HEW.

**ACTION:** Final rule

**SUMMARY:** This rule revises the regulation requirements for States in determining residence of applicants and recipients under title I, IV-A, X, XIV, or XVI (AABD) of the Social Security Act. It supplements the definition of a resident currently contained in 45 CFR 233.40 by including in the definition of a "resident" anyone "who is living in the State, is not receiving assistance from another State and entered the State with a job commitment or to seek employment (whether or not currently employed)." This definition makes it possible for migrant and itinerant workers who have been denied financial assistance and Medicaid benefits because they move from State to State for employment purposes, to meet the residence requirement for assistance and to receive benefits if they are otherwise eligible.

**EFFECTIVE DATE:** This regulation is effective April 22, 1980. However, in

accordance with the interim final rule published in the **Federal Register** on July 17, 1979 (44 FR 41459), the new requirement became effective October 15, 1979.

**FOR FURTHER INFORMATION CONTACT:** Ms. Aleatha E. Slade, Office of Family Assistance, Office of Policy, Social Security Administration, 330 C Street, S.W., Washington, D.C. 20201, telephone (202) 426-6577.

**SUPPLEMENTARY INFORMATION:** HEW regulations at 45 CFR 233.40(a)(1) define a resident of a State as a person who is living in the State voluntarily with the intention of making his or her home there and not for a temporary purpose. That definition does not specifically address the various elements involved in determining residence and it has not been uniformly interpreted by the States. Some States have applied that definition to deny AFDC benefits to migrant and itinerant workers and their families and, as a result, these individuals have been denied Medicaid coverage.

The interim final rule amended 45 CFR 233.40 by expanding the definition of a resident to include anyone who is living in the State at the time of application, who entered the State with a commitment of a job or for the purpose of seeking employment, and who is not receiving AFDC benefits in another State. Under this definition a child is a resident of the State in which the caretaker relative resides.

The interim rule did not change the definition of a resident in 45 CFR 233.40(a)(1), but added to that definition. The expanded definition makes it possible for families of migrant and itinerant workers who previously did not meet the residence requirements to qualify as residents of a State and receive AFDC benefits if otherwise eligible.

### The Final Rule

The final rule is essentially the same as the interim final rule, with one clarifying change which is described in the response to comment 1 under the next subheading. The rule does not change the existing definition of a resident, but expands it to add a new situation under which some people not previously residents will now qualify. Under the expanded definition a person living in the State and not receiving AFDC from another State will be considered a resident if he or she entered the State with a job commitment or to seek employment in the State. This definition of "resident" will apply whether or not the person is currently employed; and, under it, an AFDC child will be considered a resident of the State in which his or her caretaker relative is a resident.

Individuals who have been receiving assistance in a State, as a resident of that State, on the basis of the existing definition, still retain their residency in that State until abandoned.

### Discussion of Comments

After publication of the interim final rule on July 17, 1979, we received 17 comments. Sixteen of the comments were from State welfare departments and public interest organizations and one was from a concerned individual. The significant comments submitted and our responses follow:

*1. Comment:* Several commenters expressed concern about the requirements that a person be living in the State at the time of application and not receiving assistance from another State. It was pointed out that migrants often live in automobiles or campers in roadside rest stops, and under other temporary conditions which might be construed as not "living in" their present State. In addition, they feared this might be restrictively interpreted by States so as to deny benefits to individuals who apply for assistance upon moving to a new State, but who on the date of application are still receiving their last month's assistance from the former State.

*Response:* The interim final rule defined a resident as one "living in the State", that is, currently making his or her home in the State. The language of the regulation does not necessitate the establishment of permanent living quarters. "Living" means physically present in the State on a day to day basis. Thus, people who are residing, even temporarily, in mobile homes or other temporary places, would meet the "living in the State" requirement.

We do, however, agree that the words "at the time of application" should be deleted in the final regulation. This phrase can be misunderstood to set requirements for eligibility at the point of application. This was not intended. An individual may be permitted to make an application before actually meeting residence requirements, even under the new definition. The requirements must be met for the period for which the State actually determines eligibility.

In order for a person to qualify under the new rule as a resident in a State, he or she must not be an AFDC recipient in another State *at the point in time that he or she gets assistance* in the new State. He or she may have been a recipient earlier that same month, and assistance from the prior State may have been paid for the entire month under that State's plan. In that case the new State would need to consider that assistance in determining need. However, if the applicant has taken the steps necessary to terminate his or her status as a "recipient" in the former State, he or she will be considered a resident of the new State, under the new rule.

*2. Comment:* Questions were raised as to whether "job commitment" implies an explicit and certain job opening, definitely available for the individual. We were also asked what documentation of such a commitment would be required.

*Response:* Whenever a person enters a State with an offer of work—whether formal or informal—he or she would satisfy the "job commitment" requirement. We do not further define what constitutes a "job commitment" or how specifically such a commitment should be documented. This would be up to State agencies. However, agencies may not restrict the type of job commitments acceptable.

*3. Comment:* It was pointed out that "seeking employment" might be interpreted to require that applicants demonstrate and document the efforts they are making to obtain employment and could result in agency workers making referrals to potential employers.

*Response:* There are numerous ways by which "seeking employment" can be demonstrated, and States may wish to use specific indicators of such "seeking." Examples of such indicators are that the applicant contacted or submitted applications to potential employers or to sources of employment; collected information about employment opportunities; had knowledge of commonly known job prospects; or had an awareness through personal or family contacts of likely job opportunities in the State.

Migrant or other workers qualifying as residents under this new rule will be required to comply with Work Incentive (WIN) Program registration and cooperation requirements in order to be eligible for AFDC. This is a requirement that extends to all AFDC recipients. Thus, State agency referrals to work opportunities could be made within normal WIN procedures in the area.

*4. Comment:* One writer asked whether the exception in § 233.40(b) applies to the definitions in § 233.40(a)(1) under the AFDC program.

*Response:* The exception in § 233.40(b) applies to the expanded definition only under the title I, X, XIV, or XVI (AABD) program in Guam, Puerto Rico, and the Virgin Islands. The interim final rule did not change the provisions of § 233.40(b) regarding this exception. We do, however, recognize

the need for clarification and simplification of that section and will revise it as part of the effort for recodification of HEW regulations.

*5. Comment:* Some commenters asked whether the State of original residence is responsible for AFDC payments to an individual who is temporarily absent from that State.

*Response:* An individual retains his or her residence in a State until residence is abandoned as specified in § 233.40(a)(2). Thus, if the temporarily absent person has retained residence in the original State, that State must continue to provide assistance (if the person is otherwise eligible). It is appropriate for a new State to include in its determination of whether an individual is a resident, under the new rule, an assessment of whether that person is receiving assistance from the prior State.

*6. Comment:* One writer felt that the language, "the child is a resident of the State in which the caretaker is a resident", could be interpreted to mean that a child is a resident of the State in which the caretaker resides even though the child is actually living in another State. As a result, the writer pointed out, AFDC eligibility would be extended to a child who is not "truly" a resident of a State.

*Response:* If a caretaker of an AFDC child established residence in a State under § 233.40(a)(1)(ii), but the child is physically present in another State, that child should be regarded as temporarily absent (under § 233.90(c)(1)(v)(B)) from the home of that caretaker. If the child's absence is not temporary, or if the child is not in fact under the care and control of the caretaker in question, then the recognition of that person as "caretaker" for AFDC purposes would be questionable.

**Comments Beyond the Scope of the Interim Final Rule**

Some comments were received, in response to the publication of the interim final rule, which did not directly concern this regulation. While these letters applauded the Department's expanded definition of a resident, they took the opportunity to present suggestions for improvement of services to migrant and itinerant workers. These suggestions included:

a. Provision of bilingual staff to assist non-English-speaking applicants.

b. More accessible offices with hours of operation extended to certain evenings of the week.

c. The development of an interstate system for provision of assistance in order to eliminate the State-by-State application and reapplication process.

d. Clarification and simplification of requirements for determining resources and for calculating income.

e. Removal of "restrictive" provisions in the Emergency Assistance and AFDC-Unemployed Parents programs which limit the availability of these program resources.

The Department welcomes these suggestions for program improvement. We will consider these recommendations in the on-going recodification of AFDC regulations which involves extensive review and updating of Federal policies, clarification and simplification of Federal requirements and making Federal regulations easier to understand and use. Where the suggestions would require a change in the statute, we will consider them as we develop legislative proposals.

**Differences Between the Interim final Rule and the Final Rule**

After consideration of all the comments, we have adopted the interim Final rule with one substantive change. We have removed from § 233.40(a)(1)(ii) the language "at the time of application". We have also made two typographical corrections.

(Sections 402(b) and 1102 of the Social Security Act as amended; 49 Stat. 627, as amended, 49 Stat. 647, as amended, 42 U.S.C. 602(b) and 1302.)

(Catalog of Federal Domestic Assistance Program No. 13.761, Public Assistance—Maintenance Assistance (State Aid).)

Dated: February 20, 1980.

**William J. Driver,**

*Commissioner of Social Security.*

Approved: April 16, 1980.

**Patricia Roberts Harris,**

*Secretary of Health, Education, and Welfare.*

Chapter II of Title 45 of the Code of Federal Regulations is amended by revising § 233.40 to read as follows:

**§ 233.40 Residence.**

(a) *Condition for plan approval.* A State plan under title I, IV—A, X, XIV, or XVI of the Social Security Act may not impose any residence requirement which excludes any individual who is a resident of the State except as provided in paragraph (b) of this section. For purposes of this section:

(1) A resident of a State is one: (i) Who is living in the State voluntarily with the intention of making his or her home there and not for a temporary purpose. A child is a resident of the State in which he or she is living other than on a temporary basis. Residence may not depend upon the reason for which the individual entered the State, except insofar as it may bear upon whether the individual is there voluntarily or for a temporary purpose; or

(ii) Who, is living in the State, is not receiving assistance from another State, and entered the State with a job commitment or seeking employment in the State (whether or not currently employed). Under this definition, the child is a resident of the State in which the caretaker is a resident.

(2) Residence is retained until abandoned. Temporary absence from the State, with subsequent returns to the State, or intent to return when the purposes of the absence have been accomplished, does not interrupt continuity of residence.

(b) *Exception.* A State plan under title I, X, XIV, or XVI need not include an individual who has been absent from the State for a period in excess of 90 consecutive days (regardless of whether the individual has maintained his or her residence in the State during this period) until he or she has been present in the State for a period of 30 consecutive days (or a shorter period specified by the State) in the case of such individual who has maintained residence in the State during such period of absence or for a period of 90 consecutive days (or a shorter period as specified by the State) in the case of any other such individual. An individual thus excluded under any such plan may not, as a consequence of that exclusion, be excluded from assistance under the State's title XIX plan if otherwise eligible under the title XIX plan (see 42 CFR 436.403).

[FR Doc. 80-12333 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-07-M

## INTERSTATE COMMERCE COMMISSION

**49 CFR Part 1033**

**[3rd Rev. S.O. No. 1432]**

## Chicago and North Western Transportation Co. Authorized To Operate Over Tracks of Chicago, Milwaukee, St. Paul and Pacific Railroad Co.

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Third Revised Service Order No. 1432.

**SUMMARY:** This order authorizes the Chicago and North Western Transportation Company (CNW) to operate over tracks of Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW) at Lake Preston, Mitchell and Sioux Falls, South Dakota; from Wolsey to but not including

Aberdeen, South Dakota; at Miloma and Montgomery, Minnesota; between Jefferson and Marathon, Iowa; between Jefferson and Waukee, Iowa, and between Manning and Huxley, Iowa, for the purpose of serving industries located adjacent to such tracks, and provides for continuation of service to shippers which would otherwise be deprived of essential railroad service.

**EFFECTIVE DATE:** 12:01 a.m., April 17, 1980, and continuing in effect until 11:59 p.m., April 30, 1980.

**FOR FURTHER INFORMATION CONTACT:** J. Kenneth Carter, (202) 275–7840.

**SUPPLEMENTARY INFORMATION:**

Decided: April 15, 1980.

By Order No. 290A, dated February 25, 1980, the United States District Court for the Northern District of Illinois, Eastern Division, authorized the Trustee of the Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW) to impose an embargo on all operations outside of the MILW "core system" as identified by the Court. The MILW was authorized to place an embargo on inbound traffic as of 11:59 p.m., February 27, 1980, and on originating traffic as of 11:59 p.m., February 29, 1980. The MILW placed Embargo No. 10–80 as directed by the Court, effective on these dates. A subsequent court order authorized the Trustee to embargo additional lines named in Embargo No. 13–80, effective 11:59 p.m., March 23, 1980.

The Chicago and North Western Transportation Company (CNW) intersects MILW lines at various locations in Iowa, South Dakota and Minnesota, and has applied to the Commission seeking authority to operate over embargoed MILW lines.

It is the opinion of the Commission that an emergency exists requiring the operation by CNW over tracks embargoed by MILW in the interest of the public; that notice and public procedure are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than 30 days notice.

*It is ordered,*

**§ 1033.1432 Third Revised Service Order No. 1432.**

(a) *Chicago and North Western Transportation Company authorized to operate over tracks embargoed by Chicago, Milwaukee, St. Paul and Pacific Railroad Company.* The Chicago and North Western Transportation Company (CNW) is authorized to operate over tracks embargoed by the Chicago, Milwaukee, St. Paul and Pacific Railroad Company (MILW) at Lake Preston, Mitchell and Sioux Falls, South Dakota; from Wolsey to but not including Aberdeen, South Dakota; at Miloma and Montgomery, Minnesota; between Jefferson and Marathon, Iowa; between Jefferson and Waukee, Iowa, and between Manning and Huxley, Iowa.*

(b) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign traffic.

(c) Compensation will be on terms established between the Trustee and the affected carrier(s); or upon failure of the parties to agree as hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by Section 11123(b)(2) of the Interstate Commerce Act.

(d) *Rates applicable.* Inasmuch as this operation by CNW over tracks previously operated by the MILW is deemed to be due to carrier's disability, the rates applicable to traffic moved over these lines shall be the rates applicable to traffic routed, to, from, or via these lines which were formerly in effect on such traffic when routed via MILW, until tariffs naming rates and routes specifically applicable via CNW become effective.

(e) In transporting traffic over these lines, CNW and all other common carriers involved shall proceed even though no contracts, agreements, or arrangements now exist between them with reference to the divisions of the rates of transportation applicable to that traffic. Divisions shall be, during the time this order remains in force, those voluntarily agreed upon by and between the carriers; or upon failure of the carriers to so agree, the divisions shall be those hereafter fixed by the Commission in accordance with pertinent authority conferred upon it by the Interstate Commerce Act.

(f) *Employees.* On March 4, 1980, a number of rail carriers and labor unions reached an agreement regarding the proper level of employee protection entitled *"Labor Protection Agreement between Railroad Parties Hereto Involved in Midwest Rail Restructuring and Employees of Such Railroads represented by the Rail Labor Organizations operating through the Rail Labor Executives' Association"* (Negotiated Labor Protection Agreement). We have reviewed the negotiated labor protection agreement and find that it adequately safeguards the interests of affected employees.

Accordingly, if CNW chooses to exercise the authority granted by this decision, it shall afford affected employees the protection contemplated by the negotiated labor protection agreement and any subsequent amendments to it.

(g) *Effective date.* This order shall become effective at 12:01 a.m., April 17, 1980.

(h) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., April 30, 1980, unless otherwise modified, amended, or vacated by order of this Commission.

(49 U.S.C. (10304–10305 and 11121–11126))

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80–12229 Filed 4–21–80; 8:45 am]

**BILLING CODE 7035–01–M**

* Addition.

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**49 CFR Part 1033**

**[S.O. No. 1373, Amdt. 1]**

## Substitution of Insulated Boxcars for Boxcars

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Amendment No. 1 to Service Order No. 1373.

**SUMMARY:** This order amends Service Order No. 1373 by establishing an expiration date of 11:59 p.m., July 31, 1980, in order to affect greater control of utilization.

**EFFECTIVE DATE:** 2:01 a.m., April 18, 1980, and continuing in effect until 11:59 p.m., July 31, 1980.

**FOR FURTHER INFORMATION CONTACT:** M. F. Clemens, Jr., (202) 275–7840.

**SUPPLEMENTARY INFORMATION:**

Decided: April 16, 1980.

Upon further consideration of Service Order No. 1373 (44 FR 21797), and good cause appearing therefor:

*It is ordered,* § 1033.1373 Service Order No. 1373 (Substitution of Insulated Boxcars for Boxcars) is amended by substituting the following paragraph (e) for paragraph (e) thereof:

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., July 31, 1980, unless otherwise modified,

amended or vacated by order of this Commission.

*Effective date.* This order shall become effective at 12:01 a.m., April 18, 1980.

(49 U.S.C. (10304–10305 and 11121–11126))

This amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 80-12230 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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## 49 CFR Part 1033

[S.O. No. 1467]

## Atchison, Topeka and Santa Fe Railway Co. To Operate Over Tracks Authorized To Be Served by the Directed Service Carrier, St. Louis Southwestern Railway Co., at Dodge City, Kans.

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Service Order No. 1467.

**SUMMARY:** This order authorizes The Atchison, Topeka and Santa Fe Railway Company to operate over tracks authorized to be served by the St. Louis Southwestern Railway Company at Dodge City, Kansas, for the purpose of providing continued rail service to shippers.

**EFFECTIVE DATE:** 12:01 a.m., April 17, 1980, and continuing in effect until 11:59 p.m., May 31, 1980.

**FOR FURTHER INFORMATION CONTACT:** J. Kenneth Carter, (202) 275–7840.

**SUPPLEMENTARY INFORMATION:**

Decided: April 16, 1980.

The St. Louis Southwestern Railway Company (SSW) is authorized to provide service as a "directed rail carrier" over the "Tucumcari line" of the Chicago, Rock Island and Pacific Railroad Company, Debtor (William M. Gibbons, Trustee) (RI) under authority of Directed Service Order No. 1453. The line also includes the RI branch line from Bucklin to Dodge City, Kansas, a distance of 26.5 miles.

The SSW is unable to provide service to shippers at Dodge City, Kansas, due to poor track conditions between Bucklin and Dodge City making it impossible for the SSW to operate between these two points. The SSW has requested the Atchison, Topeka and Santa Fe Railway Company (ATSF) to serve these shippers at Dodge City, and the ATSF has agreed to operate over these tracks in order to provide continued rail service to the shippers.

It is the opinion of the Commission that an emergency exists requiring the operation of ATSF trains over these tracks of the SSW in the interest of the public; that notice and public procedure are impracticable and contrary to the public interest; and that good cause exists for making this order effective upon less than thirty days' notice.

*It is ordered,*

**§ 1033.1467 Service Order No. 1467.**

(a) *The Atchison, Topeka and Santa Fe Railway Company to operate over tracks authorized to be served by the Directed Service Carrier, St. Louis Southwestern Railway Company, at Dodge City, Kansas.* The Atchison, Topeka and Santa Fe Railway Company (ATSF) is authorized to operate over tracks which are authorized to be served by the "directed rail carrier," St. Louis Southwestern Railway Company (SSW), at Dodge City, Kansas, for the purpose of providing continued rail service to shippers located adjacent to these tracks.

(b) *Application.* The provisions of this order shall apply to intrastate, interstate and foreign traffic.

(c) The SSW has agreed to pay any compensation owing to the RI Trustee as a result of this service by the ATSF.

(d) *Effective date.* This order shall become effective at 12:01 a.m., April 17, 1980.

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., May 31, 1980, unless otherwise modified, amended, or vacated by order of this Commission.

This action is taken under the authority of 49 U.S.C. 10304–10305 and 11123.

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 80-12233 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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## 49 CFR Part 1033

[S. O. No. 1392, Amdt. 1]

## Substitution of Trailers for Boxcars or Covered Hoppers

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Amendment No. 1 to Service Order No. 1392.

**SUMMARY:** This order amends Service Order No. 1392 by establishing its expiration date of July 31, 1980, in order to affect greater control of utilization.

**EFFECTIVE DATE:** 12:01 a.m., April 18, 1980, and continuing in effect until 11:59 p.m., July 31, 1980.

**FOR FURTHER INFORMATION CONTACT:** M. F. Clemens, Jr., (202) 275–7840.

**SUPPLEMENTARY INFORMATION:**

Decided: April 16, 1980

Upon further consideration of Service Order No. 1392, (44 FR 46461), and good cause appearing therefor:

*It is ordered,* § 1033.1392 Service Order No. 1392 Substitution of Trailers for Boxcars or Covered Hoppers is amended by substituting the following paragraph (e) for paragraph (e) thereof:

(e) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., July 31, 1980, unless otherwise modified, amended or vacated by order of this Commission.

*Effective date.* This order shall become effective at 12:01 a.m., April 18, 1980.

(49 U.S.C. (10304–10305 and 11121–11126))

This amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc 80-12234 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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## 49 CFR Part 1033

[S.O. No. 1289, Amdt. 4]

## Burlington Northern Inc. Authorized To Operate Over Tracks of Union Pacific Railroad Co. at Sterling, Colo.

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Amendment No. 4 to Service Order No. 1289.

**SUMMARY:** This amendment reestablishes an expiration date for Service Order No. 1289.

**EFFECTIVE DATES:** 12:01 a.m., April 18, 1980, and continuing in effect until 11:59 p.m., May 31, 1980.

**FOR FURTHER INFORMATION CONTACT:**

M. F. Clemens, Jr., (202) 275-7840.

**SUPPLEMENTARY INFORMATION:**

Decided: April 16, 1980.

Upon further consideration of Service Order No. 1289 (42 FR 63423; 43 FR 24694, 56671 and 44 FR 31982), and good cause appearing therefor:

*It is ordered,* § *1033.1289 Service Order No. 1289 (Burlington Northern Inc. authorized to operate over tracks of Union Pacific Railroad Company at Sterling, Colorado)* is amended by substituting the following paragraph (f) for paragraph (f) thereof:

(f) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., May 31, 1980, unless modified, amended or vacated by order of this Commission.

*Effective date.* This amendment shall become effective at 12:01 a.m., April 18, 1980.

(49 U.S.C. (10304-10305 and 11121-11126))

A copy of this amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 80-12236 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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## 49 CFR Part 1033

[Revised Service Order No. 1342-A]

## Illinois Terminal Railroad Co. Authorized To Operate Over Tracks of Illinois Central Gulf Railroad Co.; Decision

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Revised Service Order No. 1342-A.

**SUMMARY:** This order authorizes the Illinois Terminal Railroad Company to operate over tracks of Illinois Central Gulf Railroad Company.

Revised Service Order No. 1342 is being vacated.

**EFFECTIVE DATE:** 11:59 p.m., April 18, 1980.

**FOR FURTHER INFORMATION CONTACT:**

J. Kenneth Carter (202) 275-7840.

**SUPPLEMENTARY INFORMATION:**

Decided: April 16, 1980.

Upon further consideration of Revised Service Order No. 1342 (44 FR 39406), and good cause appearing therefor:

*It is ordered,* that § 1033.1342 *Illinois Terminal Railroad Company authorized to operate over tracks of Illinois Central Gulf Railroad Company,* revised Service Order No. 1342 is vacated effective 11:59 p.m., April 18, 1980.

(49 U.S.C. (10304-10305 and 11121-11126))

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 80-12347 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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## 49 CFR Part 1033

[Service Order No. 1351; Amdt. No. 2]

## Massachusetts Central Railroad Corp. Authorized to Operate Over Tracks Formely Operated by Boston and Maine Corp., Robert W. Meserve and Benjamin H. Lacy, Trustees; Decision

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Amendment No. 2 to Service Order No. 1351.

**SUMMARY:** This order amends Service Order No. 1351 by reestablishing an expiration date of July 31, 1980, consistent with Service Order No. 1424, Massachusetts Central's other temporary authority over the Boston and Maine.

**EFFECTIVE DATE:** 12:01 a.m., April 18, 1980:

Expiration date: 11:59 p.m. July 31, 1980 and continuing in effect until modified, amended or vacated by order of this Commission.

**FOR FURTHER INFORMATION CONTACT:**

J. Kenneth Carter (202) 275-7840

**SUPPLEMENTARY INFORMATION:**

Decided April 16, 1980.

Upon further consideration of Service Order No. 1351, (44 FR 879 and 39407) and good cause appearing therefor:

*It is ordered,* that § 1033.1351 *Massachusetts Central Railroad Corporation authorized to operate over tracks formerly operated by Boston and Maine Corporation, Robert W. Meserve and Benjamin H. Lacy, Trustees,* Service Order No. 1351 is amended by substituting the following paragraph (g) for paragraph (g) thereof:

(g) *Expiration date.* The provisions of this order shall expire at 11:59 p.m., July 31, 1980, unless otherwise modified, amended, or vacated by order of this Commission.

*Effective date.* This amendment shall become effective at 12:01 a.m., April 18, 1980.

(49 U.S.C. (10304-10305 and 11121-11126))

This amendment shall be served upon the Association of American Railroads, Car Service Division, as agent of all railroads subscribing to the car service and car hire agreement under the terms of that agreement, and upon the American Short Line Railroad Association. Notice of this amendment shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission, at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80-12298 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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**49 CFR Part 1033**

**[Rev. S.O. No. 1363-A]**

## Substitution of Refrigerator Cars for Boxcars

April 16, 1980.

**AGENCY:** Interstate Commerce Commission.

**ACTION:** Revised Service Order No. 1363-A.

**SUMMARY:** Revised Service Order No. 1363 authorizes the Burlington Northern Inc., to substitute two refrigerators for each boxcar ordered for shipments of sugar. This order is being vacated.

**EFFECTIVE DATE:** 11:59 p.m., April 18, 1980.

**FOR FURTHER INFORMATION CONTACT:**

J. Kenneth Carter (202) 275-7840.

Upon further consideration of Revised Service Order No. 1363, (44 FR 17138), and good cause appearing therefor:

**§ 1033.1363 [Vacated]**

*It is ordered:* That § 1033.1363 *Substitution of Refrigerator Cars for Boxcars.*

Revised Service Order No. 1363 is vacated effective 11:59 p.m., April 18, 1980.

(49 U.S.C. (10304-10305 and 11121-11126))

This order shall be served upon the Association of American Railroads, Car Service Division, as agent of the railroads subscribing to the car service and car hire agreement under the terms of that agreement and upon the American Short Line Railroad Association. Notice of this order shall be given to the general public by depositing a copy in the Office of the Secretary of the Commission, at Washington, D.C., and by filing a copy with the Director, Office of the Federal Register.

By the Commission, Railroad Service Board, members Joel E. Burns, Robert S. Turkington and John R. Michael.

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80-12334 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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**DEPARTMENT OF COMMERCE**

**National Oceanic and Atmospheric Administration**

**50 CFR Part 652**

## Atlantic Surf Clam and Ocean Quahog Fisheries; Adjustment in Allowable Atlantic Surf Clam Fishing Time

**AGENCY:** National Oceanic and Atmospheric Administration/ Commerce.

**ACTION:** Notice of adjustment in allowable Atlantic surf clam fishing time.

**SUMMARY:** This notice increases the allowable fishing time to 36 hours per week for fishing vessels harvesting Atlantic surf clams within the United States fishery conservation zone (FCZ). The increase in fishing time is intended to allow the fishermen harvesting Atlantic surf clams to harvest the full quarterly allocation of surf clams for the second quarter of 1980.

**EFFECTIVE DATE:** April 20, 1980, through June 27, 1980.

**FOR FURTHER INFORMATION CONTACT:** Allen E. Peterson, Jr., Regional Director, Northeast Region, National Marine Fisheries Service, 14 Elm Street, Gloucester, Massachusetts 01930, telephone: (617) 281-3600.

**SUPPLEMENTARY INFORMATION:** Section 652.22(a)(5) of the regulations implementing the Surf Clam Fishery Management Plan permits the Regional Director to increase the number of hours per week during which fishing for surf clams is permitted to facilitate the harvest of the full quarterly allocation. He must first determine that the quarterly allocation will not be harvested at the then-current level of fishing effort, and that the catch rate has not diminished as a result of a decline in abundance of stocks of surf clams.

It is currently estimated that the harvest of surf clams during the first quarter of 1980 fell short of the adjusted quarterly allocation by approximately 70,000 bushels. This shortfall will be added to the quarterly quota for the second quarter of 1980. With this addition, the allocation for the fourth quarter will approximate 570,000 bushels.

Although the provision of a make-up period for fishing time lost to bad weather during the first quarter of 1980 afforded relatively free opportunity to harvest surf clams, a number of factors combined to reduce the actual rate of harvest. These include the closure or slow-down of some processing plants due to market conditions and diversion of considerable processing effort away from surf clams to ocean quahogs. These factors, which are expected to continue throughout the next few months, will contribute to continued low rates of harvest unless fishing time is increased.

In evaluating an increase in allowable fishing time, the Regional Director has consulted with members of the surf clam committee and the surf clam advisory sub-panel of the Mid-Atlantic Council, together with individuals involved in the surf clam fishery. The Regional Director has determined that the quarterly allocation of surf clams will not be harvested with the current 24-hour fishing week. Further, there is no evidence that the catch rate may have diminished as a result of a decline in abundance of stocks of surf clams. The Regional Director has decided to increase allowable fishing time as required to ensure the harvest of the full quarterly allocation. Therefore, effective April 20, 1980, the allowable fishing time for surf clams will increase to 36 hours per week until June 27, 1980.

(16 U.S.C. 1801 *et seq.*)

Signed at Washington, D.C. this the 17th day April, 1980.

**Winfred H. Meibohm,**

*Executive Director, National Marine Fisheries Service.*

[FR Doc. 80-12296 Filed 4-17-80; 3:25 pm]

BILLING CODE 3510-22-M

# Proposed Rules

Federal Register
Vol. 45, No. 79
Tuesday, April 22, 1980

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 925

[Docket No. F&V A0-79-2]

### Grapes Grown in Southeastern California; Decision and Referendum Order on Proposed Marketing Agreement and Order

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

**ACTION:** Proposed rule.

**SUMMARY:** This decision proposes a marketing agreement and order regulating the handling of grapes grown in southeastern California. Producers of grapes grown in the production area will be given the opportunity to vote in a referendum to determine if they favor the proposed marketing order.

The proposed order would: establish a committee of 11 grower and handler members and one public member for local administration; authorize grade, size, quality, maturity, pack, container, and volume regulations; and allow the committee to engage in production and marketing research and development projects financed by handler assessments. The primary objective is to promote orderly marketing of grapes. Consumers would benefit from a consistent supply of good quality fruit and growers would benefit from an expanded market.

**DATES:** The representative period for purposes of the referendum herein ordered is January 1, 1979, through December 31, 1979.

**FOR FURTHER INFORMATION CONTACT:** Malvin E. McGaha, Fruit Branch, Fruit and Vegetable Division, AMS, USDA, Washington, D.C. 20250, Phone: (202) 447-5975.

**SUPPLEMENTARY INFORMATION:** Prior documents in this proceeding: Notice of Hearing; issued November 23, 1979, and published in the **Federal Register** (44 FR 67990) on November 28, 1979; and Notice of Recommended Decision; issued February 22, 1980, and published in the **Federal Register** (45 FR 12797) on February 27, 1980.

*Preliminary Statement:* The proposed marketing agreement and order were formulated on the record of the public hearing at Coachella, California, December 12-13, 1979. Notice of Hearing was published in the November 28, 1979, issue of the **Federal Register** (44 FR 67990). The notice set forth a proposed marketing order submitted by a group of producers and handlers of grapes grown in the production area.

On the basis of the evidence introducted at the hearing and the record thereof, the Deputy Administrator, Marketing Program Operations, on February 22, 1980, filed with the Hearing Clerk, U.S. Department of Agriculture, a recommended decision which contained notice of the opportunity to file written exceptions thereto by March 18, 1980.

*Rulings on Exceptions:* One exception was filed by William H. Kopke, Jr., Inc. and Interamerican Fruit and Produce Co., importers of Chilean grapes. This exception expressed concern that the order may affect the importation of Chilean grapes and requested an extension of time to present evidence in this proceeding. While the order would regulate only the handling of grapes grown in the production area, it could result in the application of comparable grade, size, quality or maturity requirements to imports of grapes. But this could occur only if Section 8e of the Agricultural Marketing Agreement Act is amended to add fresh table grapes as a commodity covered by that section. A bill (HR 5526) designed to effect such an amendment was introducted on October 10, 1979. The disposition of that bill is a matter for the Congress to decide. It is not dealt with directly in this proceeding. As to the requested extension of time, ample opportunity was given all interested persons to participate in this proceeding. On August 17, 1979, the Department issued a press release asking interested persons to submit comments on the proposed order. A hearing on the proposal was held at Coachella, California, on December 12-13, 1979. A substantial effort was made to bring the hearing to the attention of all interested persons.

The hearing was held following publication in the **Federal Register** of a notice announcing the hearing. A press release announcing the hearing was made available to the news media. The producers and handlers of grapes who submitted the proposed marketing order indicated that the order, if approved, should be made effective May 1, 1980, so as to be in effect at the beginning of the 1980 shipping season. Under the circumstances, it is impracticable to delay the grower referendum to provide further opportunity for public hearings in this proceeding. Therefore, the exception and the request for extension of time are denied.

Another exception filed by Raymond Salehar expressed the view that the program would not result in product improvement but would increase consumer costs. This view is not supported by the record and is therefore denied.

The material issues, findings and conclusions, rulings and general findings of the recommended decision published February 27, 1980, in the **Federal Register** (45 FR 12797) are hereby incorporated by reference herein and made a part hereof, subject to the following corrections:

| Page | Column | Line | Change |
|---|---|---|---|
| 12798... | 2 | 40 | "7,912" to "7,192". |
| 12800... | 2 | 19 | "marketing" to "marking". |
| 12804... | 2 | 41 | "gapes" to "grapes". |
| 12804... | 2 | 63 | "tend to "tends". |
| 12806... | 1 | 13 | "thge" to "the". |
| 12806... | 1 | 58 | "certifcate" to "certificate". |
| 12806... | 2 | 9 | "shoud" to "should". |
| 12806... | 2 | 59 | "effucuate" to "effectuate". |
| 12806... | 3 | 26 | "areas" to "area". |

*Marketing agreement and order.* Annexed hereto and made a part hereof are two documents entitled, respectively, "Marketing Agreement Regulating the Handling of Grapes Grown in a Designated Area in California," and Marketing Order Regulating the Handling of Grapes Grown in a Designated Area in California, which have been decided upon as the detailed and appropriate means of effectuating the foregoing conclusions.

*It is hereby ordered,* that this entire decision, except the annexed marketing agreement, be published in the Federal Register. The regulatory provisions of the marketing agreement are identical with those contained in the order which is published with this decision.

*Referendum order.* It is hereby directed that a referendum be conducted in accordance with the procedure for the conduct of referenda (7 CFR 900.400 *et seq.*), to determine whether the issuance of the annexed order regulating the handling of grapes grown in a designated area in California is approved or favored by producers, as defined under the terms of the order, who during the representative period were engaged in the production area in the production of the regulated commodity for fresh market.

The representative period for the conduct of such referendum is hereby determined to be January 1, 1979, to December 31, 1979.

The agents of the Secretary to conduct such referendum are hereby designated to be Roland G. Harris and John H. Clark, Fruit and Vegetable Division, AMS, U.S. Department of Agriculture, 845 S. Figueroa—Suite 540, Los Angeles, California 90017.

This rule has been reviewed under the USDA criteria for implementing Executive Order 12044, and has been classified "significant." A Final Impact Analysis is available from Malvin E. McGaha, Chief, Fruit Branch, Fruit and Vegetable Division, AMS, U.S. Department of Agriculture, Washington, D.C. 20250, Phone (202) 447-5975.

Copies of this decision are being mailed to known interested persons. Others may obtain copies from the designated referendum agents or from Mr. McGaha.

Signed at Washington, D.C., on: April 16, 1980.

Jerry Hill,

*Deputy Assistant Secretary for Marketing Services.*

**Marketing Order [1] Regulating the Handling of Grapes Grown in a Designated Area in California**

*Findings*

(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 *et seq.*), 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 a proposed marketing agreement and a proposed order, regulating the handling of grapes grown in a designated area in California.

Upon the basis of the record it is found that:

(1) The order, and all of the terms and conditions thereof, will tend to effectuate the declared policy of the act;

(2) The order regulates the handling of grapes grown in the production area in the same manner as, and is applicable only to persons in the respective classes of commercial and industrial activity specified in, a proposed marketing agreement and order upon which a hearing has been held;

(3) The order is limited in its application to the smallest regional production area which is practicable, consistently with carrying out the declared policy of the act, and the issuance of several orders applicable to subdivisions of the production area would not effectively carry out the declared policy of the act;

(4) There are no differences in the production and marketing of grapes grown in the production area which make necessary different terms and provisions applicable to different parts of such area; and

(5) All handling of grapes grown in the production area is in the current of interstate or foreign commerce or directly burdens, obstructs, or affects such commerce.

*Order Relative to Handling*

*It is therefore ordered,* That on and after the effective date hereof, the handling of grapes grown in a designated area in California shall be in conformity to and in compliance with the following terms and conditions;

The provisions of the proposed order contained in the recommended decision issued by the Deputy Administrator on February 22, 1980, and published in the **Federal Register** on February 27, 1980 (45 FR 12797), shall be and are the terms and provisions of this order, and are set forth in full herein.

## PART 925—GRAPES GROWN IN A DESIGNATED AREA OF SOUTHEASTERN CALIFORNIA

*Marketing Order [2] Regulating the Handling of Grapes Grown in a Designated Area in California.*

**Definitions**

Sec.
925.1 Secretary.
925.2 Act.
925.3 Person.
925.4 Grapes.
925.5 Production area.
925.6 Varieties.
925.7 Producer.
925.8 Handler.
925.10 Handle.
925.11 Pack.
925.12 Fiscal period.
925.13 Container.
925.14 Committee.

**Administrative Body**

925.20 Establishment and membership.
925.21 Term of office.
925.22 Nomination.
925.23 Selection.
925.24 Failure to nominate.
925.25 Acceptance.
925.26 Vacancies.
925.27 Alternate members.
925.28 Powers.
925.29 Duties.
925.30 Procedure.
925.31 Compensation and expenses.
925.32 Annual report.

**Expenses and Assessments**

925.40 Expenses.
925.41 Assessments.
925.42 Accounting.

**Research and Market Development**

925.45 Production research and market research and development.

**Regulations**

925.50 Marketing policy.
925.51 Recommendation for regulation.
925.52 Issuance of regulations.
925.53 Modification, suspension, or termination of regulations.
925.54 Special purpose shipments.

**Inspection and Certification**

925.55 Inspection and certification.

**Reports**

925.60 Reports.

**Miscellaneous Provisions**

925.61 Compliance.
925.62 Right of the Secretary.
925.63 Termination.
925.64 Proceedings after termination.
925.65 Effect of termination or amendment.
925.66 Duration of immunities.
925.67 Derogation.
925.68 Personal liability.
925.69 Separability.

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

**Definitions.**

**§ 925.1 Secretary.**

"Secretary" means the Secretary of Agriculture of the United States, or any officer or employee of the Department to whom authority has heretofore been delegated, or to whom authority may hereafter be delegated.

**§ 925.2 Act.**

"Act" means Public Act No. 10, 73d Congress (May 12, 1933), as amended and as reenacted and amended by the Agricultural Marketing Agreement Act of 1937, as amended (48 Stat. 31, as amended; 7 U.S.C. 601-674).

[1] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

[2] This order shall not become effective unless and until the requirements of § 900.14 of the rules of practice and procedure governing proceedings to formulate marketing agreements and marketing orders have been met.

**§ 925.3 Person.**

"Person" means an individual, partnership, corporation, association, or any other business unit.

**§ 925.4 Grapes.**

"Grapes" means any variety of vinifera species table grapes grown in the production area.

**§ 925.5 Production area.**

"Production area" means Imperial County, California, and that part of Riverside County and San Diego County, California, situated east of a line drawn due north and south through the Post Office in White Water, California.

**§ 925.6 Varieties.**

"Varieties" means and includes all classifications or subdivisions of Vitis vinifera table grapes.

**§ 925.7 Producer.**

"Producer" is synonymous with "grower" and means any person who produces grapes for the fresh market and who has a proprietary interest therein.

**§ 925.8 Handler.**

"Handler" is synonymous with "shipper" and means any person (except a common or contract carrier of grapes owned by another person) who handles grapes or causes grapes to be handled.

**§ 925.10 Handle.**

"Handle" is synonymous with "ship" and means to pack, sell, deliver (including delivery to a storage facility), transport, or in any way to place grapes in the current of commerce within the production area or between the production area and any point outside thereof: *Provided,* That such term shall not include the sale of grapes on the vine and except when regulations are effective pursuant to § 925.52(a)(5) shall not include the transportation or delivery of grapes to a packinghouse within the production area for preparation for market.

**§ 925.11 Pack.**

"Pack" means the specific arrangement, weight, grade or size, including the uniformity thereof, of the grapes within a container: *Provided,* That when used in or with respect to § 925.52(a)(5) such term shall mean to place grapes into containers for shipment to market as fresh grapes.

**§ 925.12 Fiscal period.**

"Fiscal period" is synonymous with "fiscal year" and means the 12 month period beginning on December 1 of one year and ending the last day of November of the following year or such other period as the committee, with the approval of the Secretary, may prescribe.

**§ 925.13 Container.**

"Container" means any lug, box, bag, crate, carton, or any other receptacle used in packing grapes for shipment as fresh grapes, and includes the dimensions, capacity, weight, marking, and any pads, liners, lids, and any or all appurtenances thereto or parts thereof. The term applies, in the case of grapes packed in consumer packages, to the master receptacle and to any and all packages therein.

**§ 925.14 Committee.**

"Committee" means the California Desert Grape Administrative Committee established under § 925.20.

**Administrative Body**

**§ 925.20 Establishment and membership.**

(a) There is hereby established a California Desert Grape Administrative Committee consisting of 12 members, each of whom shall have an alternate who shall have the same qualifications as the member. Five of the members and their alternates shall be producers or officers or employees of producers (producer members). Five of the members and their alternates shall be handlers or officers or employees of handlers (Handler members). One member and alternate shall be either a producer or handler or officer or employee thereof. One member and alternate shall represent the public.

(b) Not more than two members and not more than two alternate members shall be affiliated with the same handler entity.

(c) The committee may, with the approval of the Secretary, provide such other allocation of producer or handler membership, or both, as may be necessary to assure equitable representation.

**§ 925.21 Term of office.**

The term of office of the members and alternates shall be one fiscal period. Each member and alternate shall serve in such capacities for the portion of the term of office for which they are selected and have qualified and until their respective successors are selected and have qualified.

**§ 925.22 Nomination.**

(a) *Initial members.* Nominations for each of the initial members, together with nominations for the initial alternate members for each position, may be submitted to the Secretary by the Committee responsible for promulgation of this part. Such nominations may be made by means of a meeting of the growers and a meeting of the handlers. Such nominations, if made, shall be filed with the Secretary no later than the effective date of this part. In the event nominations for initial members and alternate members of the committee are not filed pursuant to, and within the time specified in, this section, the Secretary may select such initial members and alternate members without regard to nominations, but selections shall be on the basis of the representation provided in § 925.20.

(b) *Successor members.* The Secretary shall cause to be held, not later than November 15, of each year, meetings of producers and handlers for the purpose of making nominations for members and alternate members of the committee.

(c) Only producers, including duly authorized officers or employees of producers, who are present at such nomination meetings, may participate in the nomination and election of nominees for producer members and their alternates. Each producer entity shall be entitled to cast only one vote. If a person is both a producer and a handler of grapes, such person may participate in both producer and handler nominations.

(d) Only handlers, including duly authorized officers or employees of handlers, who are present at such nomination meetings, may participate in the nomination and election of nominees for handler members and their alternates. Each handler entity shall be entitled to cast only one vote.

(e) One member and alternate member shall be nominated by a vote of both producers and handlers and may be of either group.

(f) The public member and alternate member shall be nominated by the committee. The committee shall prescribe, with the approval of the Secretary, procedures for the nomination of the public member and qualification requirements for such member.

**§ 925.23 Selection.**

The Secretary shall select members and alternate members of the committee from persons nominated pursuant to § 925.22 or from other qualified persons.

**§ 925.24 Failure to nominate.**

If nominations are not made within the time and in the manner specified in § 925.22 the Secretary may select the members and alternate members of the committee without regard to nominations on the basis of the representation provided for in § 925.20.

**§ 925.25 Acceptance.**

Any person selected by the Secretary as a member or as an alternate member of the committee shall qualify by filing a written acceptance with the Secretary promptly after being notified of such selection.

**§ 925.26 Vacancies.**

To fill any vacancy occasioned by the failure of any person selected as a member or as an alternate member of the committee to qualify, or in the event of the death, removal, resignation, or disqualification of any member or alternate member of the committee, a successor for the unexpired term of such member or alternate member of the committee shall be nominated and selected in the manner specified in §§ 925.22 and 925.23. If the names of the nominees to fill any such vacancy are not made available to the Secretary within a reasonable time after such vacancy occurs, the Secretary may fill such vacancy without regard to nominations, which selection shall be made on the basis of the representation provided for in § 925.20.

**§ 925.27 Alternate members.**

An alternate member shall act in the place of the member during such member's absence or at such member's request, and may be assigned other program duties by the chairman or the committee. In the event of the death, removal, resignation, or disqualification of a member the alternate shall act for the member until a successor for such member is selected and has qualified. In the event that both a member and that member's alternate are unable to attend a committee meeting, the member or committee members present may designate any other alternate to serve in such member's place at the meeting if such action is necessary to secure a quorum: *Provided,* That not more than two members or alternates acting for members who are affiliated with the same handler entity shall serve as members at the same meeting.

**§ 925.28 Powers.**

The committee shall have the following powers:

(a) To administer the provisions of this part in accordance with its terms;

(b) To receive, investigate, and report to the Secretary complaints of violations of the provisions of this part;

(c) To make and adopt rules and regulations to effectuate the terms and provisions of this part; and

(d) To recommend to the Secretary amendments to this part.

**§ 925.29 Duties.**

The committees shall have, among others, the following duties:

(a) To select a chairman and such other officers as may be necessary, and to define the duties of such officers;

(b) To appoint such employees, agents, and representatives as it may deem necessary, and to determine compensation and to define the duties of each;

(c) To submit to the Secretary as soon as practicable after the beginning of each fiscal period a budget for such period, including a report in explanation of the items appearing therein and a recommendation as to the rate of assessment for such period;

(d) To keep minutes, books, and records, which will reflect all of the acts and transactions of the committee and which shall be subject to examination by the Secretary;

(e) To prepare periodic statements of the financial operations of the committee and to make copies of each such statement available to growers and handlers for examination at the office of the committee;

(f) To cause its books to be audited by a competent public accountant at least once each fiscal period and at such times as the Secretary may request;

(g) To act as intermediary between the Secretary and any grower or handler;

(h) To investigate and assemble data on the growing, handling, and marketing conditions with respect to grapes;

(i) To submit to the Secretary the same notice of meetings of the committee as is given to its members;

(j) To submit to the Secretary such available information as may be requested; and

(k) To investigate compliance with the provisions of this part.

**§ 925.30 Procedure.**

(a) Eight members of the committee shall constitute a quorum and any action of the committee shall require at least eight concurring votes;

(b) The committee may vote by telephone, telegraph, or other means of communications; and any votes so cast shall be confirmed promptly in writing: *Provided,* that if an assembled meeting is held, all votes shall be cast in person.

**§ 925.31 Compensation and expenses.**

The members of the committee, and alternates when acting as members, shall serve without compensation but may be reimbursed for expenses necessarily incurred by them in the performance of their duties under this part: *Provided,* That the committee at its discretion may request the attendance of one or more alternates at any or all meetings notwithstanding the expected or actual presence of the respective members and may pay expenses as aforesaid.

**§ 925.32 Annual report.**

The committee should, as soon as practicable, after the close of each fiscal period, prepare and mail an annual report to the Secretary and make a copy available to each grower and handler who requests a copy of the report.

**Expenses and Assessments**

**§ 925.40 Expenses.**

The committee is authorized to incur such expenses as the Secretary finds are reasonable and likely to be incurred by the committee for its maintenance and functioning and to enable it to exercise its powers and perform its duties in accordance with the provisions of this part. The funds to cover such expenses shall be acquired in the manner prescribed in § 925.41.

**§ 925.41 Assessments.**

(a) Each person who first handles grapes shall pay to the committee, upon demand, such handler's pro rata share of the expenses which the Secretary finds are reasonable and likely to be incurred by the committee during a fiscal period. The payment of assessments for the maintenance and functioning of the committee may be required under this part throughout the period it is in effect irrespective of whether particular provisions thereof are suspended or become inoperative.

(b) The Secretary shall fix the rate of assessment to be paid by each such person during a fiscal period in an amount designed to secure sufficient funds to cover the expenses which may be incurred during such period and to accumulate and maintain a reserve fund equal to approximately one fiscal period's expenses. At any time during or after a fiscal period, the Secretary may increase the rate of assessment in order to secure sufficient funds to cover any later findings by the Secretary relative to the expenses which may be incurred. Such increase shall be applied to all grapes handled during the applicable fiscal period. In order to provide funds for the administration of the provisions of this part during the first part of a fiscal period before sufficient operating income is available from assessments in the current period's shipments, the committee may accept the payment of assessments in advance, and may also borrow money for such purpose.

(c) Any assessment not paid by a handler within a period of time prescribed by the committee may be

subject to an interest or late payment charge, or both. The period of time, rate of interest, and late payment charge shall be recommended by the committee and approved by the Secretary. Subsequent to such approval, all assessments not paid within the prescribed time shall be subject to the interest or late payment charge, or both.

**§ 925.42 Accounting.**

(a) If, at the end of a fiscal period, the assessments collected are in excess of expenses incurred, such excess shall be accounted for in accordance with one of the following:

(1) If such excess is not retained in a reserve, as provided in subparagraph (2) of this paragraph, it shall be refunded proportionately to the persons from whom it was collected: *Provided,* That any sum paid by a person in excess of that person's pro rata share of the expenses during any fiscal period may be applied by the committee at the end of such fiscal period to any outstanding obligations due the committee from such person.

(2) The committee, with the approval of the Secretary, may carry over such excess into subsequent fiscal periods as a reserve: *Provided,* That funds in the reserve shall not exceed approximately one fiscal period's expenses. Such reserve funds may be used (i) to defray expenses, during any fiscal period, prior to the time the assessment income is sufficient to cover such expenses; (ii) to cover deficits incurred during any fiscal period when assessment income is less than expenses; (iii) to defray expenses incurred during any period when any or all provisions of this part are suspended or are inoperative; or (iv) to cover necessary expenses of liquidation in the event of termination of this part. Upon such termination, any funds not required to defray the necessary expenses of liquidation shall be disposed of in such manner as the Secretary may determine to be appropriate: *Provided,* That to the extent practicable such funds shall be returned pro rata to the persons from whom such funds were collected.

(b) All funds received by the committee under this part shall be used solely for the purpose specified in this part and shall be accounted for in the manner provided in this part. The Secretary may at any time require the committee and its members to account for all receipts and disbursements.

(c) Upon the removal or expiration of the term of office of any member of the committee, such member shall account for all receipts and disbursements and deliver all property and funds in such member's possession to the committee, and shall execute such assignments and other instruments as may be necessary or appropriate to vest in the committee full title to all of the property, funds, and claims vested in such member pursuant to this part.

**Research and Market Development**

**§ 925.45 Production research and market research and development.**

The committee, with the approval of the Secretary, may establish or provide for the establishment of production research, marketing research and development projects designed to assist, improve or promote the marketing, distribution and consumption or the efficient production of grapes. The expense of such projects shall be paid from funds collected pursuant to this part.

**Regulations**

**§ 925.50 Marketing policy.**

Each season prior to making any recommendation pursuant to § 925.51 the committee shall submit to the Secretary a report setting forth its marketing policy for the ensuing marketing season. Such marketing policy report shall contain information relative to:

(a) The estimated total shipments of grapes produced within the production area;

(b) The expected general quality of grapes in the production area;

(c) The expected demand conditions for grapes;

(d) The probable prices for grapes;

(e) Supplies of competing commodities, including foreign produced grapes;

(f) Trend and level of consumer income;

(g) Other factors having a bearing on the marketing of grapes; and

(h) The type of regulations expected to be recommended during the marketing season.

**§ 925.51 Recommendation for regulation.**

Upon complying with the requirements of § 925.50 the committee may recommend regulations to the Secretary whenever the committee deems that such regulations as are provided in § 925.52 will tend to effectuate the declared policy of the act.

**§ 925.52 Issuance of regulations.**

(a) The Secretary shall regulate, in the manner specified in this section, the handling of grapes upon finding from the recommendations and information submitted by the committee, or from other available information, that such regulation would tend to effectuate the declared policy of the act. Such regulation may: (1) limit the handling of any grade, size, quality, maturity, or pack, or any combination thereof, of any or all varieties of grapes during any period or periods; (2) limit the handling of any grade, size, quality, maturity, or pack of grapes differently for different varieties, or any combination of the foregoing during any period or periods; (3) limit the handling of grapes by establishing in terms of grades, sizes, or both, minimum standards of quality and maturity during any period when season average prices are expected to exceed the parity level; (4) fix the size, capacity, weight, dimensions, markings, materials, or pack of the container which may be used in handling of grapes; (5) establish holidays by prohibiting the packing of all varieties of grapes during a specified period or periods.

(b) No handler shall handle grapes that were packed during any period when such packing was prohibited by any regulation issued under paragraph (a)(5) of this section unless such grapes are handled under § 925.54.

**§ 925.53 Modification, suspension, or termination of regulations.**

(a) In the event the committee at any time finds that, by reason of changed conditions, any regulations issued pursuant to § 925.52 should be modified, suspended, or terminated, it shall so recommend to the Secretary.

(b) Whenever the Secretary finds from the recommendations and information submitted by the committee or from other available information that a regulation should be modified, suspended, or terminated with respect to any or all shipments of grapes in order to effectuate the declared policy of the act, the Secretary shall modify, suspend, or terminate such regulation. If the Secretary finds that a regulation obstructs or does not tend to effectuate the declared policy of the act, the Secretary shall suspend or terminate such regulation. On the same basis and in like manner the Secretary may terminate any such modification or suspension.

**§ 925.54 Special purpose shipments.**

(a) Regulations in effect pursuant to §§ 925.41, 925.52, or 925.55 may be modified, suspended, or terminated to facilitate handling of grapes for purposes which may be recommended by the committee and approved by the Secretary.

The committee shall, with the approval of the Secretary, prescribe such rules, regulations, and safeguards as it may deem necessary to prevent grapes handled under the provisions of this section from entering the channels

of trade for other than the specific purposes authorized by this section.

**Inspection and Certification**

**§ 925.55 Inspection and certification.**

(a) Whenever the handling of any variety of grapes is regulated pursuant to § 925.52, each handler who handles grapes shall, prior thereto, cause such grapes to be inspected by the Federal or Federal-State Inspection Service and certified as meeting the applicable requirements of such regulation: *Provided,* That inspection and certification shall not be required for grapes which previously have been so inspected and certified if such prior inspection was performed within such period as may be established pursuant to paragraph (b) of this section. Promptly after the inspection and certification each such handler shall submit, or cause to be submitted, to the committee a copy of the certificate of inspection issued with respect to such grapes.

(b) The committee may, with the approval of the Secretary, establish a period prior to shipment during which the inspection required by this section must be performed.

(c) The committee may enter into an agreement with the Federal and Federal-State Inspection Services with respect to the costs of the inspection required by paragraph (a) of this section, and may collect from handlers their respective pro rata share of such costs.

**Reports**

**§ 925.60 Reports.**

(a) Each handler shall furnish to the committee, at such times and for such periods as the committee may designate, certified reports covering, to the extent necessary for the committee to perform its functions, each shipment of grapes as follows: (1) The name of the shipper and the shipping point; (2) the car or truck license number (or name of the trucker), and identification of the carrier; (3) the date and time of departure; (4) the variety; (5) the number and type of containers in the shipment; (6) the destination; and (7) identification of the inspection certificate pursuant to which the grapes were handled.

(b) Upon request of the committee, made with the approval of the Secretary, each handler shall furnish to the committee, in such manner and at such times as it may prescribe, such other information as may be necessary to enable the committee to perform its duties under this part.

(c) Each handler shall maintain for at least two succeding fiscal periods after the end of the fiscal period in which the tranactions occurred, such records of the grapes received and disposed of by such handler as may be necessary to verify the reports such handler submits to the committee pursuant to this section.

(d) All reports and records submitted by handlers pursuant to the provisions of this section shall be received by, and at all times be in custody of one or more designated employees of the committeee. No such employee shall disclose to any person, other than the Secretary upon request therefor, data or information obtained or extracted from such reports and records which might affect the trade position, financial condition, or business operation of the particular handler from whom received: *Provided,* That such data and information may be combined, and made available to any person, in the form of general reports in which the identities of the individual handlers furnishing the information are not disclosed and may be revealed to any extent necessary to effect compliance with the provisions of this part and the regulations issued thereunder.

**Miscellaneous Provisions**

**§ 925.61 Compliance.**

Except as provided in this part, no handler shall handle grapes except in conformity with the provisions of this part and the regulations issued thereunder.

**§ 925.62 Right of the Secretary.**

The members of the committee (including successors and alternates) and any agents, employees, or representatives thereof, shall be subject to removal or suspension by the Secretary at any time. Each and every regulation, decision, determination, or other act of the committee shall be subject to the continuing right of the Secretary to disapprove of the same at any time. Upon such disapproval, the disapproved action of the committee shall be deemed null and void, except as to acts done in reliance thereon or in accordance therewith prior to such disapproval by the Secretary.

**§ 925.63 Termination.**

(a) The Secretary shall terminate or suspend the operation of any and all of the provisions of this part whenever the Secretary finds that such provisions do not tend to effectuate the declared policy of the act.

(b) The Secretary shall terminate the provisions of this part whenever it is found by referendum or otherwise that such termination is favored by a majority of the growers: *Provided,* That such majority has during the current marketing season produced more than 50 percent of the volume of grapes which were produced within the production area for shipment in fresh form. Such termination shall become effective on the first day of December subsequent to the announcement thereof by the Secretary.

(c) The provisions of this part shall, in any event, terminate whenever the provisions of the act authorizing them cease to be in effect.

**§ 925.64 Proceedings after termination.**

(a) Upon the termination of the provisions of this part, the committee shall, for the purpose of liquidating the affairs of the committee, continue as trustees of all the funds and property then in its possession, or under its control, including claims for any funds unpaid or property not delivered at the time of such termination. Any action by said trustees shall require the concurrence of a majority of the trustees.

(b) The said trustees shall: (1) continue in such capacity until discharged by the Secretary; (2) from time to time account for all receipts and disbursements and deliver all property on hand, together with all books and records of the committee and of the trustees, to such persons as the Secretary may direct; (3) upon the request of the Secretary, executive such assignments or other instruments necessary or appropriate to vest in such person, full title and right to all of the funds, property, and claims vested in the committee or the trustees pursuant thereto.

(c) Any person to whom funds, property, or claims have been transferred or delivered, pursuant to this section, shall be subject to the same obligation imposed upon the committee and upon the trustees.

**§ 925.65 Effect of termination or amendment.**

Unless otherwise expressly provided by the Secretary, the termination of this part or any regulation issued pursuant to this part, or the issuance of any amendment to either thereof, shall not: (a) affect or waive any right, duty, obligation, or liability which shall have arisen or which may thereafter arise in connection with any provision of this part or any regulation issued under this part; or (b) release or extinguish any violation of this part or any regulation issued under this part; or (c) affect or impair any rights or remedies of the Secretary or any other person with respect to any such violation.

**§ 925.66 Duration of immunities.**

The benefits, privileges, and immunities conferred upon any person by virtue of this part shall cease upon its termination, except with respect to acts done under and during the existence of this part.

**§ 925.67 Derogation.**

Nothing contained in this part is, or shall be construed to be, in derogation or in modification of the rights of the Secretary or of the United States: (a) to exercise any powers granted by the act or otherwise; or (b) in accordance with such powers, to act in the premises whenever such action is deemed advisable.

**§ 925.68 Personal liability.**

No member or alternate member of the committee and no employee or agent of the committee shall be held personally responsible, either individually or jointly with others, in any way whatsoever, to any person for errors in judgment, mistakes, or other acts, either of commission or omission, as such member, alternate, employee, or agent, except for acts of dishonesty, willful misconduct, or gross negligence.

**§ 925.69 Separability.**

If any provision of this part is declared invllid or the applicability thereof to any person, circumstance, or thing is held invalid, the validity of the remainder of this part or the applicability thereof to any other person, circumstance, or thing shall not be effected thereby.

[FR Doc. 80-12318 Filed 4-21-80; 8:45 am]
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## NUCLEAR REGULATORY COMMISSION

### 10 CFR Part 140

**[Docket No. PRM-140-2]**

### Public Citizen Litigation Group; Filing of Petition for Rule Making

**AGENCY:** U.S. Nuclear Regulatory Commission.

**ACTION:** Publication of Petition for Rule Making from Public Citizen Litigation Group.

**SUMMARY:** The Nuclear Regulatory Commission is publishing for public comment, as a petition for rule making, a letter sent to the General Counsel of the Commission on December 20, 1979 by the Public Citizen Litigation Group. This petition, which has been assigned Docket No. PRM-140-2, requests that the Commission amend its regulations relating to "Financial Protection Requirements and Indemnity Agreements" to increase the amount of liability insurance required of persons licensed to operate large commercial nuclear power plants. The General Counsel's response to the letter is also summarized in this notice.

**DATE:** Comment period expires June 23, 1980.

**ADDRESSES:** Copies of the petition for rule making and the General Counsel's response are available for public inspection in the Commission's Public Document Room, 1717 H Street, NW, Washington, DC. Copies of the petition and the General Counsel's response may be obtained by writing to the Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555.

All persons who desire to submit written comments or suggestions concerning the petition for rulemaking should send their comments to the Secretary of the Commission, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Attention: Docketing and Service Branch.

**FOR FURTHER INFORMATION CONTACT:** Joseph M. Felton, Director, Division of Rules and Records, Office of Administration, U.S. Nuclear Regulatory Commission, Washington, DC 20555, Telephone: 301-492-2711.

**SUPPLEMENTARY INFORMATION:** Representatives of the Public Citizen Litigation Group, by letter dated December 20, 1979 to Leonard Bickwit, Jr., General Counsel of the Nuclear Regulatory Commission, (NRC), have requested that the NRC amend paragraph 10 CFR 140.11(a)(4) of its regulations, which, in part, presently requires persons licensed to operate large commercial nuclear power plants to purchase $160 million in liability insurance to compensate the public in the event of a nuclear incident. Representatives of the Public Citizen Litigation Group state, "Since the insurance and the nuclear industries have the capacity to sell several hundred million dollars in additional liability insurance, the regulation is inconsistent with the direction of the Price-Anderson Act, 42 U.S.C. § 2210, *et seq.*, that the NRC require nuclear utilities to purchase the 'maximum available insurance'."

The Commission has directed that the letter be treated as a petition for rule making filed in accordance with 10 CFR 2.802 of the Commission's regulations. The letter supports its request for rule making by stating, in relevant part, as follows:

* * * In our view, the NRC's regulation is deficient because the $160 million liability insurance currently required is not the 'maximum insurance available,' as mandated by Congress. There are two facts which strongly suggest to us that at least several hundred million dollars in additional insurance could be made available for the protection of the public. First, the insurance industry currently sells reactor owners approximately $300 million in insurance to cover the loss of the reactor. Adding this figure to the $160 million sold for the protection of the public shows that the insurance industry has the capacity to sell $460 million in liability insurance. The entire $300 million could, and should by law, be purchased for the benefit of the public. We do not believe that there is any legitimate argument that the insurance industry has the capacity to sell this insurance only to utilities. In fact, we would think that the premiums for such insurance would be lower if it were sold as liability rather than property insurance. Any substantial nuclear accident will always involve substantial damage to the reactor, but not necessarily injury to the public.

* * * The second indication that the insurance industry has a greater capacity to issue insurance to protect the public is the plan currently being devised to insure utilities against protracted replacement power costs which would arise from future accidents such as that which occurred at Three Mile Island. According to a recent article in the *Washington Star* (attached), 'the accident at Three Mile Island may cost the utility between $678 million and $1.1 billion for replacement power.' Responding to this risk, electric utilities are apparently in the final stages of preparing a new private system which would insure against such losses. It is unclear whether such insurance would be underwritten by private insurance companies or by the utilities themselves. But in either event, the additional capacity must be made available to the public because the Act states that the financial protection required by the NRC may include 'private insurance' and 'self-insurance.' 42 U.S.C. 2210(b). Therefore, this newly created system establishes beyond doubt that there is a vast, untapped capacity within the nuclear industry and within the insurance industry to provide liability insurance against a catastrophic nuclear accident * * *.

In a letter dated February 19, 1980, the General Counsel responded to the petitioners by stating, in relevant part, as follows:

* * * NRC regulations implementing Section 170b of the Price-Anderson Act (42 U.S.C. 2210(b)) have historically adopted the amount provided by the nuclear liability insurance pools as the 'maximum amount available' from private sources at reasonable cost and on reasonable terms. * * * During this twenty-year period, the Price-Anderson Act has twice been thoroughly re-examined by Congress, which was aware of the Commission's implementation of this section. We have been unable to locate any legislative history indicating Congressional dissatisfaction with the insurance program then in effect. Particularly during the 1974-1975 review, when the 'secondary layer' of

retrospective premiums was developed, this matter was under close Congressional scrutiny. Nevertheless, Congress did not amend Section 170b as to primary insurance, nor did it require the Commission to alter its regulations implementing that section.

It is therefore our view that 10 CFR 140.11 was validly promulgated by the Commission. Your letter, however, presents certain policy issues which deserve more detailed consideration. * * * Whether the facts now justify an increase in the primary financial protection layer can be appropriately explored in the rule making contest. * * *

Dated at Washington, DC, this 16th day of April 1980.

For the Nuclear Regulatory Commission.

**John C. Hoyle,**

*Acting Secretary of the Commission.*

[FR Doc. 80-12135 Filed 4-21-80; 8:45 am]

BILLING CODE 7590-01-M

## SMALL BUSINESS ADMINISTRATION

## 13 CFR Part 121

## Small Business Size Determination Procedures

**AGENCY:** Small Business Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The proposed amendments set forth clarifying and procedural provisions applicable to SBA size determinations. The amendments are largely of an interpretive and technical nature reflecting existing SBA precedents and policies. The amendments help implement P.L. 95-507 size determination procedures relating to subcontracting assistance and 8(a) assistance to small business concerns. The amendments indicate SBA small business size determinations to assist other agencies.

These amendments (which refer to the present format of the size regulation), primarily relate to procedures for size protests and appeals in contrast to other recent proposed amendments to Part 121 (March 10, 1980; 45 FR 15442) which primarily involve basic changes in the size standards and in the economic theory of such standards.

**DATES:** Comments should be received not later than May 22, 1980.

**ADDRESSES:** Interested persons are invited to submit written comments to Office of General Law, Small Business Administration, 1441 L St., N.W., Washington, D.C. 20416.

**FOR FURTHER INFORMATION CONTACT:** Stephen A. Klein, Office of General Law (202) 653-6762.

**SUPPLEMENTARY INFORMATION:** Particular areas covered in the proposed amendments include:

1. Joint venture definition and subcontracting affiliations.
2. Annual receipts applicable period regarding new concerns and affiliates.
3. Recertifications.
4. Size determinations to assist other agencies.
5. Multiple Award Schedule set asides.
6. Time as of which size status is determined for set aside procurements.
7. Time as of which size status is determined for Government property sale or lease purposes.
8. Subcontracting size determinations.
9. Formal size determinations on concerns for 8(a) assistance purposes.

These amendments relate to procedural, organizational and administrative matters in connection with SBA determinations on the small business size status of concerns under the various SBA size standards. They are largely of a clarifying and technical nature in areas where SBA experience on particular size determination cases indicates the desirability of general guidelines or modifications in existing rules. To a major extent these proposed amendments reflect existing SBA policies or interpretations. A number of the amendments relate to size determinations in the Government procurement area.

SBA size determinations are made at the SBA field office in the region where the firm is located. Appeals of formal size determinations under Part 121 may be taken to the Size Appeals Board. The SBA size standards are generally in terms of a number of employees or average annual receipts and include all concerns under common ownership or control in determining whether a company is within the particular size standard applicable to the size determination. Procurement size standards utilized may vary depending on the industry category which is the principal nature of a particular procurement for which the size determination is being made. Financial assistance size standards vary in terms of the primary industry of the concern and its affiliates.

The joint venture affiliate amendment indicates that for SBA size determination purposes joint ventures are temporary in nature (e.g., a single project) and may be in corporate or other legal form. Also, it is indicated that certain subcontracting relationships may give rise to a joint venture.

With respect to the annual receipts amendment it should be noted that it restores certain interpretive language which had been omitted from the Code of Federal Regulations. The matter covers inclusion of affiliate receipts and computation of average receipts of new concerns.

A provision is added noting that recertification is not required if an SBA adverse size determination is based solely on an ineligibility restricted to a particular procurement or sale. Also, it is noted that recertifications are generally appealable at that time to the Size Appeals Board only by the concern in question (i.e., in the case of an adverse size determination on an application for recertification).

The amendment on SBA size determinations to assist other agencies could have application to size determinations relating to possible debarment proceedings by such other agencies when small business size status is an issue, and to small business size status under Government regulatory or assistance programs. It generally would apply if an agency utilizes the SBA size standards and requests an SBA size determination on the status of a particular concern. Agencies might refer to such SBA size standards in their regulations or written eligibility guidelines.

As respects size determinations on multiple award schedule small business set asides, the identity of offerors may not be disclosed until after award and the normal procedures on timeliness of protests would generally not be appropriate. Therefore, the amendment provides that a protest may be made at any time prior to the expiration of the contract period.

The amendment dealing with the time at which size is determined for procurement and property sales purposes is a codification of the present interpretation of the current regulations by the Size Appeals Board. It generally provides that size is determined as of bid/offer submission. This interpretation, adopted by the Board in a recent case, revises the Board's previous views in this area. It is preferable that this issue should be codified in the regulations rather than relying upon case law interpretation. Since this is a codification of current case law, it should be recognized that the principle is currently being applied by the Board as a case law interpretation, pending consideration of this proposed regulation.

The previous case law interpretation often determined size at both the time of bid opening and the time of the Board's decision in cases where award had not yet been made. This resulted in size certifications by bidders and offerors relating to future and uncertain points of time (e.g., bid opening and award). The present case law interpretation by the Board and the codification thereof in the

proposed regulations would resolve this ambiguity and these uncertainties by substituting a point of time that is present and certain at the time of size certification by the bidder/offeror. The intent of the Board is to assist bidders/offerors in accurately making this critical contractual certification and in making appropriate judgments and projections in the operations of their business; and to assist SBA in facilitating a more equitable and expeditious handling of size protests and appeals.

The proposed amendment for subcontracting size determinations is in response to the recommendation in the Conference Report on Pub. L. 95–507 (House of Representatives Report No. 95–1714) that SBA establish a procedure to review the eligibility of small subcontractors which have made written representations on their small business size status, when such written representations are challenged on particular procurements having small business subcontracting requirements. The size determination could be instituted by the contracting officer or other affected party, including the concern making the written representation when its representation is refused acceptance. When the subcontracting protest challenges the small business size of the concern the SBA size determinations would be made under Part 121; if the protest challenges the firm as not owned and controlled by socially and economically disadvantaged individuals, the SBA determination regarding such status would be made under procedures pursuant to Part 124 of SBA Regulations. These size determinations relate to subcontracting under Section 8(d) of the Small Business Act (see Part 125 of the SBA Regulations, 44 FR 60273, October 19, 1979; see also proposed regulations of the Office of Federal Procurement Policy, 44 FR 62093, October 29, 1979).

The amendment relating to size determinations for the SBA 8(a) program indicates that Part 121 size procedures may be utilized when appropriate to assist the existing SBA 8(a) program size determination procedures. The 8(a) regulations issued pursuant to Pub. L. 95–507 are set forth in Part 124 of the SBA Regulations (44 FR 30672, 30666; May 29, 1979). Also, special size treatment for divestiture agreements re 8(a) firms is proposed to be deleted from the Size Regulation as no longer to be applicable under Pub. L. 95–507.

Dated: April 15, 1980.

**William H. Mauk, Jr.,**

*Acting Administrator.*

Therefore, pursuant to the authority of Section 5(b)(6) of the Small Business Act (15 U.S.C. 634), the Small Business Administration proposes to amend Part 121 of its Regulations (13 CFR Part 121) as follows:

**§ 121.3–2 Definitions of terms used in part. [Amended]**

1. Section 121.3–2(a)(vii) (Control through contractual relationships) is amended by amending paragraphs (A) and (C) to read as follows:

(a) * * *

(vii) * * *

(a) Definition of a joint venture for size determination purposes: A joint venture for size determination purposes, is an association of persons and/or concerns with interests in any degree or proportion by way of contract, express or implied, consorting to engage in and carry out a single specific business venture for joint profit for which purpose they combine their efforts, property, money, skill, or knowledge, but not on a continuing or permanent basis for conducting business generally.

* * * * *

(c) Joint venture—procurement and property sale assistance. Concerns bidding on a particular procurement or property sale as joint venturers are considered as affiliated and controlling or having the power to control each other with regard to performance of the contract. Moreover, an ostensible subcontractor which is to perform primary or vital requirements of a contract may have a controlling role such to be considered a joint venturer affiliated on the contract with the prime contractor. A joint venture affiliation finding is limited to particular contracts unless the SBA size determination finds general affiliation as between the parties.

* * * * *

2. Section 121.3–2(b) (Definition of annual receipts) is amended by adding the following at the end thereof:

* * * * *

(b) * * * If a concern has been in business less than a year, its annual receipts for the purpose of a size standard based on 1 year's receipts shall be computed by determining its average weekly receipts for the period in which it has been in business and multiplying such figure by 52. If a concern has been in business less than 3 years, its average annual receipts for the purpose of a size standard based on 3 years' receipts, shall be computed by determining its average weekly receipts for the period in which it has been in business, and multiplying such figure by 52. If a concern has acquired an affiliate during the applicable accounting period, it is necessary in computing the applicant's annual receipts to include the affiliate's receipts during the entire applicable accounting period, rather than only its receipts during the period in which it has been an affiliate. The receipts of a former affiliate are not included even if such concern had been an affiliate during a portion of the applicable accounting period.

* * * * *

**§ 121.3–4 Size determinations. [Amended]**

3. Section 121.3–4(d) (regarding recertifications) is amended by adding the following at the end thereof:

* * * * *

(d) * * * Recertification shall not be required nor will the prohibition against future self-certification apply if the adverse SBA size determination is based solely on a finding of affiliation due to a joint venture (e.g., ostensible subcontracting) limited to a particular Government procurement or property sale, or is based solely on an ineligible nonmanufacturer size determination on a particular Government procurement. If SBA makes a size determination denying an application for recertification, such adverse size determination may be appealed to the Size Appeals Board. Recertifications have future effect only and, except as to timber sales size determinations, are not appealable to the Board by other than the concern in question; (however, the concern's later self-certification on subsequent set-aside procurements or property sales may be protested in the usual manner).

* * * * *

4. Section 121.3–4 (regarding size determinations) is amended by adding the following new paragraph (e) at the end thereof:

* * * * *

(e) Size determinations for compliance purposes. Upon request by other Government agencies, SBA size determinations under Part 121 may be made to assist in the enforcement or administration of regulations or contracts, as well as in connection with award of contracts or granting of assistance. SBA size determinations are findings on the size status of a concern (including its affiliates) as of a definite time (and/or a specific applicable SBA size standard) and do not rule on compliance, contractual or administrative matters which are handled by the other agencies.

5. Section 121.3–5 (regarding protests) is amended by adding the following new paragraph (e) at the end thereof:

**§ 121.3–5 Protest of small business status.**

* * * * *

(e) *Multiple Award Schedules.* Protests will be deemed timely if received by SBA at any time prior to the expiration of the contract period (including renewals) on a multiple award schedule procurement set aside for small business.

6. Section 121.3–8 (definition of small business for Government procurement) is amended by adding the following new sentence as the second sentence thereof:

**§ 121.3–8 Definition of small business for Government procurement.**

* * * The size status of a concern (including its affiliates) is determined as of the date of written self-certification as a small business as part of a concern's submission of a bid or offer and, where award has been made prior to the SBA field office size determination, as of both such date and the date of award of the contract. * * *

* * * * *

7. Section 121.3–9 (definition of small business for sale or lease of Government property) is amended by adding the following new sentence as the second sentence thereof:

**§ 121.3–9 Definition of small business for sale or lease of Government property.**

* * * The size status of a concern (including its affiliates) is determined as of the date of written self-certification as a small business as part of a concern's submission of a bid or offer and, where award has been made prior to the SBA field office size determination, as of both such date and the date of award of the contract. * * *

* * * * *

8. Section 121.3–12 (definition of small business Government subcontractors) is amended by adding a new subsection (c) as follows:

**§ 121.3–12 Definition of small business Government subcontractors.**

* * * * *

(c) The contracting officer or other affected party in connection with small business subcontracting requirements, pursuant to section 8(d) of the Small Business Act, may protest a written representation of small business status, or the refusal to accept such written representation, of a concern offering as a subcontractor on a particular procurement. The protest and related information shall be referred to the SBA Regional Office in which the concern has its principal office and a size determination shall be made under this Part 121.

**§ 121.3–2 [Amended]**

9. (a) Section 121.3–2(a) (relating to affiliation and divestiture agreements) is amended by deleting the third and fourth sentences thereof.

(b) A new § 121.3–17 is added to Part 121 of the SBA Regulations to read as follows:

**§ 121.3–17 Formal size determinations on concerns for 8(a) assistance.**

(a) As set forth in paragraph (b) of this section, SBA may make formal size determinations under this Part 121 to assist in eligibility findings of concerns under Part 124 (8(a) assistance). Eligibility for 8(a) assistance is determined by the SBA Associate Administrator for Minority Small Business and Capital Ownership Development. Such eligibility is determined with reference to the 8(a) program in general and not with reference to award of particular 8(a) procurements. The size standards of Part 121 are utilized as related to the industry classification of the 8(a) concern.

(b) The Associate Administrator for Minority Small Business and Capital Ownership Development (AAMSB–COD) or a Regional Administrator may refer a case of 8(a) size eligibility to the regional office where the concern is located for a size determination under Part 121 (which is appealable by either party to the Size Appeals Board). Such size determinations under Part 121 are advisory to the AAMSB–COD; and/or to the Administrative Law Judge in 8(a) termination proceedings under Part 124.

[FR Doc. 80–12346 Filed 4–21–80; 8:45 am]
BILLING CODE 8025–01–M

## CIVIL AERONAUTICS BOARD

**[EDR–399; Economic Regulations Docket: 38048, Dated: April 16, 1980]**

**14 CFR Part 252**

### Provision of Designated "No-Smoking" Areas Aboard Air Carriers

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of proposed rulemaking.

**SUMMARY:** Under current CAB rules, all airline passengers are entitled to a seat in the aircraft's no-smoking section even if that section must be expanded to accommodate them. The CAB proposes to permit airlines to limit this right to those with confirmed reservations who are present for boarding at least 5 minutes before the scheduled departure of their flight. This action is taken at the CAB's own initiative.

**DATES:** Comments by: June 23, 1980.

Comments and other relevant information received after this date will be considered by the Board only to the extent practicable.

Requests to be put on the Service List by: May 2, 1980.

The Docket Section prepares the Service List and sends it to each person listed, who then serves his comments on others on the list.

**ADDRESSES:** Twenty copies of comments should be sent to Docket 38048, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428. Individuals may submit their views as consumers without filing multiple copies. Copies may be examined in Room 711, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428.

**FOR FURTHER INFORMATION CONTACT:** David Schaffer, Office of the General Counsel, Civil Aeronautics Board, 1825 Connecticut Avenue, NW., Washington, D.C. 20428, 202–673–5442.

**SUPPLEMENTARY INFORMATION:** The Board has become aware of a possible problem with the rule on smoking aboard air carriers, in 14 CFR Part 252. At present, under Part 252, a passenger has the right to a seat in the no-smoking section of an aircraft even if this section has to be expanded to accommodate that passenger. Unlike other passenger rights, such as the right to denied boarding compensation when bumped from an oversold fight, the right to a seat in the no-smoking section does not depend on the passenger's arrival at the boarding gate before any deadline set by the airline. The question raised in this notice is whether passengers who want to be ensured of a no-smoking seat should have to meet a reasonable deadline for arriving at the boarding gate, such as 5 minutes before scheduled departure.

We are proposing to allow airlines to require a passenger with a confirmed reservation on a scheduled flight to be present at the boarding gate 5 minutes before scheduled departure in order to be guaranteed the right to a no-smoking seat under Part 252. Under this proposal, "stand-by" passengers who do not have confirmed reservations would also not be guaranteed the right to seats in the no-smoking section. Carriers would not, of course, be prohibited from ensuring no-smoking seats for "stand-by" passengers or those who arrive at the gate after the check-in deadline. They would, however, no longer be obliged to expand the no-smoking section to accommodate stand-bys and late

arrivals. We are concerned, however, about passengers whose lateness or lack of a confirmed reservation is due to delayed connecting flights. Those persons should if possible have the same rights concerning no-smoking seats as regular passengers, and we request comment on the feasibility and best method of ensuring that they do, along with information on how often they would be denied no-smoking seats without special protection.

Although not obligated to expand the no-smoking section for stand-bys and late arrivals, airlines would still be expected to make reasonable efforts to accommodate the desires of these passengers. What constitutes a reasonable effort would depend on the duration of the flight, the number of empty seats on the flight, the reason the passenger failed to meet the deadline, any any particular susceptibility of that passenger to smoke. The airline would at a minimum be required to determine the passenger's preference and provide a seat in the appropriate section if one is available. In addition, flight attendants could seek passengers willing to switch seats and perhaps provide incentives for them to do so.

We are especially interested in hearing whether late arrivals have presented a significant problem for airlines in complying with Part 252, whether carriers have incurred significant financial costs or other problems (e.g., stress on flight attendants) in accommodating late-arrivals, whether having to find late arrivals seats in the no-smoking section has caused delays, and whether the limitation on passengers' rights proposed here is necessary to solve these problems. Comments are also requested on whether 5 minutes before scheduled departure is the appropriate deadline, and we propose in the alternative a 10-minute or longer deadline.

We are concerned that without the amendment proposed here, airlines may have an incentive to deny people seats altogether rather than expanding the no-smoking section to accommodate them. Airlines may now cancel a person's reservation if the check-in deadline is not met and this may possibly be a way for an airline to avoid its obligations under Part 252. Many non-smoking passengers would probably prefer riding in the smoking section to missing the flight altogether. We therefore specifically request comments on the extent to which, under present rules, late-arriving passengers risk being denied a seat on the flight if they request seating in the no-smoking section.

This proposal would permit airlines to set a deadline by which passengers must be "present at the boarding gate." The carrier could not require the passenger to have actually checked in at the boarding gate by the deadline. An actual check-in requirement would make the right to a no-smoking seat dependent on the number of other passengers in the line and the speed of the carrier's boarding gate procedures.

Scheduled flights for which advance reservations are not available, such as "shuttle" services, and those where seats are not assigned in advance of boarding, would be unaffected by the proposed amendment, and would continue to offer seats in a no-smoking section to all passengers who want them. These services are designed now to accommodate and arrange passengers on a walk-on basis, making a check-in deadline for the purpose of the smoking rule unnecessary.

Accordingly, the Board proposes to amend § 252.2 of 14 CFR Part 252, *Provision of Designated "No-Smoking" Areas Aboard Air Carriers*, to read:

**§ 252.2 No-smoking areas.**

(a) Carriers shall ensure that non-smoking passengers are not unreasonably burdened by breathing smoke and to that end shall provide at a minimum:

(1) A no-smoking area for each class of service and for charter service;

(2) A no-smoking section of at least two rows of seats;

(3) Except as provided in paragraph (b) of this section, a sufficient number of seats in the no-smoking areas of the aircraft for all persons who wish to be seated there;

(4) Except as required by paragraph (b) of this section, specific provision for expansion of no-smoking areas to meet passenger demand; and

(5) Special provisions to ensure that if a no-smoking section is placed between smoking sections, the non-smoking passengers are not unreasonably burdened.

(b) On flights for which passengers may make confirmed reservations and where seats are assigned prior to boarding, carriers are not obliged to expand the no-smoking area to accommodate passengers who are not present at the boarding gate at least 5 minutes before the scheduled departure time, or who do not have confirmed reservations. If a seat is available in the established no-smoking area, however, a carrier shall seat there any enplaning passenger who so requests, regardless of boarding time or reservation status.

(Secs. 204 and 404 of the Federal Aviation Act of 1958, as amended, 72 Stat. 743, 760, 49 U.S.C. 1324, 1374.)

By the Civil Aeronautics Board.

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 80-12322 Filed 4-21-80; 8:45 am]

BILLING CODE 6320-01-M

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Food and Drug Administration

### 21 CFR Part 73

**[Docket No. 78N-0390]**

### Diluents for Cosmetic Color Additive Mixtures; Intent To Propose Rules: Request for Information

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice of Intent to Propose Rules.

**SUMMARY:** The Food and Drug Administration (FDA) announces its intention to propose regulations listing diluents for safe use in cosmetic color additive mixtures and to exempt those mixtures from the certification requirement. The agency requests comments on this contemplated proposal and information on diluents in cosmetic color additive mixtures.

**DATES:** Comments on this notice or data for the listing of diluents must be submitted by October 20, 1980.

**ADDRESSES:** Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857; requests and appropriate supporting data for the listing of diluents for cosmetic color additive mixtures should be sent to Petitions Control Branch (HFF-334), Division of Food and Color Additives, Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, DC 20204.

**FOR FURTHER INFORMATION CONTACT:** Gerad L. McCowin, Bureau of Foods (HFF-334), Food and Drug Administration, Department of Health, Education, and Welfare, 200 C St. SW., Washington, D.C. 20204, 202-472-5690.

**SUPPLEMENTARY INFORMATION:** FDA published procedural and interpretive regulations for the implementation of the Color Additive Amendments of 1960 (Pub. L. 86-618, 74 Stat. 397-407) in the **Federal Register** of June 22, 1963 (28 FR 6439). These regulations are now codified in Parts 70 through 81 (21 CFR Parts 70 through 81, formerly Part 8 (21 CFR Part 8) before recodification published in the **Federal Register** of

March 22, 1977 (42 FR 15553)). One of these regulations, § 80.35(a) (21 CFR 80.35(a), formerly 21 CFR 8.30(a)), requires the certification of all mixtures containing certified color additives intended to be used in food, drugs, and cosmetics. Section 80.35(b) exempts from certification color additive mixtures containing previously certified straight colors if the diluents used to make the mixtures are appropriately listed by regulation.

In the **Federal Register** of July 6, 1963 (28 FR 6922), FDA requested information regarding the listing of diluents for color additive mixtures for safe use in food, drugs, and cosmetics. The information that was received in response to the notice formed the basis for regulations proposed in the **Federal Register** of July 16, 1964 (29 FR 9623) to list diluents that are safe and suitable for use in the production of color additive mixtures. However, in November, 1963 the cosmetic industry filed a suit in Federal court challenging the validity of certain sections of the interpretive and procedural regulations, particularly with respect to the definitions of the terms "color additive" and "diluent" in Parts 70 and 80 as they related to the use of color additives in cosmetics.

Because the litigated issues had a direct bearing on the proposed listing of diluents for cosmetic uses, the July, 1964 proposal and resultant October 8, 1964 regulation (29 FR 13893) listed only diluents for use with foods and drugs and did not include diluents to be used in cosmetics. Also, the agency stayed the effective date of § 80.35, which sets forth the requirement for listing diluents, with regard to diluents for cosmetic color additive mixtures (29 FR 9608). This stay was later extended indefinitely (29 FR 18495; December 29, 1964).

The Court of Appeals for the Second Circuit invalidated FDA's definitions of the terms "color additives" and "diluents" to the extent that diluents and other noncolor cosmetic ingredients were to be regulated as "color additives" (*Toilet Goods Association* v. *Finch*, 419 F.2d 21 (2d Cir. 1969)). The definitions of "color additives" and "diluents," then § 8.1(f) and (m) (21 CFR 8.1(f) and (m)), and since recodified as § 70.3(f) and (m) (21 CFR 70.3(f) and (m)), were subsequently amended in the **Federal Register** of August 26, 1971 (36 FR 16902) in light of the court's holding.

The court in *Toilet Goods Association* v. *Finch* noted, however, that the Secretary "is authorized to prescribe broadly 'the conditions under which (a color additive) may be safely employed (for cosmetic uses) * * *'" § 376(b)(3), and that "§ 376(b)(4) and (5) are ample authority for the Secretary to prescribe that a particular 'dye, pigment, or other substance' may be used with certain diluents but not with others." Id., p. 28.

The agency now intends to commence rulemaking to list diluents that may safely be used in cosmetic color additive mixtures that are exempt from certification and to revoke the July, 1964 stay of the effective date for § 80.35 with regard to diluents for cosmetic color additive mixtures.

The proposed regulation would list under new § 73.2001 (21 CFR 73.2001) diluents considered safe and suitable for use in color additive mixtures (1) for cosmetics subject to ingestion; (2) for cosmetics for external use, except the eye area; and (3) for cosmetics for eye-area use. The listing of the diluents under proposed § 73.2001 would also provide for their use in color additive mixtures that are exempt from certification.

To facilitate the listing of diluents for use in color additive mixtures intended for use in any of these three cosmetic use categories, FDA requests interested persons to submit the names of diluents of interest to them, together with data and other information concerning their safe and suitable use. Because many requests, data, and comments are anticipated, FDA recommends that the submissions be made in the form prescribed in § 71.1 (21 CFR 71.1) and that any petition for the listing of a diluent be accompanied by the following supporting information:

1. A description of the proposed diluent, including chemical identity and composition; physical, chemical, and biological properties; specifications for describing component(s) and identifying and limiting reaction by-products and other impurities; and a description of methods relied upon to characterize and determine composition.

2. The proposed use of the diluent in color additive mixtures intended for cosmetic uses, including the composition(s) of the color additive mixture(s); individual and cumulative quantities of anticipated uses; and types of cosmetic uses, e.g., ingested, external, or eye-area use.

3. Data demonstrating the integrity of the diluent and color additives of the color additive mixture(s) for which the diluent is intended.

4. Data and other information, including results of appropriate animal and other biological testing demonstrating the safety of both the diluent and the color additive mixture in which used, under the conditions of intended use.

5. Data on probable individual and cumulative consumption and/or other relevant exposure from the diluent and the cumulative effect, if any, of the diluent in man or animal.

6. Proposed tolerances and other limitations on the use of the diluent, if tolerances and limitations are required to ensure its safe use.

The requests for listing along with appropriate supporting material should be sent (preferably in three copies) to Petitions Control Branch (HFF–334), Division of Food and Color Additives, Bureau of Foods, Food and Drug Administration, 200 C St. SW., Washington, DC 20204, before October 20, 1980. The agency considers the 180-day comment period to be sufficient time to gather the data requested above. Petitions received during this 180-day period need not be accompanied by the required filing fee prescribed in § 70.19(j) because such diluents, if shown to be safe, will be listed on the Commissioner's initiative as part of the initial rulemaking proceeding. Petitions submitted after issuance of the initial proposal resulting from this notice of intent shall require the $250 filing fee.

Interested persons may, on or before October 20, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this notice of intent to propose regulations. All comments must be submitted in four copies, except that individuals may submit single copies; comments must be identified with Hearing Clerk Docket No. 78N–0390. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated April 15, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–12240 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

### Office of the Secretary

### 24 CFR Parts 203, 204, 220, 234, and 235

**[Docket No. R–80–795]**

### Elimination of Application Fees and Commitment Extension Fees Charged by HUD to Mortgagees of Single Family Properties; Transmittal of Interim Rule to Congress

**AGENCY:** Department of Housing and Urban Development.

**ACTION:** Notice of transmittal of interim rule to Congress under Section 7(o) of the Department of HUD Act.

**SUMMARY:** Recently enacted legislation authorizes Congress to review certain HUD rules for fifteen (15) calendar days

of continuous session of Congress prior to each such rule's publication in the Federal Register. This Notice lists and summarizes for public information an interim rule which the Secretary is submitting to Congress for such review.

**FOR FURTHER INFORMATION CONTACT:** Burton Bloomberg, Director, Office of Regulations, Office of General Counsel, 451 7th Street, S.W., Washington, D.C. 20410 (202) 755–6207.

**SUPPLEMENTARY INFORMATION:** Concurrently with issuance of this Notice, the Secretary is forwarding to the Chairmen and Ranking Minority Members of both the Senate Banking, Housing and Urban Affairs Committee and the House Banking, Finance and Urban Affairs Committee the following rulemaking document:

24 CFR Parts 203, 204, 220, 234 and 235—Mutual Mortgage Insurance and Insured Home Improvement Loans—Coinsurance—Urban Renewal Mortgage Insurance and Insured Improvement Loans—Condominium Ownership Mortgage Insurance—Mortgage Insurance and Assistance Payments for Homeownership and Project Rehabilitation, Elimination of Application Fee

This interim rule would amend 24 CFR Parts 203, 204, 220, 234 and 235 to eliminate application fees and commitment extension fees charged by HUD to mortgagees of single family properties. It would enable mortgagees, when required, to collect the fees and pay fee appraisers or inspectors directly.

(Section 7(o) of the Department of HUD Act, 42 U.S.C. 3535(o), Section 324 of the Housing and Community Development Amendments of 1978).

Issued at Washington, D.C., April 16, 1980.

Moon Landrieu,

*Secretary, Department of Housing and Urban Development.*

[FR Doc. 80–21319 Filed 4–21–80; 8:45 am]

BILLING CODE 4210–01–M

## Office of the Assistant Secretary for Community Planning and Development

### 24 CFR Part 570

**[Docket No. R–80–788]**

## Community Development Block Grant Program; Small Cities

**AGENCY:** Department of Housing and Urban Development.

**ACTION:** Proposed rule.

**SUMMARY:** HUD is proposing to modify the regulations governing the Small Cities Community Development Block Grant Program in order to permit, on a demonstration basis, a very limited number of States to participate to a greater degree in that program.

**DATE:** Comments are due May 22, 1980. It is intended that a final rule be adopted in this proceeding in time to enable HUD to involve the State or States in the selection of FY 1981 Small Cities applications.

**ADDRESS:** All comments should be sent to the Rules Docket Clerk, Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Trudy P. McFall, Acting Director, Office of Planning and Program Coordination, Washington, DC, (202) 755–6290.

**SUPPLEMENTARY INFORMATION:** An important part of the President's Urban Policy initiatives has involved efforts to strengthen the partnership between Federal and State governments in order to better aid distressed places and people. Toward this end, the Department of Housing and Urban Development is working to involve States more closely in the Department's programs. As a part of that effort HUD is proposing, on a demonstration basis, to involve a State or States to a greater degree in the process of selecting applicants to receive grants under the Small Cities Community Development Block Grant Program (CDBG). HUD's objective is to determine whether increased State participation can further such objectives as more effective targeting and coordination of Federal and State resources to communities with the greatest need, more responsiveness to State and local priorities and plans, and greater commitment of State resources to housing and community development. To the extent these objectives are achieved, HUD may continue the demonstration in a second year.

Participation by States in the Small Cities CDBG program is provided for in Section 104(e) of the Housing and Community Development Act of 1974, as amended, and in Section 570.422 of the regulations. This section dealing with State involvement has been reserved until now pending the outcome of deliberations within HUD on appropriate roles for States in the CDBG program. The proposed rule adds the language for the reserved § 570.422.

HUD expects to involve no more than one or two States in the initial demonstration effort being established under this regulation. States expressing an interest in greater direct participation in the Small Cities CDBG program and appearing to best meet the criteria for participation would be given the opportunity to submit a proposal. The State or States will be selected to participate in the demonstration only if there is a consensus of eligible CDBG pre-applicants obtained through a process acceptable to the Secretary that they wish the State to have such a role. Furthermore, HUD expects to involve its Area Officers closely in the selection process and does ot expect to select a State without the support of the Area Office.

The State or States selected would design a system for ranking small cities to receive the Community Development Block Grants and would manage the FY 1981 pre-application and selection process for Small Cities applications within the State. The State or States would develop the selection criteria and procedures in consultation with eligible local governments and HUD. HUD would review and approve the State selection criteria to ensure that they are consistent with CDBG law. Once approved by HUD, the State selection system would be substituted for the normal Small Cities selection criteria and process and appropriate notification of such subsitution shall be provided in the Federal Register.

Using the approved selection system the State would advise HUD of the pre-applications that it is recommending for funding. Then HUD would review the recommended pre-applications for completeness, eligibility, and other appropriate programmatic requirements.

The Department has determined that an Environmental Impact Statement is not required as a result of this rule. A copy of the Finding of Inapplicability is available for inspection in the Office of the Rules Docket Clerk at the above address.

### Proposed Amendment

Accordingly, it is proposed to amend 24 CFR Part 570 by issuing reserved § 570.422 to read as follows:

**§ 570.422 State participation**

(a) *Demonstration.* The Secretary may establish an experimental demonstration program with one or more States to determine whether States' involvement in partnership with HUD, in the process of selection of Small Cities grantees increases the targeting of Federal and State resources to distressed places and to the special problems of low- and moderate-income persons and minorities, as well as increases the total amount of State resources to distressed places.

(b) *Criteria for State participation.* In order to be eligible for participation in the demonstration program, a State must obtain, through a process acceptable to HUD, a consensus of the eligible small city applicants within the State that they agree that the State should have a role

in the selection process. In evaluating State proposals HUD will select the best proposals, considering both the State's past progress in the extent of future commitment to the following criteria:

(1) Providing State funds for low- and moderate-income housing and community development which aid distressed places and expand housing choices for low- and moderate-income persons;

(2) Using plans, policies and programs which constitute a development strategy which is the basis for State decisionmaking;

(3) Demonstrating a system for targeting State resources to all distressed communities, including cities over 50,000 population, and to low- and moderate-income persons and minorities; and

(4) Having staff capacity and financial resources to undertake the demonstration.

(c) *Selection of Small City grantees.* A State which is designated by the Secretary to participate in the demonstration shall in consultation with HUD and eligible small city applicants within the State, develop selection criteria and a system for managing the pre-application solicitation and selection process. Selection criteria and the management system and selection process shall be reviewed by HUD for consistency with the requirements of the Act. After HUD notifies a State of its approval, the State selection criteria and process shall be substituted for the selection process provided in §§ 570.424 through 570.430 and appropriate notice published in the **Federal Register**; and the State shall manage the preapplication process and make recommendations for funding to HUD.

(d) *Grant approval.* HUD, which shall make the decision as to the pre-applicants which shall be funded, shall as part of the grant approval process consider (1) the State's recommendations; (2) whether the State's approved selection criteria were reasonably and consistently applied; and (3) compliance by the pre-applicants with the requirements of this subpart.

(Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301 et seq.); Title I, Housing and Community Development Act of 1977 (Pub. L. 95–123); and Sec. 7(d) Department of Housing and Urban Development Act (42 U.S.C. 3535(d); Section 7(o) of the Department of HUD Act), (42 U.S.C. 3535(o), Section 324 of the Housing and Community Development Amendments of 1978).)

Issued at Washington, D.C., March 20, 1980.

**Robert C. Embry, Jr.,**

*Assistant Secretary for Community Planning and Development.*

[FR Doc. 80-12238 Filed 4-21-80; 8:45 am]

BILLING CODE 4210-01-M

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## 24 CFR Part 600

**[Docket No. R-80-794]**

## Comprehensive Planning and Assistance; Work-Study Program

**AGENCY:** Department of Housing and Urban Development, Office of Assistant Secretary for Community Planning and Development.

**ACTION:** Advance Notice of Proposed Rulemaking.

**SUMMARY:** HUD is considering the adoption of a Rule which would totally convert the 701 Work-Study Program Guidelines into regulation form and would modify provisions in the program's administration to be effective for Fiscal Year 1981. This advance notice invites public comments on issues which should be considered in the rulemaking procedure.

**DATE: COMMENTS DUE DATE:** Comments must be received on or before June 20, 1980.

**ADDRESS:** Send comments to: Rules Docket Clerk, Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, SW., Washington, DC 20410.

**FOR FURTHER INFORMATION CONTACT:** Howard L. Tutman, Jr., Office of Planning and Program Coordination, Office of Community Planning and Development, Department of Housing and Urban Development, 451 Seventh Street, SW, Washington, DC 20410, (202) 755–6290. This is not a toll free number.

**SUPPLEMENTARY INFORMATION:** The Work-Study Guidelines will be totally converted to regulations. Although special attention is directed to the two issues discussed at the end of this Advance Notice of Proposed Rulemaking, public comment is invited on all of the requirements which are summarized below. Copies of the complete Work Study Guidelines may be obtained from the Rules Document Clerk, Office of General Counsel, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410. The 701 Work-Study Program was established by HUD in Fiscal Year 1969 and is funded under Section 701 of the Housing Act of 1954, as amended.

The purpose of the Work-Study Program is to increase the participation of economically disadvantaged minorities and other low-income individuals who traditionally have been under-represented in the professions of community planning and public administration at the State, areawide, and local government levels. The Work-Study Program is a cooperative effort between and eligible 701 grantee, institution of higher education, and work placement agency. The grantee is responsibile to HUD for overall program administration, management, evaluation and coordination of program activities carried out by other participating agencies and educational institutions.

To assist in the coordination of program acitivities, the grantee must establish a Work-Study Coordinating Committee (WSCC). Members of the WSCC are: Representatives from the grantee, educational institution(s), participating students, work placement supervisors, and a HUD field representative. The WSCC advises the grantee on program policy development and student selection, assists in the preparation of each program application, and serves as a forum for ongoing assessement of the program. The grantees, in conjunction with educational institutions and work placement agencies, identify, counsel, and recruit potential student participants for the program.

The program provides financial assistance for up to two years to qualified economically disadvantaged minorities and other low-income individuals in obtaining academic preparation and professional on-the-job training. Only graduate and undergraduate programs in community planning and public administration are eligible. Other fields such as *law, economics, psycohology, education,* and *history* are not eligible. Doctoral degree support is ineligible in all cases. Economically disadvantaged groups are: Blacks, American Indians, American Natives, Asians, Hispanics, Pacific Islanders, and other low-income individuals.

To qualify, student applicants must have demonstrated: (1) Financial need (as defined by the educational institution's office of financial aid and the Grantee), and (2) insight into minority and low-income concerns in the field of community planning, housing and community development. The student must be enrolled full time in a state, regional, or local planning, public administration, or related urban core academic program as defined by the educational institution. Students in the program work twelve to twenty hours per week in a State, areawide or local

planning agency, Indian tribe, or non-profit organization involved in comprehensive planning, land use, community development, or housing activities. Career and employment counseling services are provided to students throughout the Program. Seminars are held for the purpose of relating academic and work experiences as well as providing opportunities for students to share ideas. Financial assistance is provided by HUD in the amount of two-thirds of the costs of the project. Cost limits have been established in the following areas: (1) Student stipends—actual cost up to $5,000 maximum; (2) Tuition support—actual cost up to $2,000 maximum; (3) Additional support (tutoring, books, travel)—actual cost up to $500 per student; and (4) Administrative and Supervisory cost—actual cost up to $2,000 per student for a project involving 5 students or less, and an additional $1,000 per student for projects involving more than 5 students. However, the total administrative and supervisory cost may not exceed $25,000 per project. The minimum number of students per project is three.

HUD is inviting comments on this rulemaking and any other program suggestions.

1. *Financial Assistance to Students.* The current 701 Work-Study Guidelines authorize HUD Field Offices to negotiate variable cost standards for financial assistance to students within the ranges noted above for stipends, tuition and additional support. The prevailing hourly rate in the geographical area for initial entry positions is used for determining the local stipends levels in the field of planning and public administration. The Tuition is based upon the educational institution's tuition rate and additional support is based upon HUD's experience with the cost of these activities.

HUD has received suggestions and recommendations that these student categories of financial assistance should be changed. We are, therefore, considering the following options: (1) Allowing for flexibility in the distribution within the total assistance (5,000+2,000+500=7,500) to each student; (2) allowing the total amount of student assistance for each student to be determined by the grantee provided that the average cost per student does not exceed the $7,500; or (3) retaining current requirements. With respect to these options, should there be an established amount of financial assistance by category for students? Should HUD consider providing more flexibility in determining student support?

2. *Administrative and Supervisory Costs.* The current Work-Study Program Guidelines authorize grantees to charge administrative and supervisory costs to the program. These costs inlcude such items as program evaluation, employment counseling, extra time spent in educational counseling, student recruitment, and other services, including university supervisory costs allowable to the Work-Study Program. These costs limits are indicated in a previous section of this Advance Notice.

There have been comments by grantees that the allowances for administrative and supervisory costs are inadequate. On the other hand, the higher the allowance the lower the number of students that can be assisted. Should the allowance be: (1) Increased because of the high costs of administration and supervision, (2) reduced to allow for more students, or (3) maintained at its current level? Are there other ways this issue can be dealt with?

Findings for regulatory analysis and environment impact are not required at this stage of the rulemaking procedure.

Upon close of the comment period, if the decision is not to proceed with the rule under consideration, termination of this proceeding will not prejudice or foreclose any further rulemaking which the Secretary may initiate with respect to these matters.

(Section 701 of the Housing Act of 1954 as amended and General Services Administration, Federal Management Circular FMC 74–4, July 18, 1974.)

Issued at Washington, D.C., April 11, 1980.

**Robert C. Embry, Jr.,**

*Assistant Secretary for Community Planning and Development.*

[FR Doc. 80–12239 Filed 4–21–80; 8:45 am]

BILLING CODE 4210–01–M

## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### 26 CFR Part 1

[LR–86–79]

### Allowance of Deductions to Foreign Corporations; Public Hearing on Proposed Regulations

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Public hearing on proposed regulations.

**SUMMARY:** This document provides notice of a public hearing on proposed regulations relating to the allowance of deductions to foreign corporations doing business in the United States.

**DATES:** The public hearing will be held on June 4, 1980, beginning at 10:00 a.m. Outlines of oral comments must be delivered or mailed by May 21, 1980.

**ADDRESS:** The public hearing will be held in the I.R.S. Auditorium, Seventh Floor, 7400 Corridor, Internal Revenue Building, 1111 Constitution Avenue, N.W., Washington, D.C. The outlines should be submitted to the Commissioner of Internal Revenue, Attn: CC:LR:T (LR–86—79), Washington, D.C. 20224.

**FOR FURTHER INFORMATION CONTACT:** Charles Hayden of the Legislation and Regulations Division, Office of Chief Counsel, Internal Revenue Service, 1111 Constitution Avenue, N.W., Washington, D.C. 20224, 202–566–6870, not a toll-free call.

**SUPPLEMENTARY INFORMATION:** The subject of the public hearing is proposed regulations under sections 861 and 882 of the Internal Revenue Code of 1954. The proposed regulations appeared in the **Federal Register** for Wednesday, February 27, 1980, at page 12844 (45 FR 12844).

The rules of § 601.601(a)(3) of the "Statement of Procedural Rules" (26 CFR Part 601) shall apply with respect to the public hearing. Persons who have submitted written comments within the time prescribed in the notice of proposed rulemaking and also desire to present oral comments at the hearing on the proposed regulations should submit an outline of oral comments to be presented at the hearing and the time they wish to devote to each subject by May 21, 1980.

Each speaker will be limited to 10 minutes for an oral presentation exclusive of time consumed by questions from the panel for the Government and answers to these questions.

Because of controlled access restrictions, attendees cannot be admitted beyond the lobby of the Internal Revenue Building until 9:45 a.m.

An agenda showing the scheduling of the speakers will be made after outlines are received from the speakers. Copies of the agenda will be available free of charge at the hearing.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the **Federal Register** for Wednesday, November 8, 1978.

By direction of the Commissioner of Internal Revenue:

**Robert A. Bley,**

*Director, Legislation and Regulations Division.*

[FR Doc. 80-12321 Filed 4-21-80; 8:45 am]

BILLING CODE 4830-01-M

## Bureau of Alcohol, Tobacco and Firearms

### 27 CFR Part 178

**[Notice No. 343]**

### Sales of Firearms By Licensees at Organized Gun Shows

**AGENCY:** Bureau of Alcohol, Tobacco and Firearms (ATF).

**ACTION:** Advance notice of proposed rulemaking.

**SUMMARY:** ATF is considering amending regulations in 27 CFR Part 178 to allow sales of firearms by licensees at organized gun shows. Licenses are now issued only for the premises where an applicant regularly intends to engage in the business to be covered by the license. ATF wishes to gather information by inviting comments from the public and industry on the desirability and feasibility of allowing sales of firearms at organized gun shows.

**DATES:** Comments must be received on or before June 23, 1980.

**ADDRESS:** Send comments to: Director, Bureau of Alcohol, Tobacco and Firearms, P.O. Box 385, Washington, DC 20044 (Attn: Chief, Regulations and Procedures Division).

**FOR FURTHER INFORMATION CONTACT:** James A. Hunt, Research and Regulations Branch, 202-566-7626.

**SUPPLEMENTARY INFORMATION:** The Bureau has taken a position since enactment of the Gun Control Act of 1968 that firearms licenses are not issued to engage in the business at gun shows. This policy is reflected in Revenue Ruling 69-59 which stated the opinion that the law contemplates licensing of premises where the applicant regularly intends to engage in the business to be covered by the license rather than temporary locations.

ATF is considering a change in gun show policy and a change in regulations to allow Federal firearms licensees to sell firearms at organized gun shows held in the same State as the licensee's premises. However, before issuing proposed regulations, we ask that interested persons submit pertinent comments, opinions, or other data so we can determine:

1. Is there sufficient interest by firearms licensees in making sales at organized gun shows to warrant issuing proposed regulations?

2. If regulations provided for sales of firearms at gun shows by licensees, what, if any, would be the impact on firearms commerce, organizations which sponsor gun shows, State and local laws and ordinances, and local law enforcement?

3. Would allowing licensees to make sales of firearms at gun shows reduce or increase opportunities for criminals obtaining firearms?

4. If licensees are allowed to sell firearms at gun shows, what licensing procedures would be recommended (a separate license, an extension of the dealer's license, or some other method)?

5. Are there other considerations which should be taken into account before proposing regulations to allow licenses to sell firearms at gun shows?

#### Disclosure of Comments

Comments on this notice may be inspected in the ATF Reading Room, Office of Public Affairs, Room 4408, Benjamin Franklin Post Office Building, 12th and Pennsylvania Avenue, NW, Washington, DC during normal business hours.

#### Drafting Information

The principal author of this document is James A. Hunt, Research and Regulations Branch, Bureau of Alcohol, Tobacco and Firearms.

#### Authority

This advance notice of proposed rulemaking is issued under the authority of 18 U.S.C. 926, as amended (82 Stat. 1226).

Signed: February 28, 1980.

**G. R. Dickerson,**

*Director.*

Approved: April 10, 1980.

**Richard J. Davis,**

*Assistant Secretary—Enforcement and Operations.*

[FR Doc. 80-12228 Filed 4-21-80; 8:45 am]

BILLING CODE 4810-31-M

## POSTAL SERVICE

### 39 CFR Part 111

### Extension of City Delivery

**AGENCY:** Postal Service.

**ACTION:** Proposed rule.

**SUMMARY:** This proposed rule would permit the extension of delivery service sooner than would otherwise be the case. One of the current prerequisites for the establishment or extension of city delivery service is that fifty percent of the building lots in the area to be served must be improved with houses or business places. Under the proposed rule the fifty percent requirement could be waived if local postal delivery managers find that there is a reasonable expectation that fifty percent of the building lots in the area to be served will be improved within twelve months and that delivery would be made by the use of cluster boxes or neighborhood box units.

This proposal could result in the provision of city delivery service to customers who might not otherwise become eligible. Once service had been extended under the proposal in a particular area, the service would be available to other customers as soon as they moved into the area.

Although under the proposal the Postal Service would incur delivery service expenditures and obligations sooner than would otherwise be the case, it is anticipated that adoption of the proposal will ultimately lead to long-term cost savings by encouraging customer acceptance of an effective form of home delivery service which is less costly for the Postal Service to provide.

**DATE:** Comments must be received on or before May 22, 1980.

**ADDRESS:** Written comments should be addressed to the Assistant General Counsel, Special Projects Division, Law Department, U.S. Postal Service, Washington, D.C. 20260. Copies of written comments received will be available for public inspection and photocopying between 9 a.m. and 4 p.m., Monday through Friday, outside Room 9010, 475 L'Enfant Plaza, S.W., Washington, D.C. 20260.

**FOR FURTHER INFORMATION CONTACT:** Charles R. Braun, (202) 245-4620.

**SUPPLEMENTARY INFORMATION:** To carry out the purposes described above in the Summary, the Postal Service proposes to revise the second sentence of 155.12 of the Domestic Mail Manual by adding the exception indicated below. In order to help the reader understand the references to existing regulations in the proposed exception, existing paragraphs a and b of 155.11 are reprinted below as well even though they would not be changed.

Although exempt from the requirements of the Administrative Procedure Act (5 U.S.C. 553(b), (c)) regarding proposed rulemaking by 39 U.S.C. 410(a), the Postal Service invites comment on the following proposed revision of the Domestic Mail Manual.

which is incorporated by reference in the Federal Register. See 39 CFR 111.1

*Part 155—City Delivery*

Amend 155.1 of the Domestic Mail Manual to read in part as follows:

*155.1 Requirements for Delivery Service*

.11 Establishment.

* * * * *

a. Within the area to be served there is a population of 2,500 or more of 750 possible deliveries. (The postal population may vary greatly from the general census population because of different boundary interpretations and designations.)

b. Fifty percent of the building lots in the area to be served are improved with houses or business places. Where a house or building and its yard or ground cover more than one lot, all lots so covered are considered to be improved.

* * * * *

.12 *Extensions.* In this part the word "extension" refers to the initiation of city delivery service in any areas which are not included in the boundaries of present delivery service, but which are part of a community for which city delivery service has already been established. The delivery service requirements for extensions are the same as those listed in 155.11 for establishments, except that:

a. 155.11a does not apply to extensions; and,

b. The applicability of 155.11b may be waived if:

(1) There is a reasonable expectation that the requirements of 155.11b will be met within 12 months, and

(2) Clusterboxes or neighborhood box units will be used for delivery.

An appropriate amendment to 39 CFR 111.3 to reflect these changes will be published if the proposal is adopted.

(39 U.S.C. 401(2); 403(a); 403(b)(1); 404(a)(1); 1001(e)(1); (4), (5); 2010)

**W. Allen Sanders,**

*Associate General Counsel for General Law and Administration.*

[FR Doc. 80-12345 Filed 4-21-80; 8:45 am]

BILLING CODE 7710-12-M

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## 39 CFR Part 111

## Poisons and Controlled Substances—Nonmailability; Extension of Comment Period

**AGENCY:** Postal Service.

**ACTION:** Proposed rule; extension of time for comment.

**SUMMARY:** This notice extends the time for filing comments on a proposal that would amend regulations concerning the mailing of poisons, poisonous drugs and medicines, and controlled substances.

**DATE:** Comments must be received on or before May 28, 1980.

**ADDRESS:** Written comments should be sent or delivered to the Assistant General Counsel, Consumer Protection Division, Law Department, Room 9014, 475 L'Enfant Plaza West, S.W., Washington, D.C. 20260. Copies of all written comments received will be available for public inspection and photocopying between 9:00 AM and 4:00 PM, Monday through Friday, at the above location.

**FOR FURTHER INFORMATION CONTACT:** George C. Davis, (202) 245–4385.

**SUPPLEMENTARY INFORMATION:** On March 27, 1980, a document was published in the **Federal Register** (45 FR 20118) proposing a number of amendments to the regulations on the mailability of poisons and controlled substances. The purpose of the amendments is to reflect current administrative practices and eliminate ambiguities which might lead to mailings not permitted by statute.

In response to a request from the National Association of Mail Service Pharmacies for an additional thirty day comment period, the Postal Service will accept written comments which are received on or before May 28, 1980.

(39 U.S.C. 401(2), 18 U.S.C. 1716)

**W. Allen Sanders,**

*Associate General Counsel for General Law and Administration.*

[FR Doc. 80-12251 Filed 4-21-80; 8:45 am]

BILLING CODE 7710-12-M

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## ENVIRONMENTAL PROTECTION AGENCY

## 40 CFR Part 52

**[FRL 1471-5]**

## State and Federal Administrative Orders Revising the Michigan State Implementation Plan; Supplemental Notice of Proposed Rulemaking

**AGENCY:** U.S. Environmental Protection Agency.

**ACTION:** Proposed Rule: Proposed Approval of Revision—Supplement.

**SUMMARY:** The purpose of this notice is to provide opportunity for comment on an amendment to an Administrative Order which had been submitted by the State of Michigan to the U.S. Environmental Protection Agency (USEPA) for approval as a revision to the Michigan State Implementation Plan (SIP). The Order, issued to the Consumers Power Company J. H. Campbell Plant located in the township of Port Sheldon, Ottawa County, Michigan, was the subject of a Notice of Proposed Rulemaking on November 19, 1979 at 44 FR 66214. On February 14, 1980 Michigan submitted an amendment to the Consent Order. The amendment requires the Company to restrict its sulfur dioxide emission limitations to 414 tons rather than 490 tons per calendar day as had been required in the previous Order. This supplemental notice assesses the review of the amended Order and invites additional comments on USEPA's proposed approval of the amended Order as a SIP revision. Any orders or amendments thereto, which have been issued to major sources and extend SIP compliance dates for meeting sulfur dioxide emission limitations, must be approved by USEPA before they become effective as SIP revisions under the Clean Air Act (42 U.S.C. Section 7410). If approved by USEPA the Order, as amended, will constitute a revision to the SIP.

**DATE:** Written comments must be received by May 22, 1980.

**ADDRESSES:** Please send comments to:

Gary Gulezian, Chief, Regulatory Analysis Section, Air Programs Branch, U.S. Environmental Protection Agency, Region V, 230 South Dearborn Street, Chicago, Illinois 60604

The State Order and its amendment, supporting material and public comments received in response to this notice may be inspected and copied (for appropriate charges) during normal business hours at the above address or at:

Michigan Department of Natural Resources, Air Quality Division, State Secondary Complex, General Office Building, 7150 Harris Drive, P.O. Box 30028, Lansing, Michigan 48909.

**FURTHER INFORMATION MAY BE OBTAINED FROM:** Gary Gulezian, Chief, Regulatory Analysis Section, Air Programs Branch, (312) 886–6029.

**SUPPLEMENTARY INFORMATION:** On November 19, 1979 at 44 FR 66214 USEPA proposed to approve the Michigan Air Pollution Control Commission's request for a revision to the Michigan State Implementation Plan (SIP). The revision is a Final Order issued by the Michigan Air Pollution Control Commission (MAPCC) to Consumers Power Company. The Order extends the date by which the Company is required to bring sulfur dioxide emissions from coal fired boilers at its J. H. Campbell Plant, located in the Township of Port Sheldon, Ottawa

County, Michigan, into compliance with certain regulations contained in the federally approved Michigan State Implementation Plan (SIP).

On February 14, 1980 the Michigan Department of Natural Resources, Air Quality Division, submitted an amendment to the Order. The amendment replaces paragraph "A" entitled "Sulfur Dioxide Emission Limitations" at 44 FR 66214, 66215 of the November 19, 1979 **Federal Register** with the following paragraph:

A. *Sulfur Dioxide Emission Limitations*—(1) Beginning on January 1, 1980 and continuing to January 1, 1985, fuel burned at the Campbell Plant shall not:

(a) On an annual average exceed 3.05 percent sulfur content by weight at 12,000 Btu/pound of coal.

(b) Result in sulfur dioxide emissions greater than 414 tons on any calendar day. This emission limitation is the equivalent of burning coal which averages 3.6 percent sulfur content by weight at 12,000 Btu/pound of coal and 650 megawatts net load for 24 hours.

(c) On a daily average result in emissions of sulfur dioxide greater than a rate of 6.6 pounds per million Btu heat input.

(2) After January 1, 1985, emissions of sulfur dioxide from the Campbell plant shall not exceed the levels prescribed in Tables 3 and 4 of Rule 336.49, unless an alternate date for compliance with the levels is established by the Commission.

Michigan, in holding a public hearing on the amended Order on December 18, 1979, met the notice and hearing procedural requirements of 40 CFR 51.4 and 51.6. USEPA reviewed the amended Order and concluded that the proposed revision as amended will not interfere with the attainment and maintenance of the national ambient air quality standards. Pursuant to section 110 of the Clean Air Act, the Administrator of the United States Environmental Protection Agency must approve Final Orders which extend compliance dates as revisions to State Implementation Plans before they may become effective (42 U.S.C. 7410). Today's action reproposes approval of the Michigan Air Pollution Control Commission's amended Final Order as a revision to the Michigan SIP.

All interested persons are invited to submit written comments on the reproposed SIP revision. Written comments received by the date specified above will be considered in determining whether USEPA will approve the revision. After the close of the public comment period the Administrator of USEPA will publish in the **Federal Register** the Agency's final action on the proposed SIP revision.

Under Executive Order 12044 USEPA is required to judge whether a regulation is "significant" and therefore subject to the procedural requirements of the Order or whether it may follow other specialized development procedures. USEPA labels these other regulations "specialized." I have reviewed this proposed regulation pursuant to the guidance in USEPA's Response to Executive Order 12044, "Improving Environmental Regulations," signed March 29, 1979, by the Administrator and I have determined that it is a specialized regulation not subject to the procedural requirements of Executive Order 12044. This notice of proposed rulemaking is issued under the authority of Section 110(a) of the Clean Air Act (42 U.S.C. 7410).

Dated: March 27, 1980.

**John McGuire,**

*Regional Administrator.*

[FR Doc. 80-12299 Filed 4-21-80; 8:45 am]

BILLING CODE 6560-01-M

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**40 CFR Parts 122, 123, 124**

**[FRL 1466-6]**

## Consolidated Permit Regulations; Notice of Issuance Date For Purposes of Judicial Review

**AGENCY:** Environmental Protection Agency.

**ACTION:** Notice of Issuance Date For Purposes of Judicial Review

**SUMMARY:** EPA intends to publish soon final "consolidated permit" regulations under various statutes. Should parties desire to "race" to the courthouse in challenging the Clean Water Act portions of the regulations, EPA is announcing today when those portions will be considered issued for purposes of judicial review. The Clean Water Act portions will be considered issued at 1:00 p.m. eastern time two weeks after their publication in the **Federal Register.**

**FOR FURTHER INFORMATION CONTACT:** Edward A. Kramer, Office of Water Enforcement (EN-336), 401 M Street, SW., Washington, D.C. 20460, (202) 755-0750.

**SUPPLEMENTARY INFORMATION:** EPA proposed its "consolidated permit" regulations on June 14, 1979, (44 FR 34244), and plans to promulgate final regulations soon. These regulations will be promulgated under authority of the Resource Conservation and Recovery Act (RCRA), the Safe Drinking Water Act (SDWA), the Clean Air Act (CAA), and the Clean Water Act (CWA).

It appears likely that various industrial and environmental groups will seek judicial review of the regulations. In EPA's view, the U.S. Court of Appeals for District of Columbia Circuit is the only appropriate court to hear such cases. This is because § 7006(1) of RCRA, § 1448(a)(1) of the SDWA, and § 307(b)(1) of the CAA all provide for exclusive D.C. Circuit review of EPA's national regulations. While the CWA has no comparable provision, it would be extremely unwieldy for the parties and the courts to litigate the CWA portions of the regulations separately from the rest of the regulations.

In the event, however, that parties attempt to secure review of the CWA portions in other circuits and "race" to their favorite courthouses, it would be hepful to clarify in advance the time at which the race may begin. Consistent with EPA's recent CWA racing regulations (45 FR 26046, April 17 1980), the CWA portions of the consolidated permit regulations will be considered issued for purposes of judicial review at 1:00 p.m. eastern time on the day which is two weeks after the final regulations appear in the **Federal Register.** In that **Federal Register** publication, EPA will indicate the precise date of issuance. As explained in the preamble to EPA's recent CWA racing regulations, two courts of appeals have already upheld the legality of this "deferral" approach.

EPA will not apply the "two-week, 1:00 p.m." deferral rule to the remainder of the regulations for two reasons. First, such a deferral may be inconsistent with § 307(b)(1) of the CAA, which specifies that petitions may be filed within 60 days of the Federal Register publication date. Second, there is no need to "race" with respect to the RCRA, SDWA, and CAA portions of the regulations because the D.C. Circuit is the only court which has jurisdiction over them.

Dated: April 15, 1980.

**Michele Beigel Corash,**

*General Counsel.*

[FR Doc. 80-12185 Filed 4-21-80; 8:45 am]

BILLING CODE 6560-01-M

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**OFFICE OF MANAGEMENT AND BUDGET**

**Office of Federal Procurement Policy**

**48 CFR Part 15**

## Contracting by Negotiation

**AGENCY:** Office of Federal Procurement Policy, Office of Managment and Budget.

**ACTION:** Notice of availability and request for comment on draft Federal acquisition regulation.

**SUMMARY:** The Office of Federal Procurement Policy is making available

for public and Government agency review and comment, a segment of the draft Federal Acquisition Regulation regarding solicitation and receipt of proposals and quotations as well as preaward and postaward notifications, protests, and mistakes. Availability of additional segments for comment will be announced on later dates. The FAR is being developed to replace the current system of procurement regulations.

**DATE:** Comments must be received on or before June 20, 1980.

**ADDRESS:** Obtain copies of the draft regulation from and submit comments to William J. Maraist, Assistant Administrator for Regulations, Office of Federal Procurement Policy, 726 Jackson Place, N.W., Room 9025, Washington, D.C. 20503.

**FOR FURTHER INFORMATION CONTACT:** William Maraist (202) 395–3300.

**SUPPLEMENTARY INFORMATION:** The fundamental purpose of the FAR is to reduce proliferation of regulations; to eliminate conflicts and redundancies; and to provide an acquisition regulation that is simple, clear and understandable. The intent is not to create new policy. However, because new policies may arise concurrently with the FAR project, the notice of availability of draft regulations will summarize the section or part available for review and describe any new policies therein.

The following subparts of the draft Federal Acquisition Regulation are available upon request for public and Government agency review and comment.

## PART 15—CONTRACTING BY NEGOTIATION

### Subpart 15.4—Solicitation and Receipt of Proposals and Quotations

Sec.

15.401 Applicability.
15.402 General.
15.403 Solicitation mailing lists.
15.404 Presolicitation notices and conferences.
15.405 Solicitations for information or planning purposes.
15.406 Preparing requests for proposals and requests for quotations.
15.406–1 Uniform contract format.
15.406–2 Part I—The schedule.
15.406–3 Part II—Contract clauses.
15.406–4 Part III—Documents, exhibits, and other attachments.
15.406–5 Part IV—Representations and instructions.
15.407 Solicitation provisions.
15.408 Issuing solicitations.
15.409 Pre-proposal conferences.
15.410 Amendment of solicitations prior to closing date.
15.411 Receipt of proposals and quotations.
15.412 Late proposals, quotations, and modifications.

Sec.

15.413 Disclosure and use of information before award.

### Subpart 15.9—Preaward and Postaward Notifications, Protests, and Mistakes

15.901 Notifications to offerors.
15.902 Debriefing of unsuccessful offerors.
15.903 Protests against award.
15.904 Disclosure of mistakes.

Changes contained in these proposed FAR subparts are summarized as follows:

1. Proposed FAR Subpart 15.4 adopts a uniform contract format and a revised SF 33 that provides a table of contents corresponding to the format. The description of a uniform contract format, including general instructions for the content of each of the format's parts and sections, will provide increased Government-wide standardization in solicitations. In addition, this format groups solicitation representations and instructions in Part IV at the end of the format. This format provides for removal of Part IV at the time of the award and incorporation by reference in the distributed copies of the contract, thereby saving reproduction and mailing costs.

2. FAR 15.407 and 52.215 do not include the alternate procedure and provision for consideration of late proposals currently prescribed by FPR 1–2.802–2, since (1) treatment of late proposals or quotations lends itself to a consistent Government-wide procedure and (2) the risks of protest or unfair treatment arising under the alternate procedure are considered to outweigh the potential benefits.

3. The FAR segment contains a proposal to eliminate solicitation provisions from SF 33 and to eliminate SF 33A which is part of a larger proposal to eliminate solicitation provisions and contract clauses from standard forms, except those for small purchases, and to eliminate other standard forms that have as their only purpose the communication of the text of provisions or clauses.

The practice of printing provisions and clauses on standard forms has resulted in the obsolescence of portions of the forms and the need for corrective alterations and additions in solicitations and contracts for long periods while the forms were revised, printed, and distributed. In some cases solicitation provisions and contract clauses printed on the forms are not prescribed and set forth elsewhere in the DAR and FAR or are prescribed in the regulations in a longer version than the condensed version printed on the form.

In addition to comments on Subparts 15.4 and 15.9, commentors are requested to state their views on this proposal and to state whether there are other acquisitions besides small purchases for which they consider the printing of provisions and clauses on standard forms to be necessary.

Dated: April 15, 1980.

**LeRoy J. Haugh,**

*Associate Administrator for Regulations and Procedures.*

[FR Doc. 80–12342 Filed 4–21–80; 8:45 am]

BILLING CODE 3110–01–M

# Notices

Federal Register
Vol. 45, No. 79
Tuesday, April 22, 1980

This section of the FEDERAL REGISTER contains documents other than rules or proposed rules that are applicable to the public. Notices of hearings and investigations, committee meetings, agency decisions and rulings, delegations of authority, filing of petitions and applications and agency statements of organization and functions are examples of documents appearing in this section.

## DEPARTMENT OF AGRICULTURE

### Forest Service

### Uinta National Forest Grazing Advisory Board; Change in Notice of Meeting

The Uinta National Forest Grazing Advisory Board Meeting originally scheduled for Wednesday, April 30, 1980, at the Rodeway Inn in Provo, Utah, has been rescheduled. The meeting will be held at 9 a.m. on Friday, June 13, 1980, at the Rodeway Inn, 1292 South University Avenue, Provo, Utah.

Dated: April 14, 1980.

**Don T. Nebeker,**

*Forest Supervisor.*

[FR Doc. 80-12362 Filed 4-21-80; 8:45 am]

BILLING CODE 3410-11-M

## CIVIL AERONAUTICS BOARD

**[Order 80-4-128; Docket 37048]**

### Air Niagara, Order To Show Cause

**AGENCY:** Civil Aeronautics Board.

**ACTION:** Notice of order to show cause: Order 80-4-128.

**SUMMARY:** The Board proposes to approve the following application: Applicant: Air Niagara (1978) Ltd. Application Date: November 7, 1979, as amended on February 29, 1980; Docket 37048. Authority Sought: Approval of the transfer of the foreign air carrier permit held by Air Niagara Limited to the applicant. The permit authorizes small aircraft charters between points in Canada and points in the United States.

**OBJECTIONS:** All interested persons having objections to the Board's tentative findings and conclusions to transfer this permit, as described in the order cited above, shall, NO LATER THAN May 13, 1980, file a statement of such objections with the Civil Aeronautics Board (20 copies) and mail copies to the applicant, the Department of Transportation, the Department of State, and the Ambassador of Canada in Washington, D.C. A statement of objections must cite the docket number and must include a summary of testimony, statistical data, or other such supporting evidence.

If no objections are filed, the Secretary of the Board will enter an order which will, subject to disapproval by the President, make final the Board's tentative findings and conclusions and transfer the permit.

**ADDRESS FOR OBJECTIONS:**

Docket 37048, Docket Section, Civil Aeronautics Board, Washington, D.C. 20428.

Air Niagara (1978), Ltd., c/o William F. Clark, 196 Adelaide Street West, Toronto, Ontario, Canada M5H 1W7.

**TO GET A COPY OF THE COMPLETE ORDER:** Request it from the C.A.B. Distribution Section, Room 516, 1825 Connecticut Avenue, N.W., Washington, D.C. 20428. Persons outside the Washington metropolitan area may send a postcard request.

**FOR FURTHER INFORMATION CONTACT:** Nancy L. Pitzer, Regulatory Affairs Division, Bureau of International Aviation, Civil Aeronautics Board—202-673-5134.

By the Civil Aeronautics Board: April 16, 1980.

**Phyllis T. Kaylor,**

*Secretary.*

[FR Doc. 80-12257 Filed 4-21-80; 8:45 am]

BILLING CODE 6320-01-M

## DEPARTMENT OF COMMERCE

### International Trade Administration

### Computer Systems Technical Advisory Committee; Partially Closed Meeting

Puruant to Section 10(a)(2) of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. (1976), notice is hereby given that a meeting of the Computer Systems Technical Advisory Committee will be held on Thursday, May 8, 1980, at 9:30 a.m. in Room 5611, Main Commerce Building, 14th Street and Constitution Avenue NW., Washington, D.C.

The Computer Systems Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, January 13, 1977, and August 28, 1978, the Assistant Secretary for Administration approved the recharter and extension of the Committee, pursuant to Section 5(c)(1), of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1), and the Federal Advisory Committee Act.

The Committee advises the Office of Export Administration with respect to questions involving (A) technical matters, (B) worldwide availability and actual utilization of production technology, (C) licensing procedures which affect the level of export controls applicable to computer systems, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates, including proposed revisions of any such multilateral controls.

The Committee meeting agenda has four parts:

**General Session**

(1) Opening remarks by the Chairman.

(2) Presentation of papers or comments by the public.

(3) Report on the current work program of the Subcommittees:

(a) Technology Transfer;

(b) Foreign Availability;

(c) Hardware; and

(d) Licensing Procedures.

**Executive Session**

(4) Discussion of matters properly classified under Executive Order 11652 and 12065, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting will be open to the public; a limited number of seats will be available. To the extent time permits, members of the public may present oral statements to the Committee. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (4), the Assistant Secretary for Administration, with the concurrence of the delegate of the General Counsel, formally determined on September 6, 1978, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government in the Sunshine Act, Pub. L. 94-409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings

and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1). Such matters are specifically authorized under criteria established by an Executive Order to be kept secret in the interests of the national defense or foreign policy. All materials to be reviewed and discussed by the Committee during the Executive Session of the meeting have been properly classified under Executive Order 11652 or 12065. All Committee members have appropriate security clearances.

The complete Notice of Determination of close meetings or portions thereof of the series of meetings of the Computer Systems Technical Advisory Committee and of any Subcommittees thereof, was published in the **Federal Register** on September 14, 1978 (43 FR 41073).

Copies of the minutes of the open portions of the meeting will be available by calling Mrs. Margaret Cornejo, Policy Planning Division, Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, telephone: 202–377–2583.

For further information contact Mrs. Cornejo either in writing or by phone at the address or number shown above.

Dated: April 17, 1980.

**Kent N. Knowles,**

*Director, Office of Export Administration, U.S. Department of Commerce.*

[FR Doc. 80–12339 Filed 4–21–80; 8:45 am]

BILLING CODE 3510–25–M

## Hardware Subcommittee of the Computer Systems Technical Advisory Committee; Partially Closed Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, 5 U.S.C. App. (1976), notice is hereby given that a meeting of the Hardware Subcommittee of Computer Systems Technical Advisory Committee will be held on Tuesday, May 7, 1980, at 1:30 p.m., in Room 1851, Main Commerce Building, 14th Street and Constitution Avenue NW., Washington, D.C.

The Computer Systems Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, January 13, 1977, and August 28, 1978, the Assistant Secretary for Administration approved the recharter and extension of the Committee, pursuant to Section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and the Federal Advisory Committee Act. The Hardware Subcommittee of the Computer Systems Technical Advisory Committee was established on July 8, 1975, with the approval of the Director, Office of Export Administration, pursuant to the Charter of the Committee. And, on October 16, 1978, the Assistant Secretary for Industry and Trade approved the continuation of the Subcommittee pursuant to the charter of the Committee.

The Committee advises the Office of Export Administration with respect to questions involving (A) technical matters, (B) worldwide availability and actual utilization of production technology, (C) licensing procedures which affect the level of export controls applicable to computer systems, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates including proposed revisions of any such multilateral controls. The Hardware Subcommittee was formed to continue the work of the Performance Characteristics and Performance Measurements Subcommittee, pertaining to (1) maintenance of the processor performance tables and further investigation of total systems performance; and (2) investigation of array processors in terms of establishing the significance of these devices and determining the differences in characteristics of various types of these devices.

The Subcommittee meeting agenda has four parts:

**General Session**

1. Opening remarks by the Chairman.
2. Presentation of papers or comments by the public.
3. Final review of the performance analysis forms.

**Executive Session**

4. Discussion of matters properly classified under Executive Order 11652 or 12065, dealing with the U.S. and COCOM control program and strategic criteria related thereto.

The General Session of the meeting is open to the public; a limited number of seats will be available. To the extent time permits members of the public may present oral statements to the Subcommittee. Written statements may be submitted at any time before or after the meeting.

With respect to agenda item (4), the Assistant Secretary of Commerce for Administration, with the concurrence of the delegate of the General Counsel, formally determined on September 6, 1978, pursuant to Section 10(d) of the Federal Advisory Committee Act, as amended by Section 5(c) of the Government in the Sunshine Act, Pub. L. 94–409, that the matters to be discussed in the Executive Session should be exempt from the provisions of the Federal Advisory Committee Act relating to open meetings and public participation therein, because the Executive Session will be concerned with matters listed in 5 U.S.C. 552b(c)(1). Such matters are specifically authorized under criteria established by an Executive Order to be kept secret in the interests of national defense or foreign policy. All materials to be reviewed and discussed by the Subcommittee during the Executive Session of the meeting have been properly classified under Executive Order 11652 or 12065. All Subcommittee members have appropriate security clearances.

The complete Notice of Determination to close meetings or portions thereof of the series of meetings of the Computer Systems Technical Advisory Committee and of any Subcommittees thereof, was published in the **Federal Register** on September 14, 1978 (43 FR 41073).

Copies of the minutes of the General Session can be obtained by calling Mrs. Margaret Cornejo, Policy Planning Division, Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, phone 202–377–2583.

For further information contact Mrs. Cornejo either in writing or by phone at the address or number shown above.

Dated: April 17, 1980.

**Kent N. Knowles,**

*Director, Office of Export Administration, International Trade Administration, U.S. Department of Commerce.*

[FR Doc. 80–12338 Filed 4–21–80; 8:45 am]

BILLING CODE 3510–25–M

## Licensing Procedures Subcommittee of the Computer Systems Technical Advisory Committee; Open Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act, as amended, 5 U.S.C. App. (1976), notice is hereby given that a meeting of the Licensing Procedures Subcommittee of the Computer Systems Technical Advisory Committee will be held on Wednesday, May 7, 1980, at 9:30 a.m. in Room 1851, Main Commerce Building, 14th Street and Constitution Avenue, N.W., Washington, D.C.

The Computer Systems Technical Advisory Committee was initially established on January 3, 1973. On December 20, 1974, January 13, 1977, and August 28, 1978, the Assistant Secretary for Administration approved the recharter and extension of the Committee, pursuant to Section 5(c)(1) of the Export Administration Act of 1969, as amended, 50 U.S.C. App. Sec. 2404(c)(1) and the Federal Advisory

Committee Act. The Licensing Procedures Subcommittee of the Computer Systems Technical Advisory Committee was established on February 4, 1974. On July 8, 1975, the Director, Office of Export Administration, approved the reestablishment of this Subcommittee, pursuant to the charter of the Committee. And, on October 16, 1978, the Assistant Secretary for Industry and Trade approved the continuation of the Subcommittee pursuant to the charter of the Committee.

The Committee advises the Office of Export Administration with respect to questions involving (A) technical matters, (B) worldwide availability and actual utilization of production technology, (C) licensing procedures which may affect the level of export controls applicable to computer systems, including technical data or other information related thereto, and (D) exports of the aforementioned commodities and technical data subject to multilateral controls in which the United States participates, including proposed revisions of any such multilateral controls. The Licensing Procedures Subcommittee was formed to review the procedural aspects of export licensing and recommend areas where improvements can be made.

The Subcommittee meeting agenda has four parts:

(1) Opening remarks by the Subcommittee Chairman.

(2) Presentation of papers or comments by the public.

(3) Pending items of business:

a. Swiss Blue Import Certificate

b. Technical preevaluation of products

c. Qualified general license

d. Technical data regulations

(4) Standard formatting of license applications.

The meeting will be open for public observation and a limited number of seats will be available. To the extent time permits members of the public may present oral statements to the Subcommittee. Written statements may be submitted at any time before or after the meeting.

Copies of the minutes of the meeting will be available by calling Mrs. Margaret Cornejo, Policy Planning Division, Office of Export Administration, U.S. Department of Commerce, Washington, D.C. 20230, telephone: A/C 202-377-2583.

For further information contact Mrs. Cornejo either in writing or by phone at the address or number shown above.

Dated: April 17, 1980.

**Kent Knowles,**

*Director, Office of Export Administration, International Trade Administration, U.S. Department of Commerce.*

[FR Doc. 80-12340 Filed 4-21-80; 8:45 am]

BILLING CODE 3510-25-M

## Maritime Administration

**[Docket No. S-667]**

### Lykes Bros. Steamship Co., Inc.; Bareboat Charter of SS "Lipscomb Lykes" to the Military Sealift Command

Notice is hereby given that Lykes Bros. Steamship Co., Inc. (Lykes) has bareboat chartered the SS *Lipscomb Lykes* (C7-S-95a) to the Military Sealift Command (MSC) for a base period of three years with MSC's option for two additional one year optional periods. The range of ports will be worldwide (including coastwise and intercoastal) under the terms of the charter. Accordingly, Lykes has requested written permission under section 805(a) of the Merchant Marine Act, 1936, as amended, to permit MSC to operate the *Lipscomb Lykes* in the domestic trade.

Any person, firm or corporation having any interest (within the meaning of section 805(a)) in Lykes' request and desiring to submit comments concerning the request must by close of business on April 28, 1980 file written comments in triplicate with the Secretary, Maritime Administration, together with petition for leave to intervene. The petition shall state clearly and conscisely the grounds of interest, and the alleged facts relied on for relief.

If no petition for leave to intervene is received within the specified time or if it is determined that petitions filed do not demonstrate sufficient interest to warrant a hearing, the Maritime Administration will take such action as may be deemed appropriate.

In the event petitions regarding the relevant section 805(a) issues are received from parties with standing to be heard, a hearing will be held, the purpose of which will be to receive evidence under section 805(a) relative to whether the proposed operations (a) could result in unfair competition to any person, firm, or corporation operating exclusively in the coastwise or intercoastal service, or (b) would be prejudicial to the objects and policy of the Act relative to domestic trade operations.

(Catalog of Federal Domestic Assistance Program No. 11.504 Operating-Differential Subsidies (ODS))

By Order of the Assistant Secretary for Maritime Affairs.

Date: April 14, 1980.

**Robert J. Patton, Jr.,**

*Secretary.*

[FR Doc. 80-12186 Filed 4-21-80; 8:45 am]

BILLING CODE 3510-15-M

### U.S. Merchant Marine Academy Advisory Board; Public Meeting

Notice is hereby given of a meeting of the Advisory Board to the U.S. Merchant Marine Academy (the Board) on May 16, 1980, at 10:30 a.m. in Wiley Hall, U.S. Merchant Marine Academy (the Academy), Kings Point, New York.

The Advisory Board to the Academy was established by the Secretary of Commerce under the authority of 46 U.S.C. 1126d to examine the course of instruction and overall management of the Academy and advise the Assistant Secretary of Commerce for Maritime Affairs with respect thereto.

The Board consists of not more than seven members appointed by the Secretary of Commerce selected from segments of the maritime industry, labor, educational institutions and other fields relating to the objectives of the Academy.

The agenda for the meeting is:

1. Call meeting to order;

2. Approval of minutes of the January 24, 1980 Board Meeting;

3. Status Report of Medical Services for the Midshipmen;

4. Status Report on Recreational Facilities:

1. Report by Chairman;

2. Report by Midshipmen on Rules of Use and Operation of "the Pub";

5. Reports by Board members on Assignments:

1. Mr. Brand—Public Relations;

2. Mr. Fanchi—Facilities Modernization Program/Shallow Draft Industry Requirements;

3. Mr. Scroggins—Admissions and Minority Recruitment;

4. Dr. Carswell Peden—Academic Program Development, Faculty Upgrading and Female Midshipmen Concerns;

5. Mr. Diesel—Budgetary and Fiscal Matters;

6. Mr. Smith—Graduate Placement and Employment of Midshipmen;

7. Mr. Cannaliato—Regimental Matters;

6. Status Report on Projected Placements, Incoming Class Composition and Attrition Rates;

7. Status Report on Pending Legislation, H.R. 5451;

8. Status of 1980, 1981 Budget and Impact on the Modernization Program;

9. Report of Chairman on CY–79 Board Activities and Recommendations;

10. Setting of Date for the next Board Meeting.

This meeting is open to public observation and comment. Approximately 20 seats will be available for the public on a first come, first-served basis.

Copies of the minutes are available upon request.

Inquiries may be addressed to the Committee Control Officer, Arthur W. Friedberg, Office of Maritime Labor and Training, Room 3069A, Main Commerce Building, telephone A/C 202/377–3018.

Dated: April 15, 1980.

So ordered by Assistant Secretary of Commerce for Maritime Affairs, Maritime Administration.

**Robert J. Patton, Jr.,**

*Secretary.*

[FR Doc. 80–12187 Filed 4–21–80; 8:45 am]

BILLING CODE 3510–15–M

## COMMITTEE FOR THE IMPLEMENTATION OF TEXTILE AGREEMENTS

### Changes in Officials of the Government of Indonesia Authorized To Issue Export Visas

April 16, 1980.

**AGENCY:** Committee for the Implementation of Textile Agreements.

**ACTION:** Announcing a new list of officials of the Government of Indonesia who have been authorized to issue export visas for cotton, wool and man-made fiber apparel products exported from Indonesia.

**SUMMARY:** The Government of Indonesia has notified the United States Government that the officials named on the list that follows this notice are authorized to issue export visas for apparel products exported to the United States. This list supersedes that published previously. (See 45 FR 8084).

**EFFECTIVE DATE:** April 16, 1980.

**FOR FURTHER INFORMATION CONTACT:** Judith L. McConahy, International Trade Specialist, Office of Textiles and Apparel, U.S. Department of Commerce, Washington, D.C. 20230 (202/377–5423).

**SUPPLEMENTARY INFORMATION:** On February 6, 1980, a letter dated February 1, 1980 to the Commissioner of Customs from the Chairman of the Committee for the Implementation of Textile Agreements was published in the Federal Register (45 FR 8084), which established an export visa requirement for cotton, wool and man-made fiber apparel products, produced or manufactured in Indonesia and exported to the United States. One of the requirements is that the visas must be signed by an official authorized by the Government of Indonesia. The Government of Indonesia has requested that the officials named on the following list be recognized as authorized to issue such export visas.

**Paul T. O'Day,**

*Chairman, Committee for the Implementation of Textile Agreements.*

**Officials Authorized by the Government of the Republic of Indonesia to Issue Visas for Apparel Products Exported to the United States**

Drs. Goenardi, I. W. Suwindra, Soetadji, Ismail Daud BA., Moh D. Husni, Zainal Abidin Nurmala, Djaharudin Thahir SH., ABD. Malik Drakel, M. Ruslim Mang, Drs. G. H. Hanomangan Pane, Drs. H. Harun, H. Rizani Hasan BBA, Endang Suteja BBA, Drs. Djausman, Iswall Tembong, Drs. H. Harun Sufi, Muchlisi Ahma BA., Drs. Zaini Latief, P. H. Hattu, Drs. B. Sitompul, Drs. Maskur Damang, S. Ali Mandi BA, and At. Matondang.

Gustamin Siregar, Raja Obajir Siahaan, A. B. Harahap, Abdul Manap, Drs. Anwar Ali, M. T. Krismurti, ILGST. NGR. Rai Ardana, Drs. Paiman Manan Sastro, Abdul Cholik Pasi BA., Drs. Doni Djatmika, Drs. Koesumopranoto, Tr. Ramian Zoebir, H. Ch. Andresen, Drs. Mansyur Tadaga, Drs. Sutan M. Syah, J. A. Thalib S. H., Bondan Setiowidjoyo, N. H. Tamba, Drs. Syamsu Ridjal Amin, R. Moelyono SH., and B. H. Muskitta.

Ismoe Suwarto, Soekanto, Eddy Suhaedi, I. Simanjuntak, Ketoet Soewetere, Drs. D. Sianturi, Drs. N. Hanomangan Siregar M.A., Runtu Dogu, Burhannudin SH., Syafru'Din SH., Edward Parapat, Tawakkal Akbar, Tigor Gultom BSC., Z. S. Rinding Padang BBA, and S. Banjarnahor.

[FR Doc. 80–12331 Filed 4–21–80; 8:45 am]

BILLING CODE 3510–25–M

## DEPARTMENT OF DEFENSE

### Department of the Air Force

### Intent To Prepare a Proposed Draft Environmental Impact Statement (EIS)

The U.S. Air Force proposes to add 42 RF–4 and 24F–4 Aircraft to the existing 36 RF–4s at Bergstrom AFB, Texas and remove an Air Force Reserve (AFRES) unit consisting of eight C–130s.

Alternatives to this proposal include the beddown of only the 42 RF–4s and retaining the AFRES C–130 unit; beddown of only the 24F–4s; or taking no action. In exploring the proposed action and alternatives the environmental analysis will consider such topics as air quality and aircraft emissions; the noise environment; air space availability; socio-economic factors; and mitigation measures.

Participation in the EIS process by interested Federal, State and local agencies, as well as interested private organizations and parties is invited. The public will be involved to the maximum extent possible and is encouraged to participate in the planning process.

A scoping meeting will be held at the Regan High School auditorium, 7104 Berkman, Austin, Texas on May 7, 1980 at 7 p.m. to review the proposed action and alternatives and receive comments for the environmental analysis of the proposal.

Headquarters Tactical Air Command estimates that the draft EIS will be filed and made available for public review and comment in late August 1980.

Questions concerning the proposed action, scoping meeting and draft EIS can be directed to: Major Joel R. Newton, HQ TAC/DEEV, Langley AFB, VA 23665 (804) 764–4430.

**Carol M. Rose,**

*Air Force Federal Register, Liaison Officer.*

[FR Doc. 80–12182 Filed 4–21–80; 8:45 am]

BILLING CODE 3910–01–M

### Department of the Army

### Armed Forces Epidemiological Board; Open Meeting

1. In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463) announcement is made of the following committee meeting:

Name of committee: Armed Forces Epidemiological Board.

Date of meeting: May 15 and 16, 1980.

Time: 0900–1630 15 May. 0830–1400 16 May.

Place: Board of Regents Room, 3rd Floor, Building C of the Uniformed Services University of the Health Sciences (USUHS), National Naval Medical Center, Bethesda, Maryland.

Proposed agenda: Agenda items for the meeting include reports from AFEB Subcommittees, reports on the preventive medicine activities of the Army, Navy, and Air Force, and discussions on hepatitis B, meningococcal, and typhoid vaccines. Also included will be a review of DOD overseas medical research laboratories.

2. This meeting will be open to the public, but limited by space accommodations. Any interested person may attend, appear before, or file statements with the committee at the time and in the manner permitted by the committee. Interested persons wishing to participate should advise the Executive Secretary, DASG–AFEB, Room 1B472 Pentagon, Washington, D.C. 20310.

Dated: April 16, 1980.

Charles W. Halverson,

*CDR, MSC, USN, Executive Secretary.*

[FR Doc. 80-12214 Filed 4-21-80; 8:45 am]

BILLING CODE 3710-08-M

## Medical Research and Development Advisory Panel Ad Hoc Study Group on Pharmacology; Partially Closed Meeting

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), announcement is made of the following Committee meeting:

Name of committee: United States Army Medical Research and Development Advisory Panel Ad Hoc Study Group on Pharmacology.

Date of meeting: May 15, 1980.

Time and place: 0900 hours, Room 3092, Walter Reed Army Institute of Research, Washington, DC.

Proposed agenda: This meeting will be open to the public from 0990-1000 hrs to discuss the scientific research program of the Pharmacology Branch, Walter Reed Army Institute of Research and from 1630-1700 hrs for the summation of the meeting. Attendance by the public at open sessions will be limited to space available.

In accordance with the provisions set forth in Section 552b(c)(6), Title 5, U.S. Code and Section 10(d) of Pub. L. 92-463, the meeting will be closed to the public on May 15, 1980 from 1000-1630 hrs for the review, discussion and evaluation of individual programs and projects conducted by the U.S. Army Medical Research and Development Command, including consideration of personnel qualifications and performance, the competence of individual investigators, medical files of individual research subjects, and similar items, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Dr. Howard Noyes, Associate Director, Walter Reed Army Institute of Research, Room 1111, Building 40, Walter Reed Army Medical Center, Washington, DC 20012 (202/576-3061) will furnish summary minutes, roster of Committee members, and substantive program information.

For the Commander.

Dated: April 16, 1980.

Richard O. Spertzel,

*Colonel, VC, Executive Officer.*

[FR Doc. 80-12215 Filed 4-21-80; 8:45 am]

BILLING CODE 3710-08-M

## DEPARTMENT OF ENERGY

## Energy Information Administration

## Discontinuance of Data Collection Reports

**AGENCY:** Energy Information Administration.

**ACTION:** Notice of discontinuance of data collection forms.

**SUMMARY:** The Energy Information Administration (EIA) of the U.S. Department of Energy (DOE) hereby gives notice of the discontinuance of four data collection forms. These forms have been discontinued as a result of DOE's continuing efforts to reduce respondent reporting burden.

**EFFECTIVE:** Immediately.

**FOR FURTHER INFORMATION CONTACT:** Dr. Irene C. Montie, Director, Survey and Statistical Design Division, Energy Information Administration, Room 4146, 12th and Pennsylvania Avenue, N.W., Washington, D.C. 20461, (202) 633-9464.

**SUPPLEMENTAL INFORMATION:** In keeping with the objectives of Executive Order 12174 to eliminate paperwork burden on the public, DOE has eliminated the following four reporting requirements:

BOM-6-1347-A, Foreign Crude Oil Report.[1]

BOM-6-1348-A, Foreign Refinery Report.[1]

BOM-6-1349-A, Foreign Petroleum Movement Report.[1]

BOM-6-1320-M, District V Monthly Petroleum Report Supplement.

Respondents are no longer requested to submit these reporting documents.

The Office of Management and Budget (OMB) which is responsible for the clearance of DOE forms has been notified, as appropriate, concerning the elimination of the BOM-6-1320-M.

Issued in Washington, D.C. on April 11, 1980.

Lincoln E. Moses,

*Administrator Energy Information Administration.*

[FR Doc. 80-12348 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-01-M

## Federal Energy Regulatory Commission

**[Docket No. TC80-60]**

## Alabama-Tennessee Natural Gas Co., et al.; Order Instituting Proceedings, Establishing Procedures and Providing for Hearings To Evaluate the Impact of Natural Gas Shortages of Interstate Pipeline Companies

In the matter of Alabama-Tennessee Natural Gas Company (Docket No. TC80-60); Algonquin Gas Transmission Company (Docket No. TC80-61); Arkansas-Louisiana Gas Company (Docket No. TC80-62); Cities Service Gas Company (Docket No. TC80-63); Colorado Interstate Gas Company (Docket No. TC80-64); Columbia Gas Transmission Corporation (Docket No. TC80-65); Consolidated Gas Supply Corporation (Docket No. TC80-66); East Tennessee Natural Gas Company (Docket No. TC80-67); Eastern Shore Natural Gas Company (Docket No. TC80-68); El Paso Natural Gas Company (Docket No. TC80-69); Florida Gas Transmission Company (Docket No. TC80-70); Michigan-Wisconsin Pipe Line Company (Docket No. TC80-71); Midwestern Gas Transmission Company (Docket No. TC80-72); Mississippi River Transmission Company (Docket No. TC80-73); National Fuel Gas Supply Corporation (Docket No. TC80-74); Natural Gas Pipeline Company of America (Docket No. TC80-75); Northern Natural Gas Company (Docket No. TC80-76); Northwest Pipeline Corporation (Docket No. TC80-77); Panhandle Eastern Pipe Line Company (Docket No. TC80-78); Southern Natural Gas Company (Docket No. TC80-79); Tennessee Gas Pipeline Company (Docket No. TC80-80); Tennessee Natural Gas Lines, Inc. (Docket No. TC80-81); Texas Eastern Transmission Corporation (Docket No. TC80-82); Texas Gas Transmission Corporation (Docket No. TC80-83); Transcontinental Gas Pipe Line Corporation (Docket No. TC80-84); Transwestern Pipeline Company (Docket No. TC80-85); Trunkline Gas Company (Docket No. TC80-86); United Gas Pipe Line Company (Docket No. TC80-87).

April 15, 1980.

The purpose of this order is to initiate proceedings to accumulate factual information which will provide the Commission, the natural gas industry and the general public with an overview of the projected impact of curtailment by natural gas pipelines during the 1980-81 winter season. Data will be required in the form of testimony and exhibits from the pipelines listed in the above-styled proceedings relating to anticipated gas supply, storage operation and inventory, emergency purchases, requirements, levels of curtailment and impact of curtailment on ultimate consumers. The proceedings are necessary to insure that the Commission receives the best information available on gas supplies and potential adverse curtailment impacts prior to the 1980-81 winter season in order to be able to exercise its mandate under the Natural Gas Act to insure adequate natural gas service.

The Commission will require that each respondent pipeline named in this order present written testimony through a responsible company official relative to its FERC Form No. 16 filed in April 1980 and other matters noted herein. This testimony should contain a detailed description of the Form No. 16 filing and

[1] These reports were requested from fewer than ten respondents; therefore, they were exempt from OMB approval.

should specifically provide the following information:

(1) Total gas supply projections with (a) a detailed breakdown of deliveries from the major sources of supply that are projected to decrease from the actual level of last year on a monthly basis for the period between April 1, 1980 through March 31, 1981 and of the deliveries from the major sources of supply that are projected to increase from the actual level of last year; (b) all pertinent facts and assumptions with respect to an anticipated new suply by month (April 1, 1980 through March 31, 1981) including reasons for stated date of attachment; (c) projected emergency purchases or transportation of emergency supplies by month for the latter period with an indication of pipeline company policy of making such purchases, i.e., for system supply or direct assignment, to specific customers; (d) status of ongoing storage injections: (e) projected, total, working gas inventory anticipated in storage at beginning of heating season (November 1, 1980), and maximum working gas capacity; (f) method of making supply projections and any contingency factors in such projections; (g) exempted purchases or transportation of exempted purchases for customers by month for the projected period April 1, 1980 through March 31, 1981.

(2) (a) Scheduled storage withdrawals during the months of November, 1980 through March, 1981 (i) under normal weather conditions (ii) under uniform temperature conditions of 10 percent colder than normal for each month November 1980 through March 1980 and (iii) under a hypothetical winter with temperature conditions, of 10 percent colder than normal during November 1980 and March 1981 and 20 percent colder than normal for December 1980, and January and February 1981[1] broken down by pipeline system withdrawals and customer withdrawals when necessary; (b) a description of the pipelines storage operation plan governing storage gas withdrawal and injections; (c) a detailed description for each month (November–March) of scheduled storage operations including a description of how early winter withdrawals affect later deliverability from storage, and a description of the pipeline's contingency plans for meeting colder-than-normal winter weather later in the season.

(3) (a) The derivation of requirements used in the Form No. 16 and a full explanation of any change in requirements from the 1979 Form 16; (b) a statement of requirements for each month of the 1980–81 winter heating season (November 1980 through March 1981, assuming colder than normal temperatures as specified in (2) (a) (ii) and (iii) above.

(4) An explanation of the computation of curtailments and a study showing for each month of the 1980–81 winter heating season assuming normal weather and assuming colder than normal temperatures as specified in (2)(a) (ii) and (iii) above: (a) the systemwide aggregate curtailment; (b) systemwide curtailment as a percent of priority of service and (c) systemwide curtailment as a percent of total requirements.

(5) A discussion of problem situations which occurred during the 1979–80 winter and a description of what steps have been taken to avoid such problems in the impending winter season. Also compare such winter with possible occurrences during the type of winter as specified in (2)(a)(ii) and (iii) above.

The Commission will further require that the captioned pipelines made parties to the above-styled proceedings distribute copies of this order to their distribution company customers and direct industrial customers.[2] Concurrently therewith, the pipelines are to request that these customers provide to them a list of their customers that may be forced to shut down this winter because they lack either a supply of alternate fuel or alternate fuel equipment to off-set projected natural gas curtailments on a normal and "colder than normal winter period" as specified in (2)(a) (ii) and (iii) above.

The following data shall be supplied where industrial shut down is indicated:

(1) The amount of additional gas supply needed for each distributor or direct industrial customers to avoid plant shut-down during each month of the 1980–81 winter period, including appropriate supporting data from distributors based on the needs of each commercial or industrial consumer that may be forced to shut-down due to curtailment this winter. Indicate the approximate number of days of shut-down for each consumer on the basis of weather conditions as described above.

(2) For each distributor and consumer faced with the prospect of plant shut-down, list all self-help measures which have been undertaken to date, and other self-help measures which are planned to avoid shut-down, including actions by state authorities.

(3) List for each pipeline and distributor with projected shut-down problems, all existing and proposed contingency plans to mitigate effects of plant shut-down next winter.

The distribution customers that must be called upon to provide the information requested herein should file this data with their respective jurisdictional pipeline suppliers on or before June 16, 1980. The Commission will require that the pipelines file their reports, predicated upon this information and the testimony related thereto with the Commission by July 14, 1980. The reports submitted by the respondent pipelines are to both analyze and collate the data referred to and should be more than a mere accumulation of the mass data collected. If the filings by the pipelines are fashioned as requested, the task of assessing and providing an appropriate overview of the curtailment impact this winter by the Commission will be expedited. In the event that a distributor fails to provide the requested information, the Commission may be required to conclude that commercial and industrial customers served by such distributor will not have fuel deficiency problems that may force them to shut down during the impending winter months. The respondent pipelines to these proceedings shall provide the corresponding information requested from the distributors for their own direct industrial customers.

In the event that hearings [3] are convened with respect to particular pipelines, it is the purpose of this Commission to assure that the reports and other data presented at the hearing that we have required in this order are properly incorporated into the formal hearing record. This will facilitate the task of the Commission Staff who in turn will be charged with task of making and tendering its own report predicated upon the data obtained subsequent to the conclusion of the last hearing that may be conducted in these proceedings. No useful purpose will be served by requiring that strict evidentiary and procedural rules be followed that might tend to either delay the proceedings or

[1] The colder than normal basis should be computed on the assumption of an increase in average monthly degree day deficiency of the suggested percent in excess of historical normal as computed by the Department of Commerce. While the extreme conditions of a 20 percent colder than normal winter may not occur during the coming winter season, it is important that we develop a contingency plan in the event it might happen; such conditions were encountered during the months of December, January and February in recent years.

[2] Respondent pipelines that are the customers of other pipelines named as respondents herein need file this data only in their own docket if one exists.

[3] As used herein, the term hearing refers to a proceeding before an Administrative Law Judge wherein testimony could be introduced by any party and witnesses cross examined so that a complete record could be developed. Such record is then certified to the Commission for utilization by it and staff in evaluating the impact of the projected gas supply on the coming winter season. No briefs or a decision from the Judge is contemplated. During some of the prior years, such proceedings were utilized to clarify conflicting data or to elicit additional data on specific issues.

preclude the introduction of the data called for herein by the Commission into the hearing record. It would also not serve the purposes of the Commission to permit any hearing that may be conducted in conjunction with these proceedings to linger needlessly, or encompass issues contained within ongoing curtailment dockets.

We shall provide that any hearings that are to be conducted with respect to the respondent pipelines are to be held during July and early August, 1980 and we shall direct that any hearings required to be held with respect to these proceedings be scheduled by the Chief Administrative Law Judge during those months. In order to provide that scheduling flexibility be assured with a minimization of effort we shall provide that the Secretary may by notice cancel any proceeding set for hearing in the event that any difficulties with data or pipeline reports submitted can be eliminated between the submission date and hearing date.

Since the focus of these hearings is directed toward the accumulation of data which is wholly factual by nature, we shall forego the filing of briefs normally contemplated by the Commission. Instead we shall call upon our Staff and the other parties to file with the Commission by September 22, 1980, summary memoranda in which the data presented in these proceedings is analyzed and in which any party may be free to tender any comments that he feels warranted in light of the facts and data developed in such hearing.

In light of the facts that there may exist certain common elements of interest between the above-styled proceedings and the curtailment proceedings that are currently in various stages of determination relative to the aforementioined pipelines, we shall automatically permit any party permitted to intervene and to have all the rights of a party in the corresponding pipeline proceeding instituted herein.[4] Appropriate provision will be made for other persons interested or desiring to intervene in the above-styled proceedings.

The Economic Regulatory Administration (ERA) and the Energy Information Administration (EIA)[5] are invited to fully participate and are requested to provide for the record in these proceedings State and regional information relative to alternate fuel availability for the forthcoming winter-heating season. State energy agencies and State public service commissions are also requested to participate and to provide information relating to: (1) the lack of alternate fuel capabilities of end-users in areas subject to their jurisdiction, and; (2) local conservation measures that are either directed or coordinated by them to offset the impact of the natural gas shortage; (3) problem situations of which they are aware. All others, including interested Federal and State agencies are also invited to participate in these proceedings.

*The Commission finds:* (1) It is in the public interest and consistent with the purposes of the Natural Gas Act to schedule hearings in certain of the proceedings hereinabove named, for the purpose of determining the impact of projected curtailments of natural gas deliveries over the 1980–81 winter heating season.

(2) It is in the public interest to allow all persons permitted to intervene in the corresponding pipeline curtailment proceedings set forth in the text of this order permission to intervene in the corresponding proceeding instituted by this order.

*The Commission orders:* (A) Pursuant to the authority conferred upon the Commission under the Natural Gas Act, particularly Sections 4, 5, 7, 14 and 15 hearings shall be scheduled to be held as provided in ordering Paragraph (B) hereof in the above-styled proceedings in order to determine the impact of projected curtailment for the 1980–81 winter heating season.

(B) The hearing provided for in ordering paragraph (A) shall be convened at such times and places as provided for in a Notice to be issued by the Secretary after receipt of a recommendation made by the General Counsel and the Director of the Office of Pipeline and Producer Regulation after consultation on this matter with the Chief Administrative Law Judge. The Commission contemplates that in a number of instances, formal hearings may not be necessary and the Secretary shall be so advised by the General Counsel after consultation with OPPR, and in such event, no hearing will be convened by the Secretary. In formulating the hearing schedule to be undertaken by the General Counsel and the Director of the Office of Pipeline and Producer Regulation, manpower resources and work schedule demands of the Office of Administrative Law Judges will be given full consideration.

(C) An Administrative Law Judge to be designated by the Chief Administrative Law Judge shall preside over the hearings that will be scheduled in the above-styled proceedings noted above in Ordering Paragraphs (A) and (B) and shall prescribe relevant procedural matters not herein provided and assure the development of an adequate record with the incorporation therein of the information sought and requested by the Commission in the text of this order.

(D) Each of the respondent pipelines designated in this order shall provide on a best efforts basis, the information called for in the body of this order no later than July 14, 1980. All parties to the instant proceedings are hereby requested and all customers of the respective pipeline companies are hereby urged to provide their pipeline suppliers with the necessary information by June 16, 1980, to enable the pipelines to comply with this order. Copies of the aforementioned data shall be served upon the appropriate State regulatory bodies.

(E) An analysis in memorandum form of the information obtained in these proceedings shall be presented to the Commission by the Commission Staff and other interested parties desiring to submit such memorandum or comments to the Commission by September 22, 1980.

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[4] The curtailment proceedings relating to the twenty-eight pipelines named in the caption of this order are as follows: Alabama-Tennessee Natural Gas Company, Docket No. RP74–42; Arkansas-Louisiana Gas Company, Docket No. RP71–122; Cities Service Gas Company, Docket No. RP75–62; Columbia Gas Transmission Corporation, Docket No. RP72–89; East Tennessee Natural Gas Company, Docket No. RP75–28; Eastern Shore Natural Gas Company, Docket Nos. RP71–121 and RP72–21; El Paso Natural Gas Company, Docket No. RP72–6; Northwest Pipeline Corporation, Docket No. RP74–79; Panhandle Eastern Pipe Line Company, Docket No. RP71–119; Tennessee Natural Gas Lines, Inc., Docket No. RP74–54; Texas Eastern Transmission Corporation, Docket Nos. RP71–130 and RP–72–58; Texas Gas Transmission Corporation, Docket No. RP72–64; Transcontinental Gas Pipe Line Corporation, Docket No. RP72–99; Transwestern Pipeline Company, Docket No. RP73–101; Trunkline Gas Company, Docket No. RP71–100; United Gas Pipe Line Company, Docket Nos. RP71–29, RP71–120; Algonquin Gas Transmission Co., Docket No. RP71–131; Colorado Interstate Gas Co., Docket No. RP72–122; Consolidated Gas Supply Corp., Docket No. RP77–29; Florida Gas Transmission Co., Docket Nos. RP71–128, RP–79; Michigan Wisconsin Pipe Line Co., Docket No. RP76–50; Midwestern Gas Transmission Co., Docket Nos. RP74–29, RP–74–69; Mississippi River Transmission Corp., Docket No. RP73–6; National Fuel Gas Supply Corp., Docket No. RP74–100; Natural Gas Pipeline Co. of America, Docket No. RP70–42; Northern Natural Gas Co., Docket Nos. RP74–102, and RP76–52; Southern Natural Gas Co., Docket Nos. RP72–74, and RP74–6; Tennessee Gas Pipeline Co., Docket No. RP74–24.

[5] Economic Regulatory Administration and Energy Information Administration of the Department of Energy/the Department of Energy Organization Act, Pub. L. 95–91, 91 Stat. 565 (August 4, 1977). Even though the convening of these proceedings is for the purpose of providing a vehicle to enable the Commission to acquire the data it needs to fulfill its obligations under the Natural Gas Act to assure adequate gas service, it will also utilize data not called for herein, available from components of the DOE, thereby avoiding any duplication of efforts in collecting information required to analyze adverse curtailment impact projected for the forthcoming winter.

(F) All parties previously granted intervention in the curtailment proceedings set forth in the text of this order are permitted to intervene in and participate in the corresponding pipeline proceeding that has been instituted by this order subject to the Rules and Regulations of the Commission; *Provided, however,* that the participation of such intervenors shall be limited to matters affecting rights and interests specifically set forth in their petitions to intervene in the aforementioned curtailment proceedings and *Provided, further,* that the admission of such intervenors shall not be construed by the Commission that subject intervenors might be aggrieved because of any order or orders issued by the Commission in these proceedings.

By the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12269 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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[Docket No. GP80-77]

## Anadarko Production Co. and Pan Eastern Exploration Co.; Application for Recovery of Production Related Costs Under Section 110 of the NGPA

Issued: April 16, 1980.

Take notice that on March 24, 1980, Anadarko Production Company (Anadarko), P.O. Box 1330, Houston, Texas 77001, and Pan Eastern Exploration Company (Pan Eastern), P.O. Box 1642, Houston, Texas 77001, filed with the Federal Energy Regulatory Commission (Commission), under section 271.1105 of the Commission's regulations, a joint application for recovery of production related costs under section 110 of the Natural Gas Policy Act of 1978 (NGPA), 15 U.S.C. 3301, *et seq.*

Anadarko and Pan Eastern seeks authorization (under 18 CFR 271.1105) to collect a fifty cents per Mcf (50 cents/Mcf) allowance for off-lease gathering and compression of certain gas sold to Panhandle Eastern Pipeline Company (Panhandle) from the Renfrow Area, Grant County, Oklahoma. Any such allowance granted by the Commission under 18 CFR 271.1105 will be in addition to the otherwise applicable maximum lawful price.

Any person desiring to be heard or to protest this proceeding should, on or before May 22, 1980, file with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.W., Washington, D.C. 20426, in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered but will not 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 must file a petition to intervene in accordance with the Commission's Rules.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12270 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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[Docket No. ER80-338]

## Arizona Public Service Co.; Filing

April 16, 1980.

The filing Company submits the following:

Take notice that on April 11, 1980, Arizona Public Service Company (APS) tendered for filing as an initial rate schedule an Agreement for Sale of Energy Interchange between City of Burbank, California (Burbank) and Arizona Public Service Company (Company) dated September 12, 1979.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, DC 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before May 9, 1980. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12271 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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[Docket No. RA80-20]

## Boland Oil Co.; Extension of Time

April 16, 1980.

On April 1, 1980, Boland Oil Company filed a request for an extension of time to file a petition for review of a decision and order issued February 29, 1980, by the Department of Energy's Office of Hearings and Appeals (DOE Case No. DEE-4333). The Company requests that this extension be granted pending their receipt of the public record of another DOE case which must be relied upon in their preparation of this petition for review.

Upon consideration, notice is hereby given that an extension of time for filing a petition for review is granted to and including May 1, 1980.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 12272 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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[Docket No. CP80-302]

## Cities Service Gas Co.; Application

April 16, 1980.

Take notice that on March 27, 1980, Cities Service Gas Company (Applicant), P.O. Box 25128, Oklahoma City, Oklahoma 73125, filed in Docket No. CP80-302 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing the construction and operation of certain pipeline taps, measuring, regulating and appurtenant facilities to enable Applicant to render natural gas service to nine rural right-of-way customers, all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that the nine right-of-way grantors have requested natural gas service for which Applicant proposes to construct and operate the following facilities:

(1) Tap Applicant's Ottawa-Tonganoxie 26-inch transmission pipeline in Leavenworth County, Kansas, and construct measuring, regulating and appurtenant facilities for delivery of natural gas to Clifton Allen.

(2) Tap Applicant's Pope 6-inch gathering pipeline in Carson County, Texas, and construct measuring, regulating and appurtenant facilties for delivery of natural gas to Dennis Caldwell.

(3) Tap Applicant's Springfield 16-inch transmission pipeline in Lawrence County, Missouri, and construct measuring, regulating, and appurtenant facilities for delivery of natural gas to James L. Greiner.

(4) Tap Applicant's McLouth Storage 20-inch pipeline in Leavenworth County, Kansas, and construct measuring, regulating, and appurtenant facilities for delivery of natural gas to Gerald L. Henre.

(5) Tap Applicant's Jane 20-inch transmission pipeline in McDonald County, Missouri, and construct measuring, regulating, and appurtenant facilities for delivery of natural gas to John T. Holmes.

(6) Tap Applicant's Cleveland 4-inch transmission pipeline in Pawnee County, Oklahoma, and construct measuring, regulating, and appurtenant facilities for delivery of natural gas to Dale McAllister.

(7) Tap Applicant's Welda-Ottawa 26-inch transmission pipeline in Anderson County, Kansas, and construct measuring, regulating, and appurtenant facilities for delivery of natural gas to Merle Rogers.

(8) Tap Applicant's Colony Storage 26-inch pipeline in Anderson County, Kansas, and construct measuring, regulating, and appurtenant facilities for delivery of natural gas to John E. Rook.

(9) Tap Applicant's Parson's 10-inch transmission pipeline in Montgomery County, Kansas, and construct measuring, regulating, and appurtenant facilities for delivery of natural gas to Charles VanCleve.

At the present time, it is anticipated that the sale to Dennis Caldwell and John E. Rook would be made by Applicant on a direct sales basis, and the sale to the other seven customers would be made to The Gas Service Company for resale to those customers.

Applicant estimates that the total cost of the facilities proposed to serve the right-of-way grantors would be approximately $6,330 which costs Applicant would finance from treasury funds on hand, it is said.

It is estimated that the annual sales for each rural domestic service proposed would average approximately 250 Mcf.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 7, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commssion's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition 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 petition 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 petition 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 Applicant to appear or be represented at the hearing.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12273 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. GP80-11]**

## Columbia Gas Transmission Co.; Notice of Third-Party Protests[1]

Take notice that in accordance with the procedures established by the Federal Energy Regulatory Commission (Commission) in Order No. 23-B[2] and "Order on Rehearing of Order No. 23-B,"[3] the Staff of the Commission protested on April 4, 1980, the assertion by the Columbia Gas Transmission Company (Columbia) and certain producers that the contracts identified in Staff's protest constitute contractual authority for the producers to charge and collect any applicable maximum lawful price under the Natural Gas Policy Act of 1978 (NGPA).

Issued April 16, 1980.

Staff stated that the contracts contained in Appendix A do not provide authority for the producer to increase prices to the extent claimed by Columbia in its evidentiary submission.

Take further notice that the Associated Gas Distributors (AGD) filed a supplemental third-party protest on April 4, 1980. AGD protests that the contracts in Appendix B do not provide contractual authority for the producer to increase prices charged and collected to the applicable NGPA maximum lawful price.

Any person, other than the pipeline and the seller, desiring to be heard or to make any response with respect to these protests should file with the Federal Energy Regulatory Commission, 825 North Capital Street, N.E., Washington, D.C. 20426, on or before April 30, 1980, a petition to intervene in accordance with 18 CFR 1.8. The seller need not file for intervention because under 18 CFR 154.94(j)(4)(ii), the seller in the first sale is automatically joined as a party.

**Kenneth F. Plumb,**

*Secretary.*

**Appendix A**

| Producer | Contract date |
|---|---|
| P. P. Gunn Estate | 8-26-30 |
| Thomas W. Harvey, | 5-16-74 |

[1]The term "third-party protest" refers to a protest filed by a party who is not a party to the contract which is protested.

[2]"Order Adopting Final Regulations and Establishing Protest Procedure," Docket No. RM79-22, issued June 21, 1979.

[3]Docket No. RM79-22, issued August 6, 1979.

**Appendix A—Continued**

| Producer | Contract date |
|---|---|
| Moris A. Burns and Irene W. Burns | 8-1-77 |
| Bryan Keith | 3-18-75 |

**Appendix B**

| Producer | Contract date |
|---|---|
| Allegheny Land & Mineral Co | 12-21-79 |
| Allegheny Land & Mineral Co. | 8-21-79 |
| Cooper #1 Joint Venture and Franklyn R. Engler | 1-3-80 |
| Big B Drilling Co | 11-19-80 |
| The Chesterfield Corporation | 11-27-79 |
| Oppenheimer Energy Corp. 1978-I, *et al* | 8-6-79 |
| J & J Enterprises | 1-18-80 |
| Russell V. Johnson, Jr. and Rockwell Petroleum Co | 12-14-79 |
| Monitor Resources Corp | 10-30-79 |
| Monitor Resources Corp | 1-9-80 |
| Natural Resource Management Corp. and NRM Petroleum Corp | 10-8-79 |
| NRM Petroleum Corp | 11-19-79 |
| Nord/Montara Petroleum Corp | 1-17-80 |
| Long Associates, Inc. and P & G Exploration, Inc | 1-7-80 |
| Royal Oil & Gas Corp | 12-10-79 |
| Scott and Hussing | 12-14-79 |
| Trahan Petroleum, Inc | 1-28-80 |
| Trahan Petroleum, Inc | 1-17-80 |
| Trahan Petroleum, Inc | 1-17-80 |
| Trahan Petroleum, Inc | 10-24-79 |
| Trio Petroleum Corp | 1-15-80 |
| Trio Petroleum Corp | 1-15-80 |
| Whiteland Petroleum Corp., *et al* | 12-10-79 |
| Whiteland Petroleum Corp., *et al* | 1-14-80 |
| Charles R. Bailey & Elinor H. Bailey | 11-10-77 |
| Morris A. Burns & Irene W. Burns | 8-1-77 |
| Bryan Keith | 3-18-75 |
| Norman A. Gillingham | 9-24-46 |
| Norman A. Gillingham | 1-1-42 |
| P. P. Gunn Estate | 8-26-30 |
| Thomas W. Harvey, Trustee | 5-16-74 |

[FR Doc. 80-12274 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ER80-106]**

## Commonwealth Edison Co.; Order Accepting for Filing and Suspending Proposed Rates Denying Waiver of Notice Requirements, Granting Intervention, and Consolidating Proceedings

April 16, 1980.

On November 27, 1979, Commonwealth Edison Company (Commonwealth) submitted for filing revised tariff sheets which reflect an increase in the base cost of fuel utilized in Commonwealth's fuel adjustment clause and energy rates now under adjudication in Docket No. ER79-182. The filing was completed on February 14, 1980, in response to a notice of deficiency issued on January 25, 1980.

Commonwealth's instant submittal was made on its own initiative to comply with the provisions of the Commission's Opinion No. 63, issued September 14, 1979, in Docket No. E-9002 and ER76-122, requiring that the fuel adjustment base cost be calculated from estimated fuel costs to be incurred during the Period II last year.

Commonwealth requests waiver of notice requirements and a one-day suspension to permit an effective date of December 1, 1979. Commonwealth also requests consolidation of the instant filing with the proceedings in Docket No. ER79–182.

Notice of the filing was issued on December 4, 1979, with comments, protests or petitions to intervene due by December 24, 1979. On December 20, 1979, the Illinois cities of Naperville, Batavia, Geneva, St. Charles, Rock Falls and Rochelle filed a protest and a petition to intervene, requesting a five month suspension and consolidation of this proceeding with Docket No. ER79–182. Because corresponding charges have been made to the fuel adjustment clause and the energy rates, the proposed rates produce the same revenues as the present rates which were suspended for five months in Docket No. ER79–182 and became effective subject to refund on September 1, 1979. We shall suspend the instant filing and consolidated it with Docket No. ER79–182 for hearing and decision.

Granting Commonwealth's request for waiver of notice requirements to allow the proposed rates to become effective as of December 1, 1979 would require rebilling from that date to reflect the new energy charge and the new base fuel cost even though there would be no revenue difference. Therefore, we will deny Commonwealth's request for a waiver and suspend the proposed rates for 12 days to become effective on May 1, 1980. Thus, Commonwealth will start billing under the new rate on the first day of next month.

Further, the Commission will grant the petitions to intervene in this proceeding filed by the Illinois Cities on December 20, 1979. Inasmuch as the proposed rate change does not result in a revenue of difference in Commonwealth's general rates filed in Docket No. ER79–182, collected subject to refund, the Commission will deny petitioners request for a five month suspension of the proposed rates.

*The Commission orders:*

(A) Commonwealth's proposed rate change filed November 27, 1979, is accepted for filing and suspended for 12 days to become effective as of May 1, 1980, subject to refund.

(B) The Commission hereby denies Commonwealth's request for waiver of the Commission's notice provisions.

(C) The Illinois Cities of Naperville, Batavia, Geneva, St. Charles, Rock Falls and Rochelle shall be permitted to intervene in this proceeding subject to the Commission's rules and regulations; *provided however,* that the participation of the intervenors shall be limited to affecting asserted rights and interests specifically set forth in the petition to intervene; and *provided, further,* that the admission of such intervenors shall not be construed as recognition that they might be aggrieved by any order entered in this proceeding.

(D) It is necessary, appropriate and in the public interest that this docket be consolidated with Docket No. ER79–182 for purposes of hearing and final Commission action.

(E) The Secretary shall promptly publish this order in the **Federal Register.**

By the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80–12275 Filed 4–21–80; 8:45 am]

BILLING CODE 6450–85–M

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**[Docket No. CP69–78]**

## Consolidated Gas Supply Corp. Carnegie Natural Gas Co.; Petition To Amend

April 16, 1980.

Take notice that on March 31, 1980, Consolidated Gas Supply Corporation (Consolidated), 445 West Main Street, Clarksburg, West Virginia 26301, and Carnegie Natural Gas Company (Carnegie), 3904 Main Street, Munhall, Pennsylvania 15121, filed in Docket No. CP69–78 a joint petition to amend the order issued in the instant docket on November 22, 1968[1], as amended May 1, 1979, pursuant to Section 7(c) of the Natural Gas Act so as to authorize an additional point of exchange of natural gas, all as more fully set forth in the petition to amend which is on file with the Commission and open to public inspection.

Petitioners state that on November 22, 1968, they were authorized to exchange natural gas and to construct certain facilities necessary to effect such exchanges. By order of May 1, 1979, the Commission amended its November 22, 1968, order, which amendment authorized the exchange of natural gas between Petitioner at certain additional delivery points and the implementation of certain operational changes with respect to the exchange, it is said.

Pursuant to an agreement dated January 31, 1980, it is proposed that Consolidated deliver gas to Carnegie's 12-inch pipeline PEG–220 near the community of Wyatt, in Harrison County, West Virginia. Petitioners submit that Consolidated would construct and operate the gas supply facilities necessary to establish the additional point of exchange under its currently effective budget-type certificate authorization. It is asserted that the proposed additional exchange delivery point is required in order that Consolidated may move newly developed local supplies of gas to its interstate system.

Any person desiring to be heard or to make any protest with reference to said petition to amend should on or before May 7, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80–12276 Filed 4–21–80; 8:45 am]

BILLING CODE 6450–85–M

[1] This proceeding was commenced before the FPC. By joint regulation of October 1, 1977 (10 CFR 1000.1), it was transferred to the Commission.

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**[Project No. 785]**

## Consumers Power Co.; Issuance of Annual License

April 16, 1980.

On April 8, 1977, the Consumers Power Company, Licensee for the Calkins Bridge Project No. 785, filed an application for a new license pursuant to the Federal Power Act and the Commission's regulations. The project is located on the Kalamazoo River in Allegan County, Michigan.

The project is currently operating under an existing license which expires April 10, 1980. In order to authorize the continued operation and maintenance of the project, pending Commission action on Licensee's application, it is appropriate and in the public interest to issue an annual license to the Consumers Power Company.

Take notice that an annual license to Consumers Power Company will be in effect for the period April 11, 1980, to April 10, 1981, or until Federal takeover, or until the issuance of a new license for the project, whichever comes first, for the continued operation and maintenance of Project No. 785, subject to the terms and conditions of the original license. Take further notice that

if Federal takeover, or issuance of a new license, does not take place on or before April 10, 1981, a new annual license will be in effect each year thereafter, effective April 11 of each year, until such time as Federal takeover takes place, or a new license is issued, without further notice being given by the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12277 Filed 4/21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ER80-225]**

## Delmarva Power and Light Co.; Extension of Time

April 16, 1980.

On April 8, 1980 and April 9, 1980, the Public Service Commission of the State of Delaware and the Public Advocate of Delaware filed respective motions for an extension of time to respond to a Motion for Summary Disposition and Related Relief filed March 17, 1980, by the Atlantic City Electric Company (ACE) in the above-docketed proceeding. The motion of the Public Service Commission states that additional time is required because of a delay in the receipt of ACE's motion. The motion of the Public Advocate further states that ACE does not oppose this request for an extension of time.

Upon consideration, notice is hereby given that an extension of time for filing responses is granted to and including April 18, 1980.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12278 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ER78-415]**

## Duke Power Co.; Filing

April 16, 1980.

The filing Company submits the following:

Take notice that on April 10, 1980, Duke Power Company (Duke) submitted for filing a refund report in compliance with the Commission's letter order of January 21, 1980, in the above-referenced proceeding.

A copy of this filing has been served upon the affected parties.

Any person desiring to be heard or to protest said filing should file a protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, NE, Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8 and 1.10). All such protests should be filed on or before May 9, 1980. Protests will be considered by the Commission in determining the appropriate action to be taken. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 12279 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ER80-339]**

## Florida Power & Light Co.; Filing

April 16, 1980.

The filing Company submits the following:

Take notice that on April 11, 1980 Florida Power & Light Company (FPL) tendered for filing a revised Exhibit A to the Company's FERC Electric Tariff, Revised Volume No. 1, which provides for a new contract demand for the City of Homestead, Florida (Homestead). The proposed effective date for the contract demand for Homestead is June 1, 1980.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before May 9, 1980. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12280 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket Nos. ER79-575 AND ER80-222]**

## Georgia Power Co.; Order Accepting for Filing and Suspending Proposed Interchange Agreement Rates, Waiving Notice Requirement, Terminating Docket and Establishing Procedures

April 16, 1980.

Before Commissioners: Charles B. Curtis, Chairman; Georgiana Sheldon, Matthew Holden, Jr., and George R. Hall.

On February 1, 1980, Georgia Power Company (Georgia) tendered for filing a revised interchange agreement with Savannah Electric and Power Company (Savannah),[1] which provides for the exchange of emergency assistance, short term firm capacity and economy energy services. Savannah completed the filing requirements in this docket by filing its certificate of concurrence on February 20, 1980. Georgia requests waiver of the Commission's notice requirements to allow the revisions to become effective as of January 1, 1980. Alternatively, if the Commission orders a hearing on the proposed revisions. Georgia requests a one-day suspension with an effective date of January 2, 1980, and consolidation with the proceedings in Docket No. ER79-575.

Revisions in the rates under the interchange agreement were previously filed in Docket No. ER79-575, where the Commission accepted the rates for filing, suspended their effectiveness for one day and set the matter for investigation.[2] The procedures used in developing the charges proposed in the instant docket are identical to those used in Docket No. ER79-575 with the exception that a 15.0% return on common equity is used in developing short term capacity charges in the instant submittal. The proposed rates are based on an updating of costs which affect system operations, such as changes in installed generating capacity and changes in administrative and general expenses.

Under the terms of the proposed interchange agreement emergency energy is furnished for periods not to exceed 72 hours, after which time short-term capacity and energy, if available, is supplied. Emergency energy may be returned in kind, at the option of the supplying party, or purchased at a charge consisting: Of (1) fuel cost, (2) variable and fixed fossil production O&M, (3) allocated production and transmission A&G, (4) transmission O&M, (5) losses, (6) start-up costs (if any), and (7) purchased power costs, if applicable. Emergency energy will be deemed as having been delivered from the supplying party's highest cost unit operating at the time of the sale. This rate results in an emergency energy charge for service from Georgia of 3.4 mills/kWh plus fuel cost, losses and variable production O&M for the 1980 operating year. Savannah's proposed

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[1] Designated as: Georgia Power Company Supplement No. 4 to Rate Schedule FERC No. 798. Savannah Electric & Power Company Supplement No. 1 to Rate Schedule FERC No. 4 (concurs in Georgia Power Company Supplement No. 4 to FERC No. 798).

[2] Order Accepting for Filing and Suspending Proposed Interchange Contract Rates, Waiving Notice Requirement and Establishing Procedures, issued October 5, 1979; modified to allow for prehearing conference, in Order Granting Rehearing and Modifying Prior Order, issued December 5, 1979.

energy charge for 1980 is 3.2 mills/kWh plus fuel cost, variable production O&M and transmission losses.

Short term capacity and energy is defined as surplus, non-firm capacity and energy provided for a period not to exceed 90 days. The capacity charge is computed and varies monthly to recover estimated fossil production and transmission O&M expense, A&G expense, depreciation, payroll and property taxes, income taxes, and 15.0% on equity. The energy charge is the sum of replacement fuel cost, variable production O&M expense and compensation for transmission losses at 3%. If purchased from a third party, short term power is billed at cost plus a wheeling charge. The proposed wheeling charges for 1980 are $0.18/kW/wk for Georgia and $0.30/wk for Savannah. Based upon estimated 1980 suporting data filed by the company, the above rate results in a weekly capacity charge for short term service from Georgia varying from $1.08/kW/wk to $0.13/kW/wk. Savannah's proposed weekly capacity charges for short term service range from $1.48/kW/wk to $1.57/kW/wk. Economy energy continues to be exchanged on a split-the savings basis.

Notice of the filing was issued on February 11, 1980, with protests or petitions to intervene due on or before February 29, 1980. No responses were received.

Our review of the rates under the proposed interchange agreement in Docket No. ER80–222 indicates that the rates have not been shown to be just and reasonable and may be unjust, unreasonable, unduly discriminatory, or otherwise unlawful. Accordingly, we shall accept these proposed rates for filing and suspend them for one day, to become effective January 2, 1980, subject to refund, pending the outcome of a hearing and decision.

With respect to Georgia's request for consolidation of the instant docket with the proceedings in Docket No. ER79–575, the Commission finds consolidation to be inappropriate. The acceptance for filing of the rates in Docket No. ER80–222 for the calendar year 1980 creates a locked-in period (August 2, 1979 through January 1, 1980) for the rates contained in Docket No. ER79–575. In Docket No. ER79–575 the justness and reasonableness of the formula used to calculate the capacity charges for short term frim power transactions made during 1979 was being investigated. However, no short term firm power transactions occurred during the 1979 locked-in period. Therefore, the issue of the justness and reasonableness of the short term firm power capacity charge applicable to 1979 transactions is moot. For this reason, Staff counsel moved to terminate Docket No. ER79–575 on March 31, 1980.[3] The Commission will grant that motion. An investigation of the formula which determines the short term firm power capacity charge during 1980 will be undertaken in Docket No. ER80–222.

*The Commission orders:*

(A) The Commission hereby waives the notice requirement of § 35.3 of the Regulations.

(B) The proposed rates for emergency, short term, and economy interchanges between Georgia Power Company and Savannah Electric and Power Company proposed in the interchange agreement in Docket No. ER80–222 are hereby accepted for filing and suspended for one day, to become effective as of January 22, 1980, subject to refund.

(C) Pursuant to the authority contained in and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Section 402(a) of the Department of Energy Organization Act and by the Federal Power Act, and pursuant to the Rules of Practice and Procedure and the Regulations under the Federal Power Act (18 CFR, Chapter I), a public hearing shall be held concerning the justness and reasonableness of the rates proposed in Docket NO. ER80–222.

(D) A presiding administrative law judge to be designated by the Chief Administrative Law Judge for that purpose shall preside at a prehearing conference in this proceeding to be held in a hearing room of the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C., 20426, within 30 days of the issuance of this order for the purposes of identifying the additional cost of service data which the parties will be required to file in support of the proposed rates. The judge is authorized to establish procedural dates and rule upon all motions (except motions to consolidate and sever, and motions to dismiss) as provided in the Commission's Rules of Practice and Procedure.

(E) Docket No. ER79–575 is hereby terminated.

(F) The Secretary shall promptly publish this order in the **Federal Register.**

By the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80–12281 Filed 4–21–80; 8:45 am]

BILLING CODE 6450–85–M

[3] Staff states in its motion at note 2 that counsel for Georgia and Savannah concur and join in the motion.

**[Docket No. ES80–46]**

## Gulf States Utilities Co.; Application

April 16, 1980.

Take notice that on April 4, 1980, Gulf States Utilities Company (Applicant) filed an application with the Federal Energy Regulatory Commission, pursuant to Section 204 of the Federal Power Act, requesting authorization to enter into negotiations in connection with the issuance of up to $75,000,000 of First Mortgage Bonds and up to 3,000,000 Additional Shares of New Common Stock, without par value.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 5, 1980, file with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, petitions or protests in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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. Persons wishing to become parties to a proceeding or to participate as a party in any hearing therein must file petitions to intervene in accordance with the Commission's rules. The application is on file with the Commission and available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80–12282 Filed 4–21–80; 8:45 am]

BILLING CODE 6450–85–M

**[Docket No. CP80–304]**

## Iowa-Illinois Gas & Electric Co.; Application

April 16, 1980.

Take notice that on April 1, 1980, Iowa-Illinois Gas and Electric Company (Applicant), P.O. Box 4350, Davenport, Iowa 52808, filed in Docket No. CP80–304 an application pursuant to Section 7(c) of the Natural Gas Act for a certificate of public convenience and necessity authorizing an increase in the nominal operating pressure of 11.74 miles of 10-inch pipeline in Henry and Rock Island Counties, Illinois, along with the construction and operation of facilities to increase the operating pressure of the 11.74 miles of 10-inch pipeline in Henry and Rock Island Counties, all as more fully set forth in the application on file with the Commission and open to public inspection.

Specifically, Applicant proposes to increase the operating pressure of 11.74 miles in Henry and Rock Island Counties, Illinois, of the 14.75 miles of the existing authorized 10-inch pipeline from a nominal operating pressure of 400 psig to a nominal operating pressure of 600 psig. Applicant proposes to construct and operate facilities required to effectuate the increase, which include two new regulator stations and 0.43 mile of 6-inch pipeline, it is stated.

Applicant asserts that the proposed increase in nominal operating pressure is required in order to supply future anticipated loads and to provide adequate and reliable service in Applicant's Illinois and Davenport-Bettendorf, Iowa, service areas.

The estimated cost of the proposed pipeline work is $244,458 which cost would be financed with Applicant's current working funds, it is said.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 7, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition 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 petition 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 petition 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 Applicant to appear or be represented at the hearing.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12283 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ES80-42]**

## Iowa-Illinois Gas & Electric Co.; Application

April 16, 1980.

Take notice that on April 1, 1980, Iowa-Illinois Gas and Electric Company (Applicant) of Davenport, Iowa, filed an application seeking authority pursuant to Section 204 of the Federal Power Act, to issue up to $50,000,000 of Short-Term Notes and Commercial Paper, to be issued no later than June 30, 1981, and to mature no later than June 30, 1982.

Applicant is incorporated under the laws of the State of Illinois with its principal business office at Davenport, Iowa, and is engaged in the electric and gas utility businesses within the State of Iowa and the State of Illinois.

The notes are to be issued from time to time to banking institutions and/or sold as commercial paper to direct purchasers or through commercial paper dealers.

The proceeds from the issuance of notes will be added to working capital for ultimate application toward the cost of gross additions to utility plant.

Any person desiring to be heard or to make any protest with reference to the application should on or before May 5, 1980, file with the Federal Energy Regulatory Commission, Washington, DC 20426, petitions or protests in accordance with the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). The application is on file with the Commission and available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12284 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ST80-161]**

## Louisiana Intrastate Gas Corp.; Application for Approval of Rates

April 16, 1980.

Take notice that on April 3, 1980, Louisiana Intrastate Gas Corporation (Applicant), P.O. Box 1352, Alexandria, Louisiana 71301, filed in Docket No. ST80-161 an application pursuant to § 284.123(b)(2) of the Commission's Regulations for approval of rates charged for transporting natural gas for Texas Gas Transmission Corporation (Texas Gas), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states that it and Texas Gas entered into an agreement, dated March 31, 1980, whereby Applicant is to provide transportation service to Texas Gas for a two-year term and free of cost to Texas Gas. Applicant further states that the proposed transportation service and related rates and charges have been approved by Louisiana state authorities. Additionally, inasmuch as there would be no fee for the transportation service, such fee is fair and equitable pursuant to § 284.123(d) of the Commission's Regulations, it is stated.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 2, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 petition to intervene in accordance with the Commission's Rules.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12285 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ST80-153]**

## Louisiana Resources Co.; Application for Approval of Rates

April 16, 1980.

Take notice that on March 26, 1980, Louisiana Resources Company (Applicant), P.O. Box 3102, Tulsa, Oklahoma 74101, filed in Docket No. ST80-153 an application pursuant to § 284.123(b)(2) of the Commission's Regulations for approval of rates for gathering, treatment, processing, transportation, and delivery (transportation services) of natural gas to be provided by Applicant for Transcontinental Gas Pipe Line Corporation (Transco), all as more fully set forth in the application which is on file with the Commission and open to public inspection.

Applicant states it has contracted with Transco for the transportation, on behalf of Transco, of up to 10 billion Btu's of gas per day. For said service,

Transco would pay applicant an initial amount of 22.5 cents per million Btu of gas transported, which initial rate may vary with, but shall never exceed, those rates and charges as may be in effect from time to time for transportation services rendered by Applicant under transportation rate schedules for intrastate service on file with the Office of Conservation, Department of Natural Resources, State of Louisiana, and approved by the Commissioner of Conservation of such Office, which transportation services are comparable to those rendered under the agreement between Applicant and Transco dated November 24, 1979. Applicant asserts that the proposed rates would be fair and equitable in that they would reasonably compensate it for transportation services rendered and would not be in excess of those rates charged for comparable intrastate service.

Any person desiring to be heard or to make any protest with reference to said application should on or before May 2, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 petition to intervene in accordance with the Commission's Rules.

Kenneth F. Plumb,

*Secretary.*

[FR Doc. 80-12286 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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[Docket No. CP80-7]

## Mountain Fuel Supply Co.; Amendment to Application

April 16, 1980.

Take notice that on March 27, 1980, Mountain Fuel Supply Company (Applicant), 180 East First South Street, Salt Lake City, Utah 84139, filed in Docket No. CP80-7 pursuant to Section 7(c) of the Natural Gas Act an amendment to its application pending in the instant docket so as to revise the proposed transportation service to include service for the account of Northern Natural Gas Company (Northern), all as more fully set forth in the amendment which is on file with the Commission and open to public inspection.

Applicant, in an application filed October 1, 1979, in the instant docket proposed to transport a combined total of 300,000 Mcf of natural gas per day for Natural Gas Pipeline Company of America (NGPL) and Columbia Gas Transmission Corporation (Columbia). Applicant states that Northern has since agreed to become a participant in the Trailblazer system, having a one-third ownership interest, and to become a one-fifth owner in Overthrust Pipeline Company. Thus, Applicant proposes to transport for NGPL, Columbia, and Northern up to a combined total of 300,000 Mcf of gas per day. Applicant states that NGPL and Columbia have each agreed to reduce Applicant's obligation for transportation service to allow Applicant to commit to Northern a portion of the transportation service.

Applicant proposes to construct facilities estimated to cost $15,999,139, which would consist of a gas-driven reciprocating compressor station with a site rating of 9,300 horsepower. The cost of said facilities would be financed by funds on hand or by short-term borrowings. In all other respects, it is stated, the original application would remain the same.

Applicant states it would also construct (1) additional compression facilities at its Nightgale Compressor Station located in Sweetwater County, Wyoming, (2) approximately 0.28 mile of 20-inch diameter exchange pipeline running from the additional compressor facilities to the Colorado Interstate Gas Company segment of the Trailblazer Pipeline System, and (3) replace the meters at the Eakin Station.

It is indicated that the intial volumes of gas to be transported are estimated to be 31,000 Mcf per day for NGPL, 23,000 Mcf per day for Columbia and 95,000 Mcf per day for Northern.

Any person desiring to be heard or to make any protest with reference to said amendment should on or before May 7 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10) 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 petition to intervene in accordance with the Commission's Rules. All persons who have heretofore filed need not file again.

Kenneth F. Plumb,

*Secretary.*

[FR Doc. 80-12287 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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[Docket No. ES80-47]

## Northwestern Public Service Co.; Application

April 16, 1980.

Take notice that on April 8, 1980, the Nowthwestern Public Service Company (Applicant) filed an application with the Federal Energy Regulatory Commission, pursuant to Section 204 of the Federal Power Act, seeking authorization to issue and sell 100,000 additional shares of its Common Stock, par value $7 per share, in accordance with the terms and conditions of its Employee Stock Ownership Plan.

The Applicant is incorported under the laws of the State of Delaware, with its principal business office at Huron, South Dakota, and is qualified to do business as a foreign corporation in the States of Iowa, North Dakota and South Dakota.

Any person desiring to be heard or to protest said filing should file a petition to intervene or protest with the Federal Energy Regulatory Commission, Washingtron, D.C. 20426, in accordance with the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All such petitions or protests should be filed on or before May 5, 1980. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

Kenneth F. Plumb,

*Secretary.*

[FR Doc. 80-12288 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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[Docket No. QF80-2]

## Ottumwa Water Works; Application for Commission Certification of Qualifying Status of a Small Power Production Facility

April 16, 1980.

On April 1, 1980, Ottumwa Water Works and Hydro-Electric Plant filed with the Federal Energy Regulatory Commission an application to be certified as a qualifying small power

production facility under § 292.207 of the Commission's rules.

Ottumwa states that the facility is located on the Des Moines River within the corporate limits of Ottumwa, Iowa in Sections 23, 24, and 25, Township 72N, Range 14W, and that it is owned by the City of Ottumwa and operated under an appointed Board of Trustees.

Ottumwa states that the facility consists of a fully grated dam across the Des Moines River at Ottumwa, Iowa, creating a reservoir extending north and upstream for about 6 miles. The facility has three generators and a total installed capacity of 3 MW. The primary energy source is water, and the 1979 production was 10,835,000 kWh.

Any person desiring to be heard or objecting to the granting of qualifying status should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with sections 1.8 and 1.10 of the Commission's Rules of Practice and Procedure. All such petitions or protests must be filed within 30 days after the date of issuance of this notice and must be served on the applicant. Protests will be considered by the Commission in determining the appropriate action to be taken but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12289 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ER77-464]**

## Public Service Co. of New Mexico; Extension of Time

April 16, 1980.

On April 9, 1980, Plains Electric Generation and Transmission Cooperative, Inc., filed a request for an extension of time to file briefs opposing exceptions to the Initial Decision issued January 25, 1980, in the above-docketed proceeding. The motion states that additional time is needed because of a delay in the Company's receipt of briefs on exceptions which were filed by Commission staff and the Public Service Company of New Mexico. The motion further states that other parties to this proceeding do not oppose the requested extension.

Upon consideration, notice is hereby given that an extension of time for filing briefs opposing exceptions is granted to and including April 30, 1980.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12290 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ER80-337]**

## Southwestern Electric Power Co.; Proposed Tariff Change

April 16, 1980.

The filing Company submits the following:

Take notice that Southwestern Electric Power Company (SWEPCO) on the 10th day of April 1980, tendered for filing proposed changes in its Federal Energy Regulatory Commission Electric Service Tariffs, Rate Schedule FERC No. 66, Rate Schedule FERC No. 67 and Rate Schedule FERC No. 69. The proposed changes would increase revenues from jurisdictional sales and service by $10,416,712 based on the 12 month period ending December 31, 1980.

Proposed changes in provisions that are common to the rate for Tex-La Electric Cooperative, Inc., and the rate for municipalities are:

(1) Determination of Kilowatts of Billing shall be as presently determined but never less than 85% of the highest Kilowatts of Billing Demand established during the billing months of June, July, August and September of the eleven preceding months.

(2) The fuel adjustment clause has been rebased to the cost of fuel for the year ending December 31, 1979. Compensation will be allowed suppliers of SPA hydro energy at the rate per KWH that is equal to the cost of fuel per KWH in 1979 less the cost of fuel per KWH included in the energy rate per KWH in the superseded rate schedule. No fuel adjustment will be charged on KWH sold to customers each month that are equal to hydro KWH received by SWEPCO from those customers each month.

(3) A clause, Unrestricted Right to File Unilateral Rate Changes, as provided to Sec. 35.1(d)(2) of the Commission's rules has been included in the rate schedules.

(4) Interest at 18% per annum will be charged on all amounts unpaid after 15 days from date of bill.

Changes applicable to the rate for Tex-La are:

There will be a service charge and a demand charge for deliveries below 69 KV and for deliveries at 69 KV and above applicable for each point of delivery. The energy charge is increased from 0.4¢ per KWH to 1.2¢ per KWH.

Changes applicable to the rate for municipalities are:

A service charge has been added and the energy charge is a flat rate rather than a two-step rate.

SWEPCO states that its existing rates produce a return of only 3.53% on the net FERC rate base devoted to serving the jurisdictional customers during the 12 month period ending December 31, 1980. The revised rates are designed to yield SWEPCO a return of 11.48% for the same period. SWEPCO has and is experiencing substantial increases in all elements of its costs including fuel, labor interest, taxes, materials and supplies and in construction to provide additional capacity to meet the growing requirements of these customers. The increased rate of return is needed to help meet the increased costs to serve the jurisdictional customers whose load has increased from 12.2% of SWEPCO's peak load in 1974 to 13.7% of the SWEPCO peak in 1980.

SWEPCO proposes to make the revised rate schedules effective June 10, 1980.

Any person desiring to be heard or to protest said application should file a petition to intervene or protest with the Federal Energy Regulatory Commission, 825 North Capitol Street, N.E., Washington, D.C. 20426, in accordance with §§ 1.8 and 1.10 of the Commission's Rules of Practice and Procedure (18 CFR 1.8, 1.10). All such petitions or protests should be filed on or before May 9, 1980. Protests will be considered by the Commission in determining the appropriate action to be taken, but will not serve to make protestants parties to the proceeding. Any person wishing to become a party must file a petition to intervene. Copies of this filing are on file with the Commission and are available for public inspection.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12291 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

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**[Docket No. ER80-241]**

## Superior Water Light & Power Co.; Order Accepting for Filing, Suspending Proposed Rate Changes and Establishing Hearing Procedures

Issued April 16, 1980.

Before Commissioners: Charles B. Curtis, Chairman; Georgiana Sheldon, Matthew Holden, Jr., and George R. Hall.

On February 19, 1980, Superior Water, Light, and Power Company (SWLP) tendered for filing a revised rate schedule[1] to its sole wholesale customer—Dahlberg Light and Power

[1] SWLP's Rate Schedule is designated as Superior Water Light and Power Company Supplement No. 8 to Rate Schedule FPC No. 12 (superseding Supplement No. 6).

Company (Dahlberg). The proposed increase would result in additional revenue of $154,117, (an 8.76% increase) for the twelve month period ending December 31, 1980. SWLP proposes an effective date of April 21, 1980, for this rate.

Public notice of the proposed rate increase was issued on February 26, 1980, with responses due on or before March 17, 1980. On March 14, 1980, the Public Service Commission of Wisconsin (Wisconsin) filed a Notice of Intervention. In its notice, Wisconsin stated that it has the authority to regulate electric utilities within the State of Wisconsin.

SWLP states that its proposed rate increase is necessary in order that it may recover the proportionate share of the increase in the cost of purchased power from SWLP's supplier, Minnesota Power and Light Company (MPL), [2] and to otherwise raise, to an acceptable level, the rate of return on the investment necessary to serve its jurisdictional customer. Our review of SWLP's filing, however indicates that the proposed rates appear to yield more revenues than SWLP requires to achieve its stated objectives and may be unjust, unreasonable, unduly discriminatory, preferential, or otherwise unlawful.

Our review further revealed that certain questionable items were included. These items are (1) functionalization of general plant on a basis other than functional wage and salary ratios, (2) allocation of Research and Development contributions to Liquid Metal Fast Breeder Reactor (LMFBR), and to the Electric Power Research Institute (EPRI) to resale cost of service, (3) reclassification per books of distribution facilities and costs to transmission function, (4) directly assigned transmission facilities and related costs, (5) claiming of interest expense, for tax purposes, on a non-synchronized basis, and (6) use of a transmission allocation factor that does not reflect all system load.

Given this preliminary review, we believe that suspension of the rates, and a hearing concerning the filing is warranted. Furthermore, since SWLP is claiming that this filing is the result of increased costs due to our allowing MPL to charge increased rates, it would be unjust and unreasonable for SWLP to charge the proposed rates prior to the time that MPL is allowed to charge higher rates. Since our order of December 31, 1979 allowed MPL's proposed rates to become effective on June 1, 1980, subject to refund, we will suspend SWLP's proposed rates until June 1, 1980, subject to refund.

Because SWLP's filing is predicted preliminary on the pass-through of increased purchased power cost from MPL, we shall waive the work paper filing requirements as conditioned below, and set a pre-hearing conference within thirty days from the issuance of this order to explore the possibility of settlement. Any settlement reached in the instant docket must be made subject to the final determination of MPL's rate case in Docket No. ER80–5, subject to refund.

**The Commission Orders**

(A) SWLP's Rate Schedule Supplement No. 8 to Rate Schedule FPC No. 12 (superseding Supplement No. 6) is hereby accepted for filing and suspended until June 1, 1980, to become effective on that date subject to refund.

(B) Notice is taken that the Public Service Commission of Wisconsin has initiated its participation in this proceeding and is a party herein.

(C) SWLP's proposed rates in this proceeding shall be determined subject to the final disposition of the rates filed in the Minnesota Power and Light Company proceeding in Docket No. ER80–5 now before us, subject to refund.

(D) A pre-hearing conference shall be held in this proceeding within 30 days from the date of this order.

(E) The work paper filing required by Section 35.13 (b)(4)(iii) of the Regulations under the Federal Power Act is hereby waived. Such waiver does not prejudice any parties' right to request further information through data requests.

(F) Pursuant to the authority contained in, and subject to the jurisdiction conferred upon the Federal Energy Regulatory Commission by Section 402(a) of the Department of Energy Organizing Act and the Federal Power Act, particularly Sections 205 and 206, and pursuant to the regulations thereto, a public hearing shall be held concerning the justness and reasonableness of the proposed rates in this docket.

(G) A Presiding Administrative Law Judge, to be designated by the Chief Administrative Law Judge, shall be assigned to preside in this proceeding for that purpose. The designated law judge is authorized to establish procedureal dates and to rule on all motions (except motions to consolidate or to sever, and motions to dismiss), as provided for in the Commission's Rules of Practice and Procedure.

(H) The Secretary shall promptly publish this order in the **Federal Register.**

By the Commission.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80–12292 Filed 4–21–80; 8:45 am]

**BILLING CODE 6450–85–M**

[2] SWLP receives 90% of its bulk power requirement from MPL. In *Minnesota Power and Light Co.*, Docket No. ER80–5 (December 31, 1979), we order that MPL could charge its jurisdictional customers the rates as proposed in that proceeding, subject to refund, effective June 1, 1980. SWLP is one of MPL's jurisdictional customers. In essence, SWLP is attempting in this filing to pass its increased costs on to its customer—Dahlberg.

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**[Docket No. GP80–23]**

## Texas Gas Transmission Corp.; Protest To Charge and Collect NGPA Price

April 16, 1980.

Take notice that on March 10, 1980, Texas Gas Transmission Corporation (Texas Gas), pursuant to Section 154.94(h)(8) of the Commission's Regulations (18 CFR 154), filed a petition protesting the claim of contractual authority of the Superior Oil Company (Superior) to charge and collect from Texas Gas a certain maximum lawful price established by the Natural Gas Policy Act of 1978 (NGPA).

Texas Gas submits that Superior filed a supplemental blanket affidavit under Texas Gas' Contract No. 469 and Superiors' Rate Schedule No. 69 on January 3, 1980 seeking a unilateral rate increase to collect the Section 106(a) price. Texas Gas asserts that it is protesting this filing since the subject contract has not been executed and, consequently, does not meet the requirements of a rollover as defined under Section 106(a) of the NGPA.

Any person desiring to be heard or to make any protest concerning the protest filed in this docket should on or before May 2, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). All protests filed with the Commission will be considered by it in determining the appropriate action to be taken herein but will not serve to make the protestants parties to this proceeding. Any party wishing to become a party to this proceeding, or to participate as a party in any hearing herein, must file a petition to intervene in accordance with the Commission's Rules.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80–12293 Filed 4–21–80; 8:45 am]

**BILLING CODE 6450–85–M**

[Docket No. ST80-147]

## TUCO, Inc.; Application for Approval of Rates

April 16, 1980.

Take notice that on March 20, 1980, TUCO, Inc. (Applicant), One Houston Cetner, Houston, Texas 7700-2, filed in Docket No. ST80-147 an application pursuant to § 284.144(a)(3) of the Commission's Regulations for approval of the transporation and treating component of the proposed rates and charges for its sale of surplus gas supplies to El Paso Natural Gas Company (El Paso), all as more fully set forth in the application on file with the Commission and open to public inspection.

Applicant states that by contract dated March 10, 1980, it has agreed to sell to El Paso up to 20 billion Btu's of gas per day for a mixmum term of two years from the date of initial delivery. It is stated that the contract also provides for a price equal to Applicant's weighted average cost of purchased gas in New Mexico plus 29.0 cents per million Btu's to cover the cost of Applicant's gathering, treating, processing, transporting, and delivering the gas. Applicant asserts that its actual cost for performing the above functions would be 58.0 cents per million Btu. However, Applicant was able to negotiate to contract with El Paso which would recover only a portion of the total cost. Applicant states that the 29.0 cents per million Btu's it would charge El Paso is, nevertheless, fully cost-supported and, therefore, fair and equitable.

Any person desiring to be heard or to make any protests with reference to said application should on or before May, 1980, file with the Federal Energy Regulatory Commission, Washington, D.C. 20426, a petition to intervene or a protest in accordance with the requirements of the Commission's Rules of Practice and Procedure (18 CFR 1.8 or 1.10). 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 proceedig. Any person wishing to become a party to a proceeding or to participate as a party in any hearing therein must file a petition to intervene in accordance with the Commission's Rules.

**Kenneth F. Plumb,**

*Secretary.*

[FR Doc. 80-12294 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-85-M

## Office of Hearings and Appeals

## Objection To Proposed Remedial Orders Filed; Week of March 19 Through March 21, 1980

Notice is hereby given that during the week of March 19 through March 21, 1980, the Notices of Objection to Proposed Remedial Orders listed in the Appendix to this notice were filed with the Office of Hearings and Appeals of the Department of Energy.

On or before May 12, 1980, any person who wishes to participate in the proceeding which the Department of Energy will conduct concerning the Proposed Remedial Orders described in the Appendix to this notice must file a request to participate pursuant to 10 CFR 205.194 (44 FR 7926, February 7, 1979). Within 30 days of the publication of this notice, the Office of Hearings and Appeals will determine those persons who may participate on an active basis in this proceeding, and will prepare an official service list which it will mail to all persons who filed requests to participate. Persons may also be placed on the official service list as non-participants for good cause shown. All requests regarding this proceeding shall be filed with the Office of Hearings and Appeals, Department of Energy, Washington, D.C. 20461.

Issued in Washington, D.C.

**Melvin Goldstein,**

*Director, Office of Hearings and Appeals.*

April 15, 1980.

*Gulf Oil Corp., Houston, TX, BRO-0211.*

On March 20, 1980, Gulf Oil Corp., P.O. Box 3725, Houston, TX 77001 filed a Notice of Objection to a Proposed Remedial Order which the DOE Office of Special Counsel issued to the firm on November 13, 1979.

[FR Doc. 80-12224 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-01-M

## Issuance of Proposed Decisions and Orders; March 3 Through March 7, 1980

Notice is hereby given that during the period March 3 through March 7, 1980, the Proposed Decisions and Orders which are summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to Applications for Exception which had been filed with that Office.

Under the procedures which govern the filing and consideration of exception applications (10 CFR Part 205, Subpart D), any person who will be aggrieved by the issuance of the Proposed Decision and Order in final form may file a written Notice of Objection within ten days of service. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this Notice (April 22, 1980) or the date of receipt by an aggrieved person of actual notice, whichever occurs first. The applicable procedures also specify that if a Notice of Objection is not received from any aggrieved party within the time period specified in the regulations, the party will be deemed to consent to the issuance of the Proposed Decision and Order in final form. Any aggrieved party that wishes to contest any finding or conclusion contained in a Proposed Decison and Order must also file a detailed Statement of Objections within 30 days of the date of service of the Proposed Decision and Order. In that Statement of Objections an aggrieved party must specify each issue of fact or law contained in the Proposed Decision and Order which it intends to contest in any further proceeding involving the exception matter.

Copies of the full text of these Proposed Decisions and Orders are available in the Public Docket Room of the Office of Hearings and Appeals, Room B-120, 2000 M Street, N.W., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., e.s.t., except Federal holidays.

**Melvin Goldstein,**

*Director, Office of Hearings and Appeals.*

April 15, 1980.

**Proposed Decisions and Orders**

*Automatic Comfort Corp., Hartford, Conn., BEE-0294, gasohol*

Automatic Comfort Corporation (ACC) filed an Application for Exception from the provisions of 10 CFR Part 211. The exception request, if granted, would permit ACC to receive an increased allocation of unleaded motor gasoline for the express purpose of blending and distributing gasohol. On March 7, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted.

*City of Elberton, Elberton, Ga., BEE-0083, natural gas*

The City of Elberton filed an Application for Exception from the provisions of Section 13(b) of the FEAA of 1974. The exception request, if granted, would relieve Elberton of any obligation to prepare and submit Form EIA-149. On March 6, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

*Hardell Corp., Hagerstown, Md., DEE-4499, No. 2 heating oil*

Hardell Corporation (Hardell) filed an Application for Exception from the reporting requirements set forth in Form EIA-9. The exception request, if granted, would relieve

Hardell of the obligation to prepare and submit Form EIA–9. On March 6, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

*Travellers Construction Incorporated, Oklahoma City, Oklahoma, BEE–0504, gasohol*

Travellers Construction, Inc. filed an Application for Exception from the provisions of 10 CFR Part 211. The exception request, if granted, would increase the firm's allocation of unleaded motor gasoline so that it could blend and sell gasohol. On March 3, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

*Welsh Oil, Incorporated, Gary, Indiana, BEE–0360, gasohol*

Welsh Oil, Inc. filed an Application for Exception from the provisions of 10 CFR Part 211. The exception request, if granted, would permit Welsh to receive an increased allocation of unleaded motor gasoline for the purpose of blending and marketing gasohol. On March 7, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted.

*Whitewater Petroleum Terminals, Incorporated, Chicago, Illinois, BEE–0403, gasohol*

On November 27, 1979, Whitewater Petroleum Terminals, Inc. filed an Application for Exception from the provisions of 10 CFR 211.102. The exception request, if granted, would permit Whitewater to receive an additional allocation of motor gasoline in order to produce gasohol and regohol. On March 7, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted in part.

**Petitions Involving the Motor Gasoline Allocation Regulations**

The following firms filed Applications for Exception from the provisions of the Motor Gasoline Allocation Regulations. The exception requests, if granted, would result in an increase in the firms' base period allocation of motor gasoline. The DOE issued Proposed Decisions and Orders which determined that the exception requests be granted.

*Company Name, Case Number, and Location*

Gen. Services Adm., DEE–7664, Washington, D.C.
Mutual Oil Co., DEE–2576, Greenville, SC.

**Petitions Involving the Motor Gasoline Allocation Regulations**

The following firms filed Applications for Exception from the provisions of the Motor Gasoline Allocation Regulations. The exception requests, if granted, would result in an increase in the firms' base period allocation of motor gasoline. The DOE issued Proposed Decisions and Orders which determined that the exception requests be denied.

*Company Name, Case number and Location*

A. C. Fernald Sons, DEE–5353, Mt. Desert, ME.
Beard Oil Co., DEE–6281, Camden, SC.
Big K Oil Co., DEE–5009, Rockingham, NC.
C&H Gas & Oil, DEE–8221, Wash., DC.
Gardner, Kirk & Cowden, Inc., DEE–5468, Oklahoma City, OK.
Hasse Oil Co., BEE–0010, Ellendale, ND.
Mason Oil Co., Inc., DEE–5746, Ione, CA.
Petro-Wash, Inc., DEE–2318, Atlanta, GA.
Plaza Exxon, DEE–7614, N. Augusta, SC.
Santa FE Oil, DEE–3247, San Bernardino, CA.
Scot Oil CO., DEE–5604, Nashville, TN.
Urbano Service Stat., BEE–0613, Sunnymead, CA.

[FR Doc. 80–12225 Filed 4–21–80; 8:45 am]

BILLING CODE 6450–01–M

## Issuance of Proposed Decisions and Order; March 10 through March 14, 1980

Notice is hereby given that during the period March 10 through March 14, 1980, the Proposed Decisions and Orders which are summarized below were issued by the Office of Hearings and Appeals of the Department of Energy with regard to Applications for Exception which had been filed with that Office.

Under the procedures which govern the filing and consideration of exception applications (10 CFR, Part 205, Subpart D), and person who will be aggrieved by the issuance of the Proposed Decision and Order in final form my file a written Notice of Objective within ten days of service. For purposes of those regulations, the date of service of notice shall be deemed to be the date of publication of this Notice, April 22, 1980 or the date of receipt by an aggrieved person of actual notice, whichever occurs first. The applicable procedures also specify that if a Notice of Objection is not received from any aggrieved party within the time period specified in the regulations, the party will be deemed to consent to the issuance of the Proposed Decision and Order in final form. Any aggrieved party that wishes to contest any finding or conclusion contained in a Proposed Decision and Order must also file a detailed Statement of Objection within 30 days of the date of service of the Proposed Decision and Order. In that Statement of Objections an aggrieved party must specify each issue of fact or law contained in the Proposed Decision and Order which it intends to contest in any futher proceeding involving the exception matter.

Copies of the full text of these Proposed Decisions and Orders are available in the Public Docket Room of the Office or Hearings and Appeals, Room B–120, 2000 M Street, N.W., Washington, D.C. 20461, Monday through Friday, between the hours of 1:00 p.m. and 5:00 p.m., e.s.t., except federal holidays.

Dated April 15, 1980.

**Melvin Goldstein,**

*Director, Office of Hearings and Appeals.*

*E. J. Flemister & Son Oil Co., Sandersville, Georgia, BEE–0437*

On December 4, 1979, E. J. Flemister & Son Oil Co. filed an Application for Exception from the provisions of 10 CFR 211.102. The exception request, if granted, would permit Flemister to receive an increased allocation of unleaded motor gasoline in order to produce gasohol. On March 10, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be granted in part.

*Edgington Oil Co., Inc., Long Beach, California, BEE–0215 gasohol*

Edgington Oil Company, Inc. filed an Application for Exception from the provisions of 10 CFR, Part 211. The exception request, if granted, would establish an allocation of unleaded gasoline for the firm to permit it to blend and market gasohol. On March 13, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

*James M. Forgotson, Sr., Washington, D.C., BEE–0012 crude oil*

James M. Forgotson, Sr. filed an Application for Exception from the provisions of 10 CFR, Part 212, Subpart D. The exception request, if granted, would permit the firm to sell a certain portion of the crude oil produced for the benefit of the working owners from the Iota Nonunion Struma Sand Unit located in Acadia Parish, Louisiana, at upper tier ceiling prices. On March 11, 1980, the DOE issued a Proposed Decision and Order and tentatively determined that exception relief should be denied.

*Gardner, Kirk & Cowden, Oklahoma City, Oklahoma, BEE–0441 gasohol*

Gardner, Kirk & Cowden filed an Application for Exception from the provisions of 10 CFR, Part 211. The exception request, if granted, would permit the firm to receive an increased allocation of unleaded gasoline to permit it to expand its gasohol sales. On March 10, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

*Lumberport-Shinnston Gas Co., Lumberport, West Virginia, BEE–0643 reporting requirement*

Lumberport-Shinnston Gas Co. filed an Application for Exception from the reporting requirements set forth in Form EIA–149 ("Natural Gas Supply, Requirements, and Usage"). The exception request, if granted, would relieve the firm of the requirement to file Form EIA–149 with the Energy Information Administration. On March 10, 1980, the DOE issued a Proposed Decision and Order in which it tentatively determined that exception relieve should be granted in full.

*W.E. Schroeder, Houston, Texas, BEE–0088 crude oil*

W.E. Schroeder filed an Application for Exception from the provisions of 10 CFR, Part

212, Subpart D. The exception request, if granted, would permit the firm to sell a certain portion of the crude oil produced for the benefit of the working interest owners from the J.B. Ferguson Lease located in Wharton County, Texas, at upper tier ceiling prices. On March 11, 1980, the DOE issued a Proposed Decision and Order and tantatively determined that exception relief should be granted.

*St. Croix Valley Natural Gas Co., Inc., River Falls, WI, BEE–0760 reporting requirementsQ02*
*Natural Gas Utility District of Hawkins, County, Tennessee, Rogersville, TN, BEE–0602*

The St. Croix Valley Natural Gas Co., Inc. and the Natural Gas Utility District of Hawkins County, Tennessee filed Applications for Exception from the reporting requirements set forth in Form EIA–149 ("Natural Gas Supply, Requirements, and Usage"). The exception requests, if granted, would relieve the applicants of the requirement to file Form EIA–149 with the Energy Information Administration. On March 12, 1980, the DOE issued a Proposed Decision and Order in which it tentatively determined that exception relief should be granted which would permit the applicants to file their data in simplified form.

*T.W. Brown Oil Co., Inc., Ventura, California, BEE–0520 gasohol*

T.W. Brown Oil Co., Inc. filed an Application for Exception from the provisions of 10 CFR, Part 211. The exception request, if granted, would permit the firm to receive an increased allocation of unleaded gasoline with which to blend and sell gasohol. On March 10, 1980, the Department of Energy issued a Proposed Decision and Order which determined that the exception request be denied.

**Petitions Involving the Motor Gasoline Allocation Regulations**

The following firms filed Applications for Exception from the provisions of the Motor Gasoline Allocation Regulations. The exception requests, if granted, would result in an increase in the firms' base period allocation of motor gasoline. The DOE issued Proposed Decisions and Orders which determined that the exception requests be granted.

*Company Name, Case Number and Location*

Big Wheel, BEE–0219, Millry, AL.

**Petitions Involving the Motor Gasoline Allocation Regulations**

The following firms filed Applications for Exception from the provisions of the Motor Gasoline Allocation Regulations. The exception requests, if granted, would result in an increase in the firms' base period allocations of motor gasoline. The DOE issued Proposed Decisions and Orders which determined that the exception requests be granted.

*Company Name, Case Number and Location*

Canepa's Car Wash, DEE–6694, Stockton, CA.
E.D. Christensen, DEE–2525, Hanahan, SC.
Herbst Supply Company, DEE–2740, Wash, DC.
I.B. Lemoine, DEE–6663, Mansura, LA.
Jubilee Oil Co., DEE–2625, Chicago, IL.
S. Dakota Office of Energy Policy, BEE–0131, Rapid City, SD.
M.G. Oil Co.

[FR Doc. 80–12226 Filed 4–21–80; 8:45 am]
BILLING CODE 6450–01–M

## Western Area Power Administration

### Colorado River Storage Project, Collbran Project, Provo River Project, and Rio Grande Project, Post-1989 Marketing Plans

**AGENCY:** Western Area Power Administration, U.S. Department of Energy.

**ACTION:** Announcement of public information forum and public comment forum on the development of post–1989 marketing plans for the Colorado River Storage Project, the Collbran Project, the Provo River Project, and the Rio Grande Project (also includes any future projects constructed in the designated area).

**SUMMARY:** The Western Area Power Administration (Western) has scheduled a Public Information Forum on May 22, 1980, at 10 a.m. at the Hilton Hotel (Seasons South) in Salt Lake City, Utah, to discuss development of post-1989 marketing plans for the Colorado River Storage Project (CRSP), the Collbran Project, the Provo River Project, and the Rio Grande Project, as well as any future projects which may be constructed in the marketing area. Topics will include marketing alternatives for the above-noted projects and participating projects, present and future. The possibility of integrating or consolidating individual project marketing plans, for the marketing of the power from these resources as if from a single resource, will also be discussed. A brief description of the projects follows:

1. Colorado River Storage Project (Glen Canyon, Morrow Point, Flaming Gorge, Blue Mesa, Crystal, and Fontenelle Dams). Authorized in 1956, the Colorado River Storage Project addresses the development and use of water resources of the Upper Colorado River. Encompassing the Upper Colorado River Basin (an area equal to about one-twelfth of the continental area of the United States), CRSP storage units equalize the erratic flows of the Colorado River and its tributaries so that water delivery commitments to the Lower Basin States, as well as to farmers, municipalities, and industries in the Upper Basin, can be met.

Delivery of this water to consumers is accomplished through the participating projects. Several participating projects, such as the Paonia Project in Colorado, have been completed, and others, such as the Central Utah Project, are under construction. Additional units may be built in coming years.

The installed capacity of the CRSP powerplants is currently 1,476.0 megawatts. The average annual generation is 5,360,000 megawatthours.

2. Collbran Project (Upper Molina and Lower Molina Dams). Authorized in 1952 and in service since 1962, the Collbran Project serves western Colorado.

The installed capacity of the Collbran Project powerplants is presently 13.5 megawatts. The average annual generation is 55,000 megawatthours.

3. Provo River Project (Deer Creek Dam). Construction of the Provo River Project was authorized by the President of the United States in 1938. Power was initially produced at the Deer Creek powerplant in 1955. The plant went into service in 1958. The Deer Creek Dam spans the Provo River in central Utah.

The installed capacity of the Deer Creek powerplant is 4.95 megawatts. The average annual generation is 24,000 megawatthours.

4. Rio Grande Project (Elephant Butte Dam). The Rio Grande Project was authorized in 1905. Elephant Butte powerplant went into service in 1940.

Elephant Butte Dam is located on the Rio Grande River in southern New Mexico.

The installed capacity of the Elephant Butte powerplant is 24.3 megawatts.

The average annual generation is 68,000 megawatthours.

The Public Information Forum will provide an opportunity for questions and answers concerning development of a post-1989 marketing plan, including available power resources, electric service arrangments, allocations, etc.

Western has also scheduled a Public Comment Forum, following the Public Information Forum, to be held on July 21, 1980, beginning 9 a.m., at the Hilton Hotel (Seasons South) in Salt Lake City, Utah. The Public Comment Forum will allow interested parties the opportunity to present oral and written comments concerning the post-1989 marketing plan development. Interested parties are invited to submit written comments directly to Western's Salt Lake City Area Office and/or present written or oral views, or data, at the Public Comment Forum.

**DATES:** The Public Information Forum will be held on May 22, 1980, beginning at 10 a.m. at the Hilton Hotel (Seasons South) in Salt Lake City, Utah. The Public Comment Forum will be held July 21, 1980, beginning at 9 a.m. at the Hilton

Hotel (Seasons South) in Salt Lake City, Utah.

Following the information and comment forums, additional public meetings, if necessary, will be scheduled for the purpose of continuing consultation with interested parties in the development of post- 1989 marketing plans. Any such meetings will be scheduled and announced in advance.

**ADDRESSES:** For further information or comments concerning the Public Information and Public Comment Forums contact: Mr. A. M. Gabiola, Area Manager, Salt Lake City Area Office, Western Area Power Administration, U.S. Department of Energy, P.O. Box 11606, Salt Lake City, UT 84147, Telephone: (801) 524–5493.

**SUPPLEMENTARY INFORMATION:** Written comments concerning the post-1989 marketing plan may be submitted on or before September 19, 1980. Four (4) copies of the comments should be submitted to the following:

Mr. A. M. Gabiola, Area Manager, Salt Lake City Area Office, Western Area Power Administration, U.S. Department of Energy, P.O. Box 11606, Salt Lake City, UT 84147.

Copies of comments will be available from the following Western offices:

Western Area Power Administration, U.S. Department of Energy, Boulder City Area Office, P.O. Box 200, Boulder City, NV 89005.

Western Area Power Administration, U.S. Department of Energy, Denver Area Office, P.O. Box 2650, Fort Collins, CO 80522.

Western Area Power Administration, U.S. Department of Energy, Salt Lake City Area Office, P.O. Box 11606, Salt Lake City, UT 84147.

Administrator, Western Area Power Administration, U.S. Department of Energy, P.O. Box 3402, Golden, CO 80401.

Issued at Golden, Colorado April 15, 1980.

**Robert L. McPhail,**

*Administrator.*

[FR Doc. 80-12365 Filed 4-21-80; 8:45 am]

BILLING CODE 6450-01-M

## ENVIRONMENTAL PROTECTION AGENCY

**[FRL 1471-6; PP 7G1998/T232]**

### Abbott Laboratories; Renewal of a Temporary Exemption From the Requirement of a Tolerance

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

**ACTION:** Notice.

**SUMMARY:** A temporary exemption from the requirement of a tolerance has been renewed for residues of the mycocaracide *Hirsutella thompsonii* on citrus fruits and small fruits.

**FOR FURTHER INFORMATION CONTACT:** Mr. Franklin D. R. Gee, Product Manager (PM) 17, Room E–341, Office of Pesticide Programs (TS–767), EPA, 401 M Street, SW., Washington, DC 20460, 202/426–9417.

**SUPPLEMENTARY INFORMATION:** On March 14, 1979, the EPA announced (44 FR 15535) an extention of a temporary exemption from the requirement of a tolerance for residues of the mycocaracide *Hirsutella thompsonii* in or on the crop groupings citrus fruits and small fruits. Notice of the establishment of this temporary exemption appeared in the **Federal Register** of April 18, 1978 (43 FR 16404) in response to a pesticide petition (PP 7G1998) submitted by Abbott Laboratories, Chemical & Agricultural Products Div., North Chicago, IL 60064.

This extension expired February 24, 1980. Abbott Laboratories requested a one-year renewal of this temporary exemption both to permit continued testing to obtain additional data and to permit the marketing of the above crop groupings when treated in accordance with the provisions of the experimental use permit 275–EUP–20 that has been renewed under the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), as amended in 1972, 1975, and 1978 (92 Stat. 819; 7 U.S.C. 136).

The scientific data reported and all other relevant material were evaluated, and it was determined that a renewal of the temporary exemption would protect the public health. Therefore, the temporary exemption has been renewed on condition that the pesticide be used in accordance with the experimental use permit with the following provisions:

1. The total amount of the pesticide to be used must not exceed the quantity authorized by the experimental use permit.

2. Abbott Laboratories must immediately notify the EPA of any findings from the experimental use that have a bearing on safety. The firm must also keep records of production, distribution, and performance and on request make the records available to any authorized officer or employee of the EPA or the Food and Drug Administration.

This temporary tolerance exemption expires February 24, 1981. Residues remaining in or on citrus fruits and small fruits after this expiration date will not be considered actionable if the pesticide is legally applied during the term of and in accordance with the provisions of the experimental use permit and temporary exemption. This temporary exemption may be revoked if the experimental use permit is revoked or if any scientific data or experience with this pesticide indicate such revocation is necessary to protect the public health.

(Sec. 408(j), 68 Stat. 516, (21 U.S.C. 346a(j))

Dated: April 15, 1980.

**Douglas D. Campt,**

*Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 80-12308 Filed 4-21-80; 8:45 am]

BILLING CODE 6560-01-M

**[FRL 1472-4; OPP-C31010A]**

### Approval of Application to Conditionally Register a Pesticide Product Entailing a Changed Use Pattern

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

**ACTION:** Notice.

**SUMMARY:** This notice announces approval of an application by E. M. Industries, Inc. to amend registration of the pesticide product Funginex Emulsifiable Concentrate (EPA Reg. No. 21137–4). The proposed amendment entails a changed used pattern.

**DATE:** Written comments by May 22, 1980.

**ADDRESS:** Written comments and inquiries to: Mr. Henry Jacoby, Product Manager (PM) 21, Rm. E–305, Registration Division (TS–767), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460, 202/755–2562.

**SUPPLEMENTARY INFORMATION:** On July 8, 1977, notice was given (42 FR 35184) that E.M. Laboratories, Inc., 500 Executive Blvd., Elmsford, NY 10523, had filed an application with EPA to amend registration of the pesticide product Funginex Emulsifiable Concentrate (EPA Reg. No. 21137–4) containing 18.2% of the active ingredient triforine (*N,N'*-[1,4-piperazinediylbis (2,2,2,-trichloroethylidene]bis [formamide]). As stated in the notice, the applicant proposes a significant new use pattern from indoor use (greenhouse) on roses to outdoor use on the food crops blueberries and peaches.

This application was conditionally approved on March 7, 1980. Funginex Emulsifiable Concentrate is classified for general use.

A copy of the approved label and list of data references used to support registration are available for public inspection in the Product Manager's office. The data and other scientific information used to support registration, except for the material specifically protected by Section 10 of the Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) as amended (92 Stat. 819; 7

U.S.C. 136), are available for public inspection in accordance with section 3(c)(2) of FIFRA. Requests for data must be made in accordance with the provisions of the Freedom of Information Act and must be addressed to the Freedom of Information Office (A-101), EPA, at the above address. Such requests should: (1) Identify the product by name and registration number and (2) specify the data or information desired.

(40 CFR 162.5 and 162.6)

Dated: April 17, 1980.

**Edwin L. Johnson,**

*Deputy Assistant Administrator for Pesticide Programs.*

[FR Doc. 80-12302 Filed 4-21-80; 8:45 am]

BILLING CODE 6560-01-M

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**[FRL 1472-1; OPTS-51053]**

## Certain Chemicals; Premanufacture Notices

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

**ACTION:** Notice.

**SUMMARY:** Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before manufacture or import commences. Section 5(d)(2) requires EPA to publish in the **Federal Register** certain information about each PMN within 5 working days after receipt. This Notice announces receipt of four PMN's and provides a summary of each.

**DATE:** Written comments by May 31, 1980.

**ADDRESS:** Written comments to: Document Control Officer (TS-793), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460, 202-755-8050.

**FOR FURTHER INFORMATION CONTACT:** Mr. Douglas Rehberg, Premanufacturing Review Division (TS-794), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460, 202-426-8493.

**SUPPLEMENTARY INFORMATION:** Section 5(a)(1) of TSCA requires any person who intends to manufacture or import a new chemical substance to submit a PMN to EPA at least 90 days before manufacture or import commences. A "new" chemical substance is any substance that is not on the Inventory of existing substances compiled by EPA under Section 8(b) of TSCA. EPA first published the Initial Inventory on June 1, 1979. Notice of avilability of the Initial Inventory was published in the **Federal Register** of May 15, 1979 (44 FR 28558). The requirement to submit a PMN for new chemical substances manufactured or imported for commercial purposes became effective on July 1, 1979.

EPA has proposed premanufacture notification rules and forms in the **Federal Register** issues of January 10, 1979 (44 FR 2242) and October 6, 1979 (44 FR 59764). These regulations, however, are not yet in effect. Interested persons should consult the Agency's Interim Policy published in the **Federal Register** of May 15, 1979 (44 FR 28564) for guidance concerning premanufacture notification requirements prior to the effective date of these rules and forms. In particular, see page 28567 of the Interim Policy.

A PMN must include the information listed in Section 5(d)(1) of TSCA. Under section 5(d)(2) EPA must publish in the **Federal Register** nonconfidential information on the indentity and uses of the substance, as well as a description of any test data submitted under section 5(b). In addition, EPA has decided to publish a description of any test data submitted with the PMN and EPA will publish the identity of the submitter unless this information is claimed confidential.

Publication of the section 5(d)(2) notice is subject to section 14 concerning disclosure of confidential information. A company can claim confidentiality for any information submitted as part of a PMN. If the company claims confidentiality for the specific chemical identity or use(s) of the chemical, EPA encourages the submitter to provide a generic use description, a nonconfidential description of the potential exposures from use, and a generic name for the chemical. EPA will publish the generic name, the generic use, and the potential exposure desciption in the **Federal Register.**

If no generic use description or generic name is provided, EPA will develop one and after providing due notice to the submitter, will publish an amended **Federal Register** notice. EPA immediately will review confidentiality claims for chemical identity, chemical use, the identity of the submitter, and for health and safety studies. If EPA determines that portions of this information are not entitled to confidential treatment, the Agency will publish an amended notice and will place the information in the public file, after notifying the submitter and complying with other applicable procedures.

After receipt, EPA has 90 days to review a PMN under section 5(a)(1). The section 5(d)(2) **Federal Register** notice indicates the date when the review period ends for each PMN. Under section 5(c), EPA may, for good cause, extend the review period for up to an additional 90 days. If EPA determines that an extension is necessary, it will publish a notice in the **Federal Register.**

Once the review period ends, the submitter may manufacture the substance unless EPA has imposed restrictions. When the submitter begins to manufacture the substance, he must report to EPA, and the Agency will add the substance to the Inventory. After the substance is added to the Inventory, any company may manufacture it without providing EPA notice under section 5(a)(1)(A).

Therefore, under the Toxic Substances Control Act, summaries of the data taken from the PMN's are published herein.

Interested persons may, on or before May 31, 1980, submit to the Document Control Officer (TS-793), Rm. E-447, Office of Pesticides and Toxic Substances, 401 M St., SW, Washington, DC 20460, written comments regarding these notices. Three copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the document control number "[OPTS-51053]" and the specific PMN number. Comments received may be seen in the above office between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding holidays.

(Sec. 5, 90 Stat. 2012 15 U.S.C. 2604).

Dated: April 15, 1980.

**Blake Biles,**

*Deputy Assistant Administrator for Chemical Control.*

*PMN 80-69.* The following summary is taken from data submitted by the manufacturer in the PMN.

*Close of Review Period.* June 30, 1980.

*Manufacturer's Identity.* Claimed confidential.

*Specific Chemical Identity.* Claimed confidential. Generic name provided: Salt of hydroxy ((((((methoxy (sulfophenyl)azo)phenyl)-amino) carbonyl)amino)phenyl)azo)benzoic acid.

*Use.* This substance is the active component in a dye formulation for the coloration of textile and paper.

*Production Estimates.* Claimed confidential.

*Physical/Chemical Properties.* Dark greenish brown powder. No other data were provided.

*Toxicity Data:*

Acute oral toxicity (rat), $LD_{50}$ <5.0 g/kg, 7/10 deaths at 5 g/kg.

Acute dermal toxicity (rabbit), $LD_{50}$ >2.0 g/kg, no deaths.
Primary dermal irritation (rabbit), Extremely irritating and corrosive.
Eye irritation, Moderately irritating.

*Exposure.* Low exposure to employees and customers is expected in the preparation and use of this dye and its formulation.

The consuming public will only be exposed to textiles and paper products to which the dye is tightly bound. Approximate estimates of exposure are:

Manufacturer's employees, 750 manhours/year distributed over six employees.
User industry employees, 1,100 manhours/year distributed over 30 employees.

*Environmental Release/Disposal.* Manufacturer. Any spillage of the dry form dye of the formulation at the manufacturer's plant will be washed to the plant sewer with large amounts of water. The sewer conveys the wash water to a biological waste water treatment plant. The amount of dye which reaches the environment is negligible.

*Users.* The major users have closed recirculating water/dye systems and are required to have extensive waste water treatment systems to remove residual dye from the effluent. The amount of dye which reaches the environment is negligible.

*PMN 80-70.* The following summary is taken from data submitted by the manufacturer in the PMN.

*Close of Review Period.* June 30, 1980.

*Manufacturer's Identity.* Claimed confidential.

*Specific Chemical Identity.* Claimed confidential. Generic name provided: Sulfonic acid salt of ureylenebis-(hydroxy-[(sulfonaphthayl) azo])naphthalene.

*Use.* This substance is the active component in a dye formulation for the coloration of textile and paper.

*Production Estimates.* Claimed confidential.

*Physical/Chemical Properties.* The formulation is a dark red aqueous liquid. Density—1.07 g/cc.

*Toxicity Data:*

Acute oral toxicity (rat), LD >5.0 g/kg, no deaths.
Acute dermal toxicity (rabbit), $LD_{50}$ >2.0 g/kg, no deaths.
Primary dermal irritation (rabbit), Slightly irritating.
Eye irritation, Minimally irritating.

*Exposure.* Low exposure to employees is expected in the preparation and use of this dye and its formulation.

The consuming public will only be exposed to textiles and paper products to which the dye is tightly bound. Approximate estimates of exposure are:

Manufacturer's employees, 30 manhours/year distributed over three employees.
User industry employees, 220 manhours/year distributed over 15 employees.

*Environmental Release/Disposal.*

*Manufacturer.* Any spillage of the dye or the formulation at the manufacturer's plant will be washed to the plant sewer with large amounts of water. The sewer conveys the wash water to a biological waste water treatment plant. The amount of dye which reaches the environment is neglible.

*Users.* The major users have closed recirculating water/dye systems and are required to have extensive waste water treatment systems to remove residual dye from the effluent. The amount of dye which reaches the environment is negligible.

*PMN 80-71.* The following summary is taken from data submitted by the manufacturer in the PMN.

*Close of Review Period.* June 30, 1980.

*Manufactuer's Identity.* Claimed confidential.

*Specific Chemical Identity.* Claimed confidential. Generic name provided: Sulfonic acid of a ureylenebis(hydroxy-[(sulfo-naphthyl)azo])naphthalene compound.

*Use.* The substance will be used exclusively as an intermediate in the production of a dye.

*Production Estimates.* Claimed confidential.

*Physical/Chemcial Properties.* Appearance: Blackish brown cake. Soluble in water to some degree.

*Toxicity Data.* Acute oral toxicity (rat)—$LD_{50}$ <5.0 g/kg, no deaths. Acute dermal toxicity (rabbit)—$LD_{50}$ <2.0 g/kg, no deaths. Primary dermal irritation (rabbit)—Minimally irritating. Eye irritating (rabbit)—Minimally irritating.

*Exposure.* Low exposure to manufacturer's employees is expected in the production of this chemical.

Approximate exposure estimates:

Manufacturer's employees—840 manhours/year distributed over 15 employees.

*Environmental Release/Disposal*

*Manufacturer.* Any spillage of the wet cake will be recovered by the filter press operators and used in further processing. The residual chemical substance on the floor will be washed with large amounts of water to the plant sewer. The sewer conveys the wash water to a biological waste water treatment plant. The amount of dye which reaches the environment is negligible.

*PMN 80-72.* The following summary is taken from data submitted by the manufacture in the PMN.

*Close of Review Period.* June 30, 1980.

*Manufactuer's Identity.* Claimed confidential.

*Specific Chemical Identity.* Claimed confidential. Generic name provided: Salt of (ethenediyl)bis[hydroxphenyl)azo]-benzenesulfonic acid.

*Use.* This substance is the active component in dye formulation coloration of textile and paper.

*Production Estimates.* Claimed confidential.

*Physical/Chemical Properties.* The formulation is a dark yellow aqueous liquid. Density—1.178 g/cc.

*Toxicity Data.* Acute oral toxicity (rat—$LD_{50}$ <5.0 g/kg; 1/10 died at 5 g/k. Acute dermal toxicity (rabbit)—$LD_{50}$ <2.0 Kg, no deaths. Primary dermal toxicity (rabbit)—Not a primary irritant. Eye irritation (rabbit)—Moderately irritating.

*Exposure.* Low exposure to manufacturer's employees and customers is expected in the preparation and use of this dye and its formulation.

The consuming public will only be exposed to textiles and paper products to which dye is tightly bound. Approximate estimates of exposure are: Manufacturer's employees—36 manhours/year distributed over three employees. User Industry employees—220 manhours/year distributed over 15 employees.

*Environmental Release/Disposal*

*Manufacturer.* Any spillage of the dye or the formulation at the manufacturer's plant will be washed to the plant sewer with large amounts of water. The sewer conveys the wash water to a biological waste water treatment plant. The amount of dye which reaches the environment is negligible.

*User:* Major users have closed recirculating water/dye systems and are required to have extensive waste water treatment systems to remove residual dye the effluent.

[FR Doc. 80-12303 Filed 4-21-80; 8:45 am]
BILLING CODE 6560-01-M

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**[FRL 1471-8; OPTS-51054]**

## Certain Chemicals; Premanufacture Notices

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

**ACTION:** Notice.

**SUMMARY:** Section 5(a)(1) of the Toxic Substances Control Act (TSCA) requires any person who intends to manufacture or import a new chemical substance to submit a premanufacture notice (PMN) to EPA at least 90 days before

manufacture or import commences. Section 5(d)(2) requires EPA to publish in the **Federal Register** certain information about each PMN, within 5 working days after receipt. This Notice announces receipt of two PMN's and provides a summary of each.

**DATES:** Written comments by: PMN 80–67—June 26, 1980. PMN 80–68—June 30, 1980.

**ADDRESS:** Written comments to: Document Control Officer (TS–793, Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460, 202–755–8050.

**FOR FURTHER INFORMATION CONTACT:**

*Notice Manager, PMN No., and Telephone*

George Bagley—80–67; 202/426–3936.
Rick Green—80–68—202/426–3936.

Mail Address for Notice Managers: Premanufacturing Review Division (TS–794), Office of Pesticides and Toxic Substances, Environmental Protection Agency, 401 M St., SW., Washington, DC 20460.

**SUPPLEMENTARY INFORMATION:** Section 5(a)(1) of TSCA requires any person who intends to manufacture or import a new chemical substance to submit a PMN to EPA at least 90 days before manufacture or import commences. A "new" chemical substance is any substance that is not on the Inventory of existing substances compiled by EPA under Section 8(b) of TSCA. EPA first published the Initial Inventory on June 1, 1979. Notice of availability of the Initial Inventory was published in the **Federal Register** of May 15, 1979 (44 FR 28558). The requirement to submit a PMN for new chemical substances manufactured or imported for commercial purposes became effective on July 1, 1979.

EPA has proposed premanufacture notification rules and forms in the **Federal Register** issues of January 10, 1979 (44 FR 2242) and October 6, 1979 (44 FR 59764). These regulations, however, are not yet in effect. Interested persons should consult the Agency's Interim Policy published in the **Federal Register** of May 15, 1979 (44 FR 28564) for guidance concerning premanufacture notification requirements prior to the effective date of these rules and forms. In particular, see page 28567 of the Interim Policy.

A PMN must include the information listed in Section 5(d)(1) of TSCA. Under section 5(d)(2) EPA must publish in the **Federal Register** nonconfidential information on the identity and uses of the substance, as well as a description of any test data submitted under section 5(b). In addition, EPA has decided to publish a description of any test data submitted with the PMN and EPA will publish the identity of the submitter unless this information is claimed confidential.

Publication of the section 5(d)(2) notice is subject to section 14 concerning disclosure of confidential information. A company can claim confidentiality for any information submitted as part of a PMN. If the company claims confidentiality for the specific chemical identity or use(s) of the chemical, EPA encourages the submitter to provide a generic use dscription, a nonconfidential description of the potential exposures from use, and a generic name for the chemical. EPA will publish the generic name, the generic use, and the potential exposure descriptions in the **Federal Register.**

If no generic use description or generic name is provided, EPA will develop one and after providing due notice to the submitter, will publish an amended **Federal Register** notice. EPA immediately will review confidentiality claims for chemical identity, chemical use, the identity of the submitter, and for health and safety studies. If EPA determines that portions of this information are not entitled to confidential treatment, the Agency will publish an amended notice and will place the information in the public file, after notifying the submitter and complying with other applicable procedures.

After receipt, EPA has 90 days to review a PMN under section 5(a)(1). The section 5(d)(2) **Federal Register** notice indicates the date when the review period ends for each PMN. Under section 5(c), EPA may, for good cause, extend the review period for up to an additional 90 days. If EPA determines that an extension is necessary it will publish a notice in the **Federal Register.**

Once the review period ends, the submitter may manufacture the substance unless EPA has imposed restrictions. When the submitter begins to manufacture the substance, he must report to EPA, and the Agency will add the substance to the Inventory. After the substance is added to the Inventory, any company may manufacture it without providing EPA notice under section 5(a)(1)(A).

Therefore, under the Toxic Substances Control Act, summaries of the data taken from the PMN's are published herein.

Interested persons may, on or before the date shown under "DATES" for each specific PMN, submit to the Document Control Officer (TS–793), Rm. E–447, Office of Pesticides and Toxic Substances, 401 M St., SW, Washington, DC 20460, written comments regarding these notices. Three copies of all comments shall be submitted, except that individuals may submit single copies of comments. The comments are to be identified with the document control number "[OPTS–51054]" and the specific PMN number. Comments received may be seen in the above office between 8:00 a.m. and 4:00 p.m., Monday through Friday, excluding holidays.

(Sec. 5, 90 Stat. 2012 (15 U.S.C. 2604)).

Dated: April 15, 1980.

**Blake Biles,**

*Acting Deputy Assistant Administrator for Chemical Control.*

*PMN 80–67.* The following summary is taken from data submitted by the manufacturer in support of claims made in the PMN.

*Close of Review Period:* June 26, 1980.

*Manufacturer's Identity:* Claimed confidential.

*Specific Chemical Identity.* Claimed confidential. Generic name provided: polymer of styrene, vinylheteromonocycle, and vinyl(substituted)heteromonocyclic salt.

*Use.* Claimed confidential. The substance will be incorporated as a minor component in an article for commercial and consumer use.

**Production Estimates**

| | Kilogram per year | |
|---|---|---|
| | Minimum | Maximum |
| Production year: | | |
| First year | 500 | 1,200 |
| Second year | 3,000 | 6,000 |
| Third year | 6,000 | 11,000 |

| Physical-chemical tests | Results |
|---|---|
| Solubilities (percent): | |
| Dimethyl sulfoxide | ≧ 1.0. |
| Acetone | < 0.1. |
| Corn Oil | < 0.1. |
| Octanol | < 0.1. |
| Water | An average of 3 weight percent is soluble in water. |
| Environmental tests: | |
| COD | 2.19 g/g. |
| Secondary waste treatment compatibility study. | A solution estimated to contain 75 ppm polymer caused a 40 pct decrease in glucose metabolism. (50 pct effect concentration = 80 ppm polymer). |
| Toxicology tests: | |
| Acute oral $LD_{50}$ | Greater than 3,000 mg/kg. |
| Acute dermal $LD_{50}$ | Greater than 1,000 mg/kg. |
| Skin irritation | Slight. |
| Repeated 10-day skin application. | Slight skin irritant. |
| Skin sensitization | No evidence of sensitization. |
| Eye irritation | Slight. |
| Repeated two-week feeding study (0.1 pct or 1 pct in diet). | A 1 pct level in the diet (963 mg/kg) had no effect on weight gain, behavior, hematologic determinations, serum clinical chemistry determinations, organ weights, and gross and histopathological changes. |
| $LC_{250}$ (five aquatic species) | 0.9 ppm. |

**Exposure**

| Activity | Exposure route | Maximum number exposed | Maximum duration | | Concentration (ppm) | |
|---|---|---|---|---|---|---|
| | | | Hours/day | Days/year | Average | Peak |
| Manufacturing | Dermal and inhalation. | 16 | 0.3 | 20 | 1–10 mg/m³.. | 1–10 mg/m³ |
| Processing | Dermal and inhalation. | | 45 | | | |
| | | | 2.0 | 150 | 0–1 mg/m³..... | 0–1 mg/m³ |

The substance will be used in a contained manner such that there will be very low potential for human contact.

Environmental release/disposal:
Media..... Amount of Chemical Release (kg/yr).
Air..... Less than 10 kg/yr.
Water..... Less than 10 kg/yr.
Land..... None.

*PMN 80–68.* The following summary is taken from data submitted by the manufacturer in support of claims made in the PMN.

*Close of Review Period:* June 30, 1980.

*Manufacturer's Identity:* Claimed confidential.

*Specific Chemical Identity:* Polymer of: ϵ-Caprolactone, ethyl acrylate, hydroxpropyl-methacrylate, styrene, and acrylic acid.

*Use.* Baking enamels.

*Production Estimates.*

| Production year | Kilogram per year | |
|---|---|---|
| | Minimum | Maximum |
| First year | 750,000 | 1,500,000 |
| Second year | 1,000,000 | 2,000,000 |
| Third year | 1,000,000 | 2,000,000 |

*Toxicity Data.* None submitted.

*Exposure.*

| Activity | Exposure route | Maximum number exposed | Maximum duration | | Concentration average peak |
|---|---|---|---|---|---|
| | | | Hour per day | Day per year | |
| Manufacture | Inhalation | 2 | 1 | 312 | 1–10 ppm. |
| Processing | Inhalation | 30 | 4 | 312 | 1–10 ppm. |
| Use | Inhalation | Unknown | 8 | 312 | 1–10 ppm. |
| Disposal | Inhalation | 8 | 3 | 312 | 1–10 ppm. |

Physical state of the substance to which workers may be exposed: Fume or liquid.

*Environmental Release/Disposal.*

| | Duration of release | | Amount of chemical substance release (Kilogram per year) |
|---|---|---|---|
| | Hour per day | Day per year | |
| Manufacturing: | | | |
| Media | | | |
| Air | 1 | 312 | Less than 10. |
| Water | | | Less than 10. |
| Land | | | Less than 10. |
| Processing: | | | |
| Air | 8 | 312 | Less than 10. |
| Water | 8 | 312 | 10 to 100 |
| Land | | | None. |

[FR Doc. 80–12304 Filed 4–21–80; 8:45 am]
BILLING CODE 6560–01–M

**[FRL 1471–7; PF–178]**

## Filing of Pesticide, Food, and Feed Additive Petitions

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

**ACTION:** Notice.

**SUMMARY:** This notice announces that certain companies have filed requests with the EPA to establish tolerances for residues of pesticide chemicals on raw agricultural commodities, processed foods, and feeds.

**ADDRESS:** Written comments and inquires should be directed to the: Designated Product Manager (PM), Registration Division (TS–767), Office of Pesticide Programs, Environmental Protection Agency, 401 M St., SW, Washington, DC 20460.

Written comments may be submitted while a petition is pending before the Agency. The comments are to be identified by the document control number "[PF–178]" and the specific petition number. All written comments filed pursuant to this notice will be available for public inspection in the Product Manager's office from 8:00 a.m. to 4:00 p.m., Monday through Friday, excluding holidays.

**SUPPLEMENTARY INFORMATION:** EPA gives notice that the following pesticide petitions have been submitted to the Agency to establish tolerances for residues of pesticide chemicals on certain raw agricultural commodities, processed food, and feeds in accordance with the Federal Food, Drug, and Cosmetic Act. The analytical method for determining residues, where required, is given in each specific petition.

PP OF2327. Mobay Chemical Corp., Agricultural Chemicals Div., PO Box 4913, Kansas City, MO 64120. Proposes that 40 CFR 180.330 be amended by establishing tolerances for combined residues of the insecticide *S*-[2-(ethylsulfinyl)ethyl] *O,O*-dimethyl phosphorothioate and its cholinesterase-inhibiting metabolites in or on the raw agricultural commodities pecans at 0.01 part per million (ppm) and pecan shells at 0.05 ppm. The proposed analytical method for determining residues is gas-liquid chromatography using a phosphorus-specific detector. Product Manager (PM) 16, Mr. William Miller, Rm. E–343, 202/426–9548.

PP OF2324. Burroughs Wellcome Co., 3030 Cornwallis Rd., Research Triangle Park, NC 27709. Proposes that 40 CFR 180.378 be amended by establishing tolerances for residues of the insecticide permethrin ((3-phenoxyphenyl)methyl-3-(2,2-dichloroethenyl)-2,2-dimethylcyclopropanecarboxylate) in the raw agricultural commodities meat and meat byproducts of cattle, goats, horses, and sheep at 0.025 ppm; animal fat at 0.25 ppm; whole milk at 0.02 ppm; and milk fat at 0.2 ppm. The proposed analytical method for determining residues is mass spectrometry. PM 17, Mr. Franklin D.R. Gee, Rm. E–341, 202/426–9417.

PP OF2328. Stauffer Chemical Co., 1200 S. 47th Street, Richmond, CA 94804. Proposes that 40 CFR 180.328 be amended by establishing a tolerance for residues of the herbicide *N,N*-diethyl-2-(1-naphthalenyloxy)propionamide in or on the raw agricultural commodity pistachio nuts

at 0.1 ppm. The proposed analytical method for determining residues is gas chromatography using a nitrogen-specific Coulson conductivity detector. PM 25, Mr. Robert Taylor, Rm. 359, 202/755–2196.

FAP OH5255. Monsanto Agricultural Products Co., 1101 17th Street, NW Washington, DC 20036. Proposes that 21 CFR 193.235 be amended by establishing a food additive tolerance for residues of the herbicide glyphosate (*N*-phosphonomethylglycine) and its metabolite aminomethylphosphonic acid in or on imported processed olives at 0.1 ppm. PM 25, Mr. Robert Taylor, Rm. 359, 202/755–2196.

PP OF2331. Janssen R&D, Inc., 501 George St., New Brunswick, NJ 08903. Proposes that 40 CFR Part 180 be amended by establishing tolerances for residues of the fungicide 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1*H*-imidazole resulting from postharvest application in or on the crop grouping citrus fruit at 10 ppm (of which no more than 0.1 ppm is in edible pulp). The proposed analytical method for determining residues is high-pressure liquid chromatography with a reversed phase system using an ultraviolet detector. PM 21, Mr. Henry Jacoby, Rm. E–305, 202/755–2562.

FAP OH5254. Janssen R&D, Inc. Proposes that 21 CFR Part 193 be amended by establishing a tolerance for residues of the fungicide 1-[2-(2,4-dichlorophenyl)-2-(2-propenyloxy)ethyl]-1*H*-imidazole in dried citrus pulp at 20 ppm and that 21 CFR Part 561 be amended by establishing a tolerance for residues of the subject fungicide in citrus oil at 20 pp. PM 21, Mr. Henry Jacoby, Rm. E–305, 202/755–2562.

PP 9F2167. Auburn University, 107 Comer Hall, Auburn, AL 36830. Proposes that 40 CFR 180.126 be amended by establishing a tolerance for residues of inorganic bromides (calculated as Br) in or on the raw agricultural commodity soybeans grown in soil treated with the nematocide ethylene bromide at 125 ppm. The proposed analytical method for determining residues is gas chromatography following codistillation extraction with benzene. PM 16, Mr. William Miller, Rm. 343, 202/426–9458.

(Secs. 408(d)(1), 409(b)(5); 68 Stat. 512, 72 Stat. 1786; (7 U.S.C. 135), (21 U.S.C. 348))

Dated: April 15, 1980.

**Douglas D. Campt,**

*Director, Registration Division, Office of Pesticide Programs.*

[FR Doc. 80–12307 Filed 4–21–80; 8:45 am]

BILLING CODE 6560–01–M

## FEDERAL RESERVE SYSTEM

### National Detroit Corp. and American State Financial Corp.; Bank Holding Companies; Proposed de Novo Nonbank Activities

The bank holding companies listed in this notice have applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8) and section 225.4(b)(1) of the Board's Regulation Y (12 CFR 225.4(b)(1)), for permission to engage *de novo* (or continue to engage in an activity earlier commenced *de novo*), directly or indirectly, solely in the activities indicated, which have been determined by the Board of Governors to be closely related to banking.

With respect to each application, interested persons may express their views 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 interest, or unsound banking practices." Any comment on an application that requests a hearing must include 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 that proposal.

Each application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank indicated for that application. Comments and requests for hearings should identify clearly the specific application to which they relate, and should be submitted in writing and, except as noted, received by the appropriate Federal Reserve Bank not later than May 16, 1980.

A. *Federal Reserve Bank of Chicago* (Franklin D. Dreyer, Vice President) 230 South LaSalle Street, Chicago, Ilinois 60690:

1. National Detroit Corporation, Detroit, Michigan (mortgage banking activities; MIchigan): to engage through a wholly owned subsidiary, NBD Mortgage Company, in mortgage banking activities including making and acquiring of mortgage loans for its own account and for the accounts of others and the servicing of mortgage loans all of which have been determined to be permissible within the meaning of section 225.4(a)(1) or Regulation Y. Such activities will be conducted from an office in Detroit, Michigan and will serve the Detroit, Michigan area. Comments on this application must be received by May 13, 1980.

2. National Detroit Corporation, Detroit, Michigan (mortgage banking activities; Michigan): to engage through a wholly owned subsidiary, NBD Mortgage Company, in mortgage banking activities including making and acquiring of mortgage loans for its own account and for the accounts of others and the servicing of mortgage loans all of which have been determined to be permissible within the meaning of § 225.4(a)(1) of Regulation Y. Such activities will be conducted from an office in Portage, Michigan and will serve the greater Kalamazoo-Portage, Michigan area. Comments on this application must be received by May 13, 1980.

B. *Federal Reserve Bank of Dallas* (Anthony J. Montelaro, Assistant Vice President) 400 South Akard Street, Dallas, Texas 75222:

American State Financial Corporation, Lubbock, Texas (finance activities; Texas): to engage in making loans to officers and employees of its banking subsidiaries at preferential rates and terms for the purpose of exercising the purchase of its stock under an existing qualified stock option plan. The maximum amount of proposed loans would be $300,000 to approximately twenty-five officers and employees of the holding company's subsidiaries with the largest individual loan beign $35,000. These activities will be conducted from its office in Lubbock, Texas, serving Lubbock County, Texas.

C. *Other Federal Reserve Banks:* None.

Board of Governors of the Federal Reserve System, April 16, 1980.

**Cathy L. Petryshyn,**

*Assistant Secretary of the Board.*

[FR Doc. 80–12349 Filed 4–21–80; 8:45 am]

BILLING CODE 6210–01–M

### Circle Management Co.; Proposed Retention of Insurance Activities

Circle Management Company, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to continue to engage in the sale of credit life, health and accident insurance directly related to extensions of credit by its banking subsidiary. This activity was previously commenced through the acquisition of the assets of a going concern. These activities would be performed from Applicant's offices in Kearney, Nebraska; the geographic area to be served is Buffalo County, Nebraska. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views 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.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Kansas City.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than May 9, 1980.

Board of Governors of the Federal Reserve System, April 16, 1980.

**Cathy L. Petryshyn,**

*Assistant Secretary of the Board.*

[FR Doc. 80-12350 Filed 4-21-80; 8:45 am]

BILLING CODE 6210-01-M

### Henning Bancshares, Inc.; Formation of Bank Holding Company

Henning Bancshares, Inc., Henning, Minnesota, has applied for the Board's approval under Section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 80.16 per cent or more of the voting shares of The First National Bank of Henning, Henning, Minnesota. The factors that are considered in acting on the application are set forth in Section 3(c) of the Act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Minneapolis. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than May 15, 1980. 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.

Board of Governors of the Federal Reserve System, April 16, 1980.

**Cathy L. Petryshyn,**

*Assistant Secretary of the Board.*

[FR Doc. 80-12351 Filed 4-21-80; 8:45 am]

BILLING CODE 6210-01-M

### Kanawha Investment Co.; Proposed Retention of Kanawha Insurance Agency

Kanawha Investment Co., Kanawha, Iowa, has applied, pursuant to section 4(c)(8) of the Bank Holding Company Act (12 U.S.C. 1843(c)(8)) and § 225.4(b)(2)) of the Board's Regulation Y (12 CFR 225.4(b)(2)), for permission to continue to engage in the sale of general insurance through Kanawha Insurance Agency, Kanawha, Iowa. The geographic areas to be served are all of Hancock County, the top tier of townships in Wright County and the eastern edge of Kossuth County. Such activities have been specified by the Board in § 225.4(a) of Regulation Y as permissible for bank holding companies, subject to Board approval of Individual proposals in accordance with the procedures of § 225.4(b).

Interested persons may express their views 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.

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Chicago.

Any views or requests for hearing should be submitted in writing and received by the Secretary, Board of Governors of the Federal Reserve System, Washington, D.C. 20551, not later than May 13, 1980.

Board of Governors of the Federal Reserve System, April 16, 1980.

**Cathy L. Petryshyn,**

*Assistant Secretary of the Board.*

[FR Doc. 80-12352 Filed 4-21-80; 8:45 am]

BILLING CODE 6210-01-M

### Mountain Financial Co.; Formation of Bank Holding Company

Mountain Financial Company, Maryville, Tennessee, has applied for the Board's approval under section 3(a)(1) of the Bank Holding Company Act (12 U.S.C. 1842(a)(1)) to become a bank holding company by acquiring 100 percent of the voting shares of Bank of Maryville, Maryville, Tennessee. The factors that are considered in acting on the application are set forth in section 3(c) of the act (12 U.S.C. 1842(c)).

The application may be inspected at the offices of the Board of Governors or at the Federal Reserve Bank of Atlanta. Any person wishing to comment on the application should submit views in writing to the Reserve Bank, to be received not later than May 13, 1980. 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.

Board of Governors of the Federal Reserve System, April 16, 1980.

**Cathy L. Petryshyn,**

*Assistant Secretary of the Board.*

[FR Doc. 80-12353 Filed 4-21-80; 8:45 am]

BILLING CODE 6210-01-M

## FEDERAL TRADE COMMISSION

### Stanley I. Franklin; Early Termination of the Waiting Period of the Premerger Notification Rules

**AGENCY:** Federal Trade Commission.

**ACTION:** Granting of request for early termination of the waiting period of the premerger notification rules.

**SUMMARY:** Stanley I. Franklin is granted early termination of the waiting period provided by law and the premerger notification rules with respect to the proposed acquisition of assets of the Stone-Parkinson Corp. The grant was made by the Federal Trade Commission and the Assistant Attorney General in charge of the Antitrust Division of the Department of Justice in response to a request for early termination submitted by Stanley I. Franklin. Neither agency intends to take any action with respect to this acquisition during the waiting period.

**EFFECTIVE DATE:** April 11, 1980.

**FOR FURTHER INFORMATION CONTACT:** Joan S. Truitt, Attorney, Premerger Notification Office, Bureau of Competition, Room 303, Federal Trade

Commission, Washington, D.C. 20580 (202–523–3894).

**SUPPLEMENTARY INFORMATION:** Section 7A of the Clayton Act, 15 U.S.C. 18a, as added by Title II of the Hart-Scott-Rodino Antitrust Improvements Act of 1976, requires persons contemplating certain mergers or acquisitions to give the Commission and Assistant Attorney General advance notice and to wait designated periods before consummation of such plans. Section 7A(b)(2) of the Act permits the agencies, in individual cases, to terminate this waiting period prior to its expiration and requires that notice of this action be published in the **Federal Register.**

By direction of the Commission.

**Carol M. Thomas,**

*Secretary.*

[FR Doc. 80-12216 Filed 4-21-80; 8:45 am]

BILLING CODE 6750-01-M

## GENERAL ACCOUNTING OFFICE

### Regulatory Reports Review; Receipt of Report Proposal

The following request for clearance of a report intended for use in collecting information from the public was received by the Regulatory Reports Review Staff, GAO, on April 16, 1980. See 44 U.S.C. 3512(c) and (d). The purpose of publishing this notice in the **Federal Register** is to inform the public of such receipt.

The notice includes the title of the request received; the name of the agency sponsoring the proposed collection of information; the agency form number, if applicable; and the frequency with which the information is proposed to be collected.

Written comments on the proposed FCC request are invited from all interested persons, organizations, public interest groups, and affected businesses. Because of the limited amount of time GAO has to review the proposed request, comments (in triplicate) must be received on or before May 12, 1980, and should be addressed to Mr. John M. Lovelady, Senior Group Director, Regulatory Reports Review, United States General Accounting Office, room 5106 441 G Street, NW, Washington, DC 20548.

Further information may be obtained from Patsy J. Stuart of the Regulatory Reports Review Staff, 202–275–3532.

**Federal Communications Commission**

The FCC requests clearance of a new Form 199–C, Refund Request Form (Phase II), Under $20, authorized under the Federal Communications Commission Fee Refund Program which was mandated by the United States Circuit Court of Appeals on December 16, 1976. Form 199–C will be used by Private Radio Bureau Licensees and other respondents to request refunds of fees by FCC that were originally $20 or less. The data collected on Form 199–C will be used by FCC to determine the parties to whom refunds are due, randomly verify the amounts, and have the U.S. Treasury issue refund checks. The FCC estimates that approximately 2,500,000 refund requests will be received and that respondent burden will average one-half hour per request.

**Norman F. Heyl,**

*Regulatory Reports Review Officer.*

[FR Doc. 80-12254 Filed 4-21-80; 8:45 am]

BILLING CODE 1610-01-M

## GENERAL SERVICES ADMINISTRATION

**[Intervention Notice 114]**

### American Telephone & Telegraph Co., Federal Communications Commission; Proposed Intervention in Rulemaking Proceeding

The General Services Administration seeks to intervene in a rulemaking proceeding before the Federal Communications Commission concerning sharing and resale of common carrier domestic public switched network services. GSA represents the interest of the executive agencies of the U.S Government as users of telecommunications services.

Persons desiring to make inquiries to GSA concerning this case should submit them in writing to Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th and F Streets, N.W., Washington, DC (mailing address: General Services Administration (LT), Washington, DC 20405), telephone 202–566–0750, on or before May 22, 1980, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry shall not serve to make any persons parties of record in the proceeding.

(Sec. 201(a)(4), Federal Property and Administrative Services Act, 40 U.S.C. 481(a)(4))

Dated: April 11, 1980.

**R. G. Freeman III,**

*Administrator of General Services.*

[FR Doc. 80-12355 Filed 4-21-80; 8:45 am]

BILLING CODE 6820-25-M

**[Intervention Notice 115]**

### New Jersey Bell Telephone Co., the New Jersey Board of Public Utilities; Proposed Intervention in Telephone Rate Increase Proceeding

The General Services Administration seeks to intervene in a proceeding before the New Jersey Board of Public Utilities concerning the application of the New Jersey Bell Telephone Company for an increase in its annual telephone rates. GSA represents the interest of the executive agencies of the U.S. Government as users of telecommunications services.

Persons desiring to make inquiries to GSA concerning this case should submit them in writing to Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th and F Streets, N.W., Washington DC (mailing address: General Services Administration (LT), Washington, DC 20405), telephone 202–566–0750, on or before May 22, 1980, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry shall not serve to make any persons parties of record in the proceeding.

(Sec. 201(a)(4), Federal Property and Administrative Services Act, 40 U.S.C. 481(a)(4))

Dated: April 11, 1980.

**R. G. Freeman III,**

*Administrator of General Services.*

[FR Doc. 80-12356 Filed 4-21-80; 8:45 am]

BILLING CODE 6820-25-M

**[Intervention Notice 113]**

### New York Telephone Co., the New York Public Service Commission; Proposed Intervention in Telephone Rate Increase Proceeding

The General Services Administration seeks to intervene in a proceeding before the New York Public Service Commission concerning the application of the New York Telephone Company for an increase in its annual telephone rates. GSA represents the interest of the executive agencies of the U.S. Government as users of telecommunications services.

Persons desiring to make inquiries to GSA concerning this case should submit them in writing to Spence W. Perry, Assistant General Counsel, Regulatory Law Division, General Services Administration, 18th and F Streets, N.W., Washington DC (mailing address: General Services Administration (LT), Washington, DC 20405), telephone 202–566–0750, on or before May 22, 1980, and refer to this notice number.

Persons making inquiries are put on notice that the making of an inquiry shall not serve to make any persons parties of record in the proceeding.

(Sec. 201(a)(4), Federal Property and Administrative Services Act, 40 U.S.C. 481(a)(4))

Dated: April 11, 1980.

R. G. Freeman III,

*Administrator of General Services.*

[FR Doc. 80-12354 Filed 4-21-80; 8:45 am]

BILLING CODE 6820-25-M

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[E-80-8]

### Delegation of Authority to the Secretary of Defense

1. *Purpose.* This delegation authorizes the Secretary of Defense to represent, in conjunction with the Administrator of General Services, the consumer interests of the executive agencies of the Federal Government in proceedings before the Federal Energy Regulatory Commission involving the Power Displacement Agreement with Southern California Edison.

2. *Effective date.* This delegation is effective immediately.

3. *Delegation.* a. Pursuant to the authority vested in me by the Federal Property and Administrative Services Act of 1949, 63 Stat. 377, as amended, particularly sections 201(a)(4) and 205(d) (40 U.S.C. 481(a)(4) and 486(d)), authority is delegated to the Secretary of Defense to represent the consumer interests of the Federal executive agencies before the Federal Energy Regulatory Commission involving the application of the Edwards Air Force Base for contract rate changes. The authority delegated to the Secretary of Defense shall be exercised concurrently with the Administrator of General Services.

b. The Secretary of Defense may redelegate this authority to any officer, official, or employee of the Department of Defense.

c. This authority shall be exercised in accordance with the policies, procedures, and controls prescribed by the General Services Administration, and shall be exercised in cooperation with the responsible officers, officials, and employees thereof.

Dated: April 14, 1980.

Ray Kline,

*Acting Administrator of General Services.*

[FR Doc. 80-12189 Filed 4-21-80; 8:45 am]

BILLING CODE 6820-AM-M

## National Archives and Records Service

### Eighth Annual Report of the President on Federal Advisory Committees Covering the Calendar Year 1979; Availability of Publication

The above report is available to Federal government sources by contacting the Committee Management Secretariat (NAM), National Archives and Records Service, Washington, DC 20408, telephone (202) 357-0019.

Purchase of the report by the general public is available through the Superintendent of Documents, U.S. Government Printing Office, Washington, DC 20402. The price is $5.00, the stock number is 040-000-00419-0, and the catalog number is PR-39.10:979.

The Compilation of Agency Submissions incorporating the detailed information used to prepare the report will be available on microfilm for public inspection and/or purchase through the National Archives and Records Service at a later date which will be announced in the **Federal Register.**

Dated: April 11, 1980.

James E. O'Neill,

*Acting Archivist of the United States.*

[FR Doc. 80-12190 Filed 4-21-80; 8:45 am]

BILLING CODE 6820-26-M

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## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

## Office of Education

### National Advisory Council on Bilingual Education; Meeting

**AGENCY:** National Advisory Council on Bilingual Education.

**ACTION:** Notice.

**SUMMARY:** This notice sets forth the schedule and proposed agenda of forthcoming meetings of the National Advisory Council on Bilingual Education. Notice of these meetings is required under the Federal Advisory Committee Act (U.S.C. Appendix 1, 10(a)(2)). This document is intended to notify the general public of their opportunity to attend.

**DATES:** May 12 and 13, 1980, 9:00 a.m. to 5:00 p.m.

**ADDRESS:** Council meetings will be held at Rhode Island College, 600 Mount Pleasant Avenue, Roberts Hall-Alumni Hall, Providence, RI. For further information contact: Gloria Becerra, Office of Bilingual Education, Reporters Building, Room 421, Office of Education, 400 Maryland Avenue, S.W., Washington, D.C. 20202 (202-447-9227).

The National Advisory Council on Bilingual Education is established under section 732(a) of the Bilingual Education Act (20 U.S.C. 880b-11) to advise the Secretary of Health, Education, and Welfare and the Commissioner of Education concerning matters arising in the administration of the Bilingual Education Act.

The meetings of May 12 and 13, 1980 will be open to the public beginning at 9:00 a.m.

*May 12, 1980:* A meeting of the Council on the following subjects is scheduled from 9:00 a.m. until 5:00 p.m. The proposed agenda includes the following:

Business Meeting:
- a. Call to Order
- b. Approval of Minutes
- c. Chairperson's Report
- d. Committee Reports
- e. Ad Hoc Reports

11:00-12:30
- Office of Bilingual Education and Minority Languages Affairs (OBEMLA) Report
- ED Department
- OBEMLA Programs

1:30-3:30:
- Title I/Title VII Task Force NFIE Report
- Parent Conference

3:30-5:00:
- Annual Report
- Dissertation Report

*May 13, 1980:* The proposed agenda includes the following:

9:00-11:30:
- Rhode Island Report Local Directors

1:00-2:30:
- Massachusetts Report

2:30 until:
- f. Old Business: Action Items
- g. New Business Action Items and Agenda
- h. Public Participation
- i. Adjournment

Records will be kept of all Council proceedings and shall be available for public inspection after approval, by the Full Council, of said records has been obtained. These records will be available in Room 421, Reporters Building, 300 7th Street, S.W., Washington, D.C. Written requests for such records should be sent to 400 Maryland Avenue, S.W., Reporters Building, Room 421, Washington, D.C. 20202.

In the event that the proposed agenda is completed prior to the projected date or time, the Council will adjourn the meeting.

Signed at Washington, D.C. on April 16, 1980.

Josue M. Gonzalez,

*Director, Office of Bilingual Education.*

[FR Doc. 80-12253 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-02-M

**Food and Drug Administration**

**[Docket No. 76-0002]**

## Diethylstilbestrol (DES); Food Use of Cattle Illegally Implanted With DES

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) announces its Position Paper regarding the food use of cattle illegally implanted with DES. The position paper sets forth the conditions under which the agency will allow adulterated food derived from illegally dosed animals to be marketed.

**DATE:** The Position Paper became effective on April 15, 1980.

**FOR FURTHER INFORMATION CONTACT:** Mervin H. Shumate, Enforcement Policy Staff (HFC–20), Office of Regulatory Affairs, Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, MD 20857, 301–443–1745.

**SUPPLEMENTARY INFORMATION:** FDA has learned that DES continued to be used in cattle on and after November 1, 1979, the date on which the agency's ban on the use of DES in cattle and sheep became effective. The agency has concluded that the public interest is not well served by the discard of a large number of food-producing animals that can be reconditioned and has prepared the following Position Paper, which sets forth the conditions under which the agency will allow adulterated food derived from the illegally dosed animals to be marketed:

### FDA Position Regarding the Food Use of Cattle Illegally Implanted With DES

On June 29, 1979, the Commissioner of the Food and Drug Administration (FDA) signed a final order finding that DES cannot be safely used in cattle and sheep (44 FR 54842). That final order set up a phased market withdrawal system for DES. The manufacture and shipment of DES for such animal use was to cease on and after July 13, 1979. This date was announced in the June 29, 1979, final order and no stay, automatic or otherwise, of this date was ever granted. All use of DES implants already in the hands of cattle producers, as well as the manufacture, shipment, and use of feed containing DES was allowed to continue until October 31, 1979. On and after November 1, 1979, all use of DES in animals was to cease. The order granting this final effective date for the withdrawal of DES made two important points (44 FR 45764–5, August 3, 1979). First, the phase-out period would allow cattle producers adequate time to adjust their operations away from DES use. Second, it firmly stated "* * * it would not be appropriate to allow the unlimited continued use of remaining stocks of DES."

FDA has learned that on and after November 1, 1979, there has continued to be use of DES in cattle. As the final order of June 29, 1979, states, this activity violates multiple provisions of the Federal Food, Drug, and Cosmetic Act and cannot be condoned. However, the public interest is not well served by the discard of a large number of food-producing animals that can be reconditioned. After due consideration, the Agency has determined that the adulterated food derived from illegally dosed animals can be allowed to be marketed, but only after the conditions which are set forth below are met. The fact that FDA, exercising its enforcement discretion, will allow adulterated food, derived from illegally dosed animals, to be marketed does not excuse the violative conduct that has occurred. The Agency intends to utilize its full range of enforcement options where appropriate.

Several propositions are basic to the Agency's decision:

1. No amount of DES or the residues resulting from its use has been shown to be safe in food;

2. No safe conditions for continued use and experience to DES residues in food can be established; and

3. This decision is a unique one-time exception.

Furthermore, a regulatory agency, such as FDA, is frequently forced to act on data which are less than ideal, and in so doing employs the appropriate scientific assumptions and procedures to protect the public health. This situation requires such assumptions and procedures and this paper incorporates them.

*I. DES Implants in Cattle*

Cattle now illegally implanted with DES can be made acceptable for human consumption if special precautions are taken. It should be stressed that this conclusion is based on the premise that there will be no additional use of DES and consumption of DES-implanted tissues. The special precautions that must be taken are as follows:

1. Implants must be surgically removed from the animals.

2. If liver and kidneys from these animals are to be used as food, the animals must not be slaughtered for at least 61 days following removal of the implant.

3. If liver and kidneys are to be discarded, the animals must not be slaughtered for at least 41 days following removal of the implant.

Ordinarily, the conditions for safe use of a carcinogenic aninal drug, such as DES, are defined as those conditions that will ensure that no residue of the drug will be found in edible animal tissues when those tissues are examined with a method of analysis acceptable to the Secretary of HEW. An acceptable method (44 FR 17070; March 20, 1979) is one shown to have, among other attributes, a limit of detection equal to a residue level that has been determined to be "safe" in accordance with agency procedures and criteria. The Agency has determined that the available scientific information does not permit the determination of a DES residue level in meat that can be safety consumed on a continuous basis by the public. As a consequence, the Agency has also determined that none of the available methods of animal tissue analysis for DES residue meets the criteria for approval by the Secretary.

However, the available scientific information permits the Agency: (1) To determine a DES residue level of exposure that is not expected to have adverse public health effects provided that it occurs only once; and (2) to estimate a time after excision of DES implants when the tissues from implanted cattle will have DES residues less than that level.

The data upon which these estimations are based are incomplete. It is necessary therefore, to impose conservative assumptions wherever data are absent in order to ensure protection of the public health. Underlying all of these assumptions is the critical one, mentioned above, that consumers will never again consume tissues from animals dosed with DES.

The Agency's analysis consists of three steps:

1. Estimation of the concentration of DES residues present in edible tissues of illegally implanted steers at the time implants are removed.

2. Estimation of the level of residues resulting from the use of DES that presents a tolerable risk to the consuming public.

3. Estimation of the time after removal of the implant required for tissue residue concentrations to reach an acceptable limit, as this is defined in (2) above.

1. *Tissue Residue Concentrations at Time of Removal of Implants.* No information is available that can permit even an estimation of how long an implanted animal would have to be held for the level of residues resulting from the use of DES (tissue residues) to fall to acceptable levels without removing the impant entirely. Available data indicate

that DES implant material persists at the implant site and in the animal tissue for at least 120 days (Ref. 1, Ref. 2, Ref. 3, Ref. 4). In fact, Hale and the references cited therein indicate that DES is present and effectively promoting growth for at least 238 days. Because of this, it is necessary that the implant (i.e., the source of DES) be completely removed from the animal, and that the tissue concentration of DES residues be known at the time of implant removal.

The animals at issue have been implanted for varying lengths of time. Some have been implanted for more than a 120-day period, while others have been implanted for a month or less. Because the available data indicate no significant change over 120 days in DES concentration in tissue in implanted cattle (Ref. 1, Ref. 2), the most appropriate data for estimating tissue concentrations at time of implant removal would be those derived from tissue residue measurements made throughout the entire period of implantation.

Two studies contain data partially meeting the above requirements (Ref. 1, Ref. 2). Both studies are summarized in Table I.

Because it is scientifically correct to use all available adequate data when making estimates of this kind, the data from both studies were combined and averaged. The result of this analysis is an estimation of the average residue concentrations of DES during the time the implant is in the animal.

The edible tissues of concern are liver and muscle, because they are considered respectively the tissues in which DES remains for the longest period of time and the tissues comprising the portion of the animal that makes up the largest proportion of the human diet. The average concentrations of DES residues in these two tissues during the period of implantation are 500 ppt (parts per trillion) and 36 ppt, respectively (Table I). These concentrations are taken to represent the average tissue residue concentrations at time of removal of the illegally implanted DES.

2. *Estimation of Required Detection Limits.* Under ordinary circumstances, in order to approve a new animal drug, the FDA must have information on all tissue residues resulting from use of a drug in food-producing animals. Data derived from experimental study of the tissue residue found to have the greatest carcinogenic potency are used to estimate the concentration of the residue that is expected to yield an increased risk of cancer no greater than one case in one million lifetimes. This concentration is taken as the required limit of detection of an analytical method acceptable for measuring compliance with the "no residue" standard. If the total residue (administered drug and metabolites) resulting from the use of a drug is not detectable when such a method is used to examine edible tissues, then the drug is approvable (i.e., meets the safety standard). This safety standard is based in part on the expectation that people might consume tissues from treated animals daily over their lifetimes.

The data available on DES do not permit such a calculation to be made (44 FR 54852, September 21, 1979). Identities and concentrations of the tissue residues resulting from the use of DES have never been completely established. It is not known whether metabolites of DES present greater toxicity (including carcinogenicity) risks than DES itself.

If, however, we assume that DES is the most potent of the tissue residues resulting from its use and that cancer is the toxic effect of DES occurring at the lowest dose level, it is possible to estimate the required detection limit of an approvable method of analysis. Applying procedures used by FDA to estimate required detection limits from carcinogenicity date (44 FR 17070), the available carcinogenicity data on DES (Ref. 5) yield the following concentrations:

Liver [1]—1.2 ppt.
Muscle—0.6 ppt.

The difference in the concentrations obtained for liver and muscle results from the application of different consumption factors (i.e., people consume less liver than muscle).

Thus, if an analytical method were available to measure all residues resulting from the use of DES, and these methods were shown to be capable of measuring the above concentrations, then tissues derived from treated animals could be considered "safe" (as operationally defined at 44 FR 17070) for human consumption if they could be shown to contain "no residue" when they were examined with such an approved method of analysis.

FDA does not ordinarily estimate required detection limits unless the carcinogenicity and other forms of toxicity of all residues have been adequately examined and the most potent identified. We believe, however, that the potential risk to the public health resulting from placing full reliance on the carcinogenicity data derived from study of DES (and ignoring possible residues of greater health concern) is more than offset by the fact that the procedure ordinarily used by FDA is based on the assumption of daily, lifetime ingestion of tissues from treated animals. In the present circumstance, a single or limited exposure is all that is likely to occur, because FDA intends to act to ensure that the illegal use of DES will not recur.

3. *Estimation of the Time Required for the Expected DES Residue Levels to Deplete to 1.2 ppt (liver) and 0.6 ppt (muscle).* To estimate the time required after implant removal for tissue concentrations to deplete to 1.2 ppt in liver and 0.6 ppt in muscle, it is necessary to know the characteristics of the residue depletion curves (i.e., tissue residue concentrations as a function of time). Although we expect that DES residue concentrations will decrease over time (after implant removal), the manufacturers of DES have never supplied adequate information on depletion rates for DES after removal of implants. No useful information is available to construct a reliable depletion curve. One study indicates that the half-life of DES is at least 5.5 days for some, but not necessarily all, of the slowly depleting residues (Ref. 6). We believe the estimated half-life is an underestimate, because the manner of dosing did not permit equilibration of measured DES in the tissues.

In the absence of appropriate information, the FDA assumes the half-life for depletion of DES residue (the time required for residue concentrations to fall to one-half their original value) is seven days. This figure is consistent with that reported in the above studies and also has customarily been used by FDA for purposes of assigning required withdrawal times when animals have been treated with new drugs for strictly investigational purposes.

Using this assumption, it is estimated that the livers of illegally implanted cattle will contain "no residue" of DES after 8.7 half-lives (61 days) and the muscles of such animals will be similarly free of DES residues after 5.9 half-lives (41 days). These times are based on initial concentrations of 500 ppt (liver) and 36 ppt (muscle), desired final concentrations below 1.2 ppt (liver) and 0.6 ppt (muscle), and a depletion half-life of seven days.

Considering relative consumption and initial residue concentration in kidney, the above cited references indicate that the time required for kidney to be acceptable for human consumption is approximately 55 days. However, in

[1] Calculations made by FDA scientists immediately after the discovery of illegal uses of DES yielded acceptable concentrations of 1.8 ppt and 0.9 ppt in liver and muscle respectively. After a thorough review, we discovered that these calculations were based upon inappropriate procedures.

order to reduce confusion, we are requiring the same post-explant withdrawal period for kidney that is required for liver.

Dated: April 15, 1980.

**Mark Novitch,**

*Acting Deputy Commissioner of Food and Drugs.*

**References**


1. Rumsey, T. S., et al., "Fate of Radiocarbon in Beef Steers Implanted with $^{14}C$-Diethylstilbestrol," *Journal of Animal Science*, 40:550, 1975.
2. Ashbacher, P. W., et al., "Metabolic Fate of Diethylstilbestrol Implanted in the Ear of Steers," *Journal of Animal Science*, 40:530, 1975.
3. Hale, W. H., et al., "Absorption of Diethylstilbestrol Pellets in Steers," *Journal of Animal Science*, 18:1201, 1959.
4. Rumsey, T. S., et al., "Implant Absorption Performance and Tissue Analysis for Beef Steers Implanted with Diethylstilbestrol and Fed an All-Concentrate Diet," *Journal of Animal Science*, 39:1193, 1974.
5. Gass, G. H., et al., "Carcinogenic Dose Response Curve to Oral Diethylstilbestrol," *Journal of the National Cancer Institute*, 33:971, 1964.
6. rumsey, T. S., et al., "Depletion Patterns of Radioactivity and Tissue Residues in Beef Cattle After the Withdrawal of Oral $^{14}C$-Diethylstilbestrol," *Journal of Animal Science*, 40:539, 1975.


**Table I.**—*Estimated Average Concentrations of Residues Resulting From the Implantation of DES in Cattle*

| Study | No. of animals | Tissue | Tissue concentrations (P/t) (Days after implant) 30 | 60 | 90 | 120 | Parts per thousand |
|---|---|---|---|---|---|---|---|
| Ref. 2 [2] | 4 | Liver | 400 | 450 | 440 | 700 | |
| | | Muscle | 32 | 17 | 69 | 27 | |
| Ref. 1 [3] | 7 | Liver | 510 | 420 | 690 | (5) | Liver=500.[4] |
| | | | 490 | 570 | 520 | 320 | |
| | | Muscle | (5) | (5) | (5) | (5) | Muscle=36 ppt. |

[1] Estimated average tissue concentrations (p/t) while implant present. Data from both studies combined.
[2] Study used ethyl-labeled DES.
[3] This animal (number 477) received only one 15 mg implant rather than the two implants provided for in the formerly approved conditions of use. It has, therefore, been excluded.
[4] Average of 11 animals.
[5] None detected. Limit of detection of method used estimated to be 44 ppt. These values were not used in the average.
[6] Average of 4 animals.

*Effective date.* This Position Paper became effective April 15, 1980.

Dated: April 17, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-12237 Filed 4-17-80; 2:48 pm]

BILLING CODE 4110-03-M

**[Docket No. 79P-0317]**

## Pierce Chemical Co.; Panel Recommendation on Petition for Reclassification

**AGENCY:** Food and Drug Administration.

**ACTION:** Notice.

**SUMMARY:** The agency is publishing for public comment the recommendation of the Clinical Toxicology Section of the Clinical Chemistry and Hematology Device Panel (the Panel) that the Acetaminophen Rapid Stat Kit be reclassified from class III (premarket approval) into class II (performance standards). This recommendation was made after review of a reclassification petition filed by Pierce Chemical Co., Rockford, IL 61105. After reviewing the Panel recommendation and any public comments received, the agency will approve or deny the reclassification by order in the form of a letter to the petitioner. The agency's decision on this reclassification petition will be announced in the **Federal Register.**

**DATE:** Comments by May 22, 1980.

**ADDRESS:** Written comments to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Eugene W. Rice, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301-427-7550.

**SUPPLEMENTARY INFORMATION:** On April 23, 1979, Pierce Chemical Co., Rockford, IL 61105, submitted to the Food and Drug Administration (FDA) a premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)) (the Act) stating that it intended to market a device the manufacturer calls "Acetaminophen Rapid Stat Kit." After reviewing the information in the premarket notification, FDA determined that the device is not substantially equivalent to any device that was in commercial distribution before May 28, 1976; nor is the device substantially equivalent to a device tht has been placed in commercial distribution since that date and subsequently reclassified. Accordingly, the device is automatically classified into class III under section 513(f)(1) of the act (21 U.S.C. 360c(f)(1)).

Under section 515(a)(2) of the act (21 U.S.C. 360e(a)(2)), before a device that is in class III because of section 513(f)(1) can be marketed, it must either be reclassified under section 513(f)(2) or have an approval of an application for premarket approval under section 515 of the act (21 U.S.C. 360e), unless there is in effect for the device an investigational device exemption under section 520(g) of the act (21 U.S.C. 360j(g)).

On May 7, 1979, Pierce Chemical Co. submitted to FDA a reclassification petition for the device under section 513(f)(2) of the act, which requires FDA to refer a reclassification petition to the appropriate classification panel and to receive a recommendation on whether to approve or deny a petition. On October 19, 1979, the Clinical Toxicology Section of the Clinical Chemistry and Hematology Devices Panel reviewed the petition and recommended that the device be reclassified into class II.

To determine the proper classification of the device, the Panel considered the criteria specified in section 513(a)(1) of the act. For the purpose of classification, the Panel assigned to this generic type of device the name "Colorimetry, Acetaminophen" and described this type of device as an in vitro diagnostic test kit used for the rapid detection and quantitation of toxic levels of acetaminophen in serum.

### Summary of the Reasons for the Recommendation

The Panel gave the following reasons in support of its recommendation on reclassification:

1. The device is not an implant, is neither life sustaining nor life supporting, and does not present a potential unreasonable risk of illness or injury.

2. The device is of substantial importance in preventing impairment of human health.

3. Although general controls are not sufficient to provide reasonable assurance of the safety and

effectiveness of the device, sufficient scientific and medical data exist to establish a performance standard to provide such assurance by prescribing for this device acceptable ranges of accuracy, precision, sensitivity, and specificity.

4. This device may be used only for measuring toxic levels of acetaminophen. The labeling for the device needs to include a statement that, because of low sensitivity of the methodology in the therapeutic range, the device may not be used for measuring therapeutic levels of acetaminophen.

**Summary of Data on Which the Recommendation Is Based**

The Panel based its recommendation on the performance characteristics of the device. A step-by-step procedure for use by the analyst has been included in labeling submitted by the sponsor.

Two clinical studies were conducted on a series of 88 sera samples from patients known to have received acetaminophen. In the first study, identical sera samples were analyzed by the high-performance liquid chromatography (HPLC) methodology of Horvitz and Jatlow (Ref. 2) and the Rapid Stat procedure. The correlation coefficient of this comparison study was 0.997. There was a 0.7 milligram/deciliter (mg/dL) difference between the two procedures. In the second clinical study, patient sera samples were analyzed by the Rapid Stat procedure and the HPLC methodology of Blair (Ref. 9). The correlation coefficient was 0.988.

The precision of the methodology was established through within-run and between-run studies. Four spiked serum pools were assayed 10 times per day for 3 days. The coefficient of variation for the within-run reproducibility study ranged from 0.00 to 2.37 percent. Between-run precision was determined by assaying three spiked serum pools in 30 separate runs over a 3-week period. The coefficient of variation for this study ranged from 2.59 to 6.76 percent.

The sponsor has included in the test kit a 5 mg/dL standard solution against which the patient's sample is measured. This standard typically gives an absorbance of 0.032. The low sensitivity of the methodology in the therapeutic range requires that the device should be used only for measuring toxic levels of acetaminophen. For the measurement of therapeutic levels of acetaminophen (less than 4 mg/dL), a high performance liquid chromatography or gas chromatography method should be used (Refs. 2, 4, and 5).

**Risks to Health**

The Panel noted that failure of the device to perform satisfactorily may result in the erroneous measurement of levels of acetaminophen. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. A false-positive could result in unnecessary antidote treatment. A false-negative could result in undetected liver damage. Therefore, the Panel recommended that a standard be developed to address these risks and that development of this standard be a low priority.

**References**

The petition, the transcript of the Panel meeting, and the following material are on public file in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, where they may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday.

1. Chafetz, L., R. E. Daly, H. Schriftman, and J. J. Lomner, "Selective Colorimetric Determination of Acetaminophen," *Journal of Pharmaceutical Sciences*, 60: 463–466, 1971.

2. Horvitz, R. A., and P. I. Jatlow, "Determinations of Acetaminophen Concentration in Serum by High-Pressure Liquid Chromatography," *Clinical Chemistry*, 23:1596–1598, 1977.

3. Fletterick, C. G., T. H. Grove, and D. C. Hohnadel, "Liquid-Chromatographic Determination of Acetaminophen in Serum," *Clinical Chemistry*, 25(3):409–412, 1979.

4. Gotelli, G. R., P. M. Kabra, and L. J. Marton, "Determination of Acetaminophen and Phenacetin in Plasma by High-Pressure Liquid Chromatography," *Clinical Chemistry*, 23(6):957–959, 1977.

5. Dechtiaruk, W. A., G. F. Johnson, and H. M. Solomon, "Gas Chromatographic Method for Acetaminophen (*N*-Acetyl-*p*-Aminophenol) Based on Sequential Alkylation," *Clinical Chemistry*, 22(6):879–883, 1976.

6. Walberg, C. B., "Determination of Acetaminophen in Serum," *Journal of Analytical Toxicology*, 1:79–80, 1977.

7. Ameer, B., and D. J. Greenblatt, "Acetaminophen," *Annals of Internal Medicine*, 87:202–209, 1977.

8. Prescott, L. F., P. Roscoe, N. Wright, and S. Brown, "Plasma-Parcetamol Half-Life and Hepatic Necrosis in Patients with Paracetamol Overdosage," *Lancet*, 1:519–522, 1971.

9. Blair, D. and B. H. Rumack, "Acetaminophen in Serum and Plasma Estimated by High Pressure Liquid Chromatography; a Micro-scale Method," *Clinical Chemistry*, 23:743–745, 1977.

Interested persons may, on or before (May 22, 1980) submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857, written comments on this recommendation. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the name of the device and the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 16, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–12202 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## Public Health Service

### Migrant Health Centers; Delegations of Authority

Notice is hereby given that the following delegation and redelegations have been made regarding the authorities for migrant health centers under section 329 of the Public Health Service Act (42 U.S.C. 247d), as amended.

1. Delegation by the Secretary of Health, Education, and Welfare to the Assistant Secretary for Health, with authority to redelegate, of all the authorities vested in the Secretary under section 329 of the Public Health Service Act, as amended, excluding the authority to promulgate regulations.

2. Redelegation by the Assistant Secretary for Health to the Administrator, Health Services Administration, with authority to redelegate, of all the authorities delegated by the Secretary to the Assistant Secretary for Health under section 329 of the Public Health Service Act, as amended.

3. Redelegation by the Administrator, Health Services Administration, to the Regional Health Administrators, Public Health Service Regional offices, with authority to redelegate, of all the authorities delegated by the Assistant Secretary for Health to the Administrator, Health Services Administration, under section 329 of the Public Health Service Act, as amended, for award of grants within their respective regions other than grants that are national or multiregional in scope.

4. Redelegation by the Administrator, Health Services Administration, to the Director, Bureau of Community Health Services, Health Services Administration, with authority to redelegate, of all the authorities delegated by the Assistant Secretary for Health to the Administrator, Health Services Administration, under section 329 of the Public Health Service Act, as

amended, except those specifically delegated to the Regional Health Administrators. This redelegation includes authority for award of grants that are national or multiregional in scope.

The June 23, 1978 delegation (43 FR 29034) by the Assistant Secretary for Health to the Administrator, Health Services Administration, has been superseded insofar as it pertains to section 319 of the Public Health Service Act relating to migrant health centers. The March 1, 1976 delegation (41 FR 11341) by the Assistant Secretary for Health to the Regional Health Administrators of authority under section 319 of the Public Health Service Act has also been superseded.

Provision has been made for previous delegations and redelegations to other officials within the Health Services Administration and the Public Health Service Regional Offices of authority under section 319 of the Public Health Services Act to continue in effect for no more than 90 days from the effective date of the above delegations.

The above delegations were effective on April 2, 1980.

Dated: April 10, 1980.

**Wilford Forbush,**

*Acting Assistant Secretary for Management and Budget.*

[FR Doc. 80-12268 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-84-M

## Social Security Administration

### Redelegation of Authority to Review and Decide on Appeals of Adverse Determinations Under Pub. L. 93-502 (The Freedom of Information Act)

The Freedom of Information Act, codified at 5 U.S.C. 552, provides that Federal agencies must disclose reasonably described records to any person, except to the extent that the records are covered by any of nine exemptions. Pub. L. 93-502 establishes a 10-day limit (excluding Saturdays, Sundays and legal public holidays) following the receipt of a request for records within which an agency must notify the requestor of the agency's determination and reason for it and of the requestor's right to appeal any adverse determination to the head of the agency. It also establishes a 20-day limit (excluding Saturdays, Sundays and legal public holidays) following the receipt of an appeal of an adverse determination within which the agency must notify the requestor of its determination to affirm or revise, in whole or in part, the findings and decision in question.

Section 422.448 of Social Security Regulations No. 22 provides that, when a request for review of an adverse Freedom of Information Act decision has been filed, based on the data considered in connection with the decision and whatever other evidence and written argument is submitted by the person requesting the review or which is otherwise obtained, the Commissioner of Social Security (the Commissioner) or his designee will affirm or revise in whole or in part the findings and decision in question.

On September 4, 1979 the Commissioner redelegated his authority to review and decide on appeals of adverse determinations under Pub. L. 93-502 to the Social Security Administration's (SSA's) Deputy Commissioner (Programs). Notice of this redelegation was published at 44 FR 53314, dated September 13, 1979. Notice is now given that the Commissioner has also redelegated this authority to SSA's Deputy Commissioner (Operations).

Dated: April 8, 1980.

**William J. Driver,**

*Commissioner of Social Security.*

[FR Doc. 80-12258 Files 4-21-80; 8:45 am]

BILLING CODE 4110-07-M

## Office of the Secretary

### Control of Paperwork; Comments on Collection of Information and Data Acquisition Activity

In **Federal Register** Vol. 43 No. 159 at 36326, dated August 16, 1978, item 7b (Time of Collection) is changed from November 15, 1979 to June 15, 1980. Notice is hereby given to all States which are subject to this reporting requirement that the reporting date for the 1978-79 data requirement for VEDS is hereby extended to June 15, 1980. This action has been taken in recognition of the fact that the 1978-79 reporting year is the initial year of the VEDS system and that some States which would otherwise be in compliance with the reporting mandate have experienced start-up delays. No further extension is contemplated.

In **Federal Register** Vol. 44 No. 188 at 55424, dated September 26, 1979, item (h) (2) is changed from November 15, 1980 to December 1, 1980. Notice is hereby given to all States which are subject to this reporting requirement that the reporting date for the 1979-80 data requirement for VEDS is hereby extended to December 1, 1980. No further extension is contemplated.

Dated: April 17, 1980.

**Marie D. Eldridge,**

*Administrator, National Center for Education Statistics.*

[FR Doc. 80-12227 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-89-M

## DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT

**[Docket No. N-80-994]**

### Privacy Act of 1974; Proposed Amendment to System of Records

**AGENCY:** Department of Housing and Urban Development.

**ACTION:** Notice of proposed amendment to existing system of records.

**SUMMARY:** The Department is giving notice that it intends to amend the routine use of a system of records.

**EFFECTIVE DATE:** The amendment shall become effective without further notice May 22, 1980, unless comments are received on or before that date which would result in a contrary determination.

**ADDRESS:** Rules Docket Clerk, Room 5218, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410.

**FOR FURTHER INFORMATION CONTACT:** Robert English, Departmental Privacy Act Officer, Telephone 202-557-0605.

**SUPPLEMENTARY INFORMATION:** The Department is adding Social Security Administration and Internal Revenue Service to the routine uses section of the Income Certification Evaluation Data Files (HUD/PD&R-8) system of records to assist in the verification of income data. This addition does not require the submission of a Report on a New System since it is compatible with the purpose for which the system is maintained. The words "Social Security Administration, Internal Revenue Service—to verify income data" have been added to the routine uses section of the notice, which is published below in its entirety, as amended. Previously, the system was published at 45 FR 5840 (January 24, 1980). The prefatory statement containing General Routine Uses applicable to all of the Department's systems of records was published at 44 FR 72288 (Decmeber 13, 1979). Appendix A, which lists the addresses of HUD's field offices was published at 44 FR 72307 (December 13, 1979), and supplemented at 45 FR 6479 (January 18, 1980).

HUD/PD&R-8

SYSTEM NAME:

Income Certification Evaluation Data files

SYSTEM LOCATION:

Applied Management Science, Inc., Silver Spring, MD.

CATEGORIES OF INDIVIDUALS COVERED BY THE SYSTEM:

Tenants of Section 8, Section 236, and Public Housing projects. Projects are selected randomly from a subset of all projects, tenants are selected randomly from the set of all tenants of the projects thus sampled.

CATEGORIES OF RECORDS IN THE SYSTEM:

Family identification (name, address, Social Security Number), household demographics (age, sex, family size, income and income sources, length of tenure), verification of income data.

AUTHORITY FOR MAINTENANCE OF THE SYSTEM:

Title V, Section 501 and 502 of the Housing and Community Development Act of 1970, P.L. 91-609.

ROUTINE USES OF RECORDS MAINTAINED IN THE SYSTEM, INCLUDING CATEGORIES OF USERS AND THE PURPOSES OF SUCH USES:

See routine uses paragraphs of prefatory statement. Other routine uses: Applied Management Science, Inc.—to carry out objectives of study, Social Security Administration, Internal Revenue Service—to verify income data.

POLICIES AND PRACTICES FOR STORING, RETRIEVING, ACCESSING, RETAINING, AND DISPOSING OF RECORDS IN THE SYSTEM:

STORAGE:

In file folders and on magnetic tape/disc/drum.

RETRIEVABILITY:

Name, address, Social Security Number.

SAFEGUARDS:

Manual files will be kept in lockable cabinets in a secured area; computer records will be maintained in a separate secured area. Access to either type of record will be limited to authorized personnel.

RETENTION AND DISPOSAL:

All records will be destroyed at the completion of the study.

SYSTEM MANAGER(S) AND ADDRESS:

Director, Office of Organization and Management Information, Dept. of HUD, 451 Seventh Street, S.W., Washington, D.C. 20410

NOTIFICATION PROCEDURE:

For information, assistance, or inquiry about existence of records, contact the Privacy Act Officer at the Headquarters location, in accordance with 24 CFR Part 16. This location is given in Appendix A.

RECORD ACCESS PROCEDURES:

The Department's rules for providing access to records to the individual concerned appear in 24 CFR Part 16. If additional information or assistance is required, contact the Privacy Act Officer at the Headquarter's location. This location is given in Appendix A.

CONTESTING RECORD PROCEDURES:

The Department's rules for contesting the contents of records and appealing initial denials, by the individual concerned, appear in 24 CFR Part 16. If additional information or assistance is needed, it may be obtained by contacting: (i) in relation to contesting contents of records, the Privacy Act Officer at the Headquarters location. This location is given in Appendix A; (ii) in relation to appeals of initial denials, the HUD Departmental Privacy Appeals Officer, Office of General Counsel, Department of Housing and Urban Development, 451 Seventh Street, S.W., Washington, D.C. 20410.

RECORD SOURCE CATEGORIES:

Subject, Income Sources.

**Authority:** 5 U.S.C. 552a, 88 Stat. 1896; Sec. 7(d), Department of HUD Act (42 U.S.C. 3535(d)).

Issued at Washington, D.C., April 14, 1980.

**Vincent J. Hearing,**

*Deputy Assistant, Secretary for Administration.*

[FR Doc. 80-12232 Filed 4-21-80; 8:45 am]

BILLING CODE 4210-01-M

## DEPARTMENT OF THE INTERIOR

### Bureau of Land Management

[ES 12641]

### Alabama; Order Providing for Limited Opening of Public Lands

*Correction*

In FR Doc. 80-9880 appearing an page 21717 in the issue of Wednesday, April 2, 1980, make the following correction:

In the middle column of page 21717, the last two lines of the land description should have read:

T. 12 S., R 8 W.

Sec. 13, SE¼SE¼NE¼.

BILLING CODE: 1505-01-M

[F-14872-A and F-14872-B]

### Alaska Native Claims Selections

This decision rejects an improper State selection application and approves for conveyance certain lands in the vicinity of Kaltag, Alaska to Gana-a'Yoo, Limited.

On November 5, 1974 and December 3, 1974, Takathlee-tondin, Incorporated, for the Native village of Kaltag, filed selection applications F-14872-A and F-14872-B under the provisions of Sec. 12 of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 701; 43 U.S.C. 1601, 1611 (1976)) (ANCSA), for the surface estate of certain lands in the vicinity of Kaltag.

On April 6, 1978, in accordance with Title 10, Chapter 05, Secs. 396 and 399 of the Alaska Business Corporation Act, and as authorized by Public Law 94-204, Sec. 30 (89 Stat. 1148), the Native villages of Galena (Notaaghleedin, Limited), Kaltag (Takathlee-tondin, Incorporated), Nulato (Nik'aghun, Limited) and Koyukuk (Mineelghaadza', Limited) formed a new corporation which consolidated individual village interests into one single constituent corporation, Gana-a'Yoo, Limited.

On December 29, 1976, the State of Alaska filed general purposes selection application F-23222, as amended, for all unpatented lands in T. 11 S., R. 2 E., Kateel River Meridian, pursuant to Sec. 6(b) of the Alaska Statehood Act of July 7, 1958 (72 Stat. 339, 340; 48 U.S.C. Ch. 2, Sec. 6(b)).

Section 6(b) of the Alaska Statehood Act states that general purposes selections shall be made from the public lands of the United States in Alaska which are vacant, unappropriated, and unreserved at the time of their selection.

At the time of filing of the State's selection application, the following lands were withdrawn by Sec. 11 of ANCSA, and properly selected pursuant to Sec. 12 of ANCSA by Takathlee-tondin, for the Native village of Kaltag. Part of the following lands were segregated by Native allotment applications F-13682 Parcel D, F-13421, F-033388, F-14020 and F-14040, which were filed pursuant to the Act of May 17, 1906 (34 Stat. 197), as amended August 2, 1956 (70 Stat. 954; 43 U.S.C. 270-1 to 270-3), subject to the provisions of the Act of March 8, 1922 (42 Stat. 415; 48 U.S.C. 376-377).

Therefore, in view of the above, State selection application F-23222 is hereby rejected as to the following described lands:

**Kateel River Meridian, Alaska (Unsurveyed)**

T. 11 S., R. 2 E.
Secs. 22, 23 and 25, excluding Yukon River and its interconnecting sloughs;
Sec. 26, all;
Sec. 27, excluding Yukon River;
Sec. 28, all;
Secs. 33 to 36, inclusive, excluding Yukon River and its interconnecting sloughs.
Containing approximately 4,750 acres.

The State selected lands rejected above were not valid selections and will not be charged against the village corporation as State selected lands. Further action on the subject State selection application as to those lands not rejected herein will be taken at a later date.

Takathlee-tondin, Incorporated, in its applications, excluded the following bodies of water:

Johnny's Lake;
Unnamed slough in Secs. 33, 35 and 36, T. 13 S., R. 1 E. and Secs. 3 and 4, T. 14 S., R. 1 E., Kateel River Meridian.

Because these water bodies have been determined to be nonnavigable, they are considered to be public lands withdrawn under Sec. 11(a)(1) and available for selection by the village pursuant to Sec. 12(a) of the Alaska Native Claims Settlement Act.

Section 12(a) and 43 CFR 2651.4 (b) and (c) provide that the village corporation shall select all available lands within the township or townships within which the village is located, and that additional lands selected shall be compact and in whole sections. The regulations also provide that the area selected will not be considered to be reasonably compact if it excludes other lands available for selection within its exterior boundaries.

For these reasons, the water bodies which were improperly excluded in the applications of Takathlee-tondin, Incorporated are considered selected.

On June 25, 1974, title to U.S. Survey 4020 reverted to the United States pursuant to the Act of June 14, 1926 (44 Stat. 741), as amended. U.S. Survey 4020 was excluded from the application of Takathlee-tondin, Incorporated as patented land. However, since Sec. 12(a) of ANCSA requires that the village corporation select all of the township in which the village is located, U.S. Survey 4020 is considered selected.

As to the lands described below, the applications, as amended, are properly filed and meet the requirements of the Alaska Native Claims Settlement Act and of the regulations issued pursuant thereto. These lands do not include any lawful entry perfected under or being maintained in compliance with laws leading to acquisition of title.

In view of the foregoing, the surface estate of the following described lands, selected pursuant to Sec. 12(a) of ANCSA, aggregating approximately 105,997 acres, is considered proper for acquisition by Gana-a 'Yoo, Limited and is hereby approved for conveyance pursuant to Sec. 14(a) of ANCSA:

U.S. Survey No. 4020, Alaska, situated in the village of Kaltag, Alaska.
Containing 0.87 acres.

**Kateel River Meridian, Alaska (Unsurveyed)**

T. 12 S., R. 1 W.
Secs. 4, 5, 8 and 9, all;
Secs. 15, 16, 17 and 21, all;
Secs. 22, 27, 28 and 34, all.
Containing approximately 7,680 acres.

T. 13 S., R. 1 W.
Sec. 1, all;
Secs. 2, 3 and 11, excluding Native allotment F–13751;
Secs. 12, 13 and 14, all;
Secs. 23 and 24, all;
Sec. 25, excluding Native allotment F–13678 Parcel C;
Secs. 26 and 34, all;
Sec. 35 excluding Native allotment F–13729 Parcel B;
Sec. 36, excluding U.S. Survey 3772 and Native allotments F–13729 Parcel B and F–13678 Parcel C.
Containing approximately 8,677 acres.

T. 14 S., R. 1 W.
Sec. 1, all;
Sec. 2, excluding Native allotments F–14667 and F–17169 Parcel B;
Sec. 3, excluding Native allotments F–14141 and F–14667;
Sec. 9, excluding Native allotment F–14433;
Sec. 10, excluding Native allotments F–14141, F–14667, F–17163 Parcel B and F–14433;
Sec. 11, excluding Native allotments F–17169 Parcel B, F–17163 Parcel B and F–14667;
Secs. 12, 13 and 14, all;
Sec. 15, excluding Native allotment F–14433;
Sec. 16, excluding Native allotments F–14433 and F–17649;
Sec. 17, excluding Native allotments F–17649 and F–13727;
Sec. 18, all;
Secs. 19 and 20, excluding Native allotment F–13727;
Secs. 21, 22 and 23, all;
Secs. 24 and 25, excluding Native allotment F–16428;
Secs. 26 to 29, inclusive, all;
Secs. 33 to 36, inclusive, all.
Containing approximately 16,820 acres.

T. 15 S., R. 1 W.
Secs. 2 and 3, all;
Sec. 4, excluding Native allotments F–13672 and F–13724;
Secs. 24, 25 and 36, all
Containing approximately 3,600 acres.

T. 14 S., R. 2 W.
Secs. 13 and 14, all;
Secs. 21 to 24, inclusive, all;
Secs. 27, 28 and 29, all;
Secs. 31 and 32, all.
Containing approximately 7,015 acres.

T. 15 S., R. 2 W.
Sec. 6, all.
Containing approximately 617 acres.

T. 12 S., R. 1 W.
Sec. 24, all;
Sec. 25, excluding Native allotment F–13749 Parcel D and Yukon River;
Secs. 26, excluding Native allotment F–13749 Parcel D;
Sec. 34, excluding Native allotment F–15477;
Sec. 35, excluding Native allotments F–13749 Parcel D and F–15477 and Yukon River;
Sec. 36, excluding Native allotment F–13749 Parcel D and Yukon River.
Containing approximately 3,070 acres.

T. 13 S., R. 1 W.
Sec. 1, excluding Yukon River;
Sec. 2, excluding Native allotment F–15477 and Yukon River;
Sec. 3, excluding Native allotments F–15477 and F–13750 Parcel B and Yukon River;
Sec. 4, excluding Native allotments F–13723 Parcel B and F–13750 Parcel B and Yukon River;
Secs. 5 to 8, inclusive, all;
Sec. 9, excluding Native allotments F–13750 Parcel B, F–13723 Parcel B, F–17883, F–13678 Parcel A and F–13668 Parcel A and Yukon River;
Secs. 10 and 11, excluding Yukon River;
Secs. 12 and 13, all;
Secs. 14 and 15, excluding Yukon River;
Sec. 16, excluding Native allotments F–13668 Parcel A and F–13678 Parcel B and Yukon River;
Sec. 17, excluding Native allotments F–13678 Parcel B, F–14358 Parcel B and F–13677 Parcel B and Yukon River;
Secs. 18 and 19, all;
Sec. 20, excluding Native allotments F–13677 Parcels B and C, F–16945 Parcels A and B, and Yukon River;
Sec. 21, excluding Native allotments F–16945 Parcel B and F–13687 Parcel C and Yukon River;
Sec. 22, excluding Yukon River and its interconnecting slough;
Secs. 23 to 26, inclusive, all;
Sec. 27, excluding the interconnecting slough of Yukon River;
Sec. 28, excluding Native allotments F–13687 Parcel C, F–13690 Parcels A and B, and Yukon River and its interconnecting slough;
Sec. 29, excluding U.S. Survey 3772, U.S. Survey 4485, U.S. Survey 4020, Lot 2 of Amended U.S. Survey 2351 accepted January 9, 1974, Tract A of Amended U.S. Survey 2027 accepted January 9, 1974, Native allotments F–13690 Parcels A and B, F–13677 Parcel C and F–13732 Parcel A and Yukon River;
Sec. 30, excluding U.S. Survey 3772, U.S. Survey 4485, Native allotments F–13732 Parcel A and F–13678 Parcel C and Yukon River;
Sec. 31, excluding U.S. Survey 3772 and Native allotment F–13678 Parcel C;
Sec. 32, excluding U.S. Survey 3772, U.S. Survey 4485, Tract A of Amended U.S. Survey 2027 accepted January 9, 1974, Native allotments F–13690 Parcel A, F–13750 Parcel A, F–17169 Parcel A and F–13729 Parcel A, and Yukon River and its interconnecting slough;
Sec. 33, excluding Native allotments F–13750 Parcel A and F–13690 Parcel A and the interconnecting slough of Yukon River;
Sec. 34, all;
Sec. 35, excluding Native Allotment F–13746 Parcel B;

Sec. 36, all.
Containing approximately 16,563 acres.

T. 14 S., R. 1 E.
Sec. 3, all;
Sec. 4, excluding Native allotment F–13750 Parcel A and Yukon River;
Sec. 5, excluding Native allotments F–13750 Parcel A, F–17169 Parcel A, F–13729 Parcel A and F–027519 Parcel A and Yukon River,
Secs. 6 and 7, excluding Native allotment F–027519 Parcel A;
Sec. 8, excluding Native allotments F–027519 Parcel A and F–13728 and Yukon River;
Sec. 9, excluding Yukon River;
Secs. 10 and 15, all;
Sec. 16, excluding Yukon River;
Sec. 17, excluding Native allotments F–13728 and F–14146 and Yukon River;
Sec. 18, all;
Sec. 19, excluding Native allotments F–14146 and F–16428;
Sec. 20, excluding Native allotments F–14146, F–16945 Parcel C and F–13742 and Yukon River;
Sec. 21, excluding Native allotments F–16945 Parcel C and F–13742 and Yukon River;
Sec. 22, excluding Yukon river;
Sec. 26, excluding Native allotment F–13732 Parcel B;
Sec. 27, excluding Native allotment F–13732 Parcel B and Yukon River;
Sec. 28, excluding Native allotment F–13742 and Yukon River;
Sec. 29, excluding Native allotment F–13742;
Sec. 30, excluding Native allotment F–16428;
Secs. 31 and 32, all;
Sec. 33, excluding Native allotments F–13689 Parcel B and F–13687 Parcel A and Yukon River;
Secs. 34 and 35, excluding Yukon River.
Containing approximatley 11,960 acres.

T. 15 S., R 1 E.
Sec. 1, all;
Secs. 2, 3 and 4, excluding Yukon River;
Secs. 5 and 8, all;
Secs. 9 and 10, excluding Yukon River and its interconnecting slough;
Sec. 11, excluding Native allotment F–13691 Parcel A and Yukon River;
Sec. 12, all;
Sec. 13, excluding Native allotment F–027519 Parcel B;
Sec. 14, excluding Native allotment F–027519 Parcel B and Yukon River;
Secs. 15 to 18, inclusive, excluding Yukon River and its interconnecting sloughs;
Sec. 19, excluding Native allotment F–16444 Parcel A and the interconnecting slough of Yukon River;
Secs. 20 to 23, inclusive, excluding Yukon River and its interconnecting sloughs;
Secs. 24 and 25, all;
Secs. 26 to 36, inclusive, excluding Yukon River and its interconnecting sloughs.
Containing approximately 15,521 acres.

T. 11. S., R. 2 E.
Sec. 22, excluding Native allotments F–13421 and F–14020 and Yukon River;
Sec. 23, excluding Native allotment F–13682 Parcel D and Yukon River;
Sec. 25, excluding the interconnecting sloughs of Yukon River;
Sec. 26, all;
Sec. 27, excluding Native allotments F–13421 and F–033388 and Yukon River;
Sec. 28, excluding Native allotments F–13421 and F–033388;
Secs. 33 and 34, excluding Native allotment F–14040 and Yukon River;
Secs. 35 and 36, excluding the interconnecting sloughs of the Yukon River.
Containing approximately 4,265 acres.

T. 12 S., R. 2 E.
Sec. 4, excluding Native allotments F–16438 and F–16439 and Yukon River;
Sec. 5, excluding Native allotments F–16438 and F–16439;
Sec. 7, all;
Sec. 8, excluding Native allotment F–17125 Parcel B;
Sec. 9, excluding Native allotments F–15474 Parcel A, F–13691 Parcel C, F–18916 Parcel A and F–17125 Parcel B and Yukon River;
Secs. 16 and 17, excluding Native allotments F–17125 Parcel B and F–14145 and Yukon River;
Sec. 18, excluding native allotment F–17163 Parcel A;
Sec. 19, excluding Native allotment F–17163 Parcel A and Yukon River;
Sec. 20, excluding Yukon River;
Sec. 27, all;
Secs. 28 to 32, inclusive, excluding Yukon River;
Sec. 33, all.
Containing approximately 7,105 acreas.

T. 13 S., R. 2 E.
Secs. 4 and 5, all;
Sec. 6, excluding Yukon River;
Secs. 7 and 8, all.
Containing approximately 3,103 acres.
Aggregating approximately 105,997 acres.

The conveyance issued for the surface estate of the lands described above shall contain the following reservations to the United States:

1. The subsurface estate therein, and all rights, privileges, immunities, and appurtenances, of whatsoever nature, accruing unto said estate pursuant to the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 704; 43 U.S.C. 1601, 1613(f)); and

2. Pursuant to Sec. 17(b) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 708; 43 U.S.C. 1601, 1616(b)), the following public easements, referenced by easement identification number (EIN) on the easement maps attached to this document, copies of which will be found in case file F–14871–EE, are reserved to the United States. All easements are subject to applicable Federal, State, or Municipal corporation regulation. The following is a listing of uses allowed for each type of easement. Any uses which are not specifically listed are prohibited.

*25 Foot Trail*—The uses allowed on a twenty-five (25) foot wide trail easement are: travel by foot; dogsled, animals, snowmobiles, two and three-wheel vehicles, and small all-terain vehicles (less than 3,000 lbs. Gross Vehicle Weight (GVW)).

*One Acre Site*—the uses allowed for a site easement are: vehicle parking (e.g., aircraft, boats, ATV's, snowmobiles, cars, trucks), temporary camping, and loading or unloading. Temporary camping, loading, or unloading shall be limited to 24 hours.

a. (EIN 1 C1, C3, C6, D1) An easement for an existing access trail, twenty-five (25) feet in width, from the village of Kaltag in Sec. 29, T. 13 S.,, R. 1 E., Kateel River Meridian, southwesterly to public lands. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement. The season of use will be limited to winter use.

b. (EIN 3 C5) An easement for a proposed access trail, twenty-five (25) feet in width, from trail EIN 1 C1, C3, C6, D1 in Sec. 24, T. 14 S., R. 2 W., Kateel River Meridian, southerly to public lands. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement. The season of use will be limited to winter use.

c. (EIN 5 C5) An easement for a proposed access trail, twenty-five (25) feet in width, from trail EIN 1 C1, C3, C6, D1 in Sec. 17, T. 14 S., R. 1 W., Kateel River Meridian, northwesterly to public lands. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement. The season of use will be limited to winter use.

d. (EIN 10 C5) An easement for a proposed access trail, twenty-five (25) feet in width, from site EIN 10b C5 in Sec. 27, T. 14 S., R. 1 E., Kateel River Meridian, northeasterly to public lands. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement.

e. (EIN 10b C5) A one (1) acre site easement, upland of the ordinary high-water mark, in Sec. 27, T. 14 S., R. 1 E., Kateel River Meridian, on the left bank of the Yukon River. The uses allowed are those listed above for a one (1) acre site easement.

f. (EIN 18 C5) An easement for a proposed access trail, twenty-five (25) feet in width, from the left bank of the Yukon River at site EIN 20 C5 in Sec. 36, T. 11 S., R. 2 E., Kateel River Meridian, southeasterly to public lands. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement.

g. (EIN 20 C5) A one (1) acre site easement, upland of the ordinary high-water mark, in Sec. 36, T. 11 S., R. 2 E., Kateel River Meridian, on the left bank of the Yukon River. The uses allowed are those listed above for a one (1) acre site easement.

h. (EIN 22 C5) An easement for a proposed access trail, twenty-five (25) feet in width, from the right bank of the Yukon River in Sec. 22, T. 11 S., R. 2 E., Kateel River Meridian, westerly to public lands. The uses allowed are those listed above for a twenty-five (25) foot wide trail easement.

The grant of the above-described lands shall be subject to:

1. Issuance of a patent confirming the boundary description of the unsurveyed lands hereinabove granted after approval and filing by the Bureau of Land Management of the official plat of survey covering such lands;

2. Valid existing rights therein, if any, including but not limited to those created by any lease (including a lease issued under Sec. 6(g) of the Alaska Statehood Act of July 7, 1958 (72 Stat. 339, 341; 48 U.S.C. Ch. 2, Sec. 6(g))), contract, permit, right-of-way, or easement, and the right of the lessee, contractee, permittee, or grantee to the complete enjoyment of all rights, privileges, and benefits thereby granted to him. Further, pursuant to Sec. 17(b)(2) of the Alaska Native Claims Settlement Act of December 18, 1971 (43 U.S.C. 1601, 1616(b)(2)) (ANCSA), any valid existing right recognized by ANCSA shall continue to have whatever right of access as is now provided for under existing law; and

3. Requirements of Sec. 14(c) of the Alaska Native Claims Settlement Act of December 18, 1971 (85 Stat. 688, 703; 43 U.S.C. 1601, 1613(c)), that the grantee hereunder convey those portions, if any, of the lands hereinabove granted, as are prescribed in said section.

Gana-a 'Yoo, Limited (for the village of Kaltag) is entitled to conveyance of 115,200 acres of land selected pursuant to Sec. 12(a) of ANCSA. Together with the lands herein approved, the total acreage conveyed or approved for conveyance is 105,997 acres. The remaining entitlement of approximately 9,203 acres will be conveyed at a later date.

Pursuant to Sec. 14(f) of ANCSA, conveyance of the subsurface estate of the lands described above shall be issued to Doyon, Limited when the surface estate is conveyed to Gana-a 'Yoo, Limited, and shall be subject to the same conditions as the surface conveyance.

Within the above described lands, only the following inland water body is considered to be navigable:

*Yukon River and its interconnecting sloughs.*

In accordance with Departmental regulation 43 CFR 2650.7(d), notice of this decision is being published once in the **Federal Register** and once a week, for four (4) consecutive weeks, in the Fairbanks Daily News-Miner. Any party claiming a property interest in lands affected by this decision may appeal the decision to the Alaska Native Claims Appeal Board, P.O. Box 2433, Anchorage, Alaska 99510 with a copy served upon both the Bureau of Land Management, Alaska State Office, 701 C Street, Box 13, Anchorage, Alaska 99513 and the Regional Solicitor, Office of the Solicitor, 510 L Street, Suite 408, Anchorage Alaska 99501, also:

1. Any party receiving service of this decision shall have 30 days from the receipt of this decision to file an appeal.

2. Any unknown parties, any parties unable to be located after reasonable efforts have been expended to locate, and any parties who failed or refused to sign the return receipt shall have until May 22, 1980 to file an appeal.

3. Any party known or unknown who may claim a property interest which is adversely affected by this decision shall be deemed to have waived those rights which were adversely affected unless an appeal is timely filed with the Alaska Native Claims Appeal Board.

To avoid summary dismissal of the appeal, there must be strict compliance with the regulations governing such appeals. For further information on the manner of and requirements for filing an appeal may be obtained from the Bureau of Land Management, 701 C Street, Box 13, Anchorage, Alaska 99513.

If an appeal is taken, the parties to be served with a copy of the notice of appeal are:

State of Alaska, Department of Natural Resources, Division of Research and Development, 323 East Fourth Avenue, Anchorage, Alaska 99501.

Gana-a 'Yoo, Limited, Box 38, Galena, Alaska 99741.

Doyon, Limited, First and Hall Streets, Fairbanks, Alaska 99701.

**Ricky M. Elliott,**

*Chief, Branch of Adjudication.*

[FR Doc. 80-12311 Filed 4-21-80; 8:45 am]

BILLING CODE 4310-84-M

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**[INT DEIS 80-21]**

## Proposed Wilderness Designation of Instant Study Areas for the Arizona Strip District, Northern Mohave and Coconino Counties, Ariz.; Availability of Draft Environmental Impact Statement and Draft Suitability Report

Pursuant to section 102(2)(c) of the National Environmental Policy Act of 1969 and section 603 of the Federal Land Policy and Management Act of 1976, the Bureau of Land Management has prepared a combined document, containing the draft environmental impact statement and draft suitability report concerning proposed wilderness areas for the Arizona Strip District in Northern Mohave and Coconino Counties, Arizona. The draft document involves the impact analysis of designating two primtive areas and one natural area wilderness to be managed under section 4 of the Wilderness Act of 1964.

Comments on the draft environmental impact statement and draft suitability report will be solicited from public agencies and interested individuals, groups and organizations. The comments will be incorporated in the final environmental impact statement and suitability report. Written comments should be submitted within 45 days of the Environmental Protection Agency's notice to be published in the **Federal Register** on or about April 25, 1980. Comments are to be submitted to the State Director, Bureau of Land Management, 2400 Valley Bank Center, Phoenix, Arizona 85073.

A limited number of copies are avilable upon request to the State Director at the above address.

Public reading copies will be available for review at the following locations:

Office of Public Affairs, Bureau of Land Management, Interior Building, 18th & C Streets, N.W., Washington, D.C. 20240, Telephone (202) 343-5717.

Arizona State Office, Bureau of Land Management, 2400 Valley Bank Center, Phoenix, Arizona 85075, Telephone (602) 261-3706.

Utah State Office, Bureau of Land Management, 136 E. Temple, Salt Lake City, Utah 84111, Telephone (801) 524-4227.

Arizona Strip District Office, Bureau of Land Management, 196 E. Tabernacle, St. George, Utah 84770, Telephone (801) 673-3545.

Cedar City District Office, Bureau of Land Management, 1579 N. Main, Cedar City, Utah 84720, Telephone (801) 586-2801.

Kanab Resource Area Office, Bureau of Land Management, 320 North First East, Kanab, Utah 84741, Telephone (801) 644-2672.

Oral and written comments will also be received at formal public hearings to be held in the following cities:

Salt Lake City, Utah, Salt Palace, Room 220, May 5, 1980, 7:30 p.m.

Kanab, Utah, BLM Area Office, 320 North First East, May 6, 1980, 7:30 p.m.

St. George, Utah, Four Season Convention Center, 747 E. St. George Blvd., May 7, 1980, 7:30 p.m.

Phoenix, Arizona, Maricopa County Board of Supervisor's Auditorium, 111 S. 3rd Avenue, May 8, 1980, 7:30 p.m.

A Hearing Office will preside over the public hearings. Witnesses presenting oral comments should limit their testimony to ten (10) minutes. Written requests to testify orally should be sent to the District Manager, Arizona Strip District Office, 196 E. Tabernacle, St. George, Utah 84770.

Comments received on the draft environmental impact statement and draft suitability report, whether written or oral, will be given equal

consideration during the preparation of the final document.

Dated: April 17, 1980.

James W. Curlin,

*Deputy Assistant Secretary for Land and Water Resources.*

[FR Doc. 80-12255 Filed 4-21-80; 8:45 am]

BILLING CODE 4310-84-M

### Idaho Wilderness Inventory

In the February 8, 1980, Federal Register, a notice listed the intended final decision for Wilderness Initial Inventory for eight wilderness inventory units in the Boise, Burley, and Idaho Falls BLM districts, and indicated a 30-day period ending March 10, 1980, during which protests to the intended final decision would be received.

For the following inventory units no protests were received, therefore the decision to drop the units from further wilderness consideration is now final.

18-5 Sugar Loaf, All
18-9 Indian Creek, All
18-11 Hog Creek, All
18-12 Coonrod Gulch, All
23-1 Jim Sage[1]
35-3Sand Mountain[1]
5-5 Big Sandy[1]

[1] Portion as identified in the February 8, 1980, Federal Register notice.

This final decision is subject to appeal under the provisions of Title 43, Code of Federal Regulations (CFR), Part 4.

The decision to conduct intensive inventory on the following inventory units is under formal protest and the effective date is deferred pending a decision on the protests.

23-1 Jim Sage A, Jim Sage C
35-3 Sand Mountain
35-4 Black Knoll
35-5 Big Sandy

All inventory units under formal protest will remain under wilderness interim management until the protests have been resolved.

BLM office addresses for further information are as follows:

State Director, Box 042, Federal Building, 550 W. Fort Street, Boise, Idaho 83724.
District Manager, Burley District Office, Route 3, Box 1, Burley, Idaho 83318.
District Manager, Boise District Office, 230 Collins Road, Boise, Idaho 83702.
District Manager, Idaho Falls District Office, 940 Lincoln Road, Idaho Falls, Idaho 83401.

Dated: April 15, 1980.

Rex D. Colton,

*Acting State Director.*

[FR Doc. 80-12191 Filed 4-21-80; 8:45 am]

BILLING CODE 4310-84-M

### Idaho—Wilderness Decision

The initial inventory intended final decision for the Jim Sage wilderness inventory unit in the Burley District was published in the February 8, 1980, Federal Register.

This intended decision indicated that two parcels within the 38,520-acre unit, parcel A (7,585 acres), and parcel C (6,190 acres) would require intensive inventory in order to determine the presence or absence of wilderness characteristics. The remainder of the acreage was dropped from further wilderness consideration.

The decision to conduct intensive inventory on the two parcels was protested, with 16 letters received during the 30 days allocated for protest.

After analysis of the protest letters, the final decision is that with the exception of 684 acres in the northwest portion of parcel A, which have been impacted by roads/ways, a dumpsite, and wood cutting areas, parcel A, 6,901 acres, and parcel C, 6,190 acres, require intensive inventory.

This final decision is subject to appeal under the provisions of Title 43, Code of Federal Regulations (CFR), Part 4.

For further information on this final decision, contact the following:

District Manager, Burley District, Route 3, Box 1, Burley, Idaho 83318.
State Director, Idaho State Office, Box 042, Federal Building, 550 W. Fort Street, Boise, Idaho 83724.

Dated: April 15, 1980.

Rex D. Colton,

*Acting State Director.*

[FR Doc. 80-12192 Filed 4-21-80; 8:45 am]

BILLING CODE 4310-84-M

### California; Seasonal Closure of Public Lands Amendment

The Bureau of Land Management, Bakersfield District Office, in a notice in the Federal Register on March 13, 1980 (45 FR 16354), announced a seasonal closure of public lands and waters within one mile of Negit and Paoha Islands to public use and entry.

The notice is hereby amended to correct the cited authority for the closure and to include the description of penalties for violation of these regulations. The correct authority for the closure is under Title 43, CFR 8364.1. It is a criminal offense to knowingly and willfully violate any closure order promulgated under these regulations. The criminal penalty for any such violation is a fine of not more than $1,000 or imprisonment for not more than 12 months or both as prescribed by 43 CFR 8364.2.

Carol A. Kinderknecht,

*Acting District Manager.*

[FR Doc. 80-12357 Filed 4-21-80; 8:45 am]

BILLING CODE 4310-84-M

[Colorado 29851]

### Invitation for Coal Exploration License—MAPCO Inc.

Members of the public are hereby invited to participate with MAPCO Inc. in a program for the exploration of coal deposits owned by the United States of America in the following described lands located in Routt and Moffat Counties, Colorado:

T. 5 N., R. 89 W., 6th P.M.
Tract 43 (lying in Sections 5 and 8);
Sec. 4: Lots 1 thru 4, S½N½, S½ (All);
Sec. 5: Lots 5 thru 19;
Sec. 6: Lots 1, 2, 4, 6, 7, S½NE¼, E½SW¼, SE¼;
Sec. 7: Lots 1, 2, NE¼, E½NW¼;
Sec. 8: Lots 1 thru 17;
Sec. 9: Lots 1 thru 13;
Sec. 10: Lots 1 thru 6, 10 thru 13;
Sec. 16: Lots 1, 2, 5, 6, 7;
Sec. 17: All;
Sec. 18: SE¼;
Sec. 19: N½NE¼, NE¼NW¼;
Sec. 20: N½N½.
T. 5 N., R. 90 W., 6th P.M.
Sec. 1: Lots 5 thru 20 (All);Sec. 2: Lots 5 thru 20 (All);
Sec. 3: Lots 5 thru 20 (All);
Sec. 4: Lots 5, 6, 7, 10 thru 15, 18, 19, 20;
Sec. 9: Lots 1, 2, 3, 6, 7, 8;
Sec. 10: Lots 1 thru 10, 15, 16;
Sec. 11: Lots 1 thru 16 (All);
Sec. 12: Lots 1 thru 16 (All);
Sec. 13: Lots 1 thru 8;
Sec. 14: Lots 1 thru 8.
Containing 10,160.04 acres, more or less.

Any party electing to participate in this proposed program must send written notice of that election to the Bureau of Land Management and MAPCO Inc. directed to the following persons at the addresses shown:

Leader, Craig Team, Branch of Adjudication, Colorado State Office, Bureau of Land Management, Room 700, Colorado State Bank Building, 1600 Broadway, Denver, CO 80202; and
MAPCO Inc., 1800 South Baltimore Avenue, Tulsa, OK 74119.

Such written notice must be received by the above indicated persons at the addresses shown not later than thirty calendar days after the publication of this Notice in the Federal Register.

A copy of the exploration plan, as submitted by MAPCO Inc. is available for public review during normal business hours in the following office, under Serial Number C-29851: Bureau of Land Management, Room 701, Colorado State Bank Building, 1600 Broadway, Denver, Colorado.

The exploration plan and lands to be included in the exploration license are subject to the approval of U.S. Geological Survey and the Bureau of Land Management.

The foregoing notice is published in the **Federal Register** pursuant to 43 CFR 3410.2–1(d)(1), 43 FR 42584 at 42614 (No. 140, July 19, 1979).

**Andrew W. Heard, Jr.,**

*Leader, Craig Team Branch of Adjudication.*

[FR Doc. 80–12358 Filed 4–21–80; 8:45 am]

BILLING CODE 4310–84–M

## Fish and Wildlife Service

### Intent To Prepare an Environmental Impact Statement on the Indiana-Michigan Cooperative Anadromous Fisheries Program for the St. Joseph River

**AGENCY:** Fish and Wildlife Service, Interior.

**ACTION:** Notice.

**SUMMARY:** This Notice advises the public that the Service intends to gather information necessary for the preparation of an Environmental Impact Statement (EIS) about the release of Federal Aid funds to the states of Indiana and Michigan to develop fishery facilities on the St. Joseph River. This proposal will allow for the free movement of anadromous fish (trout and salmon) from Lake Michigan, upstream to Mishawaka in St. Joseph County, Indiana. A public meeting regarding this proposal and preparation of the EIS will also be held. This Notice is being furnished as required by the National Environmental Policy Act (NEPA) Regulations (40 CFR 1501.1) to obtain suggestions and information from other agencies and the public on the scope of issues to be discussed in the EIS. Comments and participation in this scoping process are solicited.

**DATES:** Written comments should be received by June 18, 1980. A public meeting will be held in South Bend, Indiana, on May 20, 1980, and Berrien Springs, Michigan, on May 21, 1980.

The public meeting on May 20, 1980, will be held in South Bend, Indiana, in the Century Center (Recital Hall room), 120 South St. Joseph Street at 7:00 p.m. In Berrien Springs, Michigan, the meeting will be held at the Village Community Building (The Grove) at 7:00 p.m. on May 21, 1980.

**ADDRESSEES:** Comments should be addressed to:

Regional Director, (Attention: Dale N. Martin), U.S. Fish and Wildlife Service, Federal Building, Fort Snelling, Twin Cities, Minnesota 55111

**FURTHER INFORMATION CONTACT:**

For the South Bend, Indiana, meeting:

Mr. William D. James, Indiana Department of Natural Resources, 607 State Office Building, Indianapolis, Indiana 46204 (317/232–4080)

For the Berrien Springs, Michigan, meeting:

Mr. Donald E. Reynolds, Michigan Department of Natural Resources, Stevens T. Mason Building, Lansing, Michigan 48926 (517/373–1280)

It is requested that persons planning to attend the public meetings notify either Mr. William James or Mr. Donald Reynolds at the above addresses.

**SUPPLEMENTAL INFORMATION:** The Fish and Wildlife Service (FWS) Department of the Interior, proposes to provide funds through the Federal Aid to states program to the states of Indiana and Michigan. This will be a cooperative project to provide for the free movement of anadromous fish (trout and salmon) within the waters of the St. Joseph watershed. An EIS will be developed to discuss the modification of several existing dams, the development of public access sites, and the construction of a fish hatchery in Indiana. Two dams in Michigan will require the construction of fish passage facilities (Buchanan and French Papermill). In Indiana, fish passage facilities will be required at the South Bend Dam and Uniroyal Dam. The fish passages will allow for the free movement of fish from Lake Michigan to the base of the Twin Branch Dam at Mishawaka, Indiana (a total of about 65 miles of stream).

The scoping process for the Draft EIS will be initiated by letter to interested Federal, State, and local agencies and those private organizations and affected parties who have expressed an interest in the proposal. Anyone else who has an interest in participating in the scoping process and the development of the EIS is invited to do so and should contact the Regional Director on or before May 22, 1980.

The environmental review of this project will be conducted in accordance with the requirements of the National Environmental Policy Act of 1969 as amended, Council on Environmental Quality Regulations (40 CFR, Parts 1500–1508), other appropriate Federal regulations, and FWS procedures for compliance with those regulations.

We estimate the DEIS will be made available to the public by January 1981.

Dated: April 11, 1980.

**Harvey K. Nelson,**

*Regional Director, Twin Cities, MN.*

[FR Doc. 80–12193 Filed 4–21–80; 8:45 am]

BILLING CODE 4310–55–M

## Heritage Conservation and Recreation Service

### National Register of Historic Places; Notification of Pending Nominations

Nominations for the following properities being considered for listing in the National Register were received by the Heritage Conservation and Recreation Service before April 11, 1980. Pursuant to section 1202.13 36 CFR Part 1202, written comments concerning the significance of these properities under the National Register criteria for evaluation may be forwarded to the National Register, Heritage Conservation and Recreation Service, U.S. Department of the Interior, Washington, DC 20243. Written comments should be submitted by May 7, 1980.

**Sarah G. Oldham,**

*Acting Chief, Registration Branch.*

**COLORADO**

*Jefferson County*

Evergreen vicinity, *Everhardt Ranch*, SE of Evergreen

*Rio Blanco County*

Meeker, *Hotel Meeker*, 560 Main St.

**HAWAII**

*Honolulu County*

Honolulu, *Guild, John, House*, 20001 Vancouver Dr.

**LOUISIANA**

*Ascension Parish*

Burnside vicinity, *Houmas, The*, W of Burnside off LA 22 and LA 44

*East Baton Rouge Parish*

Baton Rouge, *Hart House*, Iowa St.

*East Feliciana Parish*

Jackson vicinity, *Linwood*, 7.3 mi. S of Jackson

*Iberia Parish*

New Iberia, *Broussard, Amant, House*, 1400 E. Main St.

New Iberia, *Mintmere*, 1400 E. Main St.

*Iberville Parish*

White Castle vicinity, *Nottoway Plantation House*, NW of White Castle

*Livingston Parish*

Holden vicinity, *Macedonia Baptist Church*, N of Holden

*Natchitoches Parish*

Natchez vicinity, *Badin-Roque House*, S of Natchez

*Orleans Parish*

New Orleans, *Long, Huey P., Mansion*, 14 Audubon Blvd.
New Orleans, *Old Handleman Building*, 1824–1832 Dryades St.

*Rapides Parish*

Alexandria, *First Methodist Church*, 630 Jackson St.

*St. Martin Parish*

Breaux Bridge vicinity, *Penne, Henry, House*, W of Breaux Bridge

*St. Mary Parish*

Franklin, *Grevemberg House*, Sterling Rd.
Franklin, *Smith House*, 909 2nd St.

*St. Tammany Parish*

Mandeville, *Moore House*, 1717 Lakeshore Dr.

*West Feliciana Parish*

St. Francisville vicinity, *Laurel Hill*, NE of St. Francisville
Wakefield, *Wakefield*, U.S. 61

**MICHIGAN**

*Dickinson County*

Iron Mountain, *Dickinson County Courthouse and Jail*, 700 S. Stephenson Ave.

*Houghton County*

Calumet, *Italian Hall*, 7th and Elm Sts.
Houghton, *Shelden, Ransom B., House*, 1304 College Ave.

*Keweenaw County*

Copper Harbor vicinity, *Keweenaw Mountain Lodge and Golf Course Complex*, SW of Copper Harbor on U.S. 41

*Marquette County*

Marquette, *Upper Peninsula Brewing Company Building*, Meeske St. and U.S. 41

**MINNESOTA**

*Faribault County*

*FARIBAULT COUNTY MULTIPLE RESOURCE AREA (Partial Inventory.* This area includes: Blue Earth, *Constans Hotel*, 121–127 N. Main St.; *Faribault County Courthouse*, N. Main and 2nd Sts. (previously listed in the National Register); *Good Shepherd Episcopal Church*, Moore and 8th Sts.; *Wakefield, James B., House*, 405 E. 6th St.; Delavan vicinity, *Bullis, Adams H., House;* Minnesota Lake, *Kremer, Peter, House*, Main and 4th Sts.; Walters, *Walters Jail*, 3rd and Main Sts.; Wells, *Chicago, Milwaukee, St. Paul and Pacific Railroad Depot and Lunchroom*, 89–100 1st St., NW.; *Leland, Muret N., House*, 410 2nd Ave., SW.; Wells vicinity, *District School No. 40;* Winnebago, *Dunn, Andrew C., House*, 133 S. Maine St.; *First National Bank*, Main St. and Cleveland Ave.

**MISSISSIPPI**

*Copiah County*

Wesson, *Old Wesson Public School Building*, Off U. S. 51

**NEW MEXICO**

*Sandoval County*

Corrales, *San Ysidro Church*, Church Rd.

**NORTH CAROLINA**

*Northampton County*

Murfreesboro vicinity, *Princeton Site*

**UTAH**

*Salt Lake County*

Salt Lake City, *Wasatch Springs Plunge*, 840 N. 300 West St.

**VERMONT**

*Chittenden County*

Shelburne and vicinity, *Shelburne Farms*, Off U. S. 7

**VIRGINIA**

*Alexandria (independent city)*

*Jones Point Lighthouse and District of Columbia South Cornerstone*, Jones Point Park

*Amherst County*

Pedlar Mills vicinity, *Red Hill Farm*, W of Oedlar Mills on VA 647

*Halfax County*

South Boston vicinity, *Seaton*, N of South Boston on U. S. 501

*King William County*

Manquin vicinity, *Horn Quarter*, NW of Manquin on VA 614

*Norfolk (independent city)*

*Wells Theatre*, Tazewell St. and Monticello Ave.

**WISCONSIN**

*Burnett County*

Grantsburg, *Burnett County Abstract Company*, 214 N. Oak St.

*Dane County*

Madison, *Plouth Inn*, 3402 Monroe St.
Madison, *Thorstrand*, 1–2 Thorstrand Rd.
Madison Vicinity, *McCoy Farmhouse*, S of Madison at 2925 Syene Rd.

*Dodge County*

Richwood, *St. Joseph's Roman Catholic Church*, WI Q and Rich Rd.

*Milwaukee County*

Wauwatosa, *Sunnyhill Home*, 8000 W. Milwaukee Ave.

*Sawyer County*

Hayward, *North Wisconsin Lumber Company Office*, Florida Ave.

[FR Doc. 80-11728 Filed 4-21-80; 8:45 am]
BILLING CODE 4310-03-M

## Water and Power Resources Service

### Versippi Unit, North Dakota—Pick-Sloan Missouri Basin Program; Notice of Intent To Prepare an Environmental Impact Statement

Pursuant to Section 102(2)(C) of the National Environmental Policy Act of 1969, the Department of the Interior proposes to prepare an Environmental Impact Statement for Versippi Dam and Reservoir located on Green River about 7 miles northeast of the city of Dickinson, North Dakota.

Versippi Dam and Reservoir would be a multipurpose water resource project. The reservoir would provide municipal water for Dickinson and would include recreation and fish and wildlife developments.

Versippi Dam would be an earthfill structure about 3,300 feet long with a crest width of 30 feet and a maximum height of 81 feet. The upstream face of the embankment would have a 3-foot layer of rock riprap.

The auxiliary spillway, excavated through a saddle in the left abutment area, would be a grasslined open channel that would operate only for reservoir flood inflows exceeding a 100-year frequency. This spillway would be 1,000 feet wide and about 2,500 feet long.

Versippi Reservoir would have an active conservation capacity of 12,500 acre-feet, 100 year sediment storage of 2,300 acre-feet, dead storage of 1,000 acre-feet, and a 6,000 acre-feet firm annual yield to the city of Dickinson. The reservoir would be about 4 miles long, extending north and west from the damsite. About 4,200 acres of land will be required for the reservoir and dam.

The upper end of the reservoir upland area would be managed for wildlife. Camping and picknicking areas and related facilities would be constructed at the lower end of the reservoir. A fish stocking management program in the reservoir would be run by the North Dakota State Game and Fish Department.

Possible alternatives to constructing a dam on the Green River include: continued use of the existing facilities (Patterson Lake) which cannot meet projected water demands for the city, development of ground water supplies, and a buried pipeline from the Missouri River.

A scoping meeting was held August 7, 1979, in Dickinson, North Dakota.

Interested public entities and individuals may obtain information on the project and provide input to the draft environmental impact statement, which is expected to be completed in late 1980, by contacting: Richard McCabe, Biology Branch, Water and Power Resources Service, Missouri-Souris Projects Office, P.O. Box 1017, Bismarck, ND 58501, Telephone: FTS 783–4720, Commercial (701) 255–4011, Ext. 720.

Dated: April 14, 1980.

Clifford I. Barrett,

*Assistant Commissioner of Water and Power.*

[FR Doc. 80-12014 Filed 4-21-80: 8:45 am]

BILLING CODE 4310-09-M

## INTERSTATE COMMERCE COMMISSION

### Permanent Authority Decisions; Decision-Notice

The following applications, filed on or after March 1, 1979, are governed by Special Rule 247 of the Commission's *Rules of Practice* (49 CFR § 1100.247). These rules provide, among other things, that a petition for intervention, either in support of or in opposition to the granting of an application, must be filed with the Commission within 30 days after the date notice of the application is published in the **Federal Register**. Protests (such as were allowed to filings prior to March 1, 1979) *will be rejected.* A petition for intervention without leave must comply with Rule 247(k) which requires petitioner to demonstrate that it (1) holds operating authority permitting performance of any of the service which the applicant seeks authority to perform, (2) has the necessary equipment and facilities for performing that service, and (3) has performed service within the scope of the application either (a) for those supporting the application, or, (b) where the service is not limited to the facilities of particular shippers, from and to, or between, any of the involved points.

Persons unable to intervene under Rule 247(k) may file a petition for leave to intervene under Rule 247(l) setting forth the specific grounds upon which it is made, including a detailed statement of petitioner's interest, the particular facts, matters, and things relied upon, including the extent, if any, to which petitioner (a) has solicited the traffic or business of those supporting the application, or, (b) where the identity of those supporting the application is not included in the published application notice, has solicited traffic or business identical to any part of that sought by applicant within the affected marketplace. The Commission will also consider (a) the nature and extent of the property, financial, or other interest of the petitioner, (b) the effect of the decision which may be rendered upon petitioner's interest, (c) the availability of other means by which the petitioner's interest might be protected, (d) the extent to which petitioner's interest will be represented by other parties, (e) the extent to which petitioner's participation may reasonably be expected to assist in the development of a sound record, and (f) the extent to which participation by the petitioner would broaden the issues or delay the proceeding.

Petitions not in reasonable compliance with the requirements of the rule may be rejected. An original and one copy of the petition to intervene shall be filed with the Commission indicating the specific rule under which the petition to intervene is being filed, and a copy shall be served concurrently upon applicant's representative, or upon applicant if no representative is named.

Section 247(f) provides in part, that an applicant which does not intend to timely prosecute its application shall promptly request that it be dismissed, and that failure to prosecute an application under the procedures of the Commission will result in its dismissal.

If an applicant has introduced rates as an issue it is noted. Upon request, an applicant must provide a copy of the tentative rate schedule to any protestant.

Further processing steps will be by Commission notice, decision, or letter which will be served on each party of record. *Broadening amendments will not be accepted after the date of this publication.*

Any authority granted may reflect administrative acceptable restrictive amendments to the service proposed below. Some of the applications may have been modified to conform to the Commission's policy of simplifying grants of operating authority.

*Findings*

With the exception of those applications involving duly noted problems (e.gs., unresolved common control, unresolved fitness questions, and jurisdictional problems) we find, preliminarily, that each common carrier applicant has demonstrated that its proposed service is required by the present and future public convenience and necessity, and that each contract carrier applicant qualifies as a contract carrier and its proposed contract carrier service will be consistent with the public interest and the transportation policy of 49 U.S.C. § 10101. Each applicant is fit, willing, and able properly to perform the service proposed and to conform to the requirements of Title 49, Subtitle IV, United States Code, and the Commission's regulation. Except where specifically noted, this decision is neither a major Federal action significantly affecting the quality of the human environment nor a major regulatory action under the Energy Policy and Conservation Act of 1975.

In those proceedings containing a statement or note that dual operations are or may be involved we find, preliminarily and in the absence of the issue being raised by a petitioner, that the proposed dual operations are consistent with the public interest and the transportation policy of 49 U.S.C. § 10101 subject to the right of the Commission, which is expressly reserved, to impose such terms, conditions or limitations as it finds necessary to insure that applicant's operations shall conform to the provisions of 49 U.S.C. § 10930(a) [formerly section 210 of the Interstate Commerce Act].

In the absence of legally sufficient petitions for intervention filed within 30 days of publication of this decision-notice (or, if the application later becomes unopposed), appropriate authority will be issued to each applicant (except those with duly noted problems) upon compliance with certain requirements which will be set forth in a notification of effectiveness of the decision-notice. To the extent that the authority sought below may duplicate an applicant's other authority, such duplication shall be construed as conferring only a single operating right.

Applicants must comply with all specific conditions set forth in the following decision-notices within 30 days after publication or the application shall stand denied.

**Note.**—All applications are for authority to operate as a common carrier by motor vehicle, in interstate or foreign commerce over irregular routes, except as otherwise noted.

**Volume No. 72**

Decided: April 1, 1980.

By the Commission, Review Board Number 3, Members Parker, Fortier and Hill.

MC 3005 (Sub-11F), filed January 9, 1980. Applicant: CHICAGO KANSAS CITY FREIGHT LINE, INC., 1200 Power & Light Building, 106 West 14th St., Kansas City, MO 64105. Representative: Frank W. Taylor, Jr., 1221 Baltimore Ave., Suite 600, Kansas City, MO 64105. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), between points in Champaign, Dewitt, Ford, Iroquois, Kankakee, LaSalle, Livingston, Marshall, McLean, Peoria, Piatt, Tazewell, Vermilion and Woodford Counties, IL. (Hearing site: Kansas City, MO.)

MC 8535 (Sub-111F), filed January 8, 1980. Applicant: GEORGE TRANSFER AND RIGGING COMPANY, INC., P.O. Box 500, Parkton, MD 21120. Representative: John Guandolo, 1000 Sixteenth Street, NW., Washington, DC

20036. Transporting *air conditioning and heating equipment* from the facilities of Miller Picking Corp., at or near Davidsville, PA, to points in IL, IN, and MI. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 13134 (Sub-85F), filed January 7, 1980. Applicant: GRANT TRUCKING, INC., Box 256, Oak Hill, OH 45656. Representative: James M. Burtch, 100 East Broad St., Suite 1800, Columbus, OH 43215. Transporting *iron and steel articles,* from Huntington, WV, to points in AZ, CA, CO, DE, DC, ID, IA, KY, ME, MD, MA, MN, MO, NV, MT, NE, NH, NJ, NM, NC, ND, OH, OR, RI, SD, UT, VT, VA, WA, WV, and WY. (Hearing site: Charleston, WV, or Columbus, OH.)

MC 52704 (Sub-266F), filed January 7, 1980. Applicant: GLENN McCLENDON TRUCKING COMPANY, INC., Post Office Drawer "H" LaFayette, AL 36862. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. Transporting (a) *containers, container ends and closures,* (b) *such commodities as are dealt in by manufacturers and distributors of containers,* in mixed loads with containers, and (c) *materials, equipment and supplies* used in the manufacture and distribution of containers, container ends and closures, between those points in the United States in and east of MN, IA, MO, OK, and TX, restricted, (1) against the transportation of commodities in bulk in tank vehicles, and (2) to the transportation of traffic originating at facilities of Kerr Glass Manufacturing Corporation. (Hearing site: Atlanta, GA.)

MC 53965 (Sub-172F), filed January 7, 1980. Applicant: GRAVES TRUCK LINE, INC., 2130 South Ohio, P.O. Drawer 1387, Salina, KS 67401. Representative: Bruce A. Bullock (same address as applicant). Over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk and those requiring special equipment) between Dallas, TX, and Houston, TX, over Interstate Hwy 45, serving no intermediate points. (Hearing site: Houston, TX, or Oklahoma City, OK.)

Note.—Applicant intends to tack this authority.

MC 83835 (Sub-166F), filed January 8, 1980. Applicant: WALES TRANSPORTATION, INC., P.O. Box 226186, Dallas, TX 75266. Representative: James W. Hightower, 5801 Marvin D. Love Freeway, Suite 301, Dallas, TX 75237. Transporting (1) *contractors and industrial equipment,* (2) *self-propelled articles and* (3) *parts, materials, and supplies* used in the distribution and manufacture of commodities described in (1) and (2) above (except commodities in bulk), between the facilities of Joy Manufacturing Company at Franklin, PA, Birmingham, AL, Claremont, NH, Buffalo, NY, Michigan City, IN, Wilson, NC, New Philadelphia, OH, Colorado Springs and Denver, CO, and Wheeling, WV, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Joy Manufacturing Company. (Hearing site: Pittsburgh, PA, or Washington, D.C.)

MC 85934 (Sub-112F), filed January 9, 1980. Applicant: MICHIGAN TRANSPORTATION COMPANY, a corporation, 3601 Wyoming, P.O. Box 248, Dearborn, MI 48120. Representative: Martin J. Leavitt, 22375 Haggerty Rd, P.O. Box 400, Northville, MI 48167. Transporting *chemicals,* in bulk, in tank vehicles, from the facilities of BASF Wayandotte Corporation at or near Chicago, IL, to points in the United States (except AK and HI). (Hearing site: Chicago, IL, or Washington, D.C.)

MC 105045 (Sub-140F), filed January 7, 1980. Applicant: R. L. JEFFRIES TRUCKING CO., INC., 1020 Pennsylvania St., Evansville, IN 47701. Representative: Paul F. Sullivan, 711 Washington Building, Washington, DC 20005. Transporting *iron and steel articles* between the facilities of FabArc Steel Supply, Inc., at or near Oxford, AL, on the one hand, and, on the other, points in the United States in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Atlanta, GA, or Washington, D.C.)

MC 106074 (Sub-142F), filed January 8, 1980. Applicant: B AND P MOTOR LINES, INC., Shiloh Road and U.S. Hwy 221 South, Forest City, NC 28043. Representative: Clyde W. Carver, P.O. Box 720434, Atlanta, GA 30328. Transporting (1) *chemicals, esters, fatty alcohol, coconut oil, softeners, liquid cleaning and washing compounds, lubrication oils, and wax and fireproofing compounds,* (except in bulk), and (2) *materials and supplies* used in the manufacture and sale of the commodities in (1), (except in bulk) between Mauldin, SC, Lock Haven, PA, Linden, NJ, and Santa Fe Springs, CA, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Atlanta, GA, or Washington, D.C.)

MC 107515 (Sub-1317F), filed January 9, 1980. Applicant: REFRIGERATED TRANSPORT CO. INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, NE., 5th Floor, Lenox Towers South, Atlanta, GA 30326. Transporting *foodstuffs,* and *milk replace* (except in bulk), from Hudson, IA, and points in MN and WI, to points in AL, AR, AZ, CA, CO, CT, DE, FL, GA, ID, KY, LA, ME, MD, MA, MI, MS, MT, NH, NJ, NM, MY, NC, NV, OH, OK, OR, PA, RI, SC, TN, TX, UT, VT, VA, WA, WV, WY, and DC, restricted to the transportation of traffic originating at the facilities utilized by Land O'Lakes, Inc., and destined to points in the named States. (Hearing site: Minneapolis, MN.)

Note.—Dual operations may be involved.

MC 107515 (Sub-1318F), filed January 9, 1980. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road NE., 5th Floor—Lenox Towers South, Atlanta, GA 30326. Transporting refined sugar, except in bulk, from Gramercy, LA, to points in the United States in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: New Orleans, LA.)

Note.—Dual operations may be involved.

MC 107544 (Sub-153F), filed January 9, 1980. Applicant: LEMMON TRANSPORT COMPANY, INCORPORATED, P.O. Box 580, Marion, VA 24354. Representative: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 Eleventh St. NW., Washington, DC 20001. Transporting *chemicals,* in bulk, in tank vehicles, (1) between Atlanta, GA and Garyville, LA, on the one hand, and, on the other, points in KY, MD, NC, OH, PA, SC, TN, VA and WV, (2) between Garyville, LA, on the one hand, and, on the other, points in GA, and (3) between Muscle Shoals, AL, on the one hand, and, on the other, points in MD, NC, OH, PA, and SC. (Hearing site: Washington, DC.)

MC 111594 (Sub-90F), filed January 2, 1980. Applicant: C W TRANSPORT, INC., 610 High St., Wisconsin Rapids, WI. Representative: Edward G. Bazelon, 39 South La Salle St., Chicago, IL 60603. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), from the facilities of Richards Oil Co., at or near Savage, MN, to points in WI and the Upper Peninsula of MI, restricted to the transportation of shipments originating at the facilities of Richards Oil Company, at or near Savage, MN. (Hearing site: St. Paul, MN, or Chicago, IL.)

MC 112304 (Sub-233F), filed January 8, 1980. Applicant: ACE DORAN HAULING & RIGGING CO., 1601 Blue Rock St., Cincinnati, OH 45223. Representative: John G. Banner (same

address as applicant). Transporting (1) *metal articles,* between Aberdeen, NC, on the one hand, and, on the other, points in the United States (except AK and HI), and (2) *equipment, materials and supplies* (except in bulk), used in the processing and distribution of metal articles, in the reverse direction. (Hearing site: Washington, DC.)

MC 114284 (Sub-89F), filed January 2, 1980. Applicant: FOX-SMYTHE TRANSPORTATION CO., 1700 S. Portland, P.O. Box 82307, Oklahoma City, OK 73108. Representative: John E. Jandera, 641 Harrison St., P.O. Box 1979, Topeka, KS 66601. Transporting *meats, meat products, meat by-products and articles distributed by meat-packinghouses,* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of Wilson Foods Corporation, at Cedar Rapids, Cherokee and Des Moines, IA, and Albert Lea, MN to points in CA, restricted to the transportation of traffic originating at the above named origins and destined to the named destinations. (Hearing site: Dallas, TX, or Kansas City, MO.)

MC 114965 (Sub-66F), filed January 7, 1980. Applicant: CYRUS TRUCK LINE, INC., P.O. Box 327, Iola, KS 66749. Representative: Charles H. Apt, 104 South Washington, Iola, KS 66749. Transporting *asphalt, asphalt cements, asphalt cutback and emulsified asphalt* from the facilities of Southern State Asphalt Company at or near Nevada, MO to points in KS. (Hearing site: Kansas City, MO, or Topeka, KS.)

MC 116325 (Sub-83F), filed January 7, 1980. Applicant: JENNINGS BOND d.b.a. BOND ENTERPRISES, P.O. Box 8, Lutesville, MO 63762. Representative: Jennings Bond (same address as applicant). Transporting *malt beverages,* from Detroit, MI and St. Paul, MN, to points in MO. (Hearing site: St. Louis, MO, or Memphis, TN.)

MC 121654 (Sub-37F), filed January 9, 1980. Applicant: COASTAL TRANSPORT & TRADING CO., P.O. Box 7438, Savannah, GA 31408. Representative: Alan E. Serby, 3390 Peachtree Road, NE., 5th Floor, Lenox Towers South, Atlanta, GA 30326. Transporting *air pollution equipment* (except that which because of size or weight requires the use of special equipment), from the facilities of Anderson 2000 at or near College Park, GA, to points in Kern, San Luis Obispo, Los Angeles, and Orange Counties, CA. (Hearing site: Atlanta GA.)

**Note.**—Dual operations may be involved.

MC 121654 (Sub-38F), filed January 9, 1980. Applicant: COASTAL TRANSPORT & TRADING CO., P.O. Box 7438, Savannah, GA 31408. Representative: Alan E. Serby, 3390 Peachtree Road, NE., 5th Floor, Lenox Towers South, Atlanta, GA 30326. Transporting *refined sugar,* except in bulk, from the facilities of Colonial Sugars, Borden, Inc., at or near Kenner and Grammercy, LA, to points in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: New Orleans, LA.)

**Note.**—Dual operations may be involved.

MC 121795 (Sub-2F), filed January 8, 1980. Applicant: LAKESHORE WAREHOUSE, INC, 5151 Bellevue, Detroit, MI 48211. Representative: William B. Elmer, 21635 East Nine Mile Rd., St. Clair Shores, MI 48080. Transporting *commodities in bulk,* between points in MI, on the one hand, and, on the other, points in IL, IN, MI, and OH. (Hearing site: Lansing, MI.)

MC 123294 (Sub-74F), filed January 8, 1980. Applicant: WARSAW TRUCKING CO., INC., Sawyer Center, Route 1, Chesterton, IN 46304. Representative: H. E. Miller, Jr. (same address as applicant). Transporting *steel wire,* from Kouts, IN, to points in IL, MI, and OH. (Hearing site: Atlanta, GA.)

MC 124554 (Sub-41F), filed January 9, 1980. Applicant: LANG CARTAGE CORP., P.O. Box 1465, Waukesha, WI 53187. Representative: Richard C. Alexander, 710 N. Plankinton Ave., Milwaukee, WI 53203. *Contract carrier,* transporting *commercial and hobby art and paint materials, supplies, and equipment,* from New Berlin, WI, to points in IA, MN, and the Upper Peninsula of MI, under continuing contracts with Tri-County Art & Paint, Inc., of New Berlin, WI. (Hearing site: Milwaukee, WI, or Chicago, IL.)

MC 124774 (Sub-125F), filed January 8, 1980. Applicant: MIDWEST REFRGERATED EXPRESS, INC., 4440 Buckingham Ave., Omaha, NE 68107. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Rd., Omaha, NE 68106. Transporting *iron and steel articles,* from Chicago, IL, to the facilities of Walker Manufacturing, Inc., at Seward, NE. (Hearing site: Omaha, NE.)

MC 126514 (Sub-64F), filed January 7, 1980. Applicant: SCHAEFFER TRUCKING, INC., 5200 West Bethany Home Rd., Glendale, AZ 85301. Representative: Leonard R. Kofkin, 39 South La Salle St., Chicago, IL 60603. Transporting *photographic apparatus, equipment, materials, supplies, and products used for photographic application, manufacturing, or processing* (except commodities in bulk); (a) between the facilities of Eastman Kodak Company at Rochester, NY, on the one hand, and, on the other, Lyoth, Los Angeles, Oakland, Palo Alto, San Francisco, Travis Air Force Base, Sunnyvale, and South San Francisco, CA; (b) between the facilities of Eastman Kodak Company at Windsor, CO, on the one hand, and, on the other, Lyoth, Los Angeles, Oakland, Palo Alto, San Francisco, Travis Air Force Base, Sunnyvale, and South San Francisco, CA; (b) between the facilities of Eastman Kodak Company at Whittier, CA on the one hand, and, on the other, Phoenix, AZ, restricted to the transportation of traffic originating at or destined to the facilities of Eastman Kodak Company at Rochester, NY, Windsor, CO, and Whittier, CA. (Hearing site: Buffalo, NY.)

MC 126514 (Sub-65F), filed January 7, 1980. Applicant: SCHAEFFER TRUCKING, INC., 5200 West Bethany Home Rd., Glendale, AZ 85301. Representative: Leonard R. Kofkin, 39 South La Salle St., Chicago, IL 60603. Transporting *commodities as are dealt in or used by manufacturers and convertors of paper and paper products* (except commodities in bulk) between the facilities of Georgia-Pacific Corporation at Lyons Falls, Long Island, Plattsburgh, Thomson and Warwick, NY, Cincinnati, OH, Burlington, IA, Gary, IN, Gilman, VT, Hamlet, NC, Kalamazoo, MI, Lockport and Taylorsville, IL, Palatka, FL, Pine Bluff, AR, Reading, PA, Richmond, VA, St. Louis, MO, Tomahawk, WI, Woodland, ME, and Bellingham, WA, on the one hand, and, on the other, points in the United states (except AK and HI). (Hearing site: New York, NY.)

MC 126514 (Sub-66F), filed January 7, 1980. Applicant: SCHAEFFER TRUCKING, INC., 5200 West Bethany Home Rd., Glendale, AZ 85301. Representative: Leonard R. Kofkin, 39 South La Salle St., Chicago, IL 60603. Transporting *costume jewelry* from the facilities of Avon Products, Inc., at Suffern, NY, Mansfield, MA, and Hoboken, NJ, to Pasadena, CA. (Hearing site: New York, NY.)

MC 133095 (Sub-288F), filed January 2, 1980. Applicant: TEXAS CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Ron Duncan (same address as applicant). Transporting *aluminum and aluminum products, zinc and zinc products, copper and copper products, and other non-ferrous products* from the facilities used by Gulf Reduction Division (1) at or near Houston, TX, to points in OK, AR, KS,

TN, KY, LA, MS, AL, GA, IL, CO, and OH, and (2) from points in GA and AL to points in TX. (Hearing site: Dallas, TX.)

MC 133095 (Sub-289F), filed January 8, 1980. Applicant: TEXAS CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Ron Duncan (same address as applicant). Transporting *alcoholic liquors (except in bulk), and materials, equipment and supplies used in the manufacture and distribution of* the foregoing commodities, between Fort Smith, AR, Bardstown, and Louisville, KY, New Orleans, LA, Plainfield, IL, and points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to facilities of Hiram Walker & Sons, Inc. Hearing site: Dallas, TX.)

MC 135895 (Sub-79F), filed January 8, 1980. Applicant: B & R DRAYAGE, INC., P.O. Box 8534, Battlefield Station, Jackson, MS 39204. Representative: Douglas C. Wynn, P.O. Box 1295, Greenville, MS 38701. Transporting *malt beverages* (except in bulk), from Longview, TX, to points in LA; (2) from Perry and Albany, GA, and Eden, NC, to points in LA and MS; and (3) between Memphis, TN, and Greenwood, MS. (Hearing site: New Orleans, LA or Jackson, MS.)

MC 136315 (Sub-105F), filed January 8, 1980. Applicant: OLEN BURRAGE TRUCKING, INC., Route 9, Box 28, Philadelphia, MS 39305. Representative: Fred W. Johnson, Jr., P.O. Box 22628, Jackson, MS 39205. Transporting *iron and steel articles, and metal and battery scrap,* between points in the United States in and east of TX, OK, KS, NE, IA, and MN, restricted to the transportation of traffic originating at or destined to the facilities utilized by Commercial Metal Company. (Hearing site: Dallas, TX, or Washington, DC.)

Note.—Dual operations may be involved.

MC 136315 (Sub-106F), filed January 8, 1980. Applicant: OLEN BURRAGE TRUCKING, INC., Route 9, Box 28, Philadelphia, MS 39305. Representative: Fred W. Johnson, Jr., P.O. Box 22628, Jackson, MS 39205. Transporting *wire and wire products, and fence and fencing materials* from the facilities of Bekaert Steel Wire Corporation, at or near Van Buren, AR, to points in the United States in and east of TX, OK, KS, NE, SD and ND; and (2) *equipment, materials and supplies* (except in bulk, in tank vehicles) used in the manufacture, production and distribution of the commodities named in (1) above in the reverse direction, restricted to the transportation of traffic originating at or destined to the facilities of Bekaert Steel Wire Corporation. (Hearing site: Little Rock, AR, or Washington, DC.)

Note.—Dual operations may be involved.

MC 138635 (Sub-101F), filed January 8, 1980. Applicant: CAROLINA WESTERN EXPRESS, INC., P.O. Box 3995, Gastonia, NC 28052. Representative: W. C. Sutton (same address as applicant). Transporting *foodstuffs, except in bulk,* from Albany, GA, to points in AZ, CA, CO, FL, GA, IL, IN, LA, MA, MD, MI, MN, MO, NC, NJ, OH, OR, PA, TN, TX, UT, restricted to the transportation of traffic originating at the facilities of M&M/Mars, Snack-Master Division at Albany, GA. (Hearing site: Albany, GA, or Washington, DC.)

MC 136315 (Sub-107F), filed January 8, 1980. Applicant: OLEN BURRAGE TRUCKING, INC., Route 9, Box 28, Philadelphia, MS 39350. Representative: Fred W. Johnson, Jr., P.O. Box 22628, Jackson, MS 39205. Transporting *building materials (except in bulk),* from the facilities utilized by R. W. Smith Company, Inc., in Galveston County, TX, to those points in the US in and east of TX, OK, KS, NE, SD, and ND (except ME, VT, and NH). (Hearing site: Galveston, TX, or Washington, DC.)

Note.—Dual operations may be involved.

MC 138875 (Sub-269F), filed January 8, 1980. Applicant: SHOEMAKER TRUCKING COMPANY, a corporation, 11900 Franklin Rd., Boise, ID 83709. Representative: F. L. Sigloh (same address as applicant). Transporting (1) *building materials,* (except in bulk), (2) *lumber, lumber mill products, wood products and composition board,* and (3) *iron and steel articles,* between points in CA, CO, ID, MT, NV, OR, UT, WA, and WY. (Hearing site: Boise, ID, or Washington, DC.)

MC 139495 (Sub-519F), filed January 9, 1980. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th Street, P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwick Lane, Silver Spring, MD 20910. Transporting *flour, corn meal, and flaked potatoes* (except commodities in bulk), (1) from Decatur, AL, to points in AR, LA and TX, and (2) from Sherman, TX, to points in AL, AR, CO, KS, LA, MS, MO, and OK. (Hearing site: Washington, DC.)

MC 140914 (Sub-5F), filed January 7, 1980. Applicant: DOBSON TRUCKING, INC., P.O. Box 498, Dobson, NC 27017. Representative: Eric Meierhoefer, Suite 423, 1511 K St., N.W., Washington, DC. 20005. Transporting *fertilizer, fertilizer products and fertilizer materials,* between points in NC and SC on the one hand, and, on the other, points in VA, WV, TN, NC, and SC. (Hearing site: Greensboro, NC.)

MC 141804 (Sub-333F), filed January 3, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *vehicle parts and accessories, and motorcycles,* between Seattle, WA, Bedford Park and Chicago, IL, Los Angeles, CA, Columbus and Marysville, OH, Jacksonville, FL, Baton Rouge, LA, Newark, NJ, and Baltimore, MD. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-336F), filed January 7, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *chemicals,* except in bulk, between Long Island City, NY, Palisades Park, NJ, Rolling Meadows and Chicago, IL, Los Angeles and San Francisco, CA, Dallas, TX, Berea and Cleveland, OH, Atlanta, GA, Baton Rouge, LA, Mac Entosch, AL, and Chattanooga and Nashville, TN, restricted to the transportation of traffic originating at or destined to the facilities used by Philip A. Hunt Chemical Corporation. (Hearing site: Los Angeles, CA.)

MC 142715 (Sub-79F), filed January 2, 1980. Applicant: LENERTZ, INC., P.O. Box 479, South St. Paul, MN 55075. Representative: K. O. Patrick (same address as applicant). Transporting *such commodities as are dealt in or used by manufacturers and distributors of containers* (except commodities in bulk), from Solon, OH, to points in CO, ND, SD, NE, KS, MN, MO, IA, WI, IL, MI, IN, TN, SC, NC, GA, AL, FL and KY, restricted to the transportation of traffic originating at the named origin and destined to points in the named States. (Hearing site: Atlanta, GA, or St. Paul, MN.)

MC 142935 (Sub-11F), filed January 7, 1980. Applicant: PLASTIC EXPRESS, 2999 La Jolla St., Anaheim, CA 92806. Representative: Richard C. Celio, 2300 Camino del Sol, Fullerton, CA 92633. Transporting *such commodities and supplies as are dealt in or used by mining operations,* between points in the United States in and west of MT, NY, CO, OK, and TX. (Hearing site: Los Angeles, CA.)

MC 145955 (Sub-2F), filed January 8, 1980. Applicant: CENTRAL TRUCK SERVICE, INC., 4440 Buckingham Ave., Omaha, NE 68107. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Rd., Omaha, NE 68106. Transporting *electrical applicances and accessories,* from Franklin Park, IL, to Sioux City,

Des Moines, and Davenport, IA, Omaha, NE, Topeka, Wichita, Kansas City, KS, and Kansas City, MO. (Hearing site: Chicago, IL, or Omaha, NE.)

MC 146725 (Sub-8F), filed January 8, 1980. Applicant: FREEPORT TRANSPORT, INC., P.O. Box 27327, Salt Lake City, UT 84125. Representative: Bruce W. Shand, 430 Judge Building, Salt Lake City, UT 84111. Transporting *hardwood lumber and flooring,* from Nashville, TN, to Denver, CO, and Salt Lake City, UT. (Hearing site: Salt Lake City, UT.)

Note.—Dual operations may be involved.

MC 147285 (Sub-2F), filed January 8, 1980. Applicant: D. STARKS TRUCKING, INC., P.O. Box 365, La Salle, IL 61301. Representative: E. Stephen Heisley, 805 McLachlen Bank Bldg., 666 Eleventh St., NW., Washington, DC 20001. Transporting *agricultural chemicals,* and *materials* used in the manufacture of agricultural chemicals, between Morris and Seneca, IL, on the one hand, and, on the other, points in IN, MI, and WI. (Common control may be involved.) Condition: The person or persons appear to be engaged in common control of applicant and another regulated carrier must either file an application under section 49 U.S.C. § 11343(a), or submit an affidavit indicating why such approval is unnecessary. (Hearing site: Houston, TX, or Washington, DC.)

MC 147774 (Sub-3F), filed January 8, 1980. Applicant: SURE-WAY TRANSPORTATION, INC., 4000 I–70 Drive NW., Columbia, MO 65201. Representative: Peter A. Greene, 900 17th Street NW., Washington, DC 20006. Transporting *animal feed ingredients* from Minneapolis and Redwing, MN, to Montgomery City, MO. (Hearing site: Columbia, MO or Washington, DC.)

MC 148364 (Sub-2F), filed January 8, 1980. Applicant: COOPER AIR FREIGHT SERVICE, INC., 2710 Barris Dr., Memphis, TN 38132. Representative: Henry E. Cooper (same address as applicant). Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Memphis International Airport, Memphis, TN, and points in AR, restricted to the transportation of traffic having an immediately prior or subsequent movement by air. (Hearing site: Memphis, TN, or Little Rock, AR.)

MC 148735 (Sub-2F), filed January 7, 1980. Applicant: DONALD J. SWICEGOOD, Route 1, Box 292, Statesville, NC 28677. Representative: Ralph McDonald, P.O. Box 2246, Raleigh, NC 27602. Transporting *dry fertilizer and dry fertilizer materials,* between points in NC and SC, on the one hand, and, on the other, points in NC, SC, VA, WV, and in that part or TN on and east of Interstate Hwy 75. (Hearing site: Raleigh, NC.)

MC 149284F, filed January 7, 1980. Applicant: MARION D. DAY d.b.a. DAY'S EXPRESS, 1942 7th St., Columbus, IN 47201. Representative: Stephen M. Gentry, 1500 Main St., Speedway, IN 46224. Transporting *such commodities as are dealt in by retail department stores and hardware stores,* from the facilities of Lear Siegler, Inc., at or near Seymour, IN, and the facilities of Raaco Corporation, at or near Columbus, IN, to points in AZ, CA, CO, ID, NJ, NV, NY, OR, UT, WA, and ports of entry on the International boundary line between the United States and Canada located in MI. (Hearing site: Indianapolis, IN.)

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Decided: March 21, 1980.

By the Commission, Review Board Number 1, Members Carleton, Joyce, and Jones.

MC 30844 (Sub-676F), filed January 18, 1980. Applicant: KROBLIN REFRIGERATED XPRESS, INC., P.O. Box 21222, Tulsa, OK 74121. Representative: John P. Rhodes, P.O. Box 5000, Waterloo, IA 50704. Transporting *meats, meat products, and meat byproducts, and articles distributed by meat-packing houses,* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from Palestine, TX, to those points in the U.S. and east of OK, CO, NE, ND, SD, and in and north of AR, TN, and SC, restricted to the transportation of traffic originating at the facilities used by Vernon Calhoun Packing Co., at or near Palestine, TX. (Hearing site: Dallas, TX.)

MC 30844 (Sub-677F), filed January 21, 1980. Applicant: KROBLIN REFRIGERATED XPRESS, INC., P.O. Box 21222, Tulsa, OK 74121. Representative: John P. Rhodes, P.O. Box 5000, Waterloo, IA 50704. Transporting *alcoholic liquors, and materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (except in bulk in tank vehicles), (1) between Ft. Smith, AR, on the one hand, and, on the other, those points in the U.S. in and east of ND, SD, NE, CO, and TX, (2) between Bardstown and Louisville, KY, on the one hand, and, on the other, points in AR, GA, IL, IN, KY, MI, NY, NC, OH, PA, SC, TN, and WV (3) between New Orleans, LA, on the one hand, and, on the other, points in AL, AR, GA, MS, OK, and TX, and (4) between Plainfield, IL, on the one hand, and, on the other, points in CO, IN, IA, KS, MI, MN, MO, NE, ND, OK, and SD, restricted to the transportation of traffic originating at or destined to facilities of Hiram Walker & Sons, Inc. (Hearing site: Chicago, IL.)

MC 35334 (Sub-88F), filed January 28, 1980. Applicant: COOPER–JARRETT, INC., Hanover Plaza, Morristown, NJ 07960. Representative: William J. Hanlon (same address as applicant). Transporting *general commodities* (except those of unusual vaule, class A and B explosives, household goods as defined by the Commission, commodities in bulk, are commodities requiring special equipment), serving points in Orleans, Monroe, Ontario, Wayne Genesee, Seneca and Livingston Counties, NY as off-route points in connection with carrier's existing regular-route operations. Carrier intends to tack the authority here with its existing authority. (Hearing site: New York, NY, or Washington, DC.)

MC 52704 (Sub-267F), filed January 22, 1980. Applicant: GLENN McCLENDON TRUCKING CO., INC., P.O. Drawer "H", LaFayette, AL 36862. Representative: Archie B. Culbreth, Suite 202, 2200 Century Parkway, Atlanta, GA 30345. Transporting (1) *paper and pulpboard articles,* from the facilities of Sonoco Products Co., at or near Houston, Arlington and Longview, TX, to points in LA, MS, AR and OK, and (2) *materials, equipment and supplies* used in the manufacture or distribution of commodities named in (1) above (except commodities in bulk), in the reverse direction to TX. (Hearing site: Atlanta, GA.)

MC 58035 (Sub-25F), filed January 21, 1980. Applicant: TRANS-WESTERN EXPRESS, LTD., 48 East 56th Ave., Denver, CO 80216. Representative: Paul D. Amen (same address as applicant). Transporting *construction materials, equipment and supplies,* between points in CO, WY, MT, SD, and ND. (Hearing site: Denver, CO.)

MC 59655 (Sub-38F), filed January 17, 1980. Applicant: SHEEHAN CARRIERS, INC., 62 Lime Kiln Road, Suffern, NY 10901. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Transporting (1) *foodstuffs, and materials, equipment, and supplies* used in the manufacture and sale of foodstuffs (except commodities in bulk), (1) between Millsboro, DE, on the one hand, and, on the other, points in ME, NH, VT, MA, CT, RI, NJ, NY, PA, OH, MD, VA, and DC; (2) between Seaford,

DE, on the one hand, and, on the other, points in ME, VT, NH, MA, CT, RI, NJ, NY, PA, OH, MD, VA, DC, and Greenville, MS; (3) between Greenville, MS; and Imlay City, Bridgeport, and Memphis, MI, on the one hand, and, on the other, those points in the U.S. in and east of MN, IA, MO, KS, OK, and TX. (Hearing site: Detroit, MI, or Washington, DC.)

MC 60014 (Sub-173F), filed January 17, 1980. Applicant: AERO TRUCKING, INC., P.O. Box 308, Monroeville, PA 15146. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Transporting *iron and steel articles,* from Darlington, SC, to points in the U.S. on and east of a line beginning at this mouth of the Mississippi River, and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, thence northward along the western boundaries of Itasca and Kooching Counties, MN, to the international boundary line between the U.S. and Canada. (Hearing site: Washington, DC.)

MC 61825 (Sub-125F), filed January 18, 1980. Applicant: ROY STONE TRANSFER CORP., V.C. Drive, P.O. Box 385, Collinsville, VA 24078. Representative: John D. Stone (same address as applicant). Transporting (1) *salt and salt products, in containers,* (2) *pepper, in containers, in mixed loads with salt in containers,* and (3) *materials and supplies used in the agricultural, water treatment, food processing, wholesale grocery, and institutional supply industries, in mixed loads with salt, in containers* from (1) Jefferson Island and Weeks, LA, to points in AL, FL, GA, KY, MS, NC, SC, and TN and from (2) Watkins Glen, NY, to points in VA, north and east of a line beginning at the WV–VA State line and extending along U.S. Hwy 60 to junction U.S. Hwy 15, and then along U.S. Hwy 15 to the VA–NC State line. (Hearing site: Washington, DC.)

MC 95084 (Sub-158F), filed January 18, 1980. Applicant: HOVE TRUCK LINE, a corporation, Stanhope, IA 50246. Representative: Kenneth F. Dudley, 1501 East Main, P.O. Box 279, Ottumwa, IA 52501. Transporting *digger, derricks and aerial buckets,* between points in the U.S., (except AK, and HI) restricted to the transportation of traffic originating at or destined to the facilities of Telect, Inc., and its dealers. (Hearing site: Minneapolis, MN, or Chicago, IL.)

MC 106674 (Sub-457F), filed January 17, 1980. Applicant: SCHILLI MOTOR LINES, INC., P.O. Box 123, Remington, IN 47977. Representative: Jerry L. Johnson (same address as applicant). Transporting (1) *plastic articles and polystyrene products,* and (2) *materials, equipment and supplies* used in the manufacture, installation and distribution of the commodities named in (1), between the facilities of U.C. Industries, at (a) Tallmadge, OH, and (b) Rockford, IL, on the one hand, and, on the other, those points in the U.S. in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Chicago, IL, or Indianapolis, IN.)

MC 107295 (Sub-963F), filed January 21, 1980. Applicant: PRE-FAB TRANSIT CO., a corporation, P.O. Box 146, Farmer City, IL 61842. Representative: Todd A. Peterman (same address as applicant). Transporting *steel wire rod, and wire rod coils and bars,* from Saukville, WI, to points in MN, IA, MO, IL, MI, IN, OH, PA, NJ, and KY. (Hearing site: Chicago, IL.)

MC 107295 (Sub-969F), filed January 21, 1980. Applicant: PRE-FAB TRANSIT CO., a corporation, P.O. Box 146, Farmer City, IL 61842. Representative: Todd A. Peterman (same address as applicant). Transporting (1) *composition board,* from Phillips, WI, to points in the U.S. (except AK, and HI), and (2) *materials* used in the manufacturing and distribution of composition board (except commodities in bulk) in the reverse direction. (Hearing site: Minneapolis, MN.)

MC 107515 (Sub-1319F), filed January 22, 1980. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, N.E., 5th Floor, Lenox Towers South, Atlanta, GA 30326. Transporting (1) *such commodities dealt in or used* by Grocery Toy Stores (a) between the facilities used by Wetterau Incorporated, at or near (a) Keene, NH, (b) Charleston, SC, (c) Lexington, KY, (d) Greenville, KY, (e) Scott City, Desloge, Mexico, and Hazelwood, MO, (f) Bloomington, IN, and (g) Reading and Schuylkill Haven, PA; and (b) from points in the U.S. (except AK, and HI), to the facilities named in (a) above; and (2) *bakery products,* from the facilities used by Wetterau Incorporated, at or near (a) Atlanta, GA, and (b) Hazelwood, MO, to points in the U.S. (except AK, and HI) and (3) returned bakery products in the reverse directions. (Hearing site: Chicago, IL.)

**Note.**—Dual operations may be involved.

MC 107515 (Sub-1320F), filed January 22, 1980. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, N.E., 5th Floor, Lenox Towers South, Atlanta, GA 30326. Transporting (1) *foodstuffs,* and (2) *animal foods* (except commodities in bulk), from Napoleon, OH, to points in IL, IN, and MI. (Hearing site: Toledo, OH.)

**Note.**—Dual operations may be involved.

MC 107515 (Sub-1321F), filed January 22, 1980. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, N.E., 5th Floor, Lenox Towers South, Atlanta, GA 30326. Transporting *such commodities* as are dealt in by Department Stores (except commodities in bulk), between points in the U.S. (except AK, and HI) restricted to the transportation of traffic originating at or destined to the facilities of Target Stores (Division of Dayton-Hudson Corporation). (Hearing site: Minneapolis, MN.)

**Note.**—Dual operations may be involved.

MC 107515 (Sub-1322F), filed January 22, 1980. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, N.E., 5th Floor, Lenox Towers South, Atlanta, GA 30326. In foreign commerce only, transporting *malt beverages,* in containers, from ports of entry on the international boundary line between the U.S. and Canada in MI and NY, to points in the U.S. (except AK, and HI). (Hearing site: Buffalo, NY.)

**Note.**—Dual operations may be involved.

MC 109124 (Sub-101F), filed January 18, 1980. Applicant: SENTLE TRUCKING CORP., P.O. Box 7850, Toledo, OH 43619. Representative: James M. Burtch, 100 East Broad St., Suite 1800, Columbus, OH 43215. Transporting (1) *refractories, magnesite and magnesite products, lime, limestone, and limestone products* and (2) *materials, supplies and equipment* used in the manufacture, and installation of the commodities in (1) above, between the facilities of Basic Incorporated, in (a) Seneca County, OH (b) Gulf County, FL, and (c) Nye and Mineral Counties, NV, on the one hand, and, on the other, points in the U.S. (except AK, and HI). (Hearing site: Columbus, OH, or Washington, DC.)

MC 109124 (Sub-102F), filed January 18, 1980. Applicant: SENTLE TRUCKING CORP., P.O. Box 7850, Toledo, OH 43619. Representative: James M. Burtch, 100 East Broad St., Suite 1800, Columbus, OH 43215. Transporting (1) *adhesive, composition board, gypsum products, gypsum board paper, mineral fiber products, and paint and paint products,* (2) *building materials* (except those in (1) above), and (3) *materials, equipment, and supplies used in the manufacture, installation, and distribution* of the commodities named in (1) and (2) above,

between the facilities of United States Gypsum Company, at or near Gypsum, OH, on the one hand, and, on the other, points in AL, AR, CT, DE, FL, GA, IA, KS, LA, ME, MA, MN, MS, MO, NE, NH, NJ, NC, ND, OH, OK, RI, SC, SD, TN, TX, VT, VA, and DC. (Hearing site: Columbus, OH.)

MC 114284 (Sub-90F), filed January 18, 1980. Applicant: FOX-SMYTHE TRANSPORTATION CO., a corporation, 1700 S. Portland, P.O. Box 82307, Oklahoma City, OK 73108. Representative: John E. Janera, 641 Harrison St., Topeka, KS 66603. Transporting *meats, meat products, meat byproducts and articles distributed by meat-packing houses* (except hides and commodities in bulk), as defined in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766. from the facilities of Wilson Foods Corporation, at Marshall, MO, to points in CA, restricted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Oklahoma City, OK.)

MC 115654 (Sub-189F), filed January 17, 1980. Applicant: TENNESSEE CARTAGE CO., INC., P.O. Box 23193, Nashville, TN 37202. Representative: Henry E. Seaton, 929 Pennsylvania Bldg., 425 Thirteenth St., N.W., Washington, DC 20004. Transporting (1) *pipe covering, and rust preventative pipeline coating,* and *materials, supplies, and equipment* used in the manufacture of the commodities in (1) above between the facilities of The Kendall Company, at Franklin, KY, on the one hand, and, on the other, Los Angeles, CA, and Chicago, IL. (Hearing site: Nashville, TN.)

MC 116544 (Sub-197F), filed January 21, 1980. Applicant: ALTRUK FREIGHT SYSTEMS, INC., 1703 Embarcadero Rd., Palo Alto, CA 94303. Representative: Richard G. Lougee, P.O. Box 10061, Palo Alto, CA 94303. Transporting *non-frozen foodstuffs (except in bulk):* (a) from the facilities of Vlasic Foods, Inc. at Greenville, MS, to points in CO, FL, GA, IL, KS, LA, MO, NE, NM, OK, and TX; (b) between the facilities of Vlasic Foods, Inc. at Memphis, Bridgeport, Imlay City, MI; Millsboro, DE; Greenville, MS; and City of Industry, CA; (c) from the facilities of Vlasic Foods, Inc., at or near City of Industry, CA, to AZ, CO, OR, and WA, restricted in (b) above, against the transportation of traffic moving between points in MI. (Hearing site: San Francisco, CA, or Chicago, IL.)

MC 119875 (Sub-13F), filed January 17, 1980. Applicant: WAR-HUNT TRUCKING CO., INC., R.D. 3, P.O. Box 92–A, Allentown, PA 18104. Representative: Walter K. Swartzkopf, Jr., 407 North Front St., Harrisburg, PA 17101. Transporting *paper and paper products,* from the facilities of Diamond International Corporation, in (1) Canton, Hyde Park, Palmer, Norwood, and Springfield, MA, on the one hand, and, on the other, points in DE, IL, IN, KY, MD, NJ, NY, OH, PA, TN, VA, and DC, (2) Cincinnati, Monroe, Dayton, Lockland, Middletown, and Norwood, OH, on the one hand, and, on the other, points in CT, DE, MD, MA, NJ, NY, PA, RI, KY, IN, IL, and DC, and (3) Morris, St. Charles, and Wilmington, IL, on the one hand, and, on the other, points in CT, DE, MD, MA, NJ, NY, PA, RI, KY, OH, IN, and DC. (Hearing site: Washington, DC, or Harrisburg, PA.)

MC 125335 (Sub-98F), filed January 22, 1980. Applicant: GOODWAY TRANSPORT, INC., P.O. Box 2283, York, PA 17405. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting (1) *bananas* and (2) *agricultural commodities* otherwise exempt from regulations under 49 U.S.C. § 10526(a)(6), in mixed loads with bananas, from Charleston, SC, to points in FL, GA, MD, NY, NC, PA, TN ,VA, and DC. Condition: The person or persons who appear to be engaged in common control of applicant and another regulated carrier must either file an application under 49 U.S.C. § 111343(a), or submit an affidavit indicating why such approval is unnecessary. (Hearing site: New York City, NY, or Dallas, TX.)

MC 126844 (Sub-89F), filed January 17, 1980. Applicant: R.D.S. TRUCKING CO., INC., 1713 North Main Rd., Vineland, NJ 08360. Representative: Kenneth F. Dudley, 1501 East Main St., P.O. Box 279, Ottumwa, IA 52501. Transporting *malt beverages,* in containers, from the facilities of Van Munching Company, at or near the New York, NY, to points in IA, IL, IN, KS, KY, MI, MN, MO, NE, OH, and WI. (Hearing site: New York, NY, or Philadelphia, PA.)

MC 126844 (Sub-90F), filed January 22, 1980. Applicant: R.D.S. TRUCKING CO., INC., 1713 North Main Rd., Vineland, NJ 08360. Representative: Kenneth F. Dudley, 1501 East Main St., P.O. Box 279, Ottumwa, IA 52501. Transporting *cleaning compounds, bleach, mops and brooms, mop parts,* from Chicago, IL, to points in CO, FL, GA, IL, MI, MN, MO, NJ, NY, OH, PA, RI, TN, and TX. (Hearing site: Cincinnati, or Columbus, OH.)

MC 126844 (Sub-91F), filed January 22, 1980. Applicant: R.D.S. TRUCKING CO., INC., 1713 North Main Rd., Vineland, NJ 08360. Representative: Kenneth F. Dudley, 1501 East Main St., P.O. Box 279, Ottumwa, IA 52501. Transporting *food* (except in bulk), between points in Cumberland County, NJ, on the one hand, and, on the other, points in DE, FL, IL, IN, KS, MD, NY, and PA. (Hearing site: Washington, DC.)

MC 128294 (Sub-12F), filed January 18, 1980. Applicant: NITEHAWK EXPRESS, INC., 2334 University Ave., St. Paul, MN 55114. Representative: Joseph J. Dudley, W–1260 First National Bank Bldg., St. Paul, MN 55101. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between points in the U.S. (except AK, and HI), restricted to the transportation of traffic originating at and or destined to the facilities used by The Pilsbury Company, Burger King Corporation, Green Giant Company, Poppin Fresh Pies, Inc., Steak and Ale Restaurants of America, Inc., LaChateau Restaurants, Henrici's Restaurants, and Hoffman House Restaurants, Inc. (Hearing site: Minneapolis, MN.)

Note.—Dual operations may be involved.

MC 133655 (Sub-203F), filed January 18, 1980. Applicant: TRANS-NATIONAL TRUCK, INC., 4601 Langland Rd., P.O. Box 402535, Dallas, TX 75240. Representative: Warren L. Troupe, 2480 E. Commercial Blvd., Fort Lauderdale, FL 33308. Transporting *sugar,* in containers, from the facilities of Colonial Sugars Company, at Gramercy, LA, to points in TX. (Hearing site: Chicago, IL.)

MC 134134 (Sub-61F), filed January 28, 1980. Applicant: MAINLINER MOTOR EXPRESS, INC., 4202 Dahlman Ave., Omaha, NE 68107. Representative: James F. Crosby, P.O. Box 37205, Omaha, NE 68137. Transporting *foodstuffs,* from Erie and North East, PA, to points in OH, MI, IN, KY, WI, IL, MN, IA, MO,and KS. (Hearing site: Columbus or Cleveland, OH.)

MC 135195 (Sub-5F), filed January 17, 1980. Applicant: STOVER AIR CARGO, INCORPORATED, 3830 Wisman Lane, Quincy, IL 62301. Representative: Leonard R. Kofkin, 39 South La Salle St., Chicago, IL 60603. Transporting *general commodities,* (except commodities in bulk, those of unusual value, classes A and B explosives, household goods as defined by the Commission and those requiring special equipment) between St. Louis, MO, and points in Des Moines, Henry, Jefferson, Johnson, Lee, Linn, Louisa, Muscatine, Wapello, and Washington Counties, IA; Adams, Cook, DuPage, Hancock, Henderson, Henry,

Knox, McDonough, Peoria, Pike, Tazewell, Warren, and Woodford Counties, IL; Lincoln, Lewis, Marion, Pike, Ralls, St. Louis, and Shelby Counties, MO; restricted to the transportation of traffic having an immediately prior or subsequent movement by air. (Hearing site: Chicago, IL, or St. Louis, MO.)

MC 135205 (Sub-2F), filed January 22, 1980. Applicant: P. RODNEY HOFFMAN, INC., 247 Hopewell St., Birdsboro, PA 19508. Representative: Raymond A. Thistle, Jr., Five Cottman Court, Homestead Road and Cottman St., Jenkintown, PA 19046. Transporting *sand,* from Maurice River Township, (Cumberland County), NJ, to the facilities of the Birdsboro Corporation, in Birdsboro, Berks County, PA, and to the facilities of Hoffman storage and Warehouse Company, in Exeter Township (Berks County) PA. (Hearing site: Reading or Philadelphia, PA.)

MC 136605 (Sub-143F), filed January 21, 1980. Applicant: DAVIS BROS. DIST., INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). Transporting *Building materials,* between points in ND, SD, NE, KS, MO, IA, MN, WI, IL, IN, and MI, restricted to the transportation of traffic originating at or destined to the facilities of Emmer distribution, Inc. (Hearing site: Billings, MT, or Minneapolis, MN.)

MC 139495 (Sub-520F), filed January 17, 1980. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th St., P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwich Lane, Silver Spring, MD 20910. Transporting *alcoholic liquors, materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (except commodities in bulk, in tank vehicles), between Ft. Smith, AR, Bardstown and Louisville, KY, New Orleans, LA, and Plainfield, IL, on the one hand, and, on the other, points in the U.S. (except AK, and HI) restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: Washington, DC.)

MC 139495 (Sub-523F), filed January 18, 1980. Applicant: NATIONAL CARRIERS, INC., 1501 East 8th St., P.O. Box 1358, Liberal, KS 67901. Representative: Herbert Alan Dubin, 1320 Fenwich Lane, Silver Spring, MD 20910. Transporting *frozen foodstuffs,* from Garden City, KS, and Amarillo, TX, to points in the U.S. (except AK, and HI). (Hearing site: Washington, DC.)

MC 143394 (Sub-3F), filed January 22, 1980. Applicant: GENIE TRUCKING LINE, INC., 70 Carlisle Springs Rd., P.O. Box 840, Carlisle, PA 17013. Representative: G. Kenneth Bishop (same address as applicant). *Contract carrier,* transporting *frozen vegetables,* from Caldwell, Heyburn, Nampa, ID, and Moses Lake, WA, to Mobile, AL, under a continuing contract(s) with Fruit Distributing Company, of Mobile, AL. (Hearing site: Harrisburg, PA, or Washington, DC.)

MC 144275 (Sub-4F), filed January 21, 1980. Applicant: JK EXPRESS, INC., P.O. Box 2508, Trenton, NJ 08690. Representative: Mel P. Booker, Jr., 110 South Columbus St., Alexandria, VA 22314. *Contract carrier,* transporting *sealers, in shipper-owned trailers,* from the facilities of Cosmicoat, Inc., at or near Ewing Township, NJ, to points in MD, DE, VA, NC, PA, NY, CT, and DC, under a continuing contract(s) with Cosmicoat, Inc., of Wooster, OH. (Hearing site: Trenton, NJ, or Washington, DC.)

MC 145015 (Sub-3F), filed January 22, 1980. Applicant: P.M.E. LTD., Box 181, Group 261, R.R. 2, Winnipeg, Manitoba, Canada R3C 2E6. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. *Contract carrier* in foreign commerce only transporting *used railroad ties,* from ports of entry on the international boundary line between the U.S. and Canada in MN and ND, to points in AZ and CA, under a continuing contract(s) with Altacon Traders, Ltd., of Edmonton, Alberta, Canada. (Hearing site: Minneapolis, or St. Paul, MN.)

Note.—Dual operations may be involved.

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Decided: March 15, 1980.

By the Commission, Review Board Number 1, Members Carleton, Joyce, and Jones.

MC 15735 (Sub-32F), filed January 31, 1980. Applicant: ALLIED VAN LINES, INC., 25th Ave. and Roosevelt Rd., Broadview, IL 60153. Representative: Ronald C. Nesmith (same address as applicant). Transporting *new furniture,* from the facilities of Crown Redwood Company, at Fortuna, CA, to points in CT, DE, MD, MA, MI, MO, RI, VA, WI, MN, CO, IL, OH, IN, PA, NY, NJ, and NE. (Hearing site: Chicago, IL, or Washington, DC.)

MC 106274 (Sub-30F), filed January 31, 1980. Applicant: RAEFORD TRUCKING COMPANY, a corporation, P.O. Box 219, Sanford, NC 27330. Representative: Edward G. Villalon, 1032 Pennsylvania Bldg., Pennsylvania Ave. & 13th St., N.W., Washington, D.C. 20004. Transporting *lumber* and *lumber products* from points in IN, KY, TN, and WV, to points in NC, SC, TN, VA, and Savannah, GA. (Hearing site: Charlotte, NC.)

MC 107515 (Sub-1324F), filed January 31, 1980. Applicant: REFRIGERATED TRANSPORT CO., INC., P.O. Box 308, Forest Park, GA 30050. Representative: Alan E. Serby, 3390 Peachtree Road, N.E., 5th Floor, Lenox Towers South, Atlanta, GA 30326. Transporting (1) *Alcoholic liquors* (except in bulk, in tank vehicles) and (2) *Materials, equipment* and *supplies* used in manufacture and distribution of the commodities in (1) above between the facilities of Hiram Walker & Sons, Inc., at or near (a) Ft. Smith, AR, (b) Bardstown, and Louisville, KY, (c) New Orleans, LA, and (d) Plainfield, IL, on the one hand, and, on the other, points in the U.S. (except AK, and HI) restricted to traffic originating at or destined to the facilities named above. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 114604 (Sub-92F), filed October 22, 1979, previously noticed in the **Federal Register** on March 25, 1980. Applicant: CAUDELL TRANSPORT, INC., P.O. Drawer I, Forest Park, GA 30050. Representative: Frank D. Hall, Suite 713, 3384 Peachtree Rd., NE., Atlanta, GA 30326. Transporting *frozen foodstuffs* (except in bulk), from Memphis and Rossville, TN, to points in AL, NC, SC, GA, MS, KY, VA, and WV. This republication corrects the territorial description which should read "* * * to points in AL, NC, SC, GA, LA, MS, KY, VA, and WV * * *." (Hearing site: Atlanta, GA.)

MC 115654 (Sub-191F), filed January 31, 1980. Applicant: TENNESSEE CARTAGE CO., INC., P.O. Box 231932, Nashville, TN 37202. Representative: Henry E. Seaton, 929 Pennsylvania Building, 425 Thirteenth St., N.W., Washington, DC 20004. Transporting *confectionery* and *confectionery products,* from the facilities of Charms Company, at or near Covington, IN, to points in AL, AR, GA, IL, IN, LA, MO, MS, and Kansas City, KA. (Hearing site: Freehold, NJ.)

MC 116254 (Sub-304F), filed January 30, 1980. Applicant: CHEM-HAULERS, INC., 118 E. Mobile St., P.O. Box 339, Florence, AL 35630. Representative: Walter Harwood, P.O. Box 15214, Nashville, TN 37215. Transporting *chemicals,* in bulk, in tank vehicles, from points in Humphreys and Maury Counties, TN, Muscle Shoals and Birmingham, AL, to points in DE, MD, MA, NJ, NY, and PA. (Hearing site: Nashville, TN, or Washington, DC.)

MC 117815 (Sub-333F), filed January 29, 1980. Applicant: PULLEY FREIGHT

LINES, INC., Representative: Jack H. Blanshan, Suite 200, 205 W. Touhy Ave., Park Ridge, IL 60068. Transporting *foodstuffs,* (except frozen foodstuffs and commodities in bulk), from the facilities of Ocean Spray Cranberries, Inc., at Sulphur Springs, TX, to points in AR, IA, IL, IN, KS, KY, LA, MO, MS, NE, OK, and TN, restricted to the transportation of traffic originating at the named origin and destined to the named destinations. (Hearing site: Chicago, IL, or Milwaukee, WI.)

MC 124174 (Sub-168F), filed January 28, 1980. Applicant: MOMSEN TRUCKING CO., a corporation, 13811 "L" Street, Omaha, NE 68137. Representative: Karl E. Momsen (same address as applicant). Transporting *iron and steel articles,* from Rock Falls and Sterling, IL, to points in MO, IA, SD, KS, OK, TX, CO, WI, MI, WY, ND, KY, OH, AR, TN, PA, NY, ID, and MT. (Hearing site: Chicago, IL, or Omaha, NE.)

MC 128685 (Sub-37F), filed January 30, 1980. Applicant: DIXON BROS., INC., P.O. Drawer 8, Newcastle, WY 82701. Representative: Jerome Anderson, 100 Transwestern Bldg., Billings, MT 59101. Transporting *coal treating oil, in bulk in tank vehicles,* from Billings, MT, to points in Campbell, Converse, Sheridan and Sweetwater Counties, WY, and Decker, MT. (Hearing site: Billings, MT, or Rapid City, SD.)

MC 134134 (Sub-59F), filed January 31, 1980. Applicant: MAINLINER MOTOR EXPRESS, INC., 4202 Dahlman Ave., P.O. Box 7439, Omaha, NE 68107. Representative: Lavern R. Holdeman, 521 South 14th St., Suite 500, P.O. Box 81849, Lincoln, NE 68501. Transporting *canned goods,* from the facilities of Federated Warehouse Company, at or near East Peoria, IL to points in IA, KS, MN, MO and NE. (Hearing site: East Peoria, IL, or Omaha, NE.)

MC 134134 (Sub-60F), filed January 30, 1980. Applicant: MAINLINER MOTOR EXPRESS, INC., 4202 Dahlman Ave., Omaha, NE 68107. Representative: James F. Crosby, P.O. Box 37205, Omaha, NE 68137. Transporting *foodstuffs,* from the facilities of Borden Foods, Division of Borden, Inc., at or near Wellsboro, PA and Syracuse, NY, to points in OH, MI, IN, KY, WI, IL, MN, IA, MO, SD, NE, KS, and CO. (Hearing site: Columbus or Cleveland, OH.)

MC 134604 (Sub-6F), filed January 30, 1980. Applicant: HOWARD DULLUM, Gardner, ND 58036. Representative: Kip B. H. Erickson, 502 First National Bank Bldg., Fargo, ND 58126. Transporting *anhydrous ammonia,* in bulk, in tank vehicles, from Benson, MN, to points in ND, and SD. (Hearing site: Fargo, ND, or Minneapolis, MN.)

MC 138875 (Sub-270F), filed January 31, 1980. Applicant: SHOEMAKER TRUCKING COMPANY, a corporation, 11900 Franklin Rd., Boise, ID 83709. Representative: F. L. Sigloh (same address as applicant). Transporting (1) *building and construction materials, and (2) materials and supplies used in the manufacture and distribution of construction materials (except in bulk),* between the facilities of The Celotex Corporation at or near Tracy, CA, on the one hand, and, on the other, those points in the United States in and west of MN, IA, MO, AR and LA (except AK and HI). (Hearing site: Washington, DC, or Boise, ID.)

MC 138875 (Sub-271F), filed January 31, 1980. Applicant: SHOEMAKER TRUCKING COMPANY, a corporation, 11900 Franklin Rd., Boise, ID 83709. Representative: F. L. Sigloh (same address as applicant). Transporting *binder and baler twine* from points in MN to points in ID, MT, OR, UT, WA and KY. (Hearing site: Portland, OR, or Boise, ID.)

MC 140024 (Sub-174F), filed January 21, 1980. Applicant: J. B. MONTGOMERY, INC., 5565 East 52nd Ave., Commerce City, CO 80022. Representative: Don L. Bryce (same address as applicant). Transporting *materials, equipment* and *supplies* used in the installation of carpeting, from points in CA, to Colorado Springs and Denver, CO. (Hearing site: Denver, or Colorado Springs, CO.)

MC 140294 (Sub-9F), filed January 17, 1980. Applicant: GENERAL FREIGHTS, INC., P.O. Box 1946, Middleburg Pike, Hagerstown, MD 21740. Representative: Edward N. Button, 580 Northern Ave., Hagerstown, MD 21740. Transporting *glassware, glass ceramic ware, laminated glassware and electric appliances, and parts and accessories therefor,* between the facilities of Corning Glass Works, at or near Greencastle, PA, on the one hand, and, on the other, Baltimore, MD, and Washington, DC. (Hearing site: Greencastle, PA.)

MC 140665 (Sub-85F), filed January 30, 1980. Applicant: PRIME, INC., Route 1, Box 115–B, Urbana, MO 65767. Representative: Clayton Geer, P.O. Box 786, Ravenna, OH 44266. Transporting *paper and paper products,* from the facilities of International Paper Company, at or near Camden, AR and Bastrop, LA, to points in CA, NM, OR, TX, and WA, restricted to traffic originating at the named facilities. (Hearing site: Washington, DC, or Columbus, OH.)

MC 140665 (Sub-86F), filed January 30, 1980. Applicant: PRIME, INC., Route 1, Box 115–B, Urbana, MO 65767. Representative: Clayton Geer, P.O. Box 786, Ravenna, OH 44266. Transporting *paper and paper products,* from the facilities of International Paper Company, at or near Gardiner, OR, to points in CA, restricted to traffic originating at the above facility. (Hearing site: Washington, DC, or Columbus, OH.)

MC 141245 (Sub-17F), filed January 22, 1980. Applicant: BARRETT TRUCKING CO., INC., 16 Austin Dr., Burlington, VT 05401. Representative: Brian L. Troiano, 918 16th St., N.W., Washington, DC 20006. Transporting *malt beverages,* from the facilities of the Miller Brewing Company, at or near Fulton, NY, to points in VT, and *empty malt beverage containers,* in the reverse direction. (Hearing site: Montpelier, VT, or Washington, DC.)

MC 141655 (Sub-6F), filed January 17, 1980. Applicant: TRANS-PHOS, INC., State Road 640 and Noralyn Mine Rd., P.O. Box 2026, Bartow, FL 33830. Representative: Dan R. Schwartz, 1729 Gulf Life Tower, Jacksonville, FL 32207. Transporting *phosphate rock,* in bulk, in dump vehicles, from Agricola, FL to Port Manatee, FL. (Hearing site: Tallahassee, or Tampa, FL.)

MC 141804 (Sub-339F), filed January 17, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *chemicals* and *products used in the manufacture of chemicals, resins, plasticizers, drugs, compounds, oil* and *products manufactured from grain and flour,* between points in the U.S. (except AK and HI) restricted to traffic originating at or destined to the facilities of Henkel Corp. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-341F), filed January 21, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *such commodities as are dealt in by retail stores* (except commodities in bulk), (1) from points in CT, MD, IL, IN, MA, MO, NJ, NY, OH, PA, TN, and TX, to points in AZ, MN, CO, MT, MI, OR, UT, WA, OH, SD, ND, MO, FL and WY, and (2) from points in CA, to points in AZ, CO, MT, MN, OR, UT, WA, MI, OH, SD, ND, MO, FL, and WY, restricted to traffic destined to the facilities of Modern Merchandising, Inc. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-342F), filed January 18, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE

RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *synthetic fiber yarn,* from Fresno, CA to Miami, FL. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-344F), filed January 28, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *modular acoustical panels* (except wall panels) from all points in and west of MN, IA, MO, AR, LA, (except in AK, HI, and CA). (Hearing site: Los Angeles.)

MC 141804 (Sub-345F), filed January 29, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *rolls and sheets of plastic and plastic articles,* from those points in the U.S. in and east of ND, SD, NE, KS, OK, and TX, to points in CA, OR, and WA. (Hearing site: Los Angeles. CA.)

MC 143095 (Sub-7F), filed January 23, 1980. Applicant: NEW ENGLAND TRANSPORT, INC., LTD., P.O. Box 27, Chester Depot, VT 05144. Representative: Brian S. Stern, 2425 Wilson Boulevard, Suite 367, Arlington, VA 22201. Transporting *iron and steel articles,* from the facilities of Raritan River Steel Company, at or near Perth Amboy, NY, to points in CT, DE, IL, IN, KY, MA, MD, MI, NC, NJ, NY, OH, PA, RI, SC, VA, and WV. (Hearing site: Newark, NJ, or Washington, DC.)

MC 143775 (Sub-139F), filed January 25, 1980. Applicant: PAUL YATES, INC., 6601 West Orangewood, Glendale, AZ 85301. Representative: Michael R. Burke (same address as applicant). Transporting *meats, meat products, and meat by products, and articles distributed by meat-packing houses,* as described in Sections A and C of Appendix I to the Report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides in bulk), from Phoenix, AZ, to Los Angeles, CA, Hartford and Plainfield, CT, Jacksonville, FL, Chicago, IL, New Orleans, LA, Boston, MA, New York, NY, and Houston, TX. (Hearing site: Phoenix, AZ or Los Angeles, CA.)

Note.—Dual operations may be involved.

MC 143775 (Sub-140F), filed January 25, 1980. Applicant: PAUL YATES, INC., 6601 West Orangewood, Glendale, AZ 85301. Representative: Michael R. Burke (same address as applicant). Transporting (1) *building hardware, tools, and home accessories and* (2) *materials and supplies used in the manufacture, sales and distribution thereof,* from points in CA, to points in and east of ND, SD, NE, KS, OK, and TX. (Hearing site: Los Angeles, CA or San Francisco, CA.)

Note.—Dual operations may be involved.

MC 143775 (Sub-143F), filed January 25, 1980. Applicant: PAUL YATES, INC., 6601 West Orangewood, Glendale, AZ 85301. Representative: Michael R. Burke (same address as applicant). Transporting *carpet strip and adhesives, and nails,* (1) from Asheville, NC, to points in the United States in and east of CO, ND, SD, NE, OK, and TX and (2) Savannah, GA, to Asheville, NC. (Hearing site: Los Angeles, CA or San Francisco, CA.)

Note.—Dual operations may be involved.

MC 145715 (Sub-13F), filed January 21, 1980. Applicant: BELL TRUCKING, INC., 2504 Industrial Park Rd., Van Buren, AR 72756. Representative: Elaine M. Conway, 10 S. LaSalle St., Chicago, IL 60603. Transporting *such commodities* as are dealt in by chain grocery and food business houses (except commodities in bulk in tank vehicles), from points in the United States (except AK and HI), to the facilities of Griffin Grocery Corporation, at Van Buren, AR, restricted to traffic originating and destined to the above-named points. (Hearing site: Chicago, IL.)

MC 145765 (Sub-7F), filed January 23, 1980. Applicant: WIEST TRUCKLINE, INC., 1305 Sixth Ave., S.W., Jamestown, ND 58401. Representative: William J. Gambucci, Suite M–20, 400 Marquette Ave., Minneapolis, MN 55402. Transporting (1) *frozen bread dough,* from the facilities of Dakota Bake & Serve located at or near Jamestown, ND, and Columbus, WI, to points in CO, ID, IL, IN, IA, KS, KY, MI, MN, MO, MT, NE, NV, ND, OH, OR, SD, UT, WA, WI, and WY; and (2) *materials, equipment and supplies used in the manufacture and distribution of frozen bread dough,* from points in IL, MN, MT, and WI to the facilities of Dakota Bake & Serve located at or near Jamestown, ND, and Columbus, WI. (Hearing site: Fargo, ND or Minneapolis, MN.)

MC 146074 (Sub-2F), filed January 28, 1980. Applicant: FORT TRANSFER CO., a corporation, 225 South Maple, Morton, IL 61550. Representative: Douglas G. Brown, The INB Center—Suite 555, One North Old State Capitol Plaza, Springfield, IL 62701. Transporting *liquid agricultural chemicals,* in bulk, from points in Peoria, Tazewell and McLean County, IL to points in IN, IA, MI, OH and WI. (Hearing site: Chicago, IL.)

MC 146645 (Sub-2F), filed January 21, 1980. Applicant: ELWYN NICE TRUCKING, INC., Route 1, Morrison, IL 61270. Representative: Albert A. Andrin, 180 North La Salle St., Chicago, IL 60601. Transporting (1) *anhydrous ammonia,* in bulk, in tank vehicles, and *feed and feed ingredients,* from points in IA to points in Whiteside County, IL, (2) *gardening equipment and supplies,* from Morrison, IL to points in IN, WI, MO, OK and KS, and (3) *feed and feed ingredients,* (a) from points in IA, WI, MN, MO and MI to Rock Falls and De Kalb, IL and Onslow, IA and (b) from Rock Falls and De Kalb, IL and Onslow, IA, to points in IA, WI, MO and IL. (Hearing site: Chicago, IL.)

MC 148914 (Sub-1F), filed January 24, 1980. Applicant: ASTRO MOTOR FREIGHT SYSTEM, INC., 6th and Iron, Salem, MO 65560. Representative: Frank W. Taylor, Jr., 1221 Baltimore Ave., Suite 600, Kansas City, MO 64105. Transporting *general commodities* (except household goods, commodities which because of size or weight require the use of special equipment, classes A and B explosives, and commodities in bulk) (1) between Kansas City, MO and Rolla, MO: (a) from Kansas City over U.S. Hwy 70 to junction U.S. Hwy 63, then over U.S. Hwy 63 to Rolla, MO, and return over the same route; (b) from Kansas City over U.S. Hwy 50 to its junction with U.S. Hwy 63, then over U.S. Hwy 63 to Rolla, MO and return over the same route; (2) between Kansas City, MO and Springfield, MO, serving Springfield, MO for purposes of joinder only: (a) from Kansas City over U.S. Hwy 71 to junction MO Hwy 7, then over MO Hwy 7 to junction MO Hwy 13, then over MO Hwy 13 to Springfield, MO, and return over the same route; (b) from Kansas City over U.S. Hwy 50 to junction MO Hwy 13, then over MO Hwy 13 to Springfield, MO, and return over the same route. (Hearing site: Springfield, MO.)

MC 149214 (Sub-1F), filed January 18, 1980. Applicant: TRANSPORT ASSOCIATES, INC., 3512 Rockville Road, Indianapolis, IN 46222. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240. Transporting *audio and audio-visual recording and playing systems, accessories and component parts therefor,* from the facilities of RCA Corporation, at Bloomington and Indianapolis, IN to points in IL, MI, KS, OK and MO . (Hearing site: Indianapolis, IN.)

MC 149295, filed January 18, 1980. Applicant: H & W HOTSHOT DELIVERY SERVICE, INC., 521 Freeport, Houston, TX 77015. Representative:

Theodore L. Jones, P.O. Box 65122, Baton Rouge, LA 70896. Transporting *pipe, pipe fittings, valves, mud pumps and parts, drilling rig electrical systems and parts,* and *iron or steel plate, sheets, bars, rods, angles, beams, structural shapes, forms* and *fittings,* between points in Harris, Fort Bend, Brazoria, Liberty, Chambers, Montgomery, Austin, Waller, Galveston, Jefferson and Orange Counties, TX, on the one hand, and, on the other, points in LA, and TX. (Hearing site: Houston, TX.)

MC 149315F, filed January 25, 1980. Applicant: MALCURIA BROS. INC., R. D. #2, Box 188, Geneva, NY 14456. Representative: Morton E. Kiel, Suite 1832, 2 World Trade Center, New York, NY 10048. Transporting *salt and salt products,* from Retsof, NY, to points in PA. (Hearing site: Scranton, PA, or Washington, DC.)

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Decided: March 4, 1980.

By the Commission, Review Board Number 2, Members Eaton, Liberman, and Jensen, Members Jenson not participating.

MC 4405 (Sub-622F), filed February 5, 1980. Applicant: DEALERS TRANSIT, INC., P.O. Box 236, Tulsa, OK 74101. Representative: Michael E. Miller, 502 First National Bank Bldg., Fargo, ND 58126. Transporting (1) *trucks* and *truck chassis,* and (2) *parts, attachments and accessories* for the commodities in (1) above, between Oshkosh, WI, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Milwaukee, WI.)

MC 14215 (Sub-82F), filed February 5, 1980. Applicant: SMITH TRUCK SERVICE, INC., 1118 Commerical, Mingo Junction, OH 43938. Representative: A. Charles Tell, 100 East Broad St., Columbus, OH 43215. Transporting *aluminum articles,* from the facilities of Kaiser Aluminum & Chemical Corporation, at or near Ravenswood, WV, to those points in the United States in and east of MN, IA, MO, AR, and TX. (Hearing site: Washington, DC.)

MC 26825 (Sub-45F), filed February 6, 1980. Applicant: ANDREWS VAN LINES, INC., P.O. Box 1609, Norfolk, NE 68701. Representative: J. Max Harding, P.O. Box 82028, Lincoln, NE 68501. Transporting *new furniture and parts and accessories* for new furniture, from Los Angeles, CA, to Omaha, NE, Denver, CO, Albuquerque, NM, and Austin, TX, restricted to the transporttion of traffic orignating at the named origins and destined to the named destinations. (Hearing site: Omaha, NE.)

MC 44735 (Sub-52F), filed February 4, 1980. Applicant: KISSICK TRUCK LINES, INC., 7101 East 12th St., Kansas City, MO 64126. Representative: William B. Barker, 641 Harrison St., Topeka, KS 66603. Transporting (1) *irrigation systems, parts and accessories for irrigation systems, pipe, light poles, mast arms, brackets, bases, transmission poles, and equipment and supplies* used in the installation of the commodities in (1) above (except commodities in bulk), from the facilities of Valmont Industries, Inc., at or near Valley, NE, to points in AR, IL, IN, IA, KS, MN, MO, OK, TX, and WI, (2) *equipment, materials, and supplies* used in the manufacture of the commodities named in (1) above, in the reverse direction, (3) *used irrigation systems, parts and accessories,* for used irrigation systems, *and equipment, materials, and supplies* used in the installation of used irrigation systems, between points in AR, IL, IN, IA, KS, MN, MO, OK, TX, and WI, and (4)(a) *solar energy heating and cooling sustems,* the operation of such systems, *and woodburning heating applicances,* and (b) *materials, supplies and accessories* used in the manufacture, distribution, insallation and operation of the commodities in (4)(a) above, between the facilities of Valmont Industries, Inc., at or near Valley, NE, on the one hand, and, on the other, points in AR, IL, IA, KS, MN, MO, OK, TX, and WI. (Hearing site: Kansas City, MO, or Omaha, NE.)

MC 44735 (Sub-53F), filed February 4, 1980. Applicant: KISSICK TRUCK LINES, INC., 7101 East Twelfth St., Kansas City, MO 64126. Representative: William B. Barker, 641 Harrison St., P.O. Box 1979, Topeka, KS 66601. Transporting *lumber, lumber products, post, poles, and timber,* from points in Choctaw County, OK, to points in IL, IA, KS, MO, and NE. (Hearing site: Kansas City, MO.)

MC 60014 (Sub-174F), filed February 4, 1980. Applicant: AERO TRUCKING, INC., Box 308, Monroeville, PA 15146. Representative: A. Charles Tell, 100 East Broad St., Columbus, OH 43215. Transporting *commodities,* the transportation of which by reason of size or weight requires the use of special equipment, between points in WI, MI, IL, IN, OH, WV, VA, MD, PA, DE, NJ, NY, CT, RI, MA, VT, NH, ME, and DC, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 74755 (Sub-3F), filed February 4, 1980. Applicant: SUELZER MOVING & STORAGE, INC., 4325 Meyer Rd., Ft. Wayne, IN 46806. Representative: Alki E. Scopelitis, 1301 Merchants Plaza, Indianapolis, IN 46204. Transporting *household goods* as defined by the Commission, between points in Adams, Allen, DeKalb, Huntington, Steuben, Wells, and Whitley Counties, IN, on the one hand, and, on the other, points in AL, AR, CT, DE, WI, FL, GA, IL, IA, KS, KY, MD, MA, MI, MN, MS, MO, NE, NJ, NY, NC, OH, OK, PA, RI, SC, TN, TX, VA, WV, and DC. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 83835 (Sub-167F), filed February 8, 1980. Applicant: WALES TRANSPORTATION, INC., P.O. Box 226186, Dallas, TX 75266. Representative: James W. Hightower, 5801 Marvin D. Love Freeway, Suite 301, Dallas, TX 75237. Transporting *cement pipe, abestos pipe* and *fittings* (except in bulk), from the facilities of Cement Asbestos Products Company, at or near Ragland, AL, to those points in the United States in and east of MN, IA, MO, AR, and TX, and (2) from Van Buren, AR, to those points in the United States in and west of MN, IA, MO, AR, and LA (except AK and HI). (Hearing site: St. Louis, MO, or Dallas, TX.)

MC 94265 (Sub-341F), filed February 5, 1980. Applicant: BONNEY MOTOR EXPRESS, INC., P.O. Box 305, Route 460 West, Windsor, VA 23487. Representative: John J. Capo, P.O. Box 720434, Atlanta, GA 30328. Transporting *foodstuffs* (except in bulk), from Chicago, IL, to Cleveland, OH. (Hearing site: Chicago, IL, or Washington, DC.)

MC 105045 (Sub-142F), filed February 1, 1980. Applicant: R. L. JEFFRIES TRUCKING CO., INC., 1020 Pennsylvania Street, Evansville, IN 47701. Representative: Richard C. McGinnis, 711 Washington Bldg., Washington, DC 20005. Transporting *railway car parts,* from the facilities of Keystone Railway Equipment Co., at (a) Camp Hill, PA, and (b) Texarkana, TX, to points in the United States (except AK and HI). (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 106074 (Sub-143F), filed February 1, 1980. Applicant: B AND P MOTOR LINES, INC., P.O. Box 727, Forest City, NC 28043. Representative: George W. Clapp, P.O. Box 836, Taylors, SC 29687. Transporting *meats, meat products, meat byproducts, and articles distributed by meat packing houses,* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), between points in NC, on the one hand, and, on the other, points in CO, IL, IA, KS, MN, MO, NE, and PA. (Hearing site: Charlotte, NC, or Washington, DC.)

MC 109124 (Sub-104F), filed February 5, 1980. Applicant: SENTLE TRUCKING CORPORATION, P.O. Box 7850, Toledo, OH, 43619. Representative: James M.

Burtch, 100 E. Broad St., Suite 1800, Columbus, OH 43215. Transporting (1) *construction materials,* and (2) *materials, equipment and supplies* used in the manufacture and distribution of commodities in (1) above, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of the Celotex Corporation. (Hearing site: Tampa, FL, or Columbus, OH.)

MC 109324 (Sub-49F), filed February 1, 1980. Applicant: GARRISON MOTOR FREIGHT, INC., P.O. Box 1278, Harrison, AR 72601. Representative: Francis W. McInerny, Suite 502, 1000 16th St., NW., Washington, DC 20036. Transporting *general commodities* (except those of unusual value, household goods as defined by the Commission, classes A and B explosives, commodities in bulk, and those requiring special equipment), serving the facilities of Prince Gardner, at or near Searcy, AR, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Washington, DC.)

Note.—Applicant intends to tack this authority with its existing authority.

MC 109865 (Sub-16F), filed February 6, 1980. Applicant: VALLEY TRANSPORTATION, INC., 516 Oxford Road, Oxford, CT 06483. Representative: L. C. Major, Jr., Suite 400, Overlook Building, 6121 Lincolnia Road, Alexandria, VA 22312. Transporting (1) *passengers* and *their baggage,* in the same vehicle with passengers, in special and charter operations, beginning and ending at points in Fairfield County, CT, and extending to points in FL, restricted to the transportation of passengers having an immediately prior movement in a passenger automobile tendered to carrier for transportation or separate automobile transporters under the authority set forth in part (2), and (2) *passengers' automobiles,* in secondary movements, in truckaway service, between the points set forth in (1) above, restricted to the transportation of automobiles tendered to carrier by those passengers moving under the authority set out in part (1) above. (Hearing site: Stamford, or Greenwich, CT.)

MC 111214 (Sub-22F), filed February 4, 1980. Applicant: GREENWOOD STORAGE & TRUCKING CO., INC., P.O. Box 943, Greenwood, MS 38930. Representative: Harold H. Mitchell, Jr., P.O. Box 1295, Greenville, MS 38701. *Contract carrier,* transporting (1) *commodities* the transportation of which because of size or weight requires the use of special equipment and (2) *materials and equipment* used in the manufacture and distribution of the commodities in (1) above (except commodities in bulk), between the facilities of Hydra-Tool Corporation, at or near (a) Greenwood, MS, and (b) Topeka, KS, on the one hand, and, on the other, those points in the United States in and east of KS, NE, ND, OK, SD, and TX, under continuing contract(s) with Hydra-Tool Corporation. (Hearing site: Jackson, MS or Memphis, TN.)

MC 116544 (Sub-204F), filed February 4, 1980. Applicant: ALTRUK FREIGHT SYSTEMS, INC., 1703 Embarcadero Road, Palo Alto, CA 94303. Representative: Richard G. Lougee, P.O. Box 10061, Palo Alto, CA 94303. Transporting (1) *petroleum, petroleum products, and vehicle body sealer and sound deadener compounds,* (except commodities in bulk, in tank vehicles), and *filters,* from points in Warren County, MS, to points in AL, AR, CO, FL, GA, IL, IA, KS, LA, MN, MO, NE, OK, TX, and WI, and (2) *petroleum, petroleum products, vehicle body sealer and sound deadener compounds, filters and materials, supplies, and equipment* used in the manufacture and distribution of the commodities named above (except commodities in bulk, in tank vehicles), from points in AL, GA, IL, and OK, to points in Warren County, MS, restricted in (1) and (2) to the transportation of traffic originating at or destined to the facilities of Quaker State Oil Refining Corporation, in Warren County, MS. (Hearing site: San Francisco, CA, or Washington, DC.)

MC 117574 (Sub-346F), filed February 6, 1980. Applicant: DAILY EXPRESS, INC., P.O. Box 39, 1076 Harrisburg Pike, Carlisle, PA 17013. Representative: E. S. Moore, Jr. (same address as applicant). Transporting (1) *radioactive waste,* in containers, and (2) *equipment, materials, and supplies* used in the treatment, processing, packaging and transportation of radioactive waste, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities used by ANEFCO, Inc. NOTE: Any certificate issued in this proceeding shall be limited in term to a period of time expiring 5 years from its date of issue. (Hearing site: Washington, DC.)

MC 117574 (Sub-348F), filed February 5, 1980. Applicant: DAILY EXPRESS, INC., P.O. Box 39, 1076 Harrisburg Pike, Carlisle, PA 17013. Representative: E. S. Moore, Jr. (same address as applicant). Transporting (1) *agricultural construction, industrial and processing implements and equipment,* and (2) *attachments, accessories, and materials* for the commodities in (1) above, between points in the United States (except AK and HI), restricted to traffic originating at or destined to the facilities used by OPICO, Inc. (Hearing site: Mobile, AL, or Washington, DC.)

MC 117685 (Sub-4F), filed February 1, 1980. Applicant: CONSOLIDATED TRUCK SERVICE, INC., 1 Scout Avenue, South Kearny, NJ 07032. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, and commodities in bulk), having a prior or subsequent movement by water, from New York, NY and Baltimore, MD, to points in the United States (except AK and HI), restricted to the traffic moving on the bills of lading of freight forwarders as defined in 49 U.S.C. § 10102(8). (Hearing site: New York, NY, or Washington, DC.)

MC 117765 (Sub-285F), filed February 1, 1980. Applicant: HAHN TRUCK LINE, INC., 100 S. MacArthur, P.O. Box 75218, Oklahoma City, OK 73147. Representative: R. E. Hagan (same address as applicant). Transporting (1) *such commodities* as are dealt in by wholesale, retail, chain grocery and food business houses and feed businesses; soy products; paste, flour products; dairy based products, and (2) *materials, ingredients and supplies* used in the manufacture, distribution and sale of products in (1) above, (except in bulk), between the facilities of Ralston Purina Company, at or near Oklahoma City, OK, on the one hand, and, on the other hand, points in AR, LA, MS, NM, TN, and TX. (Hearing site: Oklahoma City, OK.)

MC 119894 (Sub-19F), filed February 4, 1980. Applicant: BOWARD TRUCK LINE, INC., 104 Roesler Road, Glen Burnie, MD 21061. Representative: M. Bruce Morgan (same address as applicant). Transporting (1) *paper, paper products,* and *woodpulp* (except commodities in bulk), and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, (except in bulk), between the facilities of Bowater Carolina Corporation, at or near Catawba, SC, on the one hand, and, on the other, points in VA on, east, and south of a line beginning at the VA–NC State line, and extending along U.S. Hwy 29 to junction Interstate Hwy 64, and extending along Interstate Hwy 64 to Norfolk, VA. (Hearing site: Charlotte, NC.)

MC 123294 (Sub-77F), filed February 4, 1980. Applicant: WARSAW TRUCKING CO., INC., Sawyer Center, Route 1,

Chesterton, IN 46304. Representative: H. E. Miller, Jr. (same address as applicant). Transporting *starch*, from Chicago and Decatur, IL, Roby and Indianapolis, IN, and Oak Creek, WI, to Troy, Urbana, and Dayton, OH. (Hearing site: Chicago, IL.)

MC 125535 (Sub-18F), filed February 1, 1980. Applicant: NATIONAL SERVICE LINES, INC., OF NEW JERSEY, 12015 Manchester Road, Suite 118, St. Louis, MO 63131. Representative: Donald S. Helm (same address as applicant). *Contract carrier*, Transporting (1) *paper, paper products, plastic* and *plastic products*, and (2) *materials, equipment and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities in bulk, in tank vehicles), between New Castle, DE, Florence, KY, Greensburg, IN, Orange, TX, and Hazelwood, MO, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, KS, OK, and TX, under continuing contract(s) with Crown Zellerbach Corporation. (Hearing site: St. Louis, MO, or Washington, DC.)

MC 127905 (Sub-4F), filed February 4, 1980. Applicant: LYNN H. SCOTT, INC., 8532 Blossvale Road, Blossvale, NY 13308. Representative: John D. Shannon, 326 Stone St., Oneida, NY 13421. Transporting *sand*, from Annsville, NY, to points in IN and MI. (Hearing site: Utica or Syracuse, NY.)

MC 129124 (Sub-29F), filed February 1, 1980. Applicant: SAMUEL J. LANSBERRY, INC., P.O. Box 58, Woodland, PA 16881. Representative: Herbert R. Nurick, P.O. Box 1166, Harrisburg, PA 17108. Transporting *salt and salt products*, from the facilities of International Salt Company, at or near Retsof, NY, to points in PA. (Hearing site: Scranton or Harrisburg, PA.)

MC 129124 (Sub-30F), filed February 1, 1980. Applicant: SAMUEL J. LANSBERRY, INC., P.O. Box 58, Woodland, PA 16881. Representative: Herbert R. Nurick, P.O. Box 1166, Harrisburg, PA 17108. Transporting *cullet*, in bulk, in dump vehicles, between points in MD, NJ, NY, OH, and PA. (Hearing site: Harrisburg or Pittsburgh, PA.)

MC 133095 (Sub-278F), filed October 18, 1979. Applicant: TEXAS CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Ron Duncan (same address as applicant). Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between the facilities of Gibson Metaluz, Inc., at Eufala, AL, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Dallas, TX.)

MC 133095 (Sub-279F), filed October 19, 1979. Applicant: TEXAS CONTINENTAL EXPRESS, INC., P.O. Box 434, Euless, TX 76039. Representative: Ron Duncan (same address as applicant). Transporting *malt beverages* (except in bulk), from the facilities of Miller Brewing Company at or near Fort Worth, TX, to points in AR, LA, MS, and TN. (Hearing site: Euless, TX.)

MC 134235 (Sub-26F), filed February 1, 1980. Applicant: KUHNLE BROTHERS, INC., P.O. Box #375, Newbury, OH 44065. Representative: Kenneth T. Johnson, Bankers Trust Bldg., Jamestown, NY 14701. Transporting *salt* and *salt products*, from the facilities of International Salt Company, at or near Retsof, NY, to points in PA. (Hearing site: Buffalo, NY.)

MC 135524 (Sub-110F), filed February 4, 1980. Applicant: G. F. TRUCKING CO., a corporation, P.O. Box 229, 1028 West Rayen Ave., Youngstown, OH 44501. Representative: George Fedorisin, 914 Salts Springs Road, Youngstown, OH 44509. Transporting *paper and paper products*, from the facilities of Western Craft Paper Group, Williamette Industries, Inc., at or near Hawesville, KY, to those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: Columbus or Cleveland, OH.)

MC 136605 (Sub-147F), filed February 4, 1980. Applicant: DAVIS TRANSPORT, INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). Transporting (1) *iron and steel articles* (2) *steel buildings, knocked down, and* (3) *parts and accessories* used in the manufacture and distribution of steel buildings, from the facilities of Soule Steel Co., in Los Angeles County, CA, to points in MT, WY, CO, NM, AZ, NV, ID, OR, WA, and UT. (Hearing site: San Francisco, CA.)

MC 136605 (Sub-148F), filed February 4, 1980. Applicant: DAVIS TRANSPORT, INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). Transporting (1) *prefabricated metal buildings, knocked down*, and (2) *parts and accessories* used in the manufacture of prefabricated metal buildings, from the facilities of Varco Pruden, Inc., at or near Turlock, CA, to points in NV, ID, MT, WY, UT, CO, NM, ND, OR, and WA. (Hearing site: San Francisco, CA.)

MC 136605 (Sub-149F), filed February 4, 1980. Applicant: DAVIS TRANSPORT, INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). Transporting *brick* and *masonry supplies*, from points in CO, to points in WY. (Hearing site: Billings, MT.)

MC 139205 (Sub-4F), filed February 1, 1980. Applicant: DOLPHIN CARTAGE, INC., 14500 Cottage Grove Ave., Dolton, IL 60419. Representative: James R. Madler, 120 W. Madison St., Chicago, IL 60602. *Contract carrier*, transporting (1) *paper and papr articles*, and (2) *materials, equipment, and supplies* used in the manufacture of paper and paper articles (except commodities in bulk), between points in (1) WI on and east of Interstate Hwy 90 and on and south of WI Hwy 23, (2) IN on and north of IN Hwy 14 and on and west of Interstate Hwy 69, (3) MI on, south and west of a line beginning at Muskegon, MI and extending along MI Hwy 46 to junction U.S. Hwy 131 then over U.S. Hwy 131 to junction MI Hwy 57, then over MI Hwy 57 to junction U.S. Hwy 27, then over U.S. Hwy 27 to junction Interstate Hwy 69, then over Interstate Hwy 69 to the IN-MI State line, and (4) IL on and north of Interstate Hwy 74, under continuing contract(s) in (1) through (4) with Packaging Corporation of America, Evanston, IL; Western Kraft Paper Group, Montgomery, IL, Lawrence Container Corp., Chicago, IL; Corrugated Supplies Corp., Chicago, IL; Container Corporation of America, Carol Stream, IL; Chicago Corrugated Box Co., Elk Grove Village, IL; and Wabash Fibre Box Company, of Chicago, IL. (Hearing site: Chicago, IL.)

MC 139244 (Sub-9F), filed February 4, 1980. Applicant: TRUCKING SERVICE, INC., P.O. Box 229, Carlinville, IL 62626. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. *Contract carrier*, transporting *bacon*, from Pittsburg, KS, and St. Louis, MO, to Denver, CO, Atlanta, GA, and Seattle, WA under continuing contract(s) with Kretschmar Brands, Inc., of Pittsburg, KS. (Hearing site: Chicago, IL, or St. Louis, MO.)

MC 140024 (Sub-177F), filed February 4, 1980. Applicant: J. B. MONTGOMERY, INC., 5565 East 52nd Ave., Commerce City, CO 80022. Representative: Don L. Bryce (same address as applicant). Transporting, *such commodities* as are dealt in by pharmaceutical supply houses (except commodities in bulk) from the facilities of the P. F. Laboratories, Inc., at or near Totowa, NJ, to the facilities of P. F. Laboratories, Inc., and its distributors at Dallas, TX. (Hearing site: Denver, CO, or Washington, DC.)

MC 140914 (Sub-7F), filed February 4, 1980. Applicant: DOBSON TRUCKING, INC., P.O. Box 498, Dobson, NC 27017. Representative: Eric Meierhoefer, Suite 423, 1511 K Street, N.W., Washington, DC 20005. Transporting *wire saw abrasive, crusher jaws, crusher jaw parts, steel shot, and cut granite products,* between Mt. Airy, NC, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, AR, and LA (Hearing site: Greensboro, NC.)

MC 141804 (Sub-353F), filed February 4, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *steel doors* and *materials, equipment,* and *supplies* used in the framing and installation of steel doors, from Cincinnati, OH, to those points in the United States in and west of MT, WY, CO, and NM. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-354F), filed February 4, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). In foreign commerce only, transporting, *general commodities* (except foodstuffs in vehicles equipped with mechnical refrigeration, meats, meat products and meat byproducts, dairy products and articles distributed by meat packing houses, as described in Sections A, B, C of Appendix I to the report in Motor Carrier, 61 M.C.C. 209 and 766, articles of unusual value, classes A & B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring the use of special equipment), from points in the United States to points in MN, IA, MO, AR, LA, MS, TN, KY, IL, WI, MI, IN, and OH, restricted to traffic having a prior movement by water. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-355F), filed February 5, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *general commodities* (except those of unusual value, household goods as described by the Commission, commodities in bulk, frozen commodities, and those requiring special equipment), from Seattle, WA, to those points in the United States in and west of MT, WY, CO, and NM. Condition: Any certificate issued here, to the extent it authorizes classes A and B explosives, shall be limited in term to a period of 5 years from its date of issuance. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-366F), filed February 4, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting (1) *such commodities* as are dealt in by grocery, hardware and drug stores, (2) *cleaning* and *building maintenance materials* and *supplies,* (3) swimming pool, spa, and *hot tub products,* (4) *chemicals,* and (5) *materials, equipment and supplies* used in the manufacture and distribution of the above commodities named in (1) thru (4) above, between points in the United States (except AK and HI) restricted (a) against commodities in bulk, and (b) to traffic originating at or destined to the facilities of Purex Corporation. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-367F), filed February 4, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *such commodities* as are dealt in by home improvement companies, between points in the United States (except AK and HI), restricted to traffic originating at or destined to the facilities of Color Tile Supermart, Inc. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-368F), filed February 5, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting, *furniture,* between points in the United States (except AK, HI, and TN), on the one hand, and, on the other, Maryville, TN. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-369F), filed February 5, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting (1) *electrical transmission equipment* and *accessories,* (2) electrical appliances and *accessories,* (3) *floor mats,* (4) *automobile accessories* and (5) *materials* used in the manufacture and distribution of the commodities in (1) through (4) above, from Los Angeles, CA, to points in CO, KS, OK, OR, TX, and WA. (Hearing site: Los Angeles, CA.)

MC 141804 (Sub-372F), filed February 4, 1980. Applicant: WESTERN EXPRESS, DIVISION OF INTERSTATE RENTAL, INC., P.O. Box 3488, Ontario, CA 91761. Representative: Frederick J. Coffman (same address as applicant). Transporting *electrical items* and *electronic equipment,* from New Orleans, LA, New York, NY, Mobile, AL, Miami, FL, and Houston, TX, to those points in the United States in and east of TX, OK, KS, NE, SD and ND. (Hearing site: Los Angeles, CA.)

MC 144115 (Sub-2F), filed October 12, 1979. Applicant: DIVERSIFIED CARRIERS, INC., 903–6th Street NW, Rochester, MN 55901. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. Transporting *meats, meat products, meat byproducts,* and *articles distributed by meat packinghouses,* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), between the facilities of (a) Lauridsen Foods, Inc., at or near Britt, IA and (b) Armour & Company, at or near Mason City, IA, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to traffic originating at or destined to the above named facilities of Lauridsen Foods, Inc. and Armour & Company. (Hearing site: St. Paul, MN.)

MC 146565 (Sub-2F), filed February 5, 1980. Applicant: WESTERN SALES TRANSPORTATION, INC., 1801 N. 11th St., Omaha, NE 68110. Representative: James F. Crosby, P.O. Box 37205, Omaha, NE 68137. Transporting (1) *aluminum foil food containers,* from the facilities of Wilkinson Manufacturing Co., at or near Ft. Calhoun, NE, to points in OH, MI, IN, WI, IL, MN, IA, MO, SD, KS, OK, and TX, and (2) *materials, equipment,* and *supplies* used in the manufacture, and distribution of aluminum foil food containers, in the reverse direction. (Hearing site: Omaha, NE.)

MC 147705 (Sub-2F), filed February 4, 1980. Applicant: E. E. REDMON TRUCKING COMPANY, INC., Box 154, Hartfield, VA 23071. Representative: E. E. Redmon, Jr. (same address as applicant). *Contract carrier,* transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) between Richmond, VA, and points in Henrico County, VA, on the one hand, and, on the other, Norfolk, VA, Newport News, VA, Portsmouth, VA, Hampton, VA, Chesapeake, VA, and Baltimore, MD, restricted to traffic having prior or subsequent movement by water, under

continuing contract(s) with A. H. Robins Co., Miller Morton Co., Elkins-Sinn, Inc., and Chapstick Co., of Richmond, VA.

**Volume No. 130**

Decided: April 4, 1980.

By the Commission, Review Board Number 2, Members Eaton, Liberman, and Jensen. Member Jensen not participating.

MC 531 (Sub-441F), filed February 20, 1980. Applicant: YOUNGER BROTHERS, INC., 4904 Griggs Rd., P.O. Box 14048, Houston, TX 77021. Representative: Wray E. Hughes (same address as applicant). Transporting *chemicals,* in bulk, in tank vehicles, from the facilities of American Cyanamid Co. at or near Bound Brook, Linden, and Woodbridge, NJ, to points in AZ, CA, CO, NM, NV, OR, TX, UT, WA, and WY. (Hearing site: Houston, TX, or Washington, DC.)

MC 11220 (Sub-202F), filed February 20, 1980. Applicant: GORDONS TRANSPORTS, INC., 185 West McLemore Ave., Memphis, TN 38101. Representative: James J. Emigh, P.O. Box 59, Memphis, TN 38101. Over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Alexandria, IN, and junction U.S. Hwy 31 and IN Hwy 28, over IN Hwy 28, serving all intermediate points. (Hearing site: Indianapolis, IN.)

Note.—Applicant intends to tack with its existing regular-route authority.

MC 29910 (Sub-255F), filed February 20, 1980. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, INC., 301 S. 11th St., Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood Ave., Fort Smith, AR 72902. Over regular routes transporting *general commodities,* except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Service Master Industries, Inc., at or near Cairo, IL, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: St. Louis, MO, or Memphis, TN.)

Note.—Applicant intends to tack with it existing regular-route authority.

MC 29910 (Sub-256F), filed February 20, 1980. Applicant: ARKANSAS-BEST FREIGHT SYSTEM, INC., 301 S. 11th St., Fort Smith, AR 72901. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood Ave., Fort Smith, AR 72902. Over regular routes transporting *general commodities,* except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), serving the facilities of Digital Equipment Company at or near Nashua and Salem, NH, as off-route points in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Boston, MA, or Washington, DC.)

Note.—Applicant intends to tack with it existing regular-route authority.

MC 47171 (Sub-161F), filed January 25, 1980. Applicant: COOPER MOTOR LINS, INC., P.O. Box 2820, Greenville, SC 29602. Representative: Harris G. Andrews (same address as applicant). Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between points in Chatham County, GA, on the one hand, and, on the other, points in CT, DE, MA, MD, NJ, NY, PA, RI, VA, and DC. (Hearing site: Washington, DC.)

MC 108341 (Sub-179F), filed February 5, 1980. Applicant: MOSS TRUCKING COMPANY, INC., 3027 N. Tryon St., P.O. Box 261125, Charlotte, NC 28213. Representative: Jack F. Counts (same address as applicant). Transporting *iron and steel articles,* from Perth Amboy, NJ, to those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: New York, NY or Washington, DC.)

MC 108341 (Sub-180F), filed February 19, 1980. Applicant: MOSS TRUCKING COMPANY, INC., 3027 N. Tryon St., P.O. Box 26125, Charlotte, NC 28213. Representative: Jack F. Counts (same address as applicant). Transporting (1) *buildings, building panels, and building parts* and (2) *materials, equipment, and supplies* used in the installation, erection, manufacture, and construction of the commodities in (1) above (except commodities in bulk), between the facilities used by Butler Manufacturing Company at or near (a) Birmingham, AL, and (b) Galesburg, IL, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

MC 108341 (Sub-181F), filed January 25, 1980. Applicant: MOSS TRUCKING COMPANY, INC., 3027 N. Tryon St., P.O. Box 26125, Charlotte, NC 28213. Representative: Jack F. Counts (same address as applicant). Transporting (1) *concrete pumping equipment,* and (2) *parts, attachments, and accessories* for concrete pumping equipment, from the facilities used by Allentown Pneumatic Gun Company at or near Allentown, PA, to those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: Philadelphia, PA or Washington, DC.)

MC 108341 (Sub-182F), filed January 25, 1980. Applicant: MOSS TRUCKING COMPANY, INC., 3027 N. Tryon St., P.O. Box 26125, Charlotte, NC 28213. Representative: Jack F. Counts (same address as applicant). Transporting (1) *commodities* which because of size or weight require the use of special equipment, and (2) *general commodities* (except those requiring the use of special equipment, commodities in bulk, and classes A and B explosives), in mixed shipments with the commodities in (1) above, between York PA, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: York, PA or Washington, DC.)

MC 108460 (Sub-70F), filed February 20, 1980. Applicant: PETROLEUM CARRIERS COMPANY, 5104 West 14th St., P.O. Box 762, Sioux Falls, SD 57101. Representative: Gary Mundhenke (same address as applicant). Transporting *liquid carbon dioxide* and *liquefied petroleum gas,* in bulk, in tank vehicles, from points in IA, KS, MN, MO, and NE, to points in IA, MN, NE, ND, and SD. Condition: Any certificate to be issued in this proceeding shall be limited, in point of time, to a period expiring 5 years from its date of issuance.

Notes.—Dual operations may be involved.

MC 111401 (Sub-599F), filed January 28, 1980. Applicant: GROENDYKE TRANSPORT, INC., P.O. Box 632, 2510 Rock Island Blvd., Enid, OK 73701. Representative: Victor R. Comstock (same address as applicant). In foreign commerce only transporting (1) *nitrosylsulphuric acid,* in bulk, in tank vehicles, from Gibbstown, NJ, to Brownsville, TX, and (2) *furfuryl alcohol,* in bulk, in tank vehicles, from Bayport, TX, to Brownsville, TX. (Hearing site: Houston, TX, or New Orleans, LA.)

MC 113651 (Sub-331F), filed January 25, 1980. Applicant: INDIANA REFRIGERATOR LINES, INC., P.O. Box 552, Riggin Rd., Muncie, IN 47305. Representative: Henry Higgs (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers of (1) toilet preparations, (2) home security equipment, (3) cigarette lighters, (4) personal care products, and (5) stationery products, (except commodities in bulk), from Andover, MA, to Louisville, KY. (Hearing site: Boston, MA, or Washington, DC.)

MC 114211 (Sub-446F), filed January 25, 1980. Applicant: WARREN

TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Kurt E. Vragel, Jr. (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers, distributors, or dealers of construction, contractors', mining, and logging equipment, between Seattle and Spokane, WA, on the one hand, and, on the other, points in the United States (including AK, but excluding HI). (Hearing site: Spokane or Pullman, WA.)

MC 114211 (Sub-447F), filed January 28, 1980. Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Kurt E. Vragel, Jr. (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers, dealers, and distributors of (1) aluminum articles, (2) contractors' equipment, and (3) self-propelled articles, (except commodities in bulk), between points in Clark County, AR, on the one hand, and, on the other, points in the United States (including AK, but excluding HI). (Hearing site: Waterloo or Cedar Rapids, IA.)

MC 115651 (Sub-83F), filed February 5, 1980. Applicant: KANEY TRANSPORTATION, INC., 7222 Cunningham Rd., Rockford, IL 61102. Representative: E. Stephen Heisley, 666 11th St., Washington, DC 20001. Transporting *chemicals,* in bulk, in tank vehicles, (1) from the facilities of Clark Chemical Company at or near Blue Island, IL, to points in IA, IN, MI, MN, MO, NE, OH, and WI, and (2) from the facilities of Dow Chemical Company at or near Chicago, IL, to points in MO. (Hearing site: Chicago, IL, or Milwaukee, WI.)

MC 119741 (Sub-259F), filed February 20, 1980. Applicant: GREEN FIELD TRANSPORT COMPANY, INC., 1515 Third Ave., N.W., P.O. Box 1235, Fort Dodge, IA 50501. Representative: D. L. Robson (same address as applicant). Transporting *foodstuffs, paper, paper products, paint, and paint products* (except commodities in bulk, in tank vehicles), (1) from the facilities of SCM Corporation at (a) Wolcott and New York, NY, (b) Thorofare, NJ, (c) Baltimore, MD, (d) Ashtabula, OH, (e) Kalamazoo, MI, (f) Marion, IN, and (g) Joliet, IL, to points in AL, AR, CO, CT, DE, FL, GA, IA, IL, IN, KS, KY, LA, MA, MD, ME, MI, MN, MO, MS, NC, ND, NE, NH, NJ, NY, OH, OK, PA, RI, SC, SD, TN, TX, VA, VT, WI, WV, and DC, (2) from Shiremanstown, PA, to points in AL, AR, FL, GA, IN, KY, LA, MI, MS, NC, OH, SC, TN, VA, and WV, and (3) from Huron, OH, to points in AL, AR, FL, GA, IN, KY, LA, MI, MS, NC, SC, TN, VA, and WV. (Hearing site: Cleveland, OH.)

MC 121600 (Sub-9F), filed February 20, 1980. Applicant: AVERITT EXPRESS, INC., P.O. Box 273, Livingston, TN 38570. Representative: Henry E. Seaton, 929 Pennsylvania Bldg., 425 13th St., N.W., Washington, DC 20004. Over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, Commodities in bulk, and those requiring special equipment), serving the facilities of Big Dollar Warehouse near Cookeville, TN, as an off-route point in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Cookeville, TN.)

MC 133591 (Sub-96F), filed February 4, 1980. Applicant: WAYNE DANIEL TRUCK INC., P.O. Box 303, Mount Vernon, MO 65712. Representative: Charles A. Daniel (same address as applicant). Transporting *containers, dishes, plates, napkins, plastic articles, and glass products,* from Toledo, OH, Springfield, MO, Riverside, Los Angeles, and Mira Loma, CA, Mexia, TX, Shreveport, LA, and Bardstown, KY, to points in AL, AR, AZ, CA, CO, IA, ID, IL, KS, KY, LA, MI, MN, MO, MS, MT, ND, NE, NM, NV, OH, OK, OR, SD, TN, TX, UT, WA, WI and WY. (Hearing site: St. Louis, MO, or Chicago, IL.)

Note.—Dual operations may be involved.

MC 135070 (Sub-157F), filed February 20, 1980. Applicant: JAY LINES, INC., P.O. Box 30180, Amarillo, TX 79120. Representative: Gailyn L. Larsen, P.O. Box 82816, Lincoln, NE 68501. Transporting *such commodities* as are dealt in or used by department stores, between the facilities of Venture Stores in IA, IL, IN, KS, MI, and MO, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: St. Louis, MO, or Dallas, TX.)

Note.—Dual operations may be involved.

MC 135111 (Sub-5F), filed February 6, 1980. Applicant: REESE TRUCKING, INC., P.O. Box 99, Dover, OH 44622. Representative: William J. Lavelle, 2310 Grant Bldg., Pittsburgh, PA 15219. *Contract carrier,* transporting (1) *chemicals,* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of chemicals (except commodities in bulk), between points in the United States (including AK, but excluding HI), under continuing contract(s) with Betz Laboratories, Inc., and Betz International, Inc., both of Trevose, PA, Betz Entec, Inc., of Horsham, PA, and Betz Process Chemicals, Inc., of Woodlands, TX. (Hearing site: Pittsburgh or Philadelphia, PA.)

MC 135111 (Sub-6F), filed February 19, 1980. Applicant: REESE TRUCKING, INC., P.O. Box 99, Dover, OH 44622. Representative: William J. Lavelle, 2310 Grant Bldg., Pittsburgh, PA 15219. *Contract carrier,* transporting *zinc slabs,* from Clarksville, TN, to Dover, OH, under continuing contract(s) with Empire-Detroit Steel Division of Cyclops Corporation, of Dover, OH. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 138000 (Sub-63F), filed February 7, 1980. Applicant: ARTHUR H. FULTON, INC., P.O. Box 86, Stephens City, VA 22655. Representative: Dixie C. Newhouse, 1329 Pennsylvania Ave., P.O. Box 1417, Hagerstown, MD 21740. Transporting (1) *aluminum ingots and sows,* and (2) *materials, equipment, and supplies* used in the manufacture of the commodities in (1) above, between Spartansburg, SC, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, AR, and LA. (Hearing site: Spartansburg, SC.)

Note.—Dual operations may be involved.

MC 138741 (Sub-104F), filed February 8, 1980. Applicant: AMERICAN CENTRAL TRANSPORT, INC., 2005 North Broadway, Joliet, IL 60435. Representative: Tom B. Kretsinger, 20 East Franklin, Liberty, MO 64068. Transporting (1) *building materials* (except commodities in bulk), and (2) *materials, equipment, and supplies* used in the manufacture, distribution, and installation of building materials (except commodities in bulk), between points in AL, AR, CO, GA, IA, IL, IN, KS, KY, LA, MD, MI, MN, MO, MS, NC, ND, NE, OH, OK, PA, SC, TN, TX, VA, WI, and WV, restricted to traffic originating at or destined to the facilities of CertainTeed Corporation. (Hearing site: Washington, DC.)

MC 138941 (Sub-41F), filed December 10, 1979. Applicant: COUNTRY WIDE TRUCK SERVICE, INC., 1110 South Reservoir St., Pomona, CA 91766. Representative: Ralph B. Matthews, P.O. Box 56387, Atlanta, GA 30343. *Contract carrier,* transporting (1) *plastic articles* (except commodities in bulk), from the facilities of Mobil Chemical Company, at or near Channahon Township and Joliet, IL, to points in the United States (except AK and HI), and (2) *materials, equipment, and supplies* used in the manufacture and distribution of plastic articles, in the reverse direction, under continuing contract(s) with Mobil Oil Corporation of Dallas, TX. (Hearing site: Los Angeles, CA.)

MC 142811 (Sub-9F), filed February 20, 1980. Applicant: S.R.I. TRUCKING CO., 1000 N. Cindy Lane, P.O. Box 925, Carpinteria, CA 93013. Representative: R. Y. Schureman, 1545 Wilshire Blvd., Los Angeles, CA 91107. *Contract carrier,* transporting *foodstuffs* from Plant City, FL, to points in IL, IN, KY, MI, OH, and TN, under continuing contract(s) with Fearn International, Inc., of Franklin Park, IL. (Hearing site: Los Angeles, CA, or Tampa, FL.)

MC 143291 (Sub-3F), filed February 6, 1980. Applicant: RAYLS BROTHERS TRANSFER, INC., Box 342, North Dixie Highway, Hoopeston, IL 60942. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. Transporting *canned goods,* and *materials, equipment, and supplies* used in the manufacture and distribution of canned goods (except commodities in bulk), between Hoopeston and Princeville, IL, Belledeau and St. Francisville, LA, and Mayville, WI, on the one hand, and, on the other, points in IA, IL, IN, KY, LA, MI, MN, MO, MS, OH, and WI. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 144061 (Sub-14F), filed January 25, 1980. Applicant: SICOMAC CARRIERS, INC., 347 Sicomac Ave., Wyckoff, NJ 07481. Representative: Jack L. Schiller, 345 Webster Ave., Brooklyn, NY 11230. *Contract carrier,* transporting (1) *liquid chemicals,* in bulk, from the facilities of Amoco Chemicals Corporation, at or near Wood River, IL, to points in the United States (except AK and HI), and (2) *liquid chemicals,* in bulk, from St. Louis, MO, to Joliet and Willow Springs, IL, restricted to the transportation of traffic having a prior movement by water, under continuing contract(s) in (1) and (2) above with Amoco Chemicals Corporation of Chicago, IL. (Hearing site: Chicago, IL.)

MC 144630 (Sub-44F), filed February 20, 1980. Applicant: STOOPS EXPRESS, INC., 2239 Malibu Court, Anderson, IN 46015. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240. Transporting *alcoholic beverages,* from Cincinnati, OH, and Frankfort, KY, to points in AL, LA, MS, and TX. (Hearing site: Indianapolis, IN, or Cincinnati, OH.)

Note.—Dual operations may be involved.

MC 145470 (Sub-4F), filed February 19, 1980. Applicant: ALL FREIGHT SYSTEMS, INC., 1026 S. 10th St., Kansas City, KS 66105. Representative: Donald J. Quinn, Suite 900, 1012 Baltimore, Kansas City, MO 64105. *Contract carrier,* transporting (1) *railway car parts,* (2) *mounted wheel sets,* and (3) *materials, equipment, and supplies* used in the manufacture, repair, and distribution of railway car parts, between the facilities of STI of Kansas, Inc., at Kansas City, MO, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with STI of Kansas, Inc., a subsidiary of North American Car Corporation, of Kansas City, MO. (Hearing site: Kansas City, MO.)

Note.—Dual operations may be involved.

MC 145761 (Sub-5F), filed February 11, 1980. Applicant: A & A TRANSPORT, INC., P.O. Box 569, Palmer, MA 01069. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Rd., Omaha, NE 68106. *Contract carrier,* transporting *such commodities* as are dealt in or used by manufacturers and distributors of (1) paper products, (2) film products, (3) photographic materials, and (4) copying products, between the facilities of James River Graphics at South Hadley and Holyoke, MA, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with James River Graphics of South Hadley, MA. (Hearing site: Boston, MA, or Omaha, NE.)

Note.—Dual operations may be involved.

MC 147021 (Sub-4F), filed January 25, 1980. Applicant: C. SUMMERS, INC., 112 Spruce St., Elizabethville, PA 17023. Representative: John W. Frame, Box 626, 2207 Old Gettysburg Rd., Camp Hill, PA 17011. In foreign commerce only, transporting *meats,* from Philadelphia, PA, and the facilities of C. Summers, Inc., at Elizabethville, PA, to points in DE, IA, IL, IN, MD, MI, MN, NJ, OH, PA, and WI, restricted to the transportation of traffic having a prior movement by water. (Hearing site: Harrisburg, PA.)

Note.—Dual operations may be involved.

MC 149360F, filed February 5, 1980. Applicant: L. B. TRANSPORT SERVICES, INC., 19114 Pioneer Blvd. Cerritos, CA 90701. Representative: Miles L. Kavaller, 315 S. Beverly Dr., Suite 315, Beverly Hills, CA 90212. *Contract carrier,* transporting *vanities and marble tiles,* from points in Los Angeles County, CA, to points in the United States (except AK and HI), under continuing contract(s) with G. J. Industries, Inc., of Panorama City, CA. (Hearing site: Los Angeles, CA).

MC 149361F, filed February 8, 1980. Applicant: EAGLE VALLEY, INC., P.O. Box 620, Shawneetown, IL 62984. Representative: Norman R. Garvin, 1301 Merchants Plaza, Indianapolis, IN 46204. Transporting (1) *malt beverages,* from Ft. Wayne and Evansville, IN, Milwaukee and LaCrosse, WI, Newport, KY, St. Paul, MN, Detroit MI, Cincinnati, OH, Memphis, TN, Newark, NJ, and Pabst, GA, to those points in IL on, south, and east of a line beginning at the IN–IL State line and extending along U.S. Hwy 50 to junction U.S. Hwy 51, and then along U.S. Hwy 51 to the Mississippi River, and (2) *malt beverage containers,* in the reverse direction. (Hearing site: Indianapolis, IN, or Chicago, IL.)

MC 150011 (Sub-1F), filed February 20, 1980. Applicant: SOUTHWEST QUALITY FOODS, INC., Route 2, Box 160–H, Wytheville, VA. Representative: Terrell C. Clark, P.O. Box 25, Stanleytown, VA 24168. Transporting (1) *foodstuffs* (except frozen), *cleaning and washing compounds, solidfied methanol, paper articles, plastic articles, scourers, toothpicks, chef hats, and straws,* from Dorsey, MD, to Elk Grove Village, IL (2) *frozen foodstuffs,* from Baltimore, MD, to Lyons, IL, (3) *foodstuffs,* from Lyons, IL, to Appalachia, VA, Greensboro, NC, and Somerset, KY, (4) *foodstuffs* (except frozen), from Indianapolis, IN, to Appalachia, VA, and Somerset, KY, and (5) *foodstuffs, cleaning and washing compounds, solidified methanol, paper articles, plastic articles, scourers, toothpicks, chef hats, and straws,* from Greensboro, NC, to Appalachia, VA. Conditions: (1) Applicant shall maintain separate accounts and records for its for-hire carrier operations as distinct from its other business activities, and (2) it shall not at the same time and in the same vehicle transport property both as a private carrier and as a for-hire carrier. (Hearing site: Roanoke, VA, or Washington, DC.)

**Passengers**

MC 148920F, filed September 26, 1980. Applicant: CHESTER L. BYRD, P.O. Box 8, Broadway, NC 27505. Representative: John M. Ballenger, 6121 Lincolnia Rd., Alexandria, VA 22312. Transporting *passengers and their baggage,* in round-trip charter operations, beginning and ending at points in Lee and Harnett Counties, NC, and extending to points in AL, CT, DE, FL, GA, IL, IN, KY, LA, MA, MD, ME, MI, MS, NC, NH, NJ, NY, OH, PA, RI, SC, TN, VA, VT, WI, WV, and DC. (Hearing site: Sanford or Fayetteville, NC.)

**Volume No. 134**

Decided: March 21, 1980.

By the Commission, Review Board Number 3, Members Parker, Fortier, and Hill.

MC 1423 (Sub-1F), filed December 6, 1979. Applicant: MELNI BUS SERVICE, INC., 29 River Road, Chatham, NJ 07928. Representative: S. Harrison Kahn, Suite 733, Investment Bldg., Washington, DC 20005. Over irregular routes, transporting *passengers and their baggage,* in the same vehicle with

passengers, and *express*, between Chatham, Chatham Township, New Vernon, Green Village, Madison, and Summit, NJ, on the one hand, and, on the other, New York, NY. (Hearing site: New York, NY.)

MC 116763 (Sub-636F), filed December 26, 1979. Applicant: CARL SUBLER TRUCKING, INC., North West Street, Versailles, OH 45380. Representative: Gary J. Jira (same address as applicant). Transporting *general commodities* (except commodities in bulk, in tank vehicles, used household furniture, commodities, the transportation of which because of size or weight require the use of special equipment, automobiles, trucks and buses as described in the Report in Descriptions in Motor Carrier Certificates, 61 MCC 209 and 766, classes A and B explosives), between points in the U.S. in and east of MN, IA, MO, OK, and TX, restricted to transportation of traffic originating at or destined to the facilities by Donn, Inc., at or near Westlake or Medina, OH, and its division Floor Systems, Inc., at or near Red Lion, PA, and Baltimore, MD. (Hearing site: Cleveland, OH.)

MC 129262 (Sub-5F), filed December 28, 1979. Applicant: AYERS AND MADDUX, INC., 1680 Hilltop Drive, Chula Vista, CA 92011. Representative: Fred H. Mackensen, 9454 Wilshire Blvd., Suite 400, Beverly Hills, CA 90212. In foreign commerce only, transporting (1) *fireplace insets and stoves*, and *parts* for fireplace insets and stoves and (2) *steel mill products*, between the port of entry on the International Boundary line between the U.S. and Mexico at Nogales, AZ, on the one hand, and, on the other, points in the U.S. (Hearing site: Los Angeles, CA, or Nogales, AZ.)

MC 146643 (Sub-14F), filed September 28, 1979. Applicant: INTER-FREIGHT TRANSPORTATION, INC., 3202 South State St., South Chicago Heights, IL 60411. Representative: Donald B. Levine, 39 South LaSalle St., Chicago, IL 60603. *Contract carrier* transporting *such commodities* as are dealt in by wholesale and retail hardware stores, (1) from Chicago, Cary, and Rosemont, IL, to Belleview, MO, Indianapolis, IN, Mankato, MN, and Cleveland, OH; and (2) from points in IN, the Lower Peninsula of MI, MN, OH, and WI, to Chicago, Cary, and Rosemont, IL, under continuing contract(s) with Cotter & Company, of Chicago, IL. (Hearing site: Chicago, IL.)

Note.—Dual operations may be involved.

MC 149223 (Sub-1F), filed January 14, 1980. Applicant: R. C. and N. R. AKIN d.b.a. AKIN TRUCKING, Route #2, Box 266, Westville, OK 74965. Representative: Greg E. Summy, P.O. Box 1540, Edmond, OK 73034. Transporting (1) *foodstuffs*, (a) from McAllen, TX to Stilwell, OK and the facilities of Zero Mountain Cold Storage, Inc., at or near Johnson, AR; and (b) from Stilwell, OK to points in TX; and (2) *materials and supplies used in the transportation and storage of foodstuffs*, from Stilwell, OK to McAllen, TX. (Hearing site: Tulsa or Oklahoma City, OK.)

**Volume No. 135**

Decided: March 17, 1980.

By the Commission, Review Board Number 3, Members Eaton, Liberman, and Jensen. Member Jensen not participating.

The following sixty-two (62) applications filed January 9, 1980, involve authority to transport *lumber, lumber products, wood products, and forest products*, from the facilities of Potlatch Corporation, in MN (all restricted to traffic originating at the named facilities): (1) MC 1718 (Sub-13F). Applicant: ALFRED M. FLATEGRAFF, d.b.a. GARDNER TRUCK LINE, P.O. Box 22, Pine River, MN 57474. Representative: Stanley C. Olsen, Jr., 7400 Metro Blvd., Suite 411, Edina, MN 55435. to those points in the United States in and west of MI, OH, IN, IL, MO, AR, and LA (except AK and HI). (2) MC 5227 (Sub-64F). Applicant: ECKLEY TRUCKING, INC., P.O. Box 201, Mead, NE 68041. Representative: A. J. Swanson, P.O. Box 1103, 300 S. Thompson Ave., Sioux Falls, SD 57101. To points in AR, IL, IN, IA, KS, KY, LA, MI, MO, NE, NY, OH, OK, PA, TN, TX, WV, and WI. (3) MC 16831 (Sub-34F). Applicant: MID SEVEN TRANSPORTATION CO., a corporation, 2323 Delaware Ave., Des Moines, IA 50317. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IL 50309. To points in IL, IN, IA, KS, KY, MI, MO, NE, ND, OH, SD, and WI. (4) MC 26396 (Sub-331F). Applicant: POPELKA TRUCKING CO., d.b.a. THE WAGGONERS, P.O. Box 31357, Billings, MT 59107. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. To points in the United States (except AK and HI). (5) MC 20992 (Sub-59F). Applicant: DOTSETH TRUCK LINE, INC., Knapp, WI 54749. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. To points in the United States (except AK and HI). (6) MC 52709 (Sub-385F). Applicant: RINGSBY TRUCK LINES, INC., 3980 Quebec St., P.O. Box 7240, Denver, CO 80207. Representative: Rick Barker (same address as applicant). To points in AZ, CA, CO, ID, IL, IN, IA, KS, MI, MO, MT, NE, NV, ND, OH, OR, PA, SD, UT, WA, WI, and WY. (7) MC 59367 (Sub-145F). Applicant: DECKER TRUCK LINE, INC., P.O. Box 915, Fort Dodge, IL 50501. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To points in CO, IL, IN, IA, KS, KY, MI, MO, NE, ND, OH, SD, WI, and WY. (8) MC 61231 (Sub-168F). Applicant: EASTER ENTERPRISES, INC., d.b.a. ACE LINE, INC., P.O. Box 1351, Des Moines, IA 50305. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To points in AR, AZ, CO, ID, IL, IN, IA, KS, KY, LA, MI, MO, MT, NE, NM, ND, OH, OK, SD, TN, TX, WA, WI,and WY. (9) MC 63562 (Sub-65F). Applicant: BN TRANSPORT INC., 6775 East Evans Ave., P.O. Box 22694—Wellshire Station, Denver, CO 80224. Representative: Cecil L. Goettsch, 1100 Des Moines Bldg., Des Moines, IL 50309. To those points in the Uniteed States in and west of MI, OH, KY, TN, and MS (except AK and HI). (10) MC 82841 (Sub-281F). Applicant: HUNT TRANSPORTATION, INC., 10770 "I" St., Omaha, NE 68127. Representative: Donald L. Stern, 7171 Mercy Rd., Suite 610, Omaha, NE 68106. To points in CO, IL, IN, IA, KS, KY, MI, MO, MT, NE, NY, ND, OH, PA, SD, WV, WI, and WY. [Note: Dual operations may be involved.] (11) MC 95084 (Sub-159F). Applicant: HOVE TRUCK LINE, a corporation, Stanhope, IA 50246. Representative: Kenneth F. Dudley, P.O. Box 279, 1501 E. Main St., Ottumwa, IA 52501. To points in AR, IL, IN, IA, KS, KY, MI, MO, NE, OH, OK, PA, SD, TN, VA, WV, and WI. (12) MC 95876 (Sub-339F). Applicant: ANDERSON TRUCKING SERVICE, INC., 203 Cooper Ave. No., St. Cloud, MN 56301 Representative: William L. Libby (same address as applicant). To points in the United States (except AK and HI). (13) MC 103993 (Sub-1031F). Applicant: MORGAN DRIVE-AWAY, INC., 28651 U.S. 20 West, Elkhart, IN 46515. Representative: Paul D. Borghesani (same address as applicant). To those points in the United States in and east of ND, SD, NE, KS, OK, and TX.

(14) MC 105501 (Sub-43F). Applicant: TERMINAL WAREHOUSE CO. a corporation, 1851 Radisson Rd. N.E., Blaine, MN 55434. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To points in ID, IL, IN, IA, KS, MI, MO, MT, NE, and, oh, sd, wi, and WY. (15) MC 106674 (Sub-458F). Applicant: SCHILLI MOTOR LINES, INC., P.O. Box 123, Remington, IN 47977. Representative: Jerry L. Johnson (same address as applicant). To those points in the United States in and east of MN, IA, MO, AR, and LA. (16)

MC 106707 (Sub-22F). Applicant: ADAMS TRUCKING, INC., 1711 West Second St., Webster City, IA 50595. Representative: Ronald D. Adams (same address as applicant). To points in IL, IN, IA, KY, MI, MO, NE, OH, and WI. (17) MC 107162 (Sub-66F). Applicant: NOBLE GRAHAM TRANSPORT, INC., Rural Route 1, Brimley, MI 49715. Representative: Michael S. Varda, 121 South Pinckney St., Madison, WI 53703. To points in IL, IN, IA, KY, MD, MI, MO, NY, OH, PA, VA, WV, and WI. [Note: Dual operations may be involved.] (18) MC 107295 (Sub-965F). Applicant: PRE-FAB TRANSIT CO., a corporation, P.O. Box 146, Farmer City, Il 61842. Representative: Todd A. Peterman (same address as applicant). To points in the United States (except AK and HI). (19) MC 108119 (Sub-233F). Applicant: E. L. MURPHY TRUCKING CO., a corporation, P.O. Box 43010, St. Paul, MN 55164. Representative: Mark E. Moser, 1340 West Main, Auburn, WA 98002. To points in the United States (except AK and HI). (20) MC 108223 (Sub-30F). Applicant: CENTURY-MERCURY MOTOR FREIGHT, INC., P.O. Box 43050, St. Paul, MN 55164. Representative: Warren K. Wahoske (same address as applicant). To points in IL, IN, IA, KS, KY, MI, MO, NE, NY, ND, OH, PA, SD, WV, and WI. (21) MC 109397 (Sub-497F). Applicant: TRI-STATE MOTOR TRANSIT CO., a DE corporation, P.O. Box 113, Joplin, MO 64801. Representative: A. N. Jacobs (same address as applicant). To points in the United States (except AK and HI). (22) MC 109692 (Sub-88F). Applicant: GRAIN BELT TRANSPORTATION CO., a corporation, Route #13, Kansas City, MO 64161. Representative: Warren H. Sapp, P.O. Box 16047, Kansas City, MO 64112. To points in AR, IL, IN, IA, KS, KY, MI, MO, NE, OH, OK, TN, TX, and WI. (23) MC 109818 (Sub-79F). Applicant: WENGER TRUCK LINE, INC., P.O. Box 3427, Davenport, IA 52804. Representative: Larry D. Knox, 600 Hubbell Bldg., Des Moines, IA 50309. To those points in the United States in and east of MT, WY, CO, and NM. (24) MC 113666 (Sub-193F). Applicant: FREEPORT TRANSPORT, INC., Drawer "A", 1200 Butler Rd., Freeport, PA 16229. Representative: D. R. Smetanick (same address as applicant). To points in the United States (except AK and HI). (25) MC 113855 (Sub-508F). Applicant: INTERNATIONAL TRANSPORT, INC., a ND corporation, 2450 Marion Rd. SE, Rochester, MN 55901. Representative: Thomas J. Van Osdel, 502 First National Bank Bldg., Fargo, ND 58126. To points in IL, IN, IA, KS, MI, MO, MT, NE, NY, ND, OH, PA, SD, and WI. (26) MC 114211 (Sub-439F). Applicant: WARREN TRANSPORT, INC., P.O. Box 420, Waterloo, IA 50704. Representative: Adelor J. Warren (same address as applicant). To points in the United States (except AK and HI). (27) MC 114632 (Sub-277F). Applicant: APPLE LINES, INC., a NE corporation, P.O. Box 287, Madison, SD 57042. Representative: David E. Peterson (same address as applicant). To points in the United States (except AK and HI). [Note: Dual operations may be involved.] (28) MC 115730 (Sub-82F). Applicant: THE MICKOW CORP., an IN corporation, P.O. Box 1774, 531 S.W. Sixth St., Des Moines, IA 50306. Representative: Cecil L. Goettsch, 1100 Des Moines Bldg., Des Moines, IA 50307. To points in CO, IL, IN, IA, KS, MI, MO, NE, OH, OK, SD, TX, and WI. (29) MC 115931 (Sub-107F). Applicant: BEE LINE TRANSPORTATION, INC., P.O. Box 3987, Missoula, MT 59801. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. To points in CA, CO, ID, IL, IN, IA, KS, KY, MI, MO, MT, NE, NV, ND, OH, OR, PA, SD, UT, WA, WV, WI, and WY. (30) MC 117068 (Sub-125F). Applicant: MIDWEST SPECIALIZED TRANSPORTATION, INC., P.O. Box 6418, North Hwy 63, Rochester, MN 55901. Representative: Paul F. Sullivan, 711 Washington, Bldg., Washington, DC 20005. To points in CO, ID, IL, IN, IA, KS, KY, MI, MO, MT, NE, NY, NC, ND, OH, OK, OR, PA, SD, TN, WA, WI, and WY. (31) MC 118838 (Sub-66F). Applicant: GABOR TRUCKING, INC., R.R. 4, Detroit Lakes, MN 56501. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To points in the United States (except AK and HI). (32) MC 119641 (Sub-182F). Applicant: RINGLE EXPRESS, INC., 450 E. Ninth St., Fowler, IN 47944. Representative: Alki E. Scopelitis, 1301 Merchants Plaza, Indianapolis, IN 46204. To points in IL, IN, IA, MI, OH, and WI. (33) MC 119700 (Sub-67F). Applicant: STEEL HAULERS, INC., 306 Ewing Ave., Kansas City, MO 64125. Representative: Frank W. Taylor, Jr., 1221 Baltimore Ave., Suite 600, Kansas City, MO 64105. To points in AR, IL, IN, IA, KS, KY, LA, MI, MS, MO, OH, OK, TX, and WI. (34) MC 119777 (Sub-452F). Applicant: LIGON SPECIALIZED HAULER, INC., Hwy 85, East Madisonville, KY 42431. Representative: Carl U. Hurst, P.O. Drawer "L", Madisonville, KY 42431. To points in the United States (except AK and HI). (35) MC 123048 (Sub-477F). Applicant: DIAMOND TRANSPORTATION SYSTEM, INC., 5021 21st St., Racine, WI 53406. Representative: John L. Bruemmer, 121 West Doty St., Madison, WI 53703. To points in IL, IN, IA, MI, OH, and WI. (36) MC 123407 (Sub-631F). Applicant: SAWYER TRANSPORT, INC., a MN corporation, Sawyer Center, Rt. 1, Chesterton, IN 46304. Representative: H. E. Miller, Jr. (same address as applicant). To points in the United States (except AK and HI). (37) MC 124174 (Sub-167F). Applicant: MOMSEN TRUCKING CO., a corporation, 13811 "L" St., Omaha, NE 68137. Representative: Karl E. Momsen (same address as applicant). To those points in the United States in and east of ND, SD, NE, CO, OK, and TX. [Note: Dual operations may be involved.] (38) MC 124692 (Sub-326F). Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). To points in the United States (except AK and HI). (39) MC 125470 (Sub-57F). Applicant: MOORE'S TRANSFER, INC., P.O. Box 1151, Norfolk, NE 68701. Representative: Lavern R. Holdeman, 521 South 14th St., Suite 500, P.O. Box 81849, Lincoln, NE 68501. To those points in the United States in and west of WI, IL, MO, AR, and LA (except AK and HI). (40) MC 127651 (Sub-60F). Applicant: EVERETT G. ROEHL, INC., East 29th St., Box 7, Marshfield, WI 54449. Representative: Richard A. Westley, 4506 Regent St., Suite 100, Madison, WI 53705. To points in AR, IL, IN, IA, KS, KY, MI, MO, NE, OH, PA, TN, and WI. (41) MC 128685 (Sub-38F). Applicant: DIXON BROS., INC., P.O. Drawer 8, Newcastle, WY 82701. Representative: Jerome Anderson, 100 Transwestern Bldg., Billings, MT 59101. To points in CO, IL, IN, IA, KS, MI, MO, MT, NE, ND, SD, WI, and WY. (42) MC 129645 (Sub-80F). Applicant: SMEESTER BROS., INC., 1330 South Jackson St., Iron Mountain, MI 49801. Representative: John M. Nader, 1600 Citizens Plaza, Louisville, KY 40202. To those points in the United States in and east of ND, SD, NE, KS, OK, and TX. (43) MC 135231 (Sub-43F). Applicant: NORTH STAR TRANSPORT, INC., Rt. 1, Hwy 1 and 59 West, Thief River Falls, MN 56701. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. To points in the United States (except AL, FL, GA, LA, MS, SC, HI, and AK). [Note: Dual operations may be involved.] (44) MC 135524 (Sub-106F). Applicant: G. F. TRUCKING CO., a corporation, P.O. Box 229, 1028 West Rayen Ave., Youngstown, OH 44501. Representative: George Fedorisin, 914 Salts Springs Rd., Younstown, OH 44509. To those points in the United States in and east of MN, IA, MO, AR, and LA. (45) MC 135924 (Sub-22F). Applicant: SIMONS TRUCKING CO., INC., 3851

River Rd., Grand Rapids, MN 55744. Representative: Samuel Rubenstein, P.O. Box 5, Minneapolis, MN 55440. To points in the United States (except AK and HI). (46) MC 136605 (Sub–144F). Applicant: DAVIS BROS. DIST., INC., P.O. Box 8058, Missoula, MT 59807. Representative: Allen P. Felton (same address as applicant). To points in the United States (except AK and HI). (47) MC 138144 (Sub-58F*). Applicant: FRED OLSON CO., INC., 6022 West State St., Milwaukee, WI 53213. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. To points in the United States (except AK and HI). (48) MC 138627 (Sub-89F). Applicant: SMITHWAY MOTOR XPRESS, INC., P.O. Box 404, Fort Dodge, IA 50501. Representative: Arlyn L. Westergren, Suite 106, 7101 Mercy Rd., Omaha, NE 68106. To points in AR, IL, IN, IA, KS, KY, MI, MO, NE, ND, OH, OK, SD, TN, and WI. (49) MC 139615 (Sub-32F). Applicant: D.R.S. TRANSPORT, INC., P.O. Box 29, Oskaloosa, IA 52577. Representative: Larry D. Knox, 600 Hubbell Bldg., Des Moines, IA 50309. To points in AL, CO, IL, IN, IA, KS, KY, MI, MO, NE, NY, OH, PA, TN, WV, WI, and WY. (50) MC 140186 (Sub-42F), Applicant: TIGER TRANSPORTATION, INC., P.O. Box 2248, Missoula, MT 59801. Representative: Joel E. Guthals, P.O. Box 21115, Billings, MT 59104. To points in CA, ID, IL, IA, KS, MO, MT, NE, ND, OR, SD, WA, and WI. (51) MC 141489 (Sub-12F). Applicant: HUNTER TRUCKING, INC., a NE corporation, 805 32nd Ave., Council Bluffs, IA 51501. Representative: Donald L. Stern, Suite 610, 7171 Mercy Rd., Omaha, NE 68106. To those points in the United States in and west of MI, OH, KY, TN, and AL (except AK and HI). (52) MC 142059 (Sub-118F). Applicant: CARDINAL TRANSPORT, INC., 1830 Mound Rd., Joliet, IL 60436. Representative: Jack Riley (same address as applicant). To points in the United States (except AK and HI). (53) MC 142189 (Sub-44F). Applicant: C. M. BURNS, d.b.a. WESTERN TRUCKING, 521 Lincoln Ave., Baker, MT 59313. Representative: Michael R. Griffith, Box 980, Baker, MT 59313. To points in ID, IL, IN, IA, KS, MI, MO, MT, NE, ND, OH, OR, SD, UT, WA, WI, and WY. (54) MC 142772 (Sub-9F). Applicant: HRDLICKA ENTERPRISES, INC., Route 7, Box 59, Chippewa Falls, WI 54729. Representative: Samuel Rubenstein, P.O. Box 5, Minneapolis, MN 55440. To points in PA and those in the United States in and west of OH, KY, TN, and AL (except AK and HI). (55) MC 143032 (Sub-31F). Applicant: THOMAS J. WALCZYNSKI, d.b.a. WALCO TRANSPORT, 3112 Truck Center Dr., Duluth, MN 55806. Representative: William J. Gambucci, Suite M–20, 400 Marquette Ave., Minneapolis, MN 55402. To points in IL, IN, IA, KY, MI, MO, NE, ND, OH, PA, SD, WV, and WI. (56) MC 144757 (Sub-2F). Applicant: DAKOTA PACIFIC TRANSPORT, INC., 308 West Blvd., Rapid City, SD 57701. Representative: J. Maurice Andren, 1734 Sheridan Lake Rd., Rapid City, SD 57701. To points in AR, CO, IL, IA, KS, MO, MT, NE, ND, OK, SD, WI, and WY. [Note: Dual operations may be involved.] (57) MC 145664 (Sub-15F). Applicant: STALBERGER, INC., 223 South 50th Ave. West, Duluth, MN 55806. Representative: Robert L. Kalenda, 921 First Street North, P.O. Box 966, St. Cloud, MN 56301. To points in IL, IN, IA, KS, KY, MI, MO, NE, NY, ND, OH, PA, SD, and WI. (58) MC 145765 (Sub-8F). Applicant: WIEST TRUCKLINE, INC., 1305 Sixth Ave., S.W., Jamestown, ND 58401. Representative: William J. Gambucci, Suite M–20, 400 Marquette Ave. Minneapolis, MN 55402. To points in CO, ID, IL, IN, IA, KS, KY, MI, MO, MT, NE, ND, OH, OK, OR, SD, WA, WI, and WY. [Note: Dual operations may be involved.] (59) MC 146133 (Sub-2F). Applicant: HALVOR LINES, INC., P.O. Box 6087, Duluth, MN 55806. Representative: Andrew R. Clark, 1000 First National Bank Bldg., Minneapolis, MN 55402. To points in the United States (except AK and HI). [Note: Dual operations may be involved.] (60) MC 146605 (Sub-4F*). Applicant: EVENSON BROS., INC., 835 1st St. SW, Pelican Rapids, MN 56572. Representative: Thomas J. Van Osdel, 502 First National Bank Bldg., Fargo, N.D. 58126. To points in CO, IL, IN, IA, KS, MI, MO, NE, ND, OH, SD, and WI. [Note: Dual operations may be involved.] (61) MC 146756 (Sub-5F). Applicant: WAGNER TRUCKING, INC., 6585 Dawn Way, Inver Grove, MN 55075. Representative: Stanley C. Olsen, Jr., 7400 Metro Blvd., Suite 411, Edina, MN 55435. To points in IL, IN, IA, KS, MI, MO, MT, NE, ND, OH, SE, and WI. (62) MC 149275F. Applicant: GNAN TRUCKING, INC., Route 8, Box 367, Brainerd, MN 56401. Representative: Charles E. Nieman, 615 Minnesota Federal Bldg., Minneapolis, MN 55402. To points in IL, IA, KS, MO, MT, NE, ND, SD, and WI. Restriction: All above are restricted to traffic originating at the named facilities. *Condition: The person or persons who appear to be engaged in common control of applicant and another regulated carrier must either file an application under 49 U.S.C. § 11343 or submit an affidavit indicating why such approval is unnecessary. (Hearing site: St. Paul, MN, or Chicago, IL.)

MC 143059 (Sub-113F), filed December 10, 1979. Applicant: MERCER TRANSPORTATION CO., a corporation, P.O. Box 35610, Louisville, KY 40232. Representative: J. L. Stone (same address as applicant). Transporting *Lumber, lumber products, wood products, and forest products,* from the facilities of Potlatch Corporation, in MN, to points in the United States (except AK and HI), restricted to traffic originating at the named facilities. (Hearing site: St. Paul, MN, or Chicago, IL.)

MC 118468 (Sub-58F), filed January 9, 1980. Applicant: UMTHUN TRUCKING CO., a corporation, 910 South Jackson St., Eagle Grove, IA 50533. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. *Contract carrier,* transporting *lumber, lumber products, wood products, and forest products,* from the facilities of Potlatch Corporation, in MN, to points in ID, IL, IN, IA, KS, KY, MI, MO, MT, NE, ND, OH, OR, SD, WA, WI, and WY, under continuing contract(s) with Potlatch Corporation, of Lewiston, ID. (Hearing site: St. Paul, MN, or Chicago, IL.)

Note.—Dual operations may be involved.

MC 133233 (Sub-68F), filed January 9, 1980. Applicant: CLARENCE L. WERNER d.b.a. WERNER ENTERPRISES, I–80 and Hwy 50, P.O. Box 37308, Omaha, NE 68137. Representative: James F. Crosby, I–80 and Hwy 50, P.O. Box 37205, Omaha, NE 68137. *Contract carrier,* transporting *lumber, lumber products wood products and forest products,* from the facilities of Potlatch Corporation, in MN, to those points in the United States in and west of MI, IN, IL, MO, AR, and LA (except AK and HI), under continuing contract(s) with Potlatch Corporation, of Lewiston, ID. (Hearing site: St. Paul, MN, or Chicago, IL.)

Note.—Dual operations may be involved.

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Decided: March 31, 1980.

By the Commission; Review Board Number 3, Members Parker, Fortier, and Hill.

MC 11012 (Sub-4F), filed February 20, 1980. Applicant: JENKINS-SIMMONS TRANSPORTATION CO., INC., 678 Adams St., North Abington, MA 02351. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181. Transporting *paper and paper products,* between Tewksbury, MA, on the one hand, and, on the other, points in RI. (Hearing site: Boston, MA or Portland, ME.)

MC 32882 (Sub-140F), filed February 25,, 1980. Applicant: MITCHELL BROS. TRUCK LINES, a corporation, 3841

North Columbia Blvd., Portland, OR 97217. Representative: David J. Lister, P.O. Box 17039, Portland, OR 97217. Transporting *talc*, in bags, from Three Forks and Dillon, MT, to points in ID, WY, UT, AZ, NV, CA, OR, and WA. (Hearing site: Los Angeles, CA.)

Note.—The person or persons who appear to be engaged in common control must either file an application under 49 U.S.C. § 11343, or submit an affidavit indicating why such approval is unnecessary.

MC 32882 (Sub-142F), filed February 26, 1980. Applicant: MITCHELL BROS. TRUCK LINES, a corporation, 3841 North Columbia Boulevard, Portland, OR 97217. Representative: David J. Lister, P.O. Box 17039, Portland, OR 97217. Transporting *such commodities* as are dealt in, manufactured by, or used by Woodgrain Moulding Co., Div. of Dames Moulding, Inc., between the facilities of Woodgrain Moulding Co., Div. of Dames Moulding, Inc., at or near (1) Phoenix, AZ, (2) Corona and Woodland, CA, (3) Greeley, CO, (4) Americus, GA, (5) Fruitland, ID, (6) Bristol, ID, (7) Saline, KS, (8) Vicksburg, MS, (9) Lakeview and Newburg, OR, and (10) Mansfield, TX, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Woodgrain Moulding Co., Div. of Dames Moulding, Inc. (Hearing site: Salt Lake City, UT.)

MC 42092 (Sub-7F), filed February 4, 1980. Applicant: ACME INTER-CITY FREIGHT LINES, a corporation, 414 2nd Ave. South, Seattle, WA 98101. Representative: George H. Hart, 1100 IBM Bldg., Seattle, WA 98101. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), over regular routes, between Olympia and Shelton, WA over U.S. Hwy 101. (Hearing site: Seattle, WA.)

MC 44302 (Sub-13F), filed February 20, 1980. Applicant: DEFAZIO EXPRESS, INC. 1028 Springbrook Ave., Moosic, PA 18507. Representative: John L. Alfano, 550 Mamaroneck Ave., Harrison, NY 10528. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between the facilities of Scranton/Wilkes Barre Warehouse, Inc., at or near Scranton, PA, on the one hand, and, on the other, points in CT, DE, ME, MD, MA, NH, NJ, NY, OH, RI, VT, and DC, restricted to the transportation of traffic originating at or destined to the named points. (Hearing site: New York, NY.)

Note.—Dual operations may be involved.

MC 44932 (Sub-18F), filed February 25, 1980. Applicant: W. W. YOUNG & SON, INC., 11861 S. Cottage Grove Ave., Chicago, IL 60628. Representative: Jerome J. Netko (same address as applicant). Transporting *scrap iron and steel*, in bulk, in dump vehicles, between points in Kenosha, Brown, Fond du Lac, Eau Claire, Waupaca, Racine, Walworth, Rock, Green, Dane, and Dodge Counties, WI, on the one hand, and, on the other, Chicago, Peoria, and Danville, IL. (Hearing site: Chicago, IL.)

MC 61592 (Sub-486F), filed February 25, 1980. Applicant: JENKINS TRUCK LINE, INC., P.O. Box 697, Jeffersonville, IN 47130. Representative: E. A. DeVine, P.O. Box 737, Moline, IL 61265. Transporting *alcoholic liquors*, and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (except in bulk, in tank vehicles), between Ft. Smith, AR, Bardstown and Louisville, KY, New Orleans, LA, and Plainfield, IL, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: Springfield or Chicago, IL.)

MC 71642 (Sub-35F), filed December 26, 1979. Applicant: CONTRACTUAL CARRIERS, INC., Harmony Industrial Park, Newark, DE 19711. Representative: Samuel W. Earnshaw, 833 Washington Bldg., Washington, DC 20005. *Contract carrier* transporting (1) *paper and paper products*, and (2) *materials and supplies* used in the production of the commodities in (1) above, between Newark, DE, on the one hand, and, on the other, points in DE, CT, IN, IA, KS, MA, NJ, NY, OH, PA, RI, TN, TX, and VA, under a continuing contract(s) with Westvaco Corporation, of Newark, DE. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 71642 (Sub-36F), filed February 1, 1980. Applicant: CONTRACTUAL CARRIERS, INC., Harmony Industrial Park, Newark, DE 19711. Representative: Samuel W. Earnshaw, 833 Washington Bldg., Washington, DC 20005. *Contract carrier* transporting *plastic and plastic products*, between Greensboro, MD, on the one hand, and, on the other, points east of a line beginning at the mouth of the Mississippi River, and extending along the Mississippi River to its junction with the western boundary of Itasca County, MN, then northward along the Western boundaries of Itasca and Koochiching Counties, MN, to the International Boundary line between the United States and Canada, under continuing contract(s) with J. L. Moorshead Co., Inc. of Greensboro, MD. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 72243 (Sub-63F), filed February 20, 1980. Applicant: THE AETNA FREIGHT LINES, INC., P.O. Box 350, Warren, OH 44482. Representative: Edward G. Villalon, 1032 Pennsylvania Bldg., Pennsylvania Ave. and 13th St. NW, Washington, DC 20004. Transporting *aluminum articles*, from the facilities of Norandal USA, Inc., at or near Huntingdon, TN, to points in IL, IN, MD, MA, NJ, NY, OH, and PA. (Hearing site: Nashville, TN or Washington, DC.)

MC 82492 (Sub-254F), filed February 20, 1980. Applicant: MICHIGAN & NEBRASKA TRANSIT CO., INC., 2109 Olmstead Rd., P.O. Box 2853, Kalamazoo, MI 49003. Representative: Neil E. Hannan (same address as applicant) Transporting *sodium bicarbonate*, in bags, from the facilities of Church & Dwight Co., Inc., at or near Old Fort, OH, to points in IL, IN, IA, KY, KS, MI, MN, MO, NE, ND, SD, TN, and WI, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Chicago, IL or New York, NY.)

MC 82492 (Sub-255F), filed February 20, 1980. Applicant: MICHIGAN & NEBRASKA TRANSIT CO., INC., 2109 Olmstead Rd., P.O. Box 2853, Kalamazoo, MI 49003. Representative: Neil E. Hannan (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers and distributors of printed matter (except in bulk), from the facilities of Danner Press Corporation, at or near Canton, OH, to points in IA, IL, IN, KS, KY, MI, MN, MO, NE, ND, SD, TN, and WI, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Chicago, IL or Columbus, OH.)

MC 82492 (Sub-256F), filed February 20, 1980. Applicant: MICHIGAN & NEBRASKA TRANSIT CO., INC., 2109 Olmstead Rd., P.O. Box 2853, Kalamazoo, MI 49003. Representative: Neil E. Hannan (same address as applicant). Transporting *paper and paper products* and *plastic products* (except in bulk, in tank vehicles), from the facilities of Brown Company, at or near Kalamazoo, MI, to points in (a) IL, IN, KY, ND, OH, SD, TN, and WI, (b) points in PA on and west of U.S. Hwy 219, and (c) points in NY in and west of Broome, Cortland, Onondaga, and Oswega Counties, restricted to the

transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Chicago, IL or Washington, DC.)

MC 87103 (Sub-46F), filed February 19, 1980. Applicant: MILLER TRANSFER AND RIGGING CO., P.O. Box 322, Cuyahoga Falls, OH 44222. Representative: Edward P. Bocko (same address as applicant). Transporting (1) *air purification units, fabricated iron and steel articles and commodities* which, because of size or weight require the use of special handling or special equipment and (2) *equipment, materials and supplies* used in the manufacture, production or distribution of the commodities named in (1) above, (except commodities in bulk) between the facilities of Holmes Bros. Manufacturing Company at Danville, IL, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to shipments originating at or destined to the named facilities. (Hearing site: Indianapolis, IN or Washington, DC.)

Note.—Dual operations may be involved.

MC 87103 (Sub-47F), filed February 19, 1980. Applicant: MILLER TRANSFER AND RIGGING CO., a corporation, P.O. Box 322, Cuyahoga Falls, OH 44222. Representative: Edward P. Bocko (same address as applicant). Transporting (1) *mining machinery and parts, for mining machinery* and (2) *equipment, materials and supplies* used in the manufacture and distribution of the commodities named in (1) above (except commodities in bulk) between the facilities of Lee Norse Company at Charleori, PA on the one hand, and, on the other, points in east of MN, IA, MO, OK and TX, restricted to shipments originating at or destined to the named facilities. (Hearing site: Pittsburgh, PA or Washington, DC.)

Note.—Dual operations may be involved.

MC 107002 (Sub-575F), filed February 20, 1980. Applicant: MILLER TRANSPORTERS, INC., P.O. Box 1123, Jackson, MS 39205. Representative: John J. Borth, P.O. Box 8573, Battlefield Station, Jackson, MS 39204. Transporting *chemicals* and *materials* used in the manufacture of chemicals, in bulk, in tank vehicles, between Tunica, MS, on the one hand, and, on the other, points in the U.S. (except AK and HI). (Hearing site: Memphis, TN.)

MC 107012 (Sub-502F), filed February 21, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Hwy. 30 West, P.O. Box 988, Fort Wayne, IN 46801. Representative: David D. Bishop (same address as applicant). Transporting (1) *conduits and ducts,* and (2) *parts and accessories* for the commodities in (1) above, from the facilities of GI Industry, Inc., at or near Anaheim, CA, to points in the US (except AK and HI). (Hearing site: Los Angeles, CA or Washington, DC.)

MC 107012 (Sub-503F), filed February 28, 1980. Applicant: NORTH AMERICAN VAN LINES, INC., 5001 U.S. Highway 30 West, P.O. Box 988, Fort Wayne 46801. Representative: David D. Bishop, (same address as applicant). Transporting *polyurethane foam,* (a) from Corry, PA, to points in IL, IN, MN, MO, MI, NC, OH, WI and (b) from Milan, TN, to points in IL, IN, IA, KS, MI, MO, NE, OH and WI. (Hearing sites: Boston, MA or Washington, DC.)

MC 108053 (Sub-171F), filed February 20, 1980. Applicant: LITTLE AUDREY'S TRANSPORTATION CO., INC. P.O. Box 129, Fremont, NE 68025. Representative: Arnold L. Burke, 180 North LaSalle St., Chicago, IL 60601. Transporting *canned goods,* from points in WA to points in the US (except AK and HI). (Hearing site: Seattle, WA.)

MC 108523 (Sub-14F), filed February 20, 1980. Applicant: POLMAN TRANSFER, INC., Rte. 3, Box 470, Wadena, MN 56482. Representative: Robert P. Sack, P.O. Box 6010, West St. Paul, MN 55118. *Contract carrier* transporting *canned and preserved foodstuffs,* from the facilities of Heinz USA at or near (a) Fremont, OH, Holland, MI, and Pittsburgh, PA, to points in IL, IA, MN, ND, SD, and WI, and (b) Muscatine and Iowa City, IA, to points in IL, MN, ND, SD, and WI, under continuing contract(s) with Heinz USA, Division of H.J. Heinz Company, of Pittsburgh, PA. (Hearing site: St. Paul, MN.)

Note.—Dual operations may be involved.

MC 109823 (Sub-5F), filed February 29, 1980. Applicant: McGAUGHEY BROS., INC., Third & Center Streets, Leetsdale, PA 15056. Representative: Arthur J. Diskin, 806 Frick Bldg., Pittsburgh, PA 15219. Transporting (1) *building and construction materials* (except in bulk), from the facilities of The Celotex Corporation, at Lockland, OH, to points in PA; and (2) *materials, equipment, and supplies* used in the manufacture and installation of the commodities in (1) above, in the reverse direction. (Hearing site: Washington, DC or Pittsburgh, PA.)

MC 114273 (Sub-704F), filed February 20, 1980. Applicant: CRST, INC., P.O. Box 68, Cedar Rapids, IA 52406. Representative: Kenneth L. Core (same address as applicant). Transporting *such commodities* as are dealt in or used by manufacturers of heating and cooling systems (except commodities in bulk), between points in the US (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities used by Lennox Industries, Inc. (Hearing site: Chicago, IL or Washington, DC.)

MC 114273 (Sub-705F), filed February 20, 1980. Applicant: CRST, INC., P.O. Box 68, Cedar Rapids, IA 52406. Representative: Kenneth L. Core (same address as applicant). Transporting *general commodities* (except in bulk, in tank vehicles, and classes A and B explosives), between Richmond, VA, on the one hand, and, on the other, those points in the US in and east of MN, IA, NE, KS, OK, and TX, restricted to the transportation of traffic originating at or destined to the facilities of Wards Company, Inc., and its wholly-owned subsidiaries Dixie Hi-Fi and Circuit City. (Hearing site: Chicago, IL or Washington, DC.)

MC 114273 (Sub-706F), filed February 20, 1980. Applicant: CRST, INC., P.O. Box 68, Cedar Rapids, IA 52406. Representative: Kenneth L. Core (same address as applicant). Transporting *petroleum products and chemicals,* from Cincinnati, OH, to points in IL, IA, KS, MD, MN, MO, MI, GA, WI, NJ, NY, NC, TN, and VA. (Hearing site: Chicago, IL or Washington, DC.)

MC 114273 (Sub-707F), filed March 4, 1980. Applicant: CRST, INC., P.O. Box 68, Cedar Rapids, IA 52406. Representative: Kenneth L. Core (same address as applicant). Transporting *(1) Woodpulp board, (2) woodpulp, (3) paper and paper articles,* from the facilities of the Chesapeake Corporation at West Point, VA to those points in the United States in and east of ND, SD, NE, KS, OK and TX. (Hearing site: Chicago, IL or Washington, DC.)

MC 115092 (Sub-105F), filed December 26, 1979. Applicant: TOMAHAWK TRUCKING, INC., P.O. Box 0, Vernal, UT 84078. Representative: Walter Kobos, 1016 Kehoe Drive, St. Charles, IL 60174. Transporting (1) *wall board and insulating board,* and (2) *materials and supplies* used in the installation of the commodities in (1) above, (except in bulk), from the facilities of Grefco, Inc., a subsidiary of General Refractories Co., at or near Ontario, CA, to those points in the United States in and west of MN, IA, MO, AR, and LA (except AK and HI). (Hearing site: Salt Lake City, UT, or Los Angeles, CA.)

MC 115162 (Sub-518F), filed February 28, 1980. Applicant: POOLE TRUCK LINE, INC., P.O. Drawer 500, Evergreen, AL 36401. Representative: Robert E. Tate (same address as applicant). Transporting (1) *plastic and plastic articles,* and (2) *materials and supplies* used in the manufacture and distribution

of plastic and plastic articles (except commodities in bulk, in tank vehicles), between Evansville, IN, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, KS, OK, an TX. (Hearing site: Evansville, IN or Louisville, KY.)

MC 116092 (Sub-9F), filed February 1, 1980. Applicant: E. J. PERSONS TRANSPORT, LTD., 411 Rivere, Cowansville, Quebec, Canada JSK IN4. Representative: Jack Goodman, 39 South La Salle St., Chicago, IL 60603. In foreign commerce only, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between the ports of entry on the International Boundary line between the United States and Canada at or near Highgate Springs, VT, on the one hand, and, on the other, Highgate Springs, VT. (Hearing site: Montpelier, VT.)

MC 116273 (Sub-252F), filed February 19, 1980. Applicant: D & L TRANSPORT, INC., 3800 South Laramie Avenue, Cicero, IL 60650. Representative: William R. Lavery (same address as applicant). Transporting *dry plastics* in bulk, in tank vehicles, from Detroit, MI, to IN, IL, IA, NY, PA, WV, and WI. (Hearing site: Chicago, IL.)

MC 116763 (Sub-645F), filed March 3, 1980. Applicant: CARL SUBLER TRUCKING, Inc., North West Street, Versailles, OH 45380. Representative: Gary J. Jira (same address as applicant). Transporting *general commodities* (except classes A and B explosives, commodities in bulk, in tank vehicles, household goods as defined by the Commission, those commodities which because of size or weight requires the use of special equipment, automobiles, trucks and buses) and between the facilities of Kimberly-Clark Corporation, Richmond County, GA, on the one hand, and, on the other, points in the United States, restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Milwaukee, WI.)

MC 117883 (Sub-266F), filed February 26, 1980. Applicant: SUBLER TRANSFER, INC., One Vista Drive Versailles, OH 45380. Representative: Robert Von Aschen, P.O. Box 62, Versailles, OH 45380. Transporting *brick, brick products,* and *such commodities* as are dealt in, used by or distributed by manufacturers of brick and brick products (except in bulk) from the facilities of Harmer Clay Products, at or near Cheswick, PA, to points in IL, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 118263 (Sub-89F), filed August 2, 1979. Applicant: COLDWAY CARRIERS, INC., P.O. Box 2038, Clarksville, IN 47130. Representative: William P. Whitney, Jr., 708 McClure Bldg., Frankfort, KY 40601. Transporting *bakery products* (in vehicles equipped with mechanical refrigeration), from the facilities of the Eckel Baking Company at Clearwater, FL, to those points in the United States in and east of MN, IA, MO, AR, and LA, restricted to the transportation of traffic originating at or destined to points in the above destinations. (Hearing site: Tampa or St. Petersburg, FL.)

MC 118803 (Sub-17F), filed February 19, 1980. Applicant: ATLANTIC TRUCK LINES, INC., 45 Gilpin Avenue, Hauppauge, NY 11787. Representative: Morton E. Kiel, Suite 1832, 2 World Trade Center, New York, NY 10048. *Contract carrier,* transporting: (1) Dry plastic materials (except in bulk), and (2) *materials, supplies and equipment* used in the manufacture, distribution and sale of the commodities in (1) above (except in bulk), (1) between points in IA, IL, NJ, NY, OH, and WV, on the one hand, and, on the other, points in the United States in and east of MN, IA, NE, KS, OK and TX, and (2) between points in TX and LA, on the one hand, and, on the other, those points in the United States in and east of MN, IA, NE, KS, OK, AR and LA, under continuing contract(s) with Polymer Materials div. of Georgia-Pacific Corporation at Farmingdale, NY. (Hearing site: New York, NY.)

MC 119493 (Sub-357F), filed February 19, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, Missouri 64801. Representative: Thomas D. Boone (same address as applicant). Transporting: (1) *iron and steel articles* (2) *machinery, materials and supplies* used in the manufacture and distribution of the commodities in (1) (except commodities in bulk), between Newton County, MO, on the one hand, and on the other, points in the United States (except AK and HI). (Hearing site: Joplin or Kansas City, MO.)

MC 119493 (Sub-358F), filed February 19, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone, Traffic Manager (same address as applicant). Transporting *flour, starch, and grain products* (except commodities in bulk), from points in KS (except Buhler, Inman, McPherson, Whitewater, and Hutchinson) to points in AL, AR, FL, GA, LA, MS, MO, OK, TN and TX. (Hearing site: Kansas City, MO or Topeka, KS.)

MC 119493 (Sub-359F), filed February 19, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting: (1) *iron and steel articles,* and (2) *materials, equipment and supplies* used in the manufacture, distribution, and installation of the commodities in (1) above (except commodities in bulk), between Memphis, TN; Newton, NC; Salyersville, KY; Sherman, TX; and Winfield, AL on the one hand, and, on the other, points in the U.S. (except AK and HI). (Hearing site: Birmingham, AL or Atlanta, GA.)

MC 119493 (Sub-360F), filed February 27, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting (1) *furniture, and furniture parts,* and (2) *materials and supplies* used in the manufacture and distribution of the commodities in (1) above, (except commodities in bulk), between points in TX, on the one hand, and, on the other, those points in the United States in and west of MT, WY, CO, and NM. (Hearing site: Dallas or Ft. Worth, TX.)

MC 119493 (Sub-361F), filed February 27, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between the facilities of Kimberly-Clark Corporation, Richmond County, GA, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Madison, WI or Minneapolis, MN.)

MC 119493 (Sub-362F), filed February 27, 1980. Applicant: MONKEM COMPANY, INC., P.O. Box 1195, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting *such commodities* as are dealt in by discount and retail department stores (except commodities in bulk), between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Target Stores Division of Dayton-Hudson Corporation. (Hearing site: Minneapolis, or St. Paul, MN.)

MC 119493 (Sub-363F), filed February 27, 1980. Applicant: MONKEM

COMPANY, INC., P.O. Box 1196, Joplin, MO 64801. Representative: Thomas D. Boone (same address as applicant). Transporting (1) *rubber articles,* and (2) *plastic articles,* and (3) *materials, equipment and supplies* used in the manufacture and distribution of the commodities in (1) and (2) above, (except commodities in bulk, in tank vehicles), between the facilities of Entek Corporation of America, at or near Irving, TX, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Dallas or Ft. Worth, TX.)

MC 126063 (Sub-14F), filed November 26, 1979. Applicant: BIRD TRUCKING, INC., 1370 Swaner Rd., Salt Lake City, UT 84104. Representative: Bruce W. Shand, 430 Judge Bldg., Salt Lake City, UT 84111. *Contract carrier* transporting *meats, meat products, meat by-products, and articles distributed by meat-packing houses,* as described in sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766, from the facilities of Intermountain Protein Products, Inc., at or near West Jordan, UT, to points in CA, CO, ID, OR, TX, and UT, under continuing contract(s) with Intermountain Protein Products, Inc. (Hearing site: Salt Lake City, UT.)

MC 120822 (Sub-4F), filed February 25, 1980. Applicant: INDUSTRIAL FREIGHT SYSTEM, INC., 9120 San Fernando Rd., Sun Valley, CA 91352. Representative: M. Gamel (same address as applicant). Transporting *general commodities* (except commodities in bulk, in tank vehicles, and classes A and B explosives), moving on bills of lading of freight forwarders as defined in Section 10102(8), between points in CA, on the one hand, and, on the other, points in AZ, NV, NM, OR, and WA. (Hearing site: Los Angeles or San Francisco, CA.)

Note.—The person or persons who appear to be engaged in common control must either file an application under 49 U.S.C. § 11343, or submit an affidavit indicating why such approval is unnecessary.

MC 124692 (Sub-330F), filed February 25, 1980. Applicant: SAMMONS TRUCKING, a corporation, P.O. Box 4347, Missoula, MT 59806. Representative: J. David Douglas (same address as applicant). Transporting *mining and construction equipment, and materials and supplies,* from the facilities of Frontier-Kemper Construction at or near Evansville, IN to those points in the United States in and west of MI, WI, IL, MO, AR, and LA (except AK and HI). (Hearing site: Chicago, IL.)

MC 125433 (Sub-373F), filed January 24, 1980. Applicant: F–B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Rd., Salt Lake City, UT 84104. Representative: John B. Anderson (same address as applicant). Transporting (1) *hose, and hose fillings,* from the facilities of Swan Hose Division Amerace Corporation at or near (a) Stillwater, OK, (b) Dallas and Farmers Branch, TX, (c) Elkton and Lexington, TN, (d) Bucyrus and Columbus, OH, (e) Sparks, NV, (f) Elk Grove Village, IL, and (g) Los Angeles and Santa Fe Springs, CA, to points in the United States (except AK and HI), and (2) *equipment, materials, and supplies* used in the manufacture and distribution of the commodities in (1) above, in the reverse direction. (Hearing site: Columbus, OH.)

MC 125433 (Sub-391F), filed February 22, 1980. Applicant: F–B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Rd., Salt Lake City, UT 84104. Representative: John B. Anderson (same address as applicant). Transporting *insulation,* in bags, from Pueblo, CO to points in NM. (Hearing site: Denver, CO or Salt Lake City, UT.)

MC 125433 (Sub-392F), filed February 25, 1980. Applicant: F–B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Rd., Salt Lake City, UT 84104. Representative: John B. Anderson (same address as applicant). Transporting *water beds* and *accessories* for water beds, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Mountain States Water Bed Distribution, Inc. (Hearing site: Denver, CO or Salt Lake City, UT.)

MC 125433 (Sub-393F), filed February 27, 1980. Applicant: F–B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). Transporting (1) *Chemicals,* and (2) *additives used in petroleum and gas exploration,* (except commodities in bulk in (1) and (2) above) between points in the United States (except AK and HI), Restricted to the transportation of traffic originating at or destined to the facilities of Van Waters & Rogers. (Hearing site: Denver, CO.)

MC 125433 (Sub-394F), filed February 28, 1980. Applicant: F–B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Road, Salt Lake City, UT 84104. Representative: John B. Anderson (same as applicant). (1) *Batteries, and battery accessories,* and (2) *material, equipment and supplies* used in the manufacture and distribution of batteries, between the facilities used by ESB Incorporated, Division of Exide Corporation, at Horsham, PA, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Chicago, IL.)

MC 125433 (Sub-395F), filed February 29, 1980. Applicant: F–B TRUCK LINE COMPANY, a corporation, 1945 South Redwood Rd., Salt Lake City, UT 84104. Representative: John B. Anderson (same address as applicant). Transporting *lumber and lumber mill products,* between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Rehcon, Inc. (Hearing site: Omaha, NE or Salt Lake City, UT.)

MC 126822 (Sub-82F), filed February 28, 1980. Applicant: WESTPORT TRUCKING COMPANY, 15580 South 169 Highway, Olathe, KS 66061. Representative: John T. Pruitt, 15580 South 169 Highway, Olathe, KS 66061. Transporting (1) *Nonalcoholic beverages,* and (2) *empty containers* between the facilities of Shasta Beverages, Inc., at Lenexa, KS, and points in AR, IL, MO, NE, and OK. (Hearing site: Kansas City, MO.)

MC 126822 (Sub-83F), filed February 29, 1980. Applicant: WESTPORT TRUCKING COMPANY, 15580 South 169 Hwy., Olathe, KS 66061. Representative: John T. Pruitt (same address as applicant). Transporting *Transporting nonalcoholic cocktail mixes,* from Byhalia, MS, to points in the United States (except AK and HI). (Hearing site: Kansas City, MO.)

MC 134783 (Sub-65), filed February 19, 1980. Applicant: DIRECT SERVICE, INC., 940 East 66th Street, P.O. Box 2491, Lubbock, TX 79408. Representative: Charles M. Williams, 350 Capitol Life Center, 1600 Sherman Street, Denver, CO 80203. Transporting *meats, meat byproducts, dairy products,* and articles distributed by meat-packing houses as described in Sections A, B and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of John Morrell & Co., at or near (1) Lubbock, TX, to points in IL, IN, IA, KS, MN and WI, and (2) El Paso, TX, to points in AL, AR, DE, FL, GA, IL, IN, IA, KY, KS, LA, ME, MI, MN, MS, NH, NC, RI, SC, SD, TN, VT, WI, and DC, restricted to the transportation of traffic originating at the named facilities. (Hearing site: Chicago, IL or Lubbock, TX.)

Note.—Dual operations may be involved.

MC 134922 (Sub-323F), filed February 21, 1980. Applicant: B. J. McAdams, INC., Rt. 6, Box 15, North Little Rock, AR

72118. Representative: Bob McAdams, (same address as applicant). Transporting *meats, packing-house products and commodities* used by packinghouses as described in Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), between the facilities of Lauridsen Foods, Inc. at or near Britt, IA and Armour and Company at Mason City, IA, on the one hand, and, on the other, points in the U.S. (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Lauridsen Foods, Inc., and Armour and Company. (Hearing site: Phoenix, AZ or Little Rock, AR.)

MC 135033 (Sub-9F), filed Febraury 25, 1980. Applicant: SILVEY REFRIGERATED CARRIERS, INC., 7000 West Center Rd., Suite 325, Omaha, NE 68106. Representative: Robert M. Cimino, (same address as applicant). *Contract carrier* transporting *rubber, canvas and leather products,* from Taneytown. MD, Loveland, OH, and points in NY and MA, to the facilities of The Philadelphia Company in Omaha, NE, under continuing contract(s) with The Philadelphia Company of Omaha, NE., (Hearing site: Omaha, NE.)

Note.—Dual operations may be involved.

MC 135113 (Sub-2F), filed November 6, 1979. Applicant: DORIN, INC., Georgia Hwy. 83 South, Madison, GA 30650. Representative: John P. Tucker, Jr., Suite 202, 2200 Century Parkway, Atlanta, GA 30345. *Contract carrier,* transporting *general commodities* (except commodities in bulk, classes A and B explosives, household goods, as defined by the Commission, and those requiring special equipment), between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Wellington Technical Industries, Inc., and its subsidiaries, Wellington Publication Press, Inc., Wellington Synthetic Fibers. Inc., Dorin, Inc., Wellington Puritan Mills, Inc., Puritan Marine Flotation, Inc., and Barberton Puritan Plastic Products, Inc., under continuing contract(s) with Wellington Technical Industries, Inc., of Madison, GA, and its subsidiaries Wellington Publication Press, Inc., of Baltimore, MD, Wellington Synthetic Fibers, Inc., of Paterson, NJ, Dorin, Inc., of Madison, GA, Wellington Puritan Mills, Inc., of Madison, GA, Puritan Marine Flotation, Inc., Of Eatonton, GA, and Barberton Puritan Plastic Products, Inc., of Barberton, OH. (Hearing site: Atlanta, GA.)

MC 135482 (Sub-5F), filed January 3, 1980. Applicant: CEMENT TRANSPORT, LTD., P.O. Box 761, Valley City, ND, 58072. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. *Contract carrier* transporting *flyash,* from points in WI to points in ND, under continuing contract(s) with Beyer's Cement, Inc. (Hearing site: Fargo, ND.)

MC 135482 (Sub-6F), filed January 4, 1980. Applicant: CEMENT TRANSPORT, LTD., P.O. Box 761, Valley City, ND 58072. Representative: Gene P. Johnson, P.O. Box 2471, Fargo, ND 58108. *Contract carrier* transporting *cement, lime, and flyash,* from Bismarck, Grand Forks, and Valley City, ND, to points in MN and SD, under continuing contract(s) with Beyer's Cement, Inc. (Hearing site: Fargo, ND.)

MC 135762 (Sub-12F), filed January 11, 1980. Applicant: JOHN H. NEAL, INC., P.O. Box 3877, 6004 Highway 271 South, Fort Smith, AR 72913. Representative: Don A. Smith, P.O. Box 43, 510 North Greenwood, Fort Smith, AR 72902. *Contract carrier* transporting (1) *new furniture,* from Fort Smith, AR, to points in the United States (except AK and HI), and (2) *equipment, materials, and supplies* used in the manufacture and distribution of the commodities in (1) above, in the reverse direction, under continuing contract(s) in (1) and (2) above with Garrison Furniture Company. (Hearing site: Little Rock, AR or Washington, DC.)

MC 135873 (Sub-12F), filed January 3, 1980. Applicant: K.S.S. TRANSPORTATION CORP., P.O. Box 3052, Rte. 1 and Adams Station, New Brunswick, NJ 08902 Representative: Daniel C. Sullivan, 10 South LaSalle St., Suite 1600, Chicago, IL 60603. *Contract carrier* transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between points in the United States (except AK and HI), under continuing contract(s) with Aunt Nellie's Foods, Inc., Beatrice Foods Co., Brookside Enterprises, Inc., Fort Smith Table and Furniture Co., Harman International Ind., Inc., E. W. Kneip, Inc., Martha White Foods, Inc., Peter Eckrich and Sons, Inc., and Samsonite Corporation. (Hearing site: Chicago, IL.)

Note.—A primary purpose of the application is to convert a portion of the private fleet of Beatrice Foods Co., and to obtain ability to cross-haul freight between Beatrice Foods Co., and other contracting shippers who are wholly owned subsidiaries. Applicant is a wholly owned subsidiary of Beatrice Foods Co.

MC 136182 (Sub-9F), filed February 25, 1980. Applicant: B & C MOTOR FREIGHT, INC., P.O. Box 166, Peru, IN 46970. Representative: Donald W. Smith, P.O. Box 40248, Indianapolis, IN 46240. Transporting *fertilizer,* from Louisville, KY, to points in IN and OH. (Hearing site: Atlanta, GA or Washington, DC.)

MC 136363 (Sub-20F), filed February 18, 1980. Applicant: J & P PROPERTIES, INC., P.O. Box 1146, Apopka, FL 32703. Representative: James E. Wharton, Suite 811, Metcalf Building, 100 South Orange Ave., Orlando, FL 32801. Transporting (1) *transformers and transformer parts,* and (2) *materials and supplies* used in the manufacture of the commodities in (1) above, from the facilities of RTE Corporation at Waukesha, WI to points in TX, LA, MS, AL, SC, NC, GA, FL and OR. (Hearing site: Miami, Jacksonville, or Orlando, FL.)

MC 136512 (Sub-19F), filed February 19, 1980. Applicant: SPACE CARRIERS, INC., 444 Lafayette Road, St. Paul, MN 55101. Representative: James E. Ballenthin, 630 Osborn Building, St. Paul, MN 55102. Transporting *such commodities* as are dealt in by department stores, between points in the United States (except AK and HI) restricted to the transportation of traffic originating at or destined to the facilities of Target Stores, division of Dayton-Hudson Corporation. (Hearing site: St. Paul, MN.)

MC 136553 (Sub-74F), (correction), filed May 21, 1979, published in the **Federal Register,** issue of October 23, 1979, and republished, as corrected, this issue: Applicant: ART PAPE TRANSFER, INC., 1080 East 12th Street, Dubuque, IA 52001. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. Transporting (1) *coolant filters, metal chip conveyors, and machines for washing parts,* from Dubuque, IA, to points in IL, IN, MI, and WI; and (2) *materials and supplies* used in the manufacture of the commodities in (1) above, (except commodities in bulk), in the reverse direction. (Hearing site: Chicago, IL.)

Note.—The purpose of this republication is to correctly describe the commodity description.

MC 136782 (Sub-28F), filed January 18, 1980. Applicant: R.A.N. TRUCKING COMPANY, a corporation, P.O. Box 128, Eau Claire, PA 16030. Representative: Daniel C. Sullivan, 10 S. LaSalle St., Suite 1600, Chicago, IL 60603. Transporting (1) *dairy products and fresh and cured meats,* from points in IN and OH to New York, NY, Trenton and Camden, NJ, Philadelphia, PA, and Wilmington, DE, points in PA in and

west of Fulton, Huntingdon, Mifflin, Centre, Clinton and Potter Counties and those points in OH east of a line beginning at Cleveland, OH and extending along OH Hwy 21 to junction U.S. Hwy 250, then along U.S. Hwy 250 to junction Interstate Hwy 77, then along Interstate Hwy 77 to junction U.S. Hwy 40 at or near Cambridge, OH, then along U.S. Hwy 40 to the OH-WV State line, including points on the named highways: (2)(a) *food products,* and (b) *equipment, materials and supplies* used in the production, sale and distribution of the commodities named in (2)(a) above, (except commodites in bulk), between points in IN and OH, on the one hand, and, on the other, New York, NY, Trenton and Camden, NJ, Philadelphia, PA, and Wilmington, DE, points in PA in and west of Fulton, Huntingdon, Mifflin, Centre, Clinton and Potter Counties, PA and those in OH east of a line beginning at Cleveland, OH and extending along OH Hwy 21 to junction U.S. Hwy 250, then along U.S. Hwy 250 to junction Interstate Hwy 77, then along Interstate Hwy 77 to junction U.S. Hwy 40 at or near Cambridge, OH, then over U.S. Hwy 40 to the OH-WV State line, including points on the named highways. (Hearing site: Pittsburgh, PA or New York, NY.)

MC 136782 (Sub-29F), filed January 18, 1980. Applicant: R.A.N. TRUCKING COMPANY, a corporation, P.O. Box 128, Eau Claire, PA 16030. Representative: Daniel C. Sullivan, 10 S. LaSalle St., Suite 1600, Chicago, IL 60603. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and commodities requiring special equipment), from New York, NY and points in Lackawanna, Monroe, Northhampton, Pike, Susquehanna, and Wyoming Counties, PA, to those points in PA in and west of Fulton, Huntingdon, Mifflin, Centre, Clinton and Potter Counties, PA and those in OH east of a line beginning at Cleveland, OH, and extending along OH Hwy 21 to junction U.S. Hwy 250, then along U.S. Hwy 250 to junction Interstate Hwy 77, then along Interstate Hwy 77 to junction U.S. Hwy 40 at or near Cambridge, OH, and then along U.S. Hwy 40 to the OH-WV State line, including points on the named highways, Ft. Wayne and South Bend, IN, Cincinnati and Lorain, OH; and Wheeling, WV. (Hearing site: Pittsburgh, PA or Chicago, IL.)

MC 138882 (Sub-352F), filed February 28, 1980. Applicant: WILEY SANDERS TRUCK LINES, INC., P.O. Drawer 707, Troy, AL 36081. Representative: John J. Dykema (same address as applicant). Transporting: *Non-ferrous metal scrap* between points in AL, AR, CO, GA, IL, IN, IA, KS, KY, LA, MI, MN, MS, MO, NJ, NY, NC, OH, OK, PA, SC, TN, TX, VA, WV and WI. (Hearing site: St. Louis, MO or Montgomery, AL.)

MC 140033 (Sub-87F), filed March 3, 1980. Applicant: COX REFRIGERATED EXPRESS, INC., 10606 Goodnight Lane, Dallas, TX 75235. Representative: D. Paul Stafford, P.O. Box 45338, Dallas, TX, 75245. Transporting *ice cream, fruit juices, milk, cream and yogurt,* in mechanically refrigerated vehicles from Dallas, Sulpher Springs, and McKinney, TX, to Miami, FL, Phoenix, AZ, Santa Anna, CA, and Denver, CO. (Hearing site: Dallas, TX.)

**Note.**—Dual operations may be involved).

MC 140033 (Sub-88F), filed March 3, 1980. Applicant: COX REFRIGERATED EXPRESS, INC., 10606 Goodnight Lane, Dallas, TX, 75220. Representative: D. Paul Stafford, P.O. Box 45538, Dallas, TX 75245. Transporting prepared *bakery goods* except frozen, from Dallas, TX, Marietta, OK, and Louisville, KY, to points in ID, OR, CA, CO, NM, AR, NY, PA, LA, MA, RI, UT, AZ, and TX. (Hearing site: Dallas, TX.)

**Note.**—Dual operations may be involved.

MC 140162 (Sub-5F), filed February 25, 1980. Applicant: SCHNEIDER MOTORWAYS, INC., R. R. —#1, Postville, IA 52162. Representative: Richard D. Howe, 600 Hubbell Bldg., Des Moines, IA 50309. Transporting (1) *cheese,* from the facilities of Gunder Coop Cheese Factory at or near Postville, IA, to Plymouth, WI and Van Wert, OH, and (2) *materials and supplies* used in the manufacture and distribution of cheese, in the reverse direction. (Hearing site: Des Moines, IA or Minneapolis, MN.)

**Note.**—Common control may be involved.

MC 140612 (Sub-83F), filed February 26, 1980. Applicant: ROBERT F. KAZIMOUR, P.O. Box 2207, Cedar Rapids, IA 52406.Representative: J. L. Kazimour (same address as applicant). Transporting *such commodities* as are dealt in or used by retail stores (except foodstuffs, alcoholic beverages, and commodities in bulk, in tank vehicles), between Northridge, CA, on the one hand, and, on the other, points in AZ, CO, CT, DE, FL, ID, MD, MA, ME, MT, NC, NH, NJ, NM, NV, NY, OR, PA, RI, SC, UT, VA, VT, WA, and WY. (Hearing site: Los Angeles, CA.)

MC 141532 (Sub-74F), filed March 3, 1980. Applicant: PACIFIC STATES TRANSPORT, INC., 3328 East Valley Road, Renton, WA 98055. Representative: Henry C. Winters 525 Evergreen Building, Renton, WA 98055. Transporting *glass,* from the facilities of Guardian Industries Corporation at or near Corsicana, TX to points in the U.S. (except AK and HI). (Hearing site: Fort Worth, TX.)

MC 141532 (Sub-75F), filed February 25, 1980. Applicant: PACIFIC STATES TRANSPORT, INC., 3328 East Valley Rd., Renton, WA 98055. Representative: Henry C. Winters, 525 Evergreen Bldg., Renton, WA 98055. Transporting *aluminum and aluminum products,* from the facilities of Kaiser Aluminum & Chemical Corporation at Trentwood, WA, to points in AR, IA, IL, IN, KS, KY, LA, MI, MO, NJ, NY, OH, OK, PA, TN, TX, WI, and WV. (Hearing site: San Francisco, CA.)

MC 142452 (Sub-2F), filed February 27, 1980. Applicant: RIMAR TRANSPORT, INC. 850 Curie Road, North Brunswick, NJ 08902. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 Eleventh Street, NW, Washington, DC 20001. *Contract carrier,* Transporting (1) *iron and steel articles* and (2) *materials, equipment and supplies* (except in bulk, in tank vehicles), used in the manufacture, and distribution of the commodities in (a) above, between the facilitties of Baldwin Steel Company, at or near Jersey City, NJ, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, OK, and TX, under a continuing contract(s) with Baldwin Steel Company, of Jersey City, NJ. (Hearing site: New York, NY.)

MC 143103 (Sub-7F), filed January 17, 1980. Applicant: CHEROKEE LINES, INC., P.O. Box 152, Cushing OK 74023. Representative: Donald L. Stern, Suite 610, 7171 Mercy Rd., Omaha, NE 68106. *Contract carrier* transporting *foodstuffs,* from the facilities of Avoset Foods Corporation at Gustine, CA, to points in the United States (except AK, HI, CO, CT, DE, IL, IN, IA, KS, KY, MD, MA, MI, MN, MO, NE, NH, NJ, NY, OH, OR, PA, RI, VT, VA, WA, WV, WI, and DC, under continuing contract(s) with Avoset Foods Corporation. (Hearing site: San Francisco or Los Angeles, CA.)

**Note.**—Dual operations may be involved.

MC 143183 (Sub-12F), filed December 19, 1979. Applicant: L. M. ROACH d.b.a. D & L TRUCKING COMPANY. P.O. Box 1741, Wilmington, NC 28402. Representative: Ralph McDonald P.O. Box 2246 Raleigh, NC 27602. Transporting *salt* from Wilmington, NC to points in GA and SC. (Hearing site: Wilmington or Raleigh, NC.)

MC 143503 (Sub-29F), filed March 3, 1980. Applicant: MERCHANTS HOME DELIVERY SERVICE, INC., P.O. Box

5067, Oxnard, CA 93031. Representative: T. M. Brown, P.O. Box 1540, Edmond, OK 73034. Transporting *new furniture, furnishings,* and *appliances,* from St. Paul, MN to points in St. Croix, Pierce, Barron, Buffalo, Chippewa, Dunn, Eau Claire, Pepin, and Polk Counties, WI. (Hearing site: Miami, FL, or Minneapolis, MN.)

MC 143522 (Sub-3F), filed February 25, 1980. Applicant: CONSOLIDATED CARRIERS, INC., 121 Sunrise Dr., Irwin, PA 15642. Representative: Patrick E. Quinn, P.O. Box 9596, Chattanooga, TN 37412. Transporting *foodstuffs* (except in bulk), from the facilities of Borden Foods at or near (a) Waterloo and Syracuse, NY, (b) Wellsboro, PA, and (c) Van Wert, OH, to points in the United States (except AK and HI). (Hearing site: Columbus, OH.)

MC 143553 (Sub-4F), filed February 20, 1980. Applicant: CONTINENTAL TRANSPORT SYSTEMS, INC., P.O. Box 236, Versailles, CT 06383. Representative: Ronald I. Shapss, 450 7th Ave., New York, NY 10001. *Contract carrier* transporting *kraft linerboard,* and *materials, supplies, and equipment* used in the manufacture of kraft linerboard, between Riceboro, GA, on the one hand, and, on the other, Edison, NJ, Reading, PA, New Haven, CT, and Lowell, MA, under continuing contract(s) with Interstate Container Corporation, of New Haven, CT. (Hearing site: New Haven, CT.)

MC 143702 (Sub-9F), filed December 21, 1979. Applicant: ALL FREIGHT SYSTEMS, INC., 1026 South 10th St., Kansas City, KS 66105. Representative: Donald J. Quinn, 1012 Baltimore, Kansas City, MO 64105. Transporting (1) *automotive parts and accessories,* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, between the facilities of Standard Motor Products, Inc., at Edwardsville, KS, on the one hand, and, on the other, Dallas and Houston, TX, and points in Bronx County, NY. (Hearing site: Kansas City, MO.)

Note.—Dual operations may be involved.

MC 144122 (Sub-72F), filed February 29, 1980. Applicant: CARRETTA TRUCKING, INC., South 160, Rte. 17 North, Paramus, NJ 07652. Representative: Charles J. Williams, 1815 Front St., Scotch Plains, NJ 07076. Transporting (1) *plastic pellets, plastic resin, plastic film, and plastic articles* (except commodities in bulk), and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above (except commodities in bulk), between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Pantasote Corporation of New York. (Hearing site: New York, NY.)

Note.—Dual operations may be involved.

MC 144622 (Sub-151F), filed February 19, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant). Transporting: *such commodities as are dealt in by grocery and food business houses (except frozen commodities and commodities in bulk)* from the facilities of the Clorox Company at Houston, TX to points in LA, AR, and OK. (Hearing site: Little Rock, AR).

Note.—Dual operations may be involved.

MC 144622 (Sub-152F), filed February 20, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant). Transporting *such commodities* as are dealt in by discount and retail department stores (except commodities in bulk), between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Target Stores, Division of Dayton-Hudson Corporation. (Hearing site: Little Rock, AR.)

Note.—Dual operations may be involved.

MC 144622 (Sub-153F), filed February 19, 1980. Applicant: GLENN BROS. TRUCKING, INC., P.O. Box 9343, Little Rock, AR 72219. Representative: Phillip G. Glenn (same address as applicant). Transporting *foodstuffs* (except in bulk) from the facilities M&M MARS, Snackmaster Division at Albany, GA, to points in AZ, CA, CO, FL, GA, IL, IN, LA, MA, MD, MI, MN, MO, NC, NJ, OH, OR, PA, TN, TX, and UT. (Hearing site: Little Rock, AR.)

Note.—Dual operations may be involved.

MC 144643 (Sub-11F), filed February 20, 1980. Applicant: VINGI BROTHERS TRUCKING CO., INC., 28 Oakdale Ave., Johnston, RI 02919. Representative: William F. Poole, 41 Bea Drive, North Kingstown, RI 02852. *Contract carrier* transporting (1)(a) *wire displays, plain steel wire, and cardboard cartons,* and (b) *equipment, parts, and accessories* used in the manufacture and distribution of the commodities in (a) above, from the facilities used by Eastern Wire Products Company, at or near Providence, RI, to points in the US (except AK and HI); and (2) *tubing, steel wire on carriers,* and *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above, in the reverse direction, under continuing contract(s) with Eastern Wire Products Co., of Providence, RI. (Hearing site: Providence, RI or Boston, MA.)

MC 144963 (Sub-2F), filed February 19, 1980. Applicant: W.E. BATTLES d.b.a. JOBBERS FREIGHT SERVICE, 111 North College St., Grangeville, ID 83530. Representative: Timothy R. Stivers, P.O. Box 162, Boise, ID 83701. Transporting *such commodities* as are dealt in by auto, truck and tractor supply houses; *welding supplies;* and Transporting *compressed gases* in containers, between Spokane, WA, on the one hand, and, on the other, the facilities of (a) Clarkston Auto Parts at or near Clarkston, WA; (b) Black Auto Parts, Brown Motors, Inc., and John Hoene Implement & Idaho County Sales at or near Grangeville, ID; (c) Monty's Kamiah Auto Center and Olive Auto Parts at or near Kamiah, ID; (d) C-Mac Auto Parts and Industrial Parts & Machine, Inc., at or near Lewiston, ID; (e) McGraw's Auto Parts at or near Moscow, ID; and (f) Valley Motor Parts at or near Orofino, ID. (Hearing site: Boise, ID.)

MC 145072 (Sub-32F), filed November 7, 1979. Applicant: M.S. CARRIERS, INC., 7372 Eastern Ave., Germantown, TN 38138. Representative: A. Doyle Cloud, Jr., 2008 Clark Tower, 5100 Poplar Ave., Memphis, TN 38137. Transporting (1) *equipment, materials, and supplies* used in the manufacture of heating and refrigeration equipment, and (2) Transporting *steel and aluminum,* from points in IL, IN, MI, NJ, NY, OH, and PA to the facilities of McQuay-Perfex, Inc., at Fairbault, MN, and Spirit Lake, IA. (Hearing site: Memphis, TN.)

Note.—Dual operations may be involved.

MC 145152 (Sub-177F), filed February 20, 1980. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72701. Transporting *dry animal food,* in bags, from Red Bay, AL and Tupelo, MS, to points in the US (except AK, AL, CA, CO, HI, ID, MN, MS, MT, ND, NE, NM, NV, OR, SD, TN, UT, WA, and WY), restricted to the transportation of traffic originating at the facilities of Sunshine Mills, Inc., at or near Red Bay, AL and Tupelo, MS. (Hearing site: Florence, AL or Fayetteville, AR.)

MC 145152 (Sub-178F), filed February 25, 1980. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, P.O. Box 1065 Fayetteville, AR 72701. Transporting (1) *rolled mesh and cage wire, and outer cartons and styrofoam liners,* from Blue Isle and Chicago, IL,

and Kansas City, MO, to Rogers, AR; (2) *rolled mesh and cage wire,* from Chicago, IL, to Anton, TX; and (3) *animal feed* (except in bulk) from Oklahoma City, OK, to Rogers, AR, and Anton, TX. (Hearing site: Fayetteville, AR.)

MC 145152 (Sub-179F), filed February 25, 1980. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72701. Transporting (1) *foodstuffs* between the facilities of Vlasic Foods, Inc., at or near Imlay City, Bridgeport, and Memphis, MI, on the one hand, and, on the other, Greenville, MS, (2) *foodstuffs* (except frozen) between the facilities of Vlasic Foods, Inc., at or near Greenville, MS, on the one hand, and, on the other, points in AL, AR, CO, GA, KS, KY, LA, MO, NM, OK, TN and TX, and (3) *foodstuffs* (except frozen) between the facilities of Vlasic Foods, Inc., at or near Imlay City, Bridgeport and Memphis, MI, on the one hand, and, on the other, points in IA, IL, IN, MN, ND, NE, NY, OH, PA, SD and WI. (Hearing site: Detroit, MI, or Fayetteville, AR.)

MC 145152 (Sub-180F), filed February 28, 1980. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72701. Transporting *iron and steel pipe fittings,* from the facilities of Tube-Line Corporation, at or near (a) Long Island City, NY, and (b) Houston, TX, to points in the United States (except AK and HI). (Hearing site: New York, or Fayetteville, AR.)

MC 145152 (Sub-181F), filed February 29, 1980. Applicant: BIG THREE TRANSPORTATION, INC., P.O. Box 706, Springdale, AR 72764. Representative: Don Garrison, P.O. Box 1065, Fayetteville, AR 72701. Transporting (1) *charcoal, charcoal briquets, hickory chips, vermiculite, charcoal lighter fluid, compressed sawdust wax-impregnated fireplace logs,* and *barbecue equipment,* and *barbecue equipment,* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) above (except in bulk), from (a) Dothan, AL, to points in AZ, CA, CO, NM, and TX, (b) Burnside, KY, to points in IL, IN, MI, OH, and WI, (c) Springfield, MO, to points in AZ, CA, NV, UT, and WA, and (d) Belle, MO, to points in AZ, CO, IA, IL, KS, MN, ND, NE, NM, OK, SD, TX, and WI. (Hearing site: Louisville, KY, or Fayetteville, AR.)

MC 145842 (Sub-12F), filed February 19, 1980. Applicant: SUNDERMAN TRANSFER, INC., P.O. Box 63, Windom, MN 56101. Representative: Carl E. Munson, 469 Fischer Bldg., Dubuque, IA 52001. Transporting *meats, meat products and meat by-products, dairy products, and articles distributed by meat-packing houses,* as described in sections A, B, and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides, and commodities in bulk), (1) between the facilities of Lauridsen Foods, Inc., at or near Britt, IA, and the facilities of Armour and Company, at or near Mason CIty, IA, on the one hand, and, on the other, points in IL, KS, MI, MN, MO, NE, ND, SD, and WI; (2) from Worthington, MN, to points in IL, IA, KS, MI, MO, NE, ND, SD, and WI; and (3) from the facilities used by John Morrell & Co., at or near Worthington, MN, to points in IL, KS, MI, MO, NE, SD, and WI, restricted in (1) and (2) above the traffic originating at or destined to the facilities used by Lauridsen Foods, Inc., at or near Britt, IA, and Armour and Company, at Mason City, IA, or Worthington, MN, and in (3) above, to traffic originating at the facilities used by John Morrell & Co. (Hearing site: Omaha, NE or Minneapolis, MN.)

Note.—Dual operations may be involved.

MC 145872 (Sub-6F), filed January 24, 1980. Applicant: TREVIS BERRY TRANSPORTATION, a corporation, 655 Luchessa, P.O. Box 1802, Gilroy, CA 95020. Representative: Eugene Q. Carmody, 15523 Sedgeman St., San Leandro, CA 94579. *Contract carrier* transporting (1) *fibreboard products, paper products, and pulpboard products,* and (2) *materials and supplies* used in the manufacture and distribution of the commodities in (1) above, from the facilities of Champion International Corp., at or near San Jose, CA, to Reno and Sparks, NV, under continuing contract(s) with Champion International Corp., of Hamilton, OH. (Hearing site: San Francisco, CA.)

MC 146343 (Sub-8F), filed February 21, 1980. Applicant: SOUTHERN EXPRESS CORPORATION, 308 South Ocean Blvd., Pompano, FL 33062. Representative: Daniel R. Sumner, 131 Airport Rd., Warwick, RI 02889. *Contract carrier* transporting *dry fertilizer* and *materials, equipment, and supplies* used in the manufacture and distribution of dry fertilizer (except in bulk), between Lexington, KY, on the one hand, and, on the other, points in the U.S. (except AK and HI), under continuing contract(s) with International Spike, Inc., of Lexington, KY. (Hearing site: Washington, DC.)

MC 146452 (Sub-3F), filed December 10, 1979. Applicant: ALBERTSON'S, INC., P.O. Box 20, Boise, ID 83726. Representative: William H. Grady, 1100 Norton Building, Seattle, WA 98104. *Contract carrier* transporting *such commodities* as are dealt in by wholesale, retail and chain grocery stores (except in bulk), from points in WA, OR, UT, and ID to Fremont, CA, under continuing contract(s) with Fleming Foods Company, of Oklahoma City, OK. (Hearing site: Boise, ID.)

MC 146462 (Sub-2F), filed October 31, 1979. Applicant: JIM PECORILLA TRUCKING, 3600 Shawnee Drive, Carson City, NV 89701. Representative: Robert G. Harrison, 4299 James Drive, Carson City, NV 89701. Transporting (1) *paving materials, sand, rock, gravel, cinders, base material, hot and cold mix,* between points in Washoe, Storey, Lyon, Carson CIty, and Douglas Counties, NV, on the one hand, and, on the other, points in Modoc, Lassen, Plumas, Nevada, Sierra, Placer, El Dorado, Alpine, Tuolumne, Stanislaus, Sacramento, San Francisco, Marin, Alameda, Contra Costa, San Mateo, Santa Clara, and San Joaquin Counties, CA, and (2) *decorative rock,* from points in Sonoma, El Dorado, Amador, Santa Cruz, Placer, Santa Clara, Lake, and Solano Counties, CA, to points in Washoe County, NV. (Hearing site: Carson City, NV.)

MC 146782 (Sub-30F), filed February 28, 1980. Applicant: ROBERTS CONTRACT CARRIER CORPORATION, 300 First Avenue, South, Nashville, TN 37201. Representative: James Rex Raines (same address as applicant). Transporting (1) *iron and steel articles* and (2) *equipment materials and supplies* used in manufacture of the commodities in (1) above (except in bulk), between the facilities of Harrington and Kings South, Inc., at or near Cleveland, TN, on the one hand, and, on the other, points in AL, AR, FL, GA, IL, IN, KY, MI, NC, NJ, OH, OK, PA, SC, TX, VA and WV. Restricted to the transportation of traffic originating at or destined to the named facilities. (Hearing site: Nashville, TN.)

MC 146852 (Sub-2F), filed October 17, 1979. Applicant: JOHN SATTERFIELD, d.b.a. QUALITY FARMS, P.O. Box 32801, 1401 W. Fort St., Detroit, MI 48203. Representative: John Satterfield (applicant). *Contract carrier* transporting (1) *frozen prepared foods,* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of frozen prepared foods, between Red Hook and Germantown, NY, on the one hand, and, on the other, points in AL, AR, CT, DE, FL, GA, IL, IN, KY, LA, MA, MD, MI, MO, MS, NC, NJ, OH, OK, PA, SC, TN, TX, VA, WI, WY

and DC, under continuing contract(s) with Orchard Hill Farms, Inc., of Red Hook, NY. (Hearing site: Detroit, MI, or Washington, DC.)

MC 147003 (Sub-8F), filed February 19, 1980. Applicant: RAWHIDE CARRIERS, INC., P.O. Box 1171, Grand Island, NE 68801. Representative: Darryl Pauly (same address as applicant). Transporting *refuse containers,* and *parts, materials and supplies* used in the manufacture and distribution of refuse containers (except commodities in bulk, in tank vehicles), (1) from the facilities used by Ram Kan Manufacturing, at or near Lincoln, NE, to points in AR, CO, IA, KS, MN, MO, OK, TX, and WY, and (2) from Chicago, IL, and Kansas City, KS, to the facilities used by Ram Kan Manufacturing at or near Lincoln, NE. (Hearing site: Lincoln or Omaha, NE.)

MC 147013 (Sub-4F), filed February 20, 1980. Applicant: RDL, INC., P.O. Box 286, Gambrills, MD 21054. Representative: Chester A. Zyblut, 366 Executive Bldg., 1030 15th St. NW., Washington, DC 20005. Transporting *confectionery,* from the facilities of M & M Mars Co., Division of Mars Co., at (a) Hackettstown, NJ, (b) Chicago, IL, (c) Cockeysville, MD, (d) Elizabethtown, PA, and (e) Waco, TX, to points in NJ, IL, PA, LA, OK, AR, AZ, TX, CA, OR, MO, CO, OH, and GA. (Hearing site: Washington, DC.)

MC 148153 (Sub-1F), filed August 21, 1979. Applicant: WALBON & COMPANY, a partnership, 3242 Old Highway 8, Minneapolis, MN 55418. Representative: Stanley C. Olsen, Jr., 7400 Metro Boulevard, Suite 411, Edina, MN 55435. *Contract carrier,* transporting (1) *corner bead and steel studs,* and (2) *materials, supplies and accessories* used in the manufacturing and installation of the commodities in (1) above (except in bulk), between the facilities of Clinch-On-Corners, Inc., at or near (a) New Brighton, MN, and (b) Brooksville, FL, on the one hand, and, on the other, those points in the United States in and east of ND, SD, NE, CO, OK, and TX, under continuing contract(s) with Clinch-On-Corners, Inc., of New Brighton, MN. (Hearing site: Minneapolis, MN.)

MC 148202 (Sub-4F), filed January 11, 1980. Applicant: K & W ENTERPRISES, INC., 6223 Triport Court, Greensboro, NC 27410. Representative: Kim G. Meyer, P.O. Box 56387, Atlanta, GA 30343. *Contract carrier* transporting (1) *new internal combustion diesel engines, and new automotive and industrial transmissions,* and (2) *parts* for the commodities in (1) above, (a) from points in MI and IN to the facilities of Covington Diesel, Inc., at or near Greensboro, NC, and the facilities of Covington Power Products, Inc., at or near New Bern, NC, and (b) from the destination facilities in (a) above, to points in GA, FL, LA, TX, and CA, under continuing contract(s) with Covington Diesel, Inc., and Covington Power Products, Inc. (Hearing site: Greensboro, NC or Atlanta, GA.)

MC 148393 (Sub-4F), filed February 19, 1980. Applicant: J. L. McCOY, INC., P.O. Box 525, Ravenswood, WV 26164. Representative: John M. Friedman, 2930 Putnam Avenue, Hurricane, WV 25526. Transporting (1) *parts, materials, supplies and equipment* used in the manufacture and production of automobiles (except commodities in bulk), between South Charleston, WV, and Westmoreland, PA; and (2) *metal powders, and materials, equipment and supplies* used in the production thereof (except commodities in bulk), between Ridgeway, PA, on the one hand, and, on the other, those points in the United States in and east of MN, IA, MO, AR, and TX. (Hearing site: Charleston, WV.)

MC 148423 (Sub-5F), filed February 19, 1980. Applicant: AVANT TRUCKING COMPANY, INC., P.O. Box 216, Gray, GA 31032. Representative: R. Napier Murphy, 700 Home Federal Bldg., Macon, GA 31201. Transporting *raw sugar,* in bulk, from points in FL to points in GA. (Hearing site: Atlanta or Macon, GA.)

Note.—Dual operations may be involved.

MC 148992 (Sub-2F), filed February 26, 1980. Applicant: ERNEST W. JETT and JAMES L BAREFOOT, d.b.a. J AND B PIGGYBACK SERVICE, P.O. Box 113, Seville, GA 31084. Representative: C. E. Walker, P.O. Box 7381, Suite 235, Martin Bldg., Columbus, GA 31908. Transporting *general commodities* (except commodities in bulk, household goods as defined by the Commission, and classes A and B explosives), between Cordele, GA, on the one hand, and, on the other, points in Ben Hill, Bibb, Coffee, Crisp, Dodge, Dooly, Dougherty, Houston, Laurens, Macon, Peach, Pulaski, Sumpter, Telfair, Tift, Toombs, Turner, Wilcox, Wheeler, and Worth Counties, GA, restricted to traffic having a prior or subsequent movement by rail. (Hearing site: Atlanta, GA.)

MC 149042 (Sub-1F), filed February 19, 1980. Applicant: JBT SERVICE, INC., P.O. Box 971, Oshkosh, WI 54902. Representative: Michael J. Wyngaard, 150 East Gilman Street, Madison, WI 53703. *Contract carrier,* transporting *precast concrete products,* (a) from the facilities of Duwe Concrete Industries, Inc., at or near Oshkosh, WI, to points in IA, IL, IN, MI, and MN, under continuing contract(s) with Duwe Concrete Industries, Inc., of Oshkosh, WI, and (b) from Omro, WI, to points in IA, IL, IN, MI and MN, under continuing contract(s) with Precast Concrete Specialties, Inc., of Omro, WI. (Hearing site: Madison or Milwaukee, WI.)

MC 149132 (Sub-2F), filed February 25, 1980. Applicant: T & T HAULING, INC., 231 Bayou Sara Ave., Saraland, AL 36571. Representative: Terry Simison (same address as applicant). Transporting *calcium chloride and drilling fluids,* in vacuum transports, between the facilities of Dowell Division of Dow Chemical Corporation and Seachem Corporation, at points in AL, FL, LA, and MS, on the one hand, and, on the other, points in AL, FL, LA, and MS. (Hearing site: Mobile or Birmingham, AL.)

MC 149162 (Sub-2F), filed February 28, 1980. Applicant: A. L. N. CHEMICAL PACKAGING CO., a corporation, 581 Webb Industrial Drive, Marietta, GA 30062. Representative: William Addams, Suite 212, 5299 Roswell Road, NE, Atlanta, GA 30342. *Contract carrier* transporting (1) *chemicals* for water treatment, in cartons, bags, and metal drums, (2) *cleaning compounds,* in cartons, bags, and metal drums, and (3) *materials and equipment* used in the production or distribution of the commodities in (1) and (2), above, from the facilities of Calgon Corporation at (a) St. Louis, MO, and (b) Elwood City, PA, to the facilities of Calgon Corporation, at Atlanta, GA. (Hearing site: Atlanta, GA.)

MC 149172 (Sub-2F), filed February 25, 1980. Applicant: GARY HOFFMAN, 2807 Desirae, Chickasha, OK 73018. Representative: David A. Cherry, P.O. Box 1540, Edmond, OK 73034. *Contract carrier* transporting *iron and steel articles,* from Tulsa, Chickasha, and Muskogee, OK, and Lone Star and Houston, TX, to points in CO, KS, NE, OK, and TX, under continuing contract(s) with Steel and Pipe Supply Company, Inc., of Manhattan, KS, and Hoffman Pipe and Steel Company, of Chickasha, OK. (Hearing site: Kansas City, KS or Washington, DC.)

MC 149192 (Sub-2F), filed February 20, 1980. Applicant: JOHN T. SISTRUNK d.b.a., J & S TRUCKING CO., Rte. 2, Box 288D, Auburn, AL 36830. Representative: William P. Sullivan, 1320 Fenwick Lane, Suite 500, Silver Spring, MD 20910. *Contract carrier* transporting (1) *wood chips, bark, and sawdust,* from points in AL to Vienna and Monticello, GA, and (2) *green rotary cut lumber,* from Hurtsboro, AL, to Durand and Monticello, GA, under continuing contract(s) with the Georgia-Pacific

Corporation, of Augusta, GA. (Hearing site: Washington, DC or Atlanta, GA.)

MC 149372F, filed February 19, 1980. Applicant: MUSCATINE TRANSPORTATION, INC., 100 West Second Street, Muscatine, IA 52761. Representative: Robert L. Lande, First National Bank Building, Muscatine, IA 52761. Over regular routes, transporting *passengers and their baggage*, in the same vehicle with passengers, between Muscatine, IA, and the Quad City Airport at Moline, IL: from Muscatine over U.S. Hwy 61 to Interstate Hwy 280, then over Interstate Hwy 280 to IL Hwy 92, then over IL Hwy 92 to the Quad City Airport, and return over the same route serving all intermediate points. (Hearing site: Des Moines or Davenport, IA.)

MC 149382F, filed February 22, 1980. Applicant: BURT TRANSPORT, INC., North Hwy. 81, Geneva, NE 68361. Representative: Bradford E. Kistler, P.O. Box 82028, Lincoln, NE 68501. *Contract carrier* transporting *such commodities* as are dealt in or used by agricultural equipment dealers, (1) between Geneva, NE, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Geneva Implement Company, of Geneva, NE and (2) from points in the United States (except AK and HI) to Dewitt, Hebron, Kearney, Lincoln, York, and Grand Island, NE, under continuing contract(s) with Rehm Implement, Inc., of Dewitt, NE, Geo. Virus, Inc., of Hebron, NE, Hamilton International, Inc., of Lincoln, NE, York Equipment, Inc., of York, NE, Kearney International, Inc., of Kearney, NE, and Toner's, Inc., of Grand Island, NE. (Hearing site: Lincoln, NE.)

MC 150272F filed March 3, 1980. Applicant: J.J.T. TRUCKING CORP., 77–25 170th Street, Flushing, NY 11366. Representative: Roy A. Jacobs, Esq., 550 Mamaroneck Avenue, Harrison, NY 10528. Transporting *brick, tile, sand, block and concrete products (except in bulk)* between New York, NY, on the one hand, and, on the other, points in CT, NJ, and NY. (Hearing site: New York, NY.)

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Decided April 8, 1980

By the Commission Review Board Number 3, Members Parker, Fortier, 1–5 and Hill

MC 488 (Sub-17F), filed February 4, 1980. Applicant: BREMAN'S EXPRESS COMPANY, a Corporation, 318 Haymaker Rd., Monroeville, PA 15146. Representative: Joseph E. Breman, 700 Fifth Avenue Bldg., Fifth Floor, Pittsburgh, PA 15219. Transporting *vegetable tanning extract*, from Marion, OH to Curwensville, PA. (Hearing site: Pittsburgh, PA.)

MC 488 (Sub-18F), filed February 4, 1980. Applicant: BREMAN'S EXPRESS COMPANY, a corporation, 318 Haymaker Rd., Monroeville, PA 15146. Representative: Joseph E. Breman, 700 Fifth Avenue Bldg., Fifth Floor, Pittsburgh, PA 15219. Transporting *vegetable tanning extract*, from Marion, OH to Frank, WV. (Hearing site: Pittsburgh, PA.)

MC 2359 (Sub-25F), filed February 25, 1980. Applicant: DAMEO TRUCKING, INC., 568 Central Ave., Bridgewater, NJ 08807. Representative: Morton E. Kiel, Suite 1832, 2 World Trade Center, New York, NY 10048. *Contract carrier*, transporting (1)(a) *fibrous glass products and materials, insulating materials, building board, wallboard, and insulating board, asphalt and asbestos, asphalt and asbestos products and materials*, and (b) *materials, equipment, and supplies* used in connection with the production and distribution of the commodities in (a) (except commodities in bulk), between the facilities of Johns-Manville Sales Corporation at Penbryn, Winslow Township, NJ, on the one hand, and on the other, points in NC and SC; and (2) *building materials, refractory brick, and materials, equipment, and supplies* used in the installation, manufacture or distribution of the commodities in (2) (except commodities in bulk), from Manville, NJ, to points in OH and WV, under continuing contract(s) with Johns-Manville Sales Corporation, of Manville, NJ. (Hearing site: New York, NY.)

MC 13569 (Sub-58F), filed January 2, 1980. Applicant: THE LAKE SHORE MOTOR FREIGHT COMPANY, INC., 1200 South State St., Girard, OH 44420. Representative: Michael R. Werner, 167 Fairfield Rd., P.O. Box 1409, Fairfield, NJ 07006. Transporting *iron and steel articles* and *steel mill supplies*, between the facilities of United States Steel Corporation at (a) Cleveland, Lorain, and Youngstown, OH, and (b) Clairton, Dravosburg (Irvin), Duquesne, Homestead, McKeesport, Vandergrift, and West Mifflin, PA, on the one hand, and, on the other, points in AL, AR, GA, KY, MS, MO, NC, SC, TN, VA, and WV. (Hearing site: Cleveland, OH.)

MC 13569 (Sub-59F), filed February 8, 1980. Applicant: LAKE SHORE FREIGHT COMPANY, INC., 1200 South State St., Girard, OH 44420. Representative: Michael R. Werner, P.O. Box 1409, 167 Fairfield Rd., Fairfield, NJ 07006. Transporting *refractory products*, and *materials, equipment, and supplies* used in the manufacture of refractory products, between Port Kennedy, PA, on the one hand, and, on the other, points in IL, IN, MI, NY, OH, and WV.

MC 13569 (Sub-60F), filed February 25, 1980. Applicant: LAKE SHORE MOTOR FREIGHT COMPANY, INC., 1200 South State St., Girard, OH 44420. Representative: Michael R. Werner, P.O. Box 1409, 167 Fairfield Rd., Fairfield, NJ 07006. Transporting *iron and steel articles and steel mill supplies*, between points in Cuyahoga, Lorain, Mahoning, and Trumbull Counties, OH, on the one hand, and, on the other, points in IL, IN, MI, and OH, restricted to the transportation of traffic originating at or destined to the facilities of United States Steel. (Hearing site: Cleveland, OH.)

MC 22988 (Sub-16F), filed February 20, 1980. Applicant: K. G. MOORE, INC., 9 Park Ave., Hudson, NH 03051. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181. Transporting (1) *confectioneries* (except commodities in bulk), (2) *display racks and stands*, and (3) *advertising materials* for the commodities in (1) above, from the facilities of Tootsie Roll Industries, Inc., at Chicago, IL, to points in CT, DE, ME, MD, MA, NH, NJ, NY, PA, RI, and VT. (Hearing site: Boston, MA.)

MC 22988 (Sub-17F), filed February 20, 1980. Applicant: K. G. MOORE, INC., 9 Park Ave., Hudson, NH 03051. Representative: Robert G. Parks, 20 Walnut St., Suite 101, Wellesley Hills, MA 02181. Transporting (1) *such commodities* as are dealt in by retail shoe stores, and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities named in (1) above, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Morse Shoe, Inc., of Canton, MA. (Hearing site: Boston, MA.)

MC 24379 (Sub-57F), filed January 7, 1980. Applicant: LONG TRANSPORTATION COMPANY, a corporation, 14650 West Eight Mile Road, Oak Park, MI 48237. Representative: Donald G. Hichman (same address as applicant). Transporting (1) *bus stop shelters* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of bus stop shelters, between points in the borough of Bronx, NY, and points in the United States (except AK and HI). (Hearing site: New York, NY.)

MC 25798 (Sub-393F), filed February 7, 1980. Applicant: CLAY HYDER TRUCKING LINES, INC., P.O. Box 1186, Auburndale, FL 33823. Representative: Tony G. Russell (same address as

applicant). Transporting *alcoholic liquors,* and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (except commodities in bulk, in tank vehicles), (1) between Ft. Smith, AR, on the one hand, and, on the other, points in AL, FL, GA, NC, SC, VA, MO, KY, TN, OH, MI, IL, WI, MN, IA, AZ, CA, and DC; (2) between New Orleans, LA, on the one hand, and, on the other, points in AR, GA, FL, TX, AZ, CA, and NM; (3) between Bardstown and Louisville, KY, on the one hand, and, on the other, points in AR, NY, PA, NC, SC, GA, and FL; and (4) between Plainfield, IL, on the one hand, and, on the other, points in CO, IA, KS, MO, MN, NE, OK, and NM, restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc.

MC 25798 (Sub-394F), filed February 22, 1980. Applicant: CLAY HYDER TRUCKING LINES, INC., P.O. Box 1186, Auburndale, FL 33823. Representative: Tony G. Russell (same address as applicant). Transporting (1) *ceramic tile, quarry tile, building brick, and stoneware paver brick,* from those points in OH east of a line beginning at Cleveland, OH, and extending along US Hwy 42 to junction US Hwy 23, then along US Hwy 23 to the OH-KY state line, to points in CA; and (2) *ceramic tile and paving brick,* from New London, OH, to points in CA and FL. (Hearing site: Tampa, FL.)

MC 27089 (Sub-7F), filed January 7, 1980. Applicant: CHI–WAUKEE TRUCK LINES, INC., 1501 West Pershing Rd., Chicago, IL 60609. Representative: Robert J. Gill, First Commercial Bank Bldg., 410 Cortez Rd. West, Suite 406, Bradenton, FL 33507. *Contract carrier,* transporting (1) *malt beverages, carbonated beverages, cereal beverages, and beverage containers,* and (2) *advertising materials* for the commodities named in (1) between the facilities of Strohs Brewery, at or near Detroit, MI, and the facilities of Metropolitan Distributors, Inc., at or near Chicago, IL, under continuing contract(s) with Metro Distributors, Inc., of Chicago, IL.

MC 35358 (Sub-54F), filed February 8, 1980. Applicant: BERGER TRANSFER & STORAGE, INC., 3720 Macalaster Dr. NE, Minneapolis, MN 55421. Representative: Andrew R. Clark, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting *records and tapes,* from points in NY, to Indianapolis, IN.

MC 40978 (Sub-72F), filed February 4, 1980. Applicant: CHAIR CITY MOTOR EXPRESS COMPANY, a corporation, 3321 Business 141 South, Sheboygan, WI 53081. Representative: Daniel R. Dineen, 710 N. Plankinton Ave., Milwaukee, WI 53203. Transporting *appliances* from St. Cloud, MN, to points in IL, IN, MI, OH, and WI. (Hearing site: Chicago, IL, or Milwaukee, WI.)

MC 41098 (Sub-54F), filed January 7, 1980. Applicant: GLOBAL VAN LINES, INC., #1 Global Way, Anaheim, CA 92803. Representative: Alan F. Wohlstetter, 1700 K St., NW, Washington, DC 20006. Transporting *air distribution equipment terminal devices,* from Huntsville, AL, to points in the United States (except AK and HI). (Hearing site: Los Angeles, CA.)

Note.—The person or persons who appear to be engaged in common control must either file an application under 49 U.S.C. § 11343(a) [Formerly Section 5(2) of the Interstate Commerce Act], or submit an affidavit indicating why such approval is unnecessary.

MC 43038 (Sub-492F), filed February 4, 1980. Applicant: COMMERCIAL CARRIERS, INC., 20300 Civic Center Drive, 4th Floor Box CS 5027, Southfield, MI 48037. Representative: Paul H. Jones, 29725 Shacket Avenue, Madison Heights, MI 48071. Transporting *motor vehicles* (except trailers), in secondary movements, in truckaway service, between points in TX, on the one hand, and, on the other, points in AL, AR, FL, GA, KS, KY, LA, MS, MO, OK, TX and TN.

MC 48958 (Sub-210F), filed February 4, 1980. Applicant: ILLINOIS-CALIFORNIA EXPRESS, INC., 510 East 51st Avenue, P.O. Box 16404, Denver, CO 80216. Representative: Lee E. Lucero. Transporting *stone and stone products,* (except in bulk in dump vehicles), between points in AZ, AR, CA, CO, ID, IL, IN, IA, KS, MN, MO, NE, NV, MN, OH, OK, TX, UT, WI, and WY. (Hearing site: Chicago, IL, or Denver, CO.)

MC 48958 (Sub-211F), filed February 20, 1980. Applicant: ILLINOIS-CALIFORNIA EXPRESS, INC., 510 East 51st Avenue, P.O. Box 16404, Denver, CO 80216. Representative: Lee E. Lucero (same address as applicant). Regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring the use of special equipment), serving the facilities of (1) J. M. Huber Corp., at or near Borger, TX, (2) Cabot Corp., at or near Pampa, TX, and (3) Continental Carbon Co., at or near Sheerin, TX, as off-route points in connection with carrier's otherwise authorized regular-route operations. (Hearing site: Amarillo, Dallas, or Ft. Worth, TX.)

MC 50069 (Sub-557F), filed February 6, 1980. Applicant: REFINERS TRANSPORT & TERMINAL CORPORATION, 445 Earlwood Ave., Oregon, OH 43616. Representative: J. A. Kundtz, 1100 National City Bank Bldg., Cleveland, OH 44114. Transporting *asphalt and roofing materials,* from the facility of Koppers Company, Inc. at Heath, OH, to points in IN, KY, and MI. (Hearing site: Washington, DC.)

MC 52709 (Sub-386F), filed February 19, 1980. Applicant: RINGSBY TRUCK LINES, INC., P.O. Box 7240, 3980 Quebec St., Denver, CO 80207. Representative: Rick Barker (same address as applicant). Transporting *electrical appliances,* from Lenexa, KS to Minneapolis and St. Paul, MN. (Hearing site: Kansas City, MO, or Denver, CO).

MC 56679 (Sub-161F), filed February 22, 1980. Applicant: BROWN TRANSPORT CORP., 352 University Ave., SW., Atlanta, GA 30310. Representative: David L. Capps (same address as applicant). Transporting *appliances and appliance parts,* and *equipment and supplies* used in the installation and maintenance of appliances, from the facilities of the Maytag Co., at Newton, IA, to points in AL, FL, GA, KY, MS, NC, SC, and TN. (Hearing site: Atlanta, GA, or Des Monies, IA.)

MC 77479 (Sub-6F), filed February 19, 1980. Applicant: MOORE'S TRUCKING CO., P.O. Box 607, Piscataway, NJ 08854. Representative: Harold L. Reckson, 33–28 Halsey Road, Fair Lawn, NJ 07410. Transporting *general commodities,* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between points in NJ; points in NY on and south of I–Hwy 84; points in PA within a line beginning at I–Hwy 80 and the NJ–PA border, then west over I–Hwy 80 to jct I–Hwy 81, then south over I–Hwy 81 to jct. I–Hwy 83, then south over I–Hwy 83 to the MD–PA border, then east over the MD–PA border to the DE–PA border, then in a northeasterly direction along the DE–PA border to the NJ–PA border, then in a northerly direction over the NJ–PA border to the point of beginning, including points on the highways named; points in MD beginning at I–Hwy 83 and the PA–MD border, then south over I–Hwy 83 to jct I–Hwy 695, then west and south to jct. US Hwy 40, then east over US Hwy 40 to the MD–DE border, then north over the MD–DE border to the PA–MD border, then west along the PA–MD border to the point of beginning, including points on the highways named; points in DE on and

north of DE Hwy 8; and points in CT within a line beginning at I–Hwy 84 and the NY–CT border, then east over I–Hwy 84 to jct. CT Hwy 34, then south over CT Hwy 34 to jct. CT Hwy 8, then south over CT Hwy 8 to jct. I–Hwy 95, then in a southwesterly direction over I–Hwy 95 to the CT–NY border, then over the CT–NY border north to the point of beginning, including points on highways named. (Hearing site: New York, NY, or Newark, NJ.)

MC 83539 (Sub-534F), filed February 19, 1980. Applicant: C & H TRANSPORTATION CO., INC., 9757 Military Parkway, P.O. Box 270535, Dallas, TX 75227. Representative: Thomas E. James (same address as applicant). Transporting *machinery, materials, equipment, and supplies* used in the manufacture and distribution of pipe and pipe fittings, cast iron meter boxes, manhole frames and covers, (except commodities in bulk in tank vehicles), from points in the United States (including AK, but excluding HI), to the facilities of Tyler Pipe Industries, Inc. at Tyler, TX. (Hearing site: Dallas, TX, or Washington, DC.)

MC 98938 (Sub-5F), filed January 21, 1980. Applicant: SEVERANCE TRUCKING CO., INC., 7 Walnut Hill Park, Woburn, Mass 01801. Representative: Mary E. Kelley, 22 Stearns Ave., Medford, Mass 02155. Transporting *general commodities* (except those of unusual value, classes A & B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between points in MA and RI, on the one hand, and, on the other, points in NH. (Hearing site: Boston, MA.)

MC 100439 (Sub-6F), filed February 21, 1980. Applicant: D. W. HASSLER, INC., R.D. #8, York, PA 17403. Representative: Harold G. Hernly, Jr., 110 S. Columbus St., Alexandria, VA 22314. Transporting *asphalt and asphalt products,* in bulk, in tank vehicles, from Baltimore, MD, to those points in PA on and east of the eastern boundaries of Warren, Forest, Jefferson, Indiana, Westmoreland and Fayette Counties, PA. (Hearing site: Baltimore, MD, or Washington, D.C.)

MC 106398 (Sub-1059F), filed February 5, 1980. Applicant: NATIONAL TRAILER CONVOY, INC., 705 South Elgin, Tulsa, OK 74120. Representative: Gayle Gibson (same address as applicant). Transporting (1) *buildings,* complete, knocked down, or in sections, from the facilities of Star Manufacturing Company, at Cedartown, GA, to points in CO, MT, ID, ND, OK, TX, WY, UT, WA, and OR; and (2) *materials and supplies* used in the manufacture of buildings, between the facilities of Star Manufacturing Company at (a) Cedartown, GA, (b) Oklahoma City, OK, and (c) Homer City, PA. (Hearing site: Atlanta, GA.)

MC 106509 (Sub-24F), filed December 26, 1979. Applicant: YOUNGER TRANSPORTATION, INC., 4904 Griggs Rd., P.O. Box 14066, Houston, TX 77021. Representative: Wray E. Hughes (same address as applicant). Transporting (1) *iron and steel articles,* and *pipe,* from the facilities of Fort Worth Pipe Supply Co. at or near Conroe, TX, to points in the United States (including AK, but excluding HI), and (2) *materials and equipment* used in the production of the commodities in (1) above, in the reverse direction. (Hearing site: Houston, TX.)

MC 107478 (Sub-63F), filed February 22, 1980. Applicant: OLD DOMINION FREIGHT LINE, INC., 1791 Westchester Dr., P.O. Box 2006, High Point, NC 27261. Representative: Kim D. Mann, 7101 Wisconsin Ave., Washington, DC 20014. Transporting *iron and steel articles,* from the facilities of United States Steel Corporation at or near Clairton, Duquesne, Fairless, Homestead, Dravosburg, Johnstown, McKeesport, McKees Rocks, and Vandergrift, PA, and Cleveland and Lorain, OH, to points in OH on and south of I-Hwy 70, and points in AL, GA, KY, MD, NC, SC, TN, and VA. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 108119 (Sub-222F), filed January 2, 1980. Applicant: E. L. MURPHY TRUCKING COMPANY, a corporation, P.O Box 43010, St. Paul, MN 55164. Representative: James L. Nelson, 1241 Pierce Butler Route, St. Paul, MN 55104. Transporting (1) *terminal tractors and parts for terminal tractors,* and (2) *materials and supplies* used in the manufacture of the commodities in (1) above, between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of CTEC Company. (Hearing site: Seattle, WA.)

MC 108119 (Sub-234F), filed February 4, 1980. Applicant: E. L. MURPHY TRUCKING COMPANY, P.O Box 43010, St. Paul, MN 55164. Representative: James L. Nelson, 1241 Pierce Butler Rte., St. Paul, MN 55104. Transporting *tower cranes* and *parts, attachments, and accessories* for tower cranes, between points in the U.S. (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of or used by Tower Cranes of America, Inc.

MC 108119 (Sub-235F), filed February 4, 1980. Applicant: E. L. MURPHY TRUCKING COMPANY, a corporation, P.O Box 43010, St. Paul, MN 55164. Representative: James L. Nelson, 1241 Pierce Butler Rte., St. Paul, MN 55104. Transporting *portable lighting units* and *parts, attachments, and accessories* for portable lighting units, from the facilities Zip-UP, Inc., at Rock Hill, SC, to points in the United States (except AK and HI), restricted to the transportation of traffic originating at the above-named origin facilities. (Hearing site: Atlanta, GA or Washington, DC.)

MC 108119 (Sub-236F), filed February 5, 1980. Applicant: E. L. MURPHY TRUCKING COMPANY, a corporation, P.O Box 43010, St. Paul, MN 55164. Representative: James L. Nelson, 1241 Pierce Butler Route., St. Paul, MN 55104. Transporting (1) *hydraulic log loaders,* (2) *parts, attachments and accessories* for hydraulic log loaders, from the facilities of Omark Prentice Hydraulics Division of Omark Industries, Inc., at Zebulon, NC, to points in the United States (except AK and HI). (Hearing site: Atlanta, GA or Washington, DC.)

MC 108119 (Sub-239F), filed February 4, 1980. Applicant: E. L. MURPHY TRUCKING COMPANY, a corporation, P.O. Box 43010, St. Paul, MN 55164. Representative: James L. Nelson, 1241 Pierce Butler Route, St. Paul, MN 55104. Transporting: *(1) pipe, fittings, valves and hydrants and (2) parts, materials, and supplies* used in the installation of the commodities named in (1) above, from the facilities of Clow Corporation at or near Birmingham, AL, and points in Talladega County, AL, to points in the United States (except AK and HI). (Hearing site: Chicago, IL or Washington, DC.)

MC 108649 (Sub-15F), filed February 4, 1980. Applicant: STURM FREIGHTWAYS, INC., 8919 North University, Peoria, IL 61614. Representative: Leonard R. Kofkin, 39 South La Salle Street, Chicago, IL 60603. Transporting *agricultural insecticides, fungicides, and weed killing compounds* (except commodities in bulk), from Omaha, NE to points in IL. (Hearing site: Chicago, IL.)

MC 108859 (Sub-82F), filed February 19, 1980. Applicant: CLAIRMONT TRANSFER CO., 1803 Seventh Avenue, North Escanaba, MI 49829. Representative: John L. Bruemmer, 121 West Doty Street, Madison, WI 53703. I. Regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) serving the facilities of General Electric Company, at or near Mount Vernon, IN, as an off-route point in connection with carrier's otherwise authorized regular

route operations, and II. Irregular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment) from the facilities of Container Corporation of America, at or near Louisville, KY, to points in Posey County, IN. (Hearing site: Chicago, IL or Washington, DC.)

MC 109689 (Sub-368F), filed January 2, 1980. Applicant: W. S. HATCH CO., a corporation, P.O. Box 1825, Salt Lake City, UT 84110. Representative: Mark K. Boyle, 10 Broadway Bldg., Suite 400, Salt Lake City, UT 84101. Transporting *fish solubles,* in bulk, in tank vehicles, from San Diego, CA, to Denver, CO, Flagstaff, AZ, and Sparks, NV. (Hearing site: Salt Lake City, UT.)

MC 110988 (Sub-417F), filed January 8, 1980. Applicant: SCHNEIDER TANK LINES, INC., 4321 W. College Avenue, Appleton, WI 54911. Representative: Matthew J. Reid, Jr., P.O. Box 2298, Green Bay, WI 54306. Transporting *tallow,* in bulk, from the facilities of Iowa Beef Processors, Inc., at or near Holcomb, KS, to points in TX, LA, TN, MO, IA, IL, IN, MN, WI, OH, NJ, MA, PA, and NE. (Hearing site: Omaha, NE or Sioux City, IA.)

MC 112989 (Sub-122F), filed February 20, 1980. Applicant: WEST COAST TRUCK LINES, INC., 85647 Highway 99 South, Eugene, OR 97405. Representative: John W. White, Jr. (same address as applicant). Transporting *aluminum and aluminum articles,* from the facilities of Kaiser Aluminum & Chemical Corp. at Trentwood, WA, to points in AR, IL, IN, IA, KS, KY, LA, MI, MO, NJ, NY, OH, PA, TN, TX, WI, and WV. (Hearing site: San Francisco, CA.)

Note.—Dual operations may be involved.

MC 113459 (Sub-136F), filed February 4, 1980. Applicant: H. J. JEFFRIES TRUCK LINE, INC., P.O. Box 94850, Oklahoma City, OK 73143. Representative: James W. Hightower, 5801 Marvin D. Love Freeway, No. 301, Dallas, TX 75237. Transporting *clay* (except in bulk), from points in Crook and Big Horn Countries, WY, to points in AR, IL, IN, KY, LA, MI, MO, OH, OK, PA, TX, and WV. (Hearing site: Houston, TX, or Dallas, TX.)

MC 113459 (Sub-137F), filed February 25, 1980. Applicant: H. J. JEFFRIES TRUCK LINE, INC., P.O. Box 94850, Oklahoma City, OK 73143. Representative: James W. Hightower, 5801 Marvin D. Love Freeway, No. 301, Dallas, TX 75237. Transporting *clay* (except in bulk), from points in Crook and Big Horn Countries, WY, to points in IL, IN, KY, MI, MO, OH, PA, and WV, restricted to the transportation of traffic originating at or destined to the facilities used by NL Baroid. (Hearing site: Houston, TX, or Dallas, TX.)

MC 113678 (Sub-866F), filed February 23, 1980. Applicant: CURTIS, INC., 4810 Pontiac St., Commerce City, CO 80022. Representative: Roger M. Shaner (same address as applicant). Transporting *adhesives, glues, chalks, specialty chemicals, and plastic containers* (except commodities in bulk), from the facilities of Franklin Chemical Industries, Inc., at Columbus, OH, to points in AR, CA, FL, GA, IL, KY, MA, MI, NJ, NY, OR, TN, WA, and WI. (Hearing site: Columbus, OH.)

MC 113908 (Sub-502F), filed February 19, 1980. Applicant: ERICKSON TRANSPORT CORP., 2255 N. Packer Rd., P.O. Box 10068 G.S., Springfield, MO 65804. Representative: Jim G. Erickson (same address as applicant). Transporting (1) *refined, hydrogenated, deodorized soybean oil and blends of soybean oil,* in bulk, from Helena and Stuttgart, AR, to Birmingham, AL, Tampa, FL, Atlanta, GA, Hutchinson, Kansas City, and Wichita, KS, Kansas City, St. Joseph, and Springfield, MO, Albuquerque, NM, Wellston, OH, Oklahoma City, OK, and Corpus Christi, Dallas, Ft. Worth, Houston, and Paris, TX; and (2) *lecithin,* in bulk, from Helena, AR, to Chicago, IL and New Albany, IN. (Hearing site: Kansas City, MO, or Washington, DC.)

MC 114569 (Sub-367F), filed February 4, 1980. Applicant: SHAFFER TRUCKING, INC., P.O. Box 418, New Kingstown, PA 17072. Representative: N. L. Cummins (same address as applicant). Transporting *charcoal and charcoal briquettes,* from McArthur, OH and Dixie, WV to points in the United States in and east of MN, IA, MO, AR, and LA (except points in Berks, Franklin, Adams, York, Perry, Cumberland, Lancaster, Dauphin and Lebanon Counties, PA).

MC 114829 (Sub-22F), filed January 2, 1980. Applicant: GENERAL CARTAGE COMPANY, INC., P.O. Box 417, Sterling, IL 61081. Representative: Bernard J. Kompare, Suite 1600, 10 S. LaSalle St., Chicago, IL 60603. Transporting *iron and steel articles,* from Schaumburg, IL, to points in IA, under continuing contract(s) with Earle M. Jorgensen Co., of Roselle, IL. (Hearing site: Chicago, IL.)

MC 116299 (Sub-3F), filed February 4, 1980. Applicant: THE BRIDGEPORT UNITED DELIVERY COMPANY, 80 Central Ave., Bridgeport, CT 06607. Representative: Gerald A. Joseloff (same address as applicant). Transporting *such commodities* as are dealt in or used by retail department stores between points in CT, MA and RI, restricted to the transportation of traffic originating at or destined to the facilities of (a) G. Fox & Company and (b) The Outlet Company. Condition: The person or persons which appear to be in common control of applicant and another regulated carrier must either file an application for approval of common control under 49 U.S.C. § 11343, or submit affidavit indicating why such approval is unnecessary.

MC 117119 (Sub-806F), filed February 4, 1980. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, AR 72728. Representative: L. M. McLean (same address as applicant). Transporting *canned and preserved foodstuffs* (except commodities in bulk), from the facilities of Heinz USA at or near Iowa City and Muscatine, IA, and Pittsburgh, PA, to the facilities of Heinz USA at Stockton and Tracy, CA, restricted to the transportation of traffic originating at the named origins and destined to the named destinations.

MC 117119 (Sub-807F), filed February 4, 1980. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, AR 72728. Representative: L. M. McLean (same address as applicant). Transporting *desks, credenza, chairs, and file cabinets* from points in IA, IL, IN, and AL, to points in ID, restricted to the transportation of traffic originating at the indicated origins and destined to the indicated destinations.

MC 117119 (Sub-808F), filed February 4, 1980. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, AR 72728. Representative: L. M. McLean (same address as applicant). Transporting *such commodities* as are dealt in by automotive supply stores (except commodities in bulk) from points in CA, IA, IL, IN, MI, OH, OK, and TX, to the facilities of Henderson Wheel and Supply, Inc., at Salt Lake City, UT, and Boise, ID, restricted to the transportation of traffic originating at the indicated origins and destined to the name facilities.

MC 117119 (Sub-809F), filed February 5, 1980. Applicant: WILLIS SHAW FROZEN EXPRESS, INC., P.O. Box 188, Elm Springs, AR 72728. Representative: L. M. McLean (same address as applicant). Transporting: *alcoholic beverages,* (except in bulk), from points in IL, IN, KY, MI, and OH, to Boise, ID, restricted to the transportation of traffic originating at the indicated origins and destined to the named destinations. (Hearing site: Boise, ID or Portland, OR.)

MC 117119 (Sub-814F), filed February 7, 1980. Applicant: WILLIS SHAW EXPRESS, INC., P.O. Box 188, Elm Springs, AR 72728. Representative: Martin M. Geffon, P.O. 156, Mt. Laurel, NJ 08054. Transporting *such commodities* as are dealt in by department, drug and grocery stores (except commodities in bulk), from the facilities of Warner-Lambert Company at Rockford, IL, to Anaheim, CA.

MC 118089 (Sub-40F), filed February 22, 1980. Applicant: ROBERT HEATH TRUCKING, INC., 2909 Avenue C, P.O. Box 2501, Lubbock, TX 79408. Representative: Robert Heath (same address as applicant). Transporting *meats, meat products, and meat byproducts, dairy products, and articles distributed by meat-packing houses,* as described in Sections A, B, and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from the facilities of John Morrell & Co., at or near El Paso and Lubbock, TX, to points in AZ, CA, CO, ID, MT, NV, OR, UT, and WA, restricted to the transportation of traffic originating at the facilities of John Morrell & Co. (Hearing site: Chicago, IL, or Lubbock, TX.)

MC 118468 (Sub-59F), filed February 4, 1980. Applicant: UMTHUN TRUCKING CO., 910, South Jackson Street, Eagle Grove, IA 50533. Representative: William L. Fairbank, 1980 Financial Center, Des Moines, IA 50309. *Contract carrier,* transporting *lumber and wood products,* from Pariric du Chien, WI, to points in IA, under continuing contract(s) with Quality Wood Treating Inc., of Prairie du Chien, WI. (Hearing site: St. Paul, MN.)

MC 118959 (Sub-247F), filed February 20, 1980. Applicant: JERRY LIPPS, INC., 130 S. Frederick St., Cape Girardeau, MO 63701. Representative: Donald B. Levine, 39 S. LaSalle St., Chicago, IL 60603. Transporting *tires and tubes,* between Baltimore, MD, Houston, TX, New Orleans, LA, and Miami, FL on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC, or Chicago, IL.)

MC 119489 (Sub-64F), filed February 4, 1980. Applicant: CENTRAL TRANSPORTATION CO., INC., 2500 North 13th Street, P.O. Box 249, Norfolk, NE 68701. Representative: Dennis L. Hardt, P.O. Box 995, Norfolk, NE 68701. Transporting *tallow,* in bulk, in tank vehicles, from the facilities of Iowa Beef Processors, Inc. at or near Holcomb, KS to points in OH, CO, AZ, CA, NM, UT, NE, WY, TX, LA, AR, OK, TN, MO, IA, IL, IN, MN, and WI.

MC 119619 (Sub-146F), filed February 6, 1980. Applicant: DISTRIBUTORS SERVICE CO., a corporation, 2000 W. 43rd St., Chicago, IL 60609. Representative: Arthur J. Piken, Queens Office Tower, 95–25 Queens Blvd., Rego Park, NY 11374. Transporting *foodstuffs* (except commodities in bulk), from the facilities used by Purity Cheese Co., a division of Anderson Clayton Co., at Mayville, WI, to points in CT, DE, ME, MD, MA, NH, NJ, NY, OH, PA, RI, VT, VA, WV, and DC. (Hearing site: Chicago, IL.)

MC 119738 (Sub-5F), filed February 22, 1980. Applicant: HAGGARD HEAVY HAULING, INC., 3900 Reavis Barracks Road, St. Louis, MO 63125. Representative: Louis J. Amato, P.O. Box E, Bowling Green, KY 42101. Transporting *iron and steel articles,* from the facilities of Dravo Corporation, at Litchfield, IL, to points in KS and MO. (Hearing site: St. Louis, MO.)

**Note.**—The person or persons who appear to be engaged in common control must either file an application under 49 U.S.C. § 11343(a) [formerly Section 5(2) of the Interstate Commerce Act], or submit an affidavit indicating why such approval is unnecessary.

MC 119789 (Sub-668F), filed February 4, 1980. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). Transporting *confectionery* from Thibodaux, LA and York, PA to Pewaukee, WI.

MC 119789 (Sub-669F), filed February 4, 1980. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). Transporting *refined sugar,* in packages from Mathews, LA, to points in TX. (Hearing site: New Orleans, LA.)

MC 119789 (Sub-679F), filed February 20, 1980. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). Transporting (1) *plastic articles,* from Rolla, MO to points in IL, IN, KS, KY, MI, NE, NC, OH, SC, TN, and WV, and (2) *materials and supplies* used in the manufacture, distribution, and installation of plastic articles (except commodities in bulk), in the reverse direction. (Hearing site: St. Louis, MO.)

MC 119789 (Sub-680F), filed February 21, 1980. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). Transporting (1) *transformers* and *parts* for transformers (except commodities which require the use of special equipment), from Pine Bluff, AR, to points in the United States in the east of WI, IL, MO, TN, MS, LA, and TX (except FL), and (2) *materials and supplies* used in the manufacture and distribution of the commodities in (1) above, in the reverse direction. (Hearing site: Little Rock, AR.)

MC 121818 (Sub-2F), filed February 21, 1980. Applicant: REGIONAL STORAGE & TRANSPORT, INC., P.O. Box 817, North Industrial Park, Greenville, NC 27834. Representative: Ralph McDonald, P.O. Box 2246, Raleigh, NC 27602. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Rocky Mount, NC, on the one hand, and, on the other, points in NC on and east of I-Hwy 95, restricted to the transportation of traffic having a prior or subsequent movement by rail. (Hearing site: Greenville, NC.)

MC 124078 (Sub-1015F), filed February 8, 1980. Applicant: SCHWERMAN TRUCKING CO., 611 South 28th St., Milwaukee, WI 53215. Representative: Richard H. Prevette, P.O. Box 1601, Milwaukee, WI 53201. Transporting *liquid chemicals,* in bulk, in tank vehicles, from points in TX, to those points in the United States in and east of ND, SD, NE, KS, OK, and TX.

MC 124078 (Sub-1016F), filed February 21, 1980. Applicant: SCHWERMAN TRUCKING CO., a corporation, 611 South 28th St., Milwaukee, WI 53215. Representative: Richard H. Prevette, P.O. Box 1601, Milwaukee, WI 53201. Transporting *chemicals,* in bulk, in tank vehicles, (1) from points in Cobb County, GA, to points in the United States in and east of MN, IA, MO, AR, and TX, and (2) from Vienna, GA, to points in SC. (Hearing site: Atlanta, GA.)

MC 125708 (Sub-191F), filed January 4, 1980. Applicant: THUNDERBIRD MOTOR FREIGHT LINES, INC., a corporation, 425 W. 152nd Street, East Chicago, IN 46312. Representative: Anthony C. Vance, 1307 Dolley Madison Blvd., McLean, VA 22101. Transporting *paper, in rolls,* from Woodcliff, KY, Kalamazoo, MI, and Lockport, LA, to Teutopolis, IL. (Hearing site: St. Louis, MO, or Washington, DC.)

MC 125708 (Sub-195F), filed February 6, 1980. Applicant: THUNDERBIRD MOTOR FREIGHT LINES, INC., 425 W. 152nd Street, East Chicago, IN 46312. Representative: Anthony C. Vance, 1307 Dolley Madison Blvd., McLean, VA

22101. Transporting *iron and steel articles* from Jewett, TX,to points in OK, LA, AR, MS, AL, CO, NM, SC, MO, IN, IL, OH, KY, TN, MI, WI, PA, IA, and KS, restricted to the transportation of traffic originating at the facilities of Nucor Steel Corp. (Hearing site: Dallas, TX, or Washington, DC.)

MC 126118 (Sub-209F), filed January 7, 1980. Applicant: CRETE CARRIER CORPORATION, P.O. Box 81228, Lincoln, NE 68501. Representative: David R. Parker (same address as applicant). Transporting *such commodities* as are used by and dealt in by manufacturers of expanded polystryrene products, between the facilities of Dolco Packaging Corporation at or near Decatur, IN, on the one hand, and, on the other, points in the United States on and east of U.S. Hwy 85. (Hearing site: Indianapolis, IN or Lincoln, NE.)

MC 128738 (Sub-2F), filed February 25, 1980. Applicant: JOE N. QUINCE, d.b.a. QUINCE UNLOADING AND FREIGHT HANDLING, P.O. Box 595, Beloit, WI 53511. Representative: John L. Bruemmer, 121 West Doty St., Madison, WI 53703. *Contract carrier,* transporting *building materials,* from the facilities of the CertainTeed Corporation, in Cook County, IL, to (a) the facilities of the Wolohan Lumber Company, at points in IN, and (b) points in WI, under continuing contract(s) with the CertainTeed Corporation, of Valley Forge, PA, and Wolohan Lumber Company, of Saginaw, MI. (Hearing site: Madison, WI, or Chicago, IL.)

**Note.**—Dual operations may be involved.

MC 129908 (Sub-32F), filed February 19, 1980. Applicant: AMERICAN FARM LINES, INC., 8125 S.W. 15th Street, Oklahoma City, OK 73107. Representative: T. J. Blaylock (same address as applicant). Transporting *vacuum cleaners, floor polishers and vacuum cleaner bags* from the facilities of Electrolux Corportion, Bristol, VA to Riverdale, IA (Hearing site: Oklahoma City, OK, or Knoxville, TN.)

MC 133099 (Sub-16F), filed February 22, 1980. Applicant: THE GLASGLOW & DAVIS COMPANY, a Corporation, P.O. Box 1717, Salisbury, MD 21801. Representative: Daniel B. Johnson, 4304 East-West Hwy., Washington, DC 20014. Transporting *brick and block products,* from points in MD, OH, PA, VA, and WV to points in DE, MD, and VA south of the Chesapeake and Delaware Canal and east of the Chesapeake Bay. (Hearing site: Washington, DC.)

MC 133119 (Sub-176F), filed February 21, 1980. Applicant: HEYL TRUCK LINES, INC., P.O. Box 206, 200 Norka Drive, Akron, IA 51001. Representative: A. J. Swanson, P.O. Box 1103, 226 N. Phillips Ave., Sioux Falls, SD 57101. Transporting *bags and bagging material,* between Clarksdale, MS, and points in MN and ND. (Hearing site: Sioux Falls, SD, or Des Moines, IA.)

MC 135078 (Sub-65F), filed January 4, 1980. Applicant: AMERICAN TRANSPORT, INC., 7850 "F" Street, Omaha, NE 68127. Representative: Arthur J. Cerra, 2100 Ten Main Center, P.O. Box 19251, Kansas City, MO 64141. Transporting *brushes, hand tools, wooden handles, and hole saws,* from Westboro, MA, to Chicago, IL, Connersville and Hammond, IN, Detroit, MI, Pittsburgh, PA, Cleveland, OH, and Houston, TX. (Hearing site: Omaha, NE.)

**Note.**—Dual operations may be involved.

MC 135609 (Sub-7F), filed February 4, 1980. Applicant: FRED W. MOHOLLAND, P.O. Box 98, Princeton, ME 04668. Representative: Frederick T. McGonagle, 79 State St., Gorham, ME 04038. *Contract carrier,* transporting *such commodities* as are dealt in by the manufacturers or converters of (a) paper, (b) paper products and (c) woodpulp (except commodities in bulk) between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to facilities used by the Georgia-Pacific Corporation of Darien, CT.

MC 135989 (Sub-15F), filed February 6, 1980. Applicant: COAST EXPRESS, INC., 14280 Monte Vista Ave., Chino, CA 91710. Representative: William J. Lippman, Suite 330 Steele Park, 50 South Steele St., Denver, CO 80209. *Contract carrier,* transporting *canned seafoods,* and *pet foods* between Los Angeles, CA, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Star Kist Foods, Inc., of Terminal Island, CA.

MC 138279 (Sub-17F), filed February 8, 1980. Applicant: CONALCO CONTRACT CARRIER, INC., P.O. Box 968, Jackson, TN 38301. Representative: Charles W. Teske (same address as applicant). *Contract carrier,* transporting *copper and copper products* (except commodities in bulk, in tank or hopper vehicles), between Wynne, AR, Pine Hall, NC, and Zolienople, PA, on the one hand, and, on the other, points in the United States (except AK and HI), under continuing contract(s) with Cambridge-Lee Industries, Inc., of Boston, MA.

**Note.**—Dual operations may be involved.

MC 138299 (Sub-16F), filed February 19, 1980. Applicant: TRAILS TRUCKING, INC., 1825 De La Cruz Blvd., Santa Clara, CA 95050. Representative: William J. Monheim, P.O. Box 1756, Whittier, CA 90609. *Contract carrier,* transporting *insulation and plastic bottles,* from points in Orange and Los Angeles Counties, CA, to Phoenix, AZ, under a continuing contract(s) with Monsanto Company of Anaheim, CA. (Hearing site: Los Angeles, CA.)

**Note.**—Dual operations are involved.

MC 138328 (Sub-116F), filed February 21, 1980. Applicant: CLARENCE L. WERNER, d.b.a. WERNER ENTERPRISES, P.O. Box 37308, Omaha, NE 68137. Representative: James F. Crosby, P.O. Box 37205, Omaha, NE 68137. Transporting *such commodities* as are dealt in by retail and discount stores (except household goods, foodstuffs, commodities in bulk, and those which require the use of special equipment), from Los Angeles, CA and Seattle, WA, to Dodge City and Salina, KS. (Hearing site: Omaha, NE.)

**Note.**—Dual operations may be involved.

MC 138388 (Sub-10F), filed January 4, 1980. Applicant: CHESTER CAINE, JR., d.b.a CAINE TRANSFER, Box 376, Lowell, WI 53557. Representative: James A. Spiegel, Olde Towne Office Park, 6425 Odana Road, Madison, WI 53719. Transporting (a) *cheese and cheese products, synthetic cheese and synthetic cheese products,* and (b) *materials, equipment and supplies* used in the manufacture and distribution of the commodities in (a) above, (1) between points in Clayton County, IA, on the one hand, and, on the other, points in WI, and (2) between points in Clayton County, IA, on the one hand, and, on the other, Van Wert, OH. (Hearing site: Madison, WI, or Milwaukee, WI.)

MC 138469 (Sub-212F), filed February 4, 1980. Applicant: DONCO CARRIERS, INC., 4720 S. W. 20th St., Oklahoma City, OK 73128. Representative: Jack H. Blanshan, 205 West Touhy Ave., Suite 200, Park Ridge, IL 60068. Transporting (1) *alcoholic liquors,* and (2) *materials, equipment, and supplies* used in the manufacture and distribution of the commodities in (1) (except in bulk, in tank vehicles), between Fort Smith, AR, Louisville and Bardstown, KY, New Orleans, LA, and Plainsfield, IL, on the one hand, and, on the other, points in the US (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc.

MC 138469 (Sub-217F), filed February 8, 1980. Applicant: DONCO CARRIERS, INC., 4720 S. W. 20th St., Oklahoma City, OK 73128. Representative: Jack H. Blanshan, 205 West Touhy Ave., Suite

200, Park Ridge, IL 60068. Transporting *new furniture,* from Fort Worth, TX to points in the US (except AK and HI), restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations.

MC 140538 (Sub-6F), filed February 6, 1980. Applicant: LESLIE NORMAN FRED, d.b.a. NORMAN FRED, DeSoto, IL 62924. Representative: Robert T. Lawley, 300 Reisch Bldg., Springfield, IL 62701. *Contract carrier,* transporting (1) *plastic bags,* from New Albany, IN, to Carbondale, IL; (2) *plastic containers,* from Sandusky, OH to Carbondale, IL; and (3) *dairy products,* between Evansville, IN, and Carbondale, IL, under continuing contract(s) with Prairie Farms Dairy, Inc., of Carbondale, IL.

MC 140829 (Sub-337F), filed January 8, 1980. Applicant: CARGO, INC., a New Jersey Corporation, P.O. Box 206, US Hwy 20, Sioux City, IA 51102. Representative: David L. King (same address as applicant). Transporting *wooden doors, wooden screens, wooden blinds, compressed wood fire logs, and wood products,* from the facilities of McLeland-Harris Door Company, Inc., at or near Fort Worth and Mount Pleasant, TX, to points in the United States in and east of MT, WY, CO, and NM, resticted to the transportation of traffic originating at the named origins and destined to the indicated destinations. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 140829 (Sub-353F), filed February 19, 1980. Applicant: CARGO, INC., P.O. Box 206, US Hwy 20, Sioux City, IA 51102. Representative: David L. King (same address as applicant). Transporting *synthetic resin granular* (except in bulk, in tank vehicles), from Grand Prairie, TX to points in IL, IN, MI, MN, OH, and WI, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 140829 (Sub-354F), filed February 19, 1980. Applicant: CARGO, INC., (a New Jersey corporation), P.O. Box 206, U.S. Hwy 20, Sioux City, IA 51102. Representative: David L. King (same address as applicant). Transporting *foodstuffs,* in mechanical refrigerated vehicles, (except commodities in bulk, in tank vehicles), from the facilities of Anderson Clayton Foods at or near Jacksonville, IL, to points in AL, FL, GA, NC, SC, TN, VA, and WV, restricted to the transportation of traffic originating at the named origin and destined to the indicated destinations. (Hearing site: Washington, DC.)

Note.—Dual operations may be involved.

MC 141459 (Sub-16F), filed January 4, 1980. Applicant: A.G.S. ENTERPRISES, INC., 809 Columbia Boulevard, Litchfield, IL 62056. Representative: Allan C. Zuckerman, 39 South LaSalle Street, Chicago, IL 60603. Transporting *plastic and plastic articles* (except in bulk), from the facilities of International Paper Company, at Litchfield, IL, to points in AZ, CA, CO, MS, NM, NV, OR, UT, WA, and WY. (Hearing site: Chicago, IL.)

MC 141489 (Sub-10F), filed January 8, 1980. Applicant: HUNTER TRUCKING, INC., 805 32nd Ave., Council Bluffs, IA 51501. Representative: Paul D. Kratz, Suite 610, 7171 Mercy Rd., Omaha, NE 68106. Transporting *iron and steel articles,* from Chicago, IL, to the facilities of Lozier Store Fixtures, Inc. at or near Omaha, NE. (Hearing site: Omaha, NE.)

Note.—Dual operations may be involved.

MC 142059 (Sub-126F), filed February 19, 1980. Applicant: CARDINAL TRANSPORT, INC., 1830 Mount Road, Joliet, IL 60434. Representative: Jack Riley (same address as applicant). Transporting (1) *heating equipment, stoves, fireplaces, furnaces and incinerators,* and (2) *parts* for the commodities named in (1) above, from Athens, Huntsville and Sheffield, AL and Americus, GA, to points in the United States in and east of ND, SD, NE, CO, and NM, restricted to the transportation of traffic originating at the named origins. (Hearing site: Memphis, TN, or Washington, DC.)

MC 143988 (Sub-12F), filed February 4, 1980. Applicant: JAMES W. TATE, d.b.a. JAMAR TRUCKING, 2995 Sandbrook, P.O. Box 98170, Memphis, TN 38118. Representative: Thomas A. Stroud, 2008 Clark Tower, 5100 Poplar Ave., Memphis, TN 38137. Transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), from the facilities of the Memphis Defense Depot at Memphis, TN to Fort Sam Houston, Randolph AFB, Lackland AFB, Kelley AFB, Fort Bliss, Red River Army Depot at Texarkana, Corpus Christi Naval Air Station, NAS, Department of Defense facility at Kingsville, Goodfellow AFB, and Naval Auxiliary Air Station at Beeville, all in TX.

MC 144069 (Sub-9F), filed April 2, 1979. Applicant: FREIGHTWAYS, INC., Post Office Box 5204, Charlotte, NC 28225. Representative: Ralph McDonald, Post Office Box 2246, Raleigh, NC 27602. Transporting *iron and steel articles:* between points in NC, SC, GA, FL, AL, TN, KY, WV, OH, VA, MD, and DC. (Hearing site: Charlotte, NC.)

MC 144428 (Sub-10F), filed February 4, 1980. Applicant: TRUCKADYNE, INC., Route 16, Mendon, MA 01756. Representative: Michael Gallagher, 79 West Park Drive, Wakefield, MA 01880. *Contract carrier,* transporting (1) *computer cabinets, computer housings, and computer parts,* and (2) *hardware* used in the manufacture of the commodities in (1) between points in IL, on the one hand, and, on the other, points in MI, MA, and NH, under continuing contract(s) with Data General Corporation of Westboro, MA.

MC 144688 (Sub-36F), filed September 24, 1979. published in **Federal Register** issue of February 20, 1980. Applicant: READY TRUCKING, INC., 4722 Lake Mirror Place, Forest Park, GA 30050. Representative: Lavern R. Holdeman, 521 South 14th St., Suite 500, P.O. Box 81849, Lincoln, NE 68501. Transporting (1) *such commodities as are dealt in by grocery and food business houses, and* (2) *commodities used in the manufacture, sale and distribution of the commodities in (1) above,* (1) between the facilities of Hunt-Wesson Foods, Inc., at or near Atlanta, GA, Jacksonville, FL, Memphis, TN, and New Orleans, LA, on the one hand, and, on the other, points in AL, FL, GA, KY, MS, NC, SC, and TN. (Hearing site: Atlanta, GA.)

Note.—This republication broadens the territorial description.

MC 145149 (Sub-8F), filed January 7, 1980. Applicant: MATADOR SERVICE, INC., P.O. Box 2256, Wichita, KS 67201. Representative: Clyde N. Christey, Kc Credit Union Bldg., 1010 Tyler, Suite 110L, Topeka, KS 66612. Transporting *asphalts and road oils,* in bulk, in tank vehicles, from the facilities of Koch Asphalt Co., at or near Pillsbury, ND, to points in SD and MN. (Hearing site: Kansas City, MO.)

MC 145829 (Sub-15F), filed January 28, 1980. Applicant: ETI CORP., P.O. Box 1, Keasbey, NJ 08832. Representative: George A. Olsen, P.O. Box 357, Gladstone, NJ 07934. *Contract carrier,* transporting (1) *paper and paper products,* and (2) *materials, equipment and supplies* used in the manufacture and distribution of the comodities in (1) above (except commodities in bulk), between points in the United States (except AK and HI), on the one hand, and, on the other, points din MD, NJ, NY, and PA, under continuing contract(s) with the Scott Paper Company, of Philadelphia, PA. Condition: The person or persons which appear to be in common control of

applicant and another regulated carrier must either file an application for approval of common control under 49 U.S.C. § 11343, or submit an affidavit indicating why such approval is unnecessary. (Hearing site: Philadelphia, PA, or Washington, DC.)

MC 146239 (Sub-4F), filed June 15, 1979. Applicant: INTERNATIONAL FOODS TRANSPORT, INC., P.O. Box 127, Hope, NJ 07844. Representative: Ronald I. Shapss, 450 Seventh Ave., New York, NY 10001. Transporting *such commodities* as are dealt in or used by distributors and manufacturers of foodstuffs, between points in the United States (except AK and HI), under continuing contract(s) with the R. T. French Company.

MC 147348 (Sub-5F), filed January 2, 1980. Applicant: SOUTHWEST FREIGHT DISTRIBUTORS, INC., 1320 Henderson, North Little Rock, AR 72114. Representative: James M. Duckett, 927 Pyramid Life Bldg., Little Rock, AR 72201. Transporting *vacuum cleaners, floor polishers, parts and accessories* for vacuum cleaners and floor polishers, and *liquid cleaning compound* (except commodities in bulk), from Little Rock, AR, to points in TX, LA, MS, TN, MO, KS, and OK, restricted to the transportation of shipments destined to the facilities of Electrolux Division of Consolidated Foods at points in the named states. (Hearing site: Little Rock, AR.)

MC 147829 (Sub-2F), filed January 2, 1980. Applicant: GREGORY A. SAUNDERS and VIRGINIA MAY SAUNDERS, a partnership, d.b.a. S & S TRUCKING, 5 Ruth Place, Belle Vernon, PA 15012. Representative: John A. Vuono, 2310 Grant Bldg., Pittsburgh, PA 15219. Transporting (1) *glass-annealing furnaces, glass ovens, glass-making machinery,* and (2) *materials, equipment, and supplies* used in the manufacture, distribution, and installation of the commodities in (1) above, between points in CA, and those points in the United States in and east of MN, IA, MO, KS, OK, and TX, under continuing contract(s) with E. W. Bowman, Inc., of Uniontown, PA. (Hearing site: Pittsburgh, PA.)

MC 147969 (Sub-1F), filed February 4, 1980. Applicant: JOE S. BOWEN, INC., P.O. Box 262, Springdale, AR 72764. Representative: John C. Everett, 140 East Buchanan, P.O. Box A, Prairie Grove, AR 72753. Transporting *alcoholic liquors,* and *materials, equipment, and supplies* used in the manufacture and distribution of alcoholic liquors (except commodities in bulk, in tank vehicles), between Fort Smith, AR, Bardstown and Louisville, KY, New Orleans, LA, and Plainfield, IL, on the one hand, and, on the other, points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of Hiram Walker & Sons, Inc. (Hearing site: Peoria, IL or Chicago, IL.)

MC 148179 (Sub-4F), filed February 4, 1980. Applicant: V S ENTERPRISES, INC., 1717 N. Broadway, St. Louis, MO 63102. Representative: Ernest A. Brooks II, 1301 Ambassador Bldg., St. Louis, MO 63101. Transporting (1) *glass containers and glass container accessories,* from the facilities of Kerr Glass Manufacturing Corp., at or near Dunkirk, IN, and Midland Glass Company at Terre Haute, IN, to St. Louis, MO; and (2) *materials and supplies* used in the manufacture and distribution of glass containers (except commodities in bulk), from St. Louis, MO, to Dunkirk and Terre Haute, IN. (Hearing site: St. Louis, MO.)

MC 148319 (Sub-1F), filed January 2, 1980. Applicant: ELLIS B. STOFLE, d.b.a. STOFLE TRUCKING, P.O. Box 42, Tioga, TX 76271. Representative: Ellis B. Stofle (same address as applicant). Transporting *meats, meat products and meat byproducts,* from San Angelo, TX, to points in NY, NJ, CT, RI, MA, MD, PA, and DC. (Hearing site: Dallas, TX.)

MC 148678 (Sub-2F), filed January 2, 1980. Applicant: McGRATH TRUCKING, INC., 229 Old Elm St., Mansfield, MA 02048. Representative: Ronald McGrath (same address as applicant). *Contract carrier,* transporting *such commodities* as are dealt in by retail department stores, between points in MA, FL, and GA, under continuing contract(s) with Zayre Corporation, of Framingham, MA. (Hearing site: Boston or Worcester, MA.)

MC 149218 (Sub-2F), filed February 19, 1980. Applicant: SUNBELT EXPRESS, INC., 118 Hamilton Circle, Bremen, GA 30110. Representative: John J. Capo, P.O. Box 720434, Atlanta, GA 30328. Transporting *metal containers and metal container ends,* and *machinery, materials, and supplies* used in the manufacture and distribution of metal containers, between points in AL, AR, FL, GA, IL, IN, KY, LA, MO, MS, NC, OH, SC, TN, VA, and WV. (Hearing site: Atlanta, GA.)

MC 149268F, filed January 9, 1980. Applicant: B & K TRANSPORT, INC., 300 Hart St., Essexville, MI 48732. Representative: John C. Scherbarth, 22375 Haggerty Rd., P.O. Box 400, Northville, MI 48167. *Contract carrier,* transporting I. *bags, materials, equipment and supplies* used in the manufacture of bags and packaging materials between the facilities of Quality Transparent Bag, Inc., at Bay City, MI and points in the United States, under continuing contract(s) with Quality Transparent Bag, Inc. of Bay City, MI, II. *bags, materials, equipment and supplies* used in the manufacture of bags and packaging materials between the facilities of Dyna-Pak Corporation at or near Lawrenceburg, TN and points in the United States, under continuing contract(s) with Dyna-Pak Corporation of Lawrenceburg, TN, III. *grocery products* between the facilities of Bay City Milling & Grocer at Bay City, MI, and points in the United States, under continuing contract(s) with Bay City Milling & Grocer of Bay City, MI, and IV. *bags, packaging films, materials and equipment* used in the manufacture, processing, and sale of plastics and packaging materials between the facilities of Poly Industries Ltd., at Grand Rapids, MI, and points in the United States in and east of MT, WY, CO, NM, under continuing contract(s) with Poly Industries Ltd., of Grand Rapids, MI. (Hearing site: Lansing or Detroit, MI.)

MC 149329F, filed February 4, 1980. Applicant: HOWARD TRUCKING, INCORPORATED, 10955 Haddix Road, P.O. Box 411, Fairborn, OH 45324. Representative: John L. Alden, 1396 West Fifth Avenue, P.O. Box 12241, Columbus, OH 43212. *Contract carrier,* transporting *scrap metal,* in dump vehicles, between points in IN, KY, MI, OH, PA and WV, under continuing contract(s) with Pennsylvania Iron and Coal Company, of Dayton, OH. (Hearing site: Columbus, OH or Washington, DC.)

MC 149389F, filed February 19, 1980. Applicant: DELIVERY SERVICE CORPORATION, 1141 Springwells, Detroit, MI 48209. Representative: William B. Elmer, 21635 East Nine Mile Rd., St. Clair Shores, MI 48080. Transporting (1) *foodstuffs,* from the facilities of Aunt Janes Foods, Inc. at or near Croswell, MI, to points in the United States (except AK, HI, and MI), and (2) *materials and supplies* used in the manufacture and distribution of foodstuffs, in the reverse direction. (Hearing site: Detroit, MI.)

Note.—Dual Operations may be involved.

MC 150039 (Sub-1F), filed February 4, 1980. Applicant: CLEO OWENS, d.b.a. OWENS TRANSPORTATION CO., 11829 Fair Ford Ave., Norwalk, CA 90650. Representative: R. Y. Schureman, 1545 Wilshire Blvd., Los Angeles, CA 90017. *Contract carrier,* transporting *lubricating oils,* (except in bulk), from Los Angeles, CA, to points in AZ, LA, NM, OR, TX, and WA, under continuing contract(s) with Refiners Marketing Company, of Terminal Island, CA. (Hearing site: Los Angeles, CA.)

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Decided: April 8, 1980.

By the Commission, Review Board Number 1, Members Carleton, Joyce, and Jones.

MC 2359 (Sub-26F), filed February 22, 1980. Applicant: DAMEO TRUCKING, INC., 568 Central Ave., Bridgewater, NJ 08807. Representative: Morton E. Kiel, Suite 1832, 2 World Trade Center, New York, NY 10048. *Contract carrier,* transporting *talc,* in bulk, from West Windsor, VT, to Port Jervis, NY, under continuing contract(s) with Johnson & Johnson Baby Products Company, of Piscataway, NJ. (Hearing site: New York, NY.)

MC 4428 (Sub-19F), filed February 25, 1980. Applicant: HARCHELROAD TRUCKING CO., a corporation, 243 Tilford Rd., Pittsburgh, PA 15235. Representative: Arthur J. Diskin, 806 Frick Bldg., Pittsburgh, PA 15219. Transporting *iron and steel articles,* between the facilities of Jones & Laughlin Steel Corporation at (a) Aliquippa and Pittsburgh, PA, and (b) Youngstown, OH, on the one hand, and, on the other, points in the Lower Peninsula of MI. (Hearing site: Pittsburgh, PA, or Washington, DC.)

MC 29079 (Sub-146F), filed September 28, 1979, previously noticed in Federal Register issue of February 20, 1980. Applicant: BRADA MILLER FREIGHT SYSTEM, INC., P.O. Box 935, Kokomo, IN 46901. Representative: Chandler L. Van Orman, 1729 H Street, NW., Washington, DC 20006. Transporting (1) *materials, equipment, and supplies* used in the manufacture of mobile homes, (2) *material handling equipment* and *materials, equipment, and supplies* used in the manufacture of material handling equipment, (3) *iron and steel articles,* and (4) *parts, attachments, and accessories* for the commodities in (1), (2), and (3) above, between Sherman, TX, Winfield, AL, and Salyersville, KY, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC.)

Note.—This republication adds part (3) to the commodity description.

MC 29079 (Sub-172F), filed February 25, 1980. Applicant: BRADA MILLER FREIGHT SYSTEM, INC., P.O. Box 935, Kokomo, IN 46901. Representative: Chandler L. Van Orman, 1729 H. St., NW., Washington, DC 20006. Transporting (1) *metal articles,* from points in Tuscarawas County, OH, to those points in LA on and east of the Mississippi River, and points in AL, GA, MS, and TN; and (2) *materials, equipment, and supplies* used in the manufacture, sale and distribution of the commodities in (1) above, in the reverse direction. (Hearing site: Washington, DC.)

MC 29079 (Sub-173F), filed February 25, 1980. Applicant: BRADA MILLER, FREIGHT SYSTEM, INC., P.O. Box 935, Kokomo, IN 46901. Representative: Chandler L. Van Orman, 1729 H. St. NW., Washington, DC 20006. Transporting (1) *mineral fiber, mineral fiber products, and composition boards,* from the facilities of the United States Gypsum Company at (a) Gypsum, OH and (b) Walworth, WI, to those points in the United States in and east of WI, IL, MO, AR, and LA; and (2) *fabricated metal products,* and *iron and steel articles,* from the facilities of the United States Gypsum Company at (a) Franklin Park and Pinckneyville, IL, and (b) Warren, OH, to points in the United States in and east of WI, IL, MO, AR, and LA. (Hearing site: Washington, DC.)

MC 29929 (Sub-8F), filed November 16, 1979. Applicant: CANNY TRUCKING CO., INC., 6–18 Spring Forest Ave., Binghamton, NY 13905. Representative: Thomas F. X. Foley, State Hwy 34, P.O. Box F, Colts Neck, NJ 07722. Over regular routes, transporting *general commodities,* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), (1) between Binghamton and Watertown, NY, (a) over Interstate Hwy 81, and (b) over U.S. Hwy 11, (2) between Syracuse and Oswego, NY, (a) from Syracuse over Interstate Hwy 690 to junction NY Hwy 48, then over NY Hwy 48 to Oswego, and return over the same route, and (b) over NY Hwy 57, (3) between Rochester and Utica, NY, from Rochester over Interstate Hwy 490 to junction Interstate Hwy 90, then over Interstate 90 to Utica, and return over the same route, (4) between junction Interstate Hwy 90 and Interstate Hwy 690, and junction Interstate Hwy 90 and Interstate Hwy 481, from junction Interstate Hwy 90 and Interstate Hwy 690 over Interstate Hwy 690 to junction Interstate Hwy 481, then over Interstate Hwy 481 to junction Interstate Hwy 90, and return over the same route, (5) between Horseheads and Cortland, NY, from Horseheads over NY Hwy 17 to junction NY Hwy 13, then over NY Hwy 13 to Cortland, and return over the same route, (6) between Horseheads, NY, and junction NY Hwy 14 and Interstate Hwy 90, from Horseheads over NY Hwy 17 to junction NY Hwy 14, then over NY Hwy 14 to junction Interstate Hwy 90, and return over the same route, (7) between junction NY Hwy 79 and Interstate Hwy 81, and junction NY Hwy 14 and Interstate Hwy 90, from junction NY Hwy 79 and Interstate Hwy 81, over NY Hwy 79 to junction NY Hwy 96, then over NY Hwy 96 to junction NY Hwy 96A, then over NY Hwy 96A to junction U.S. Hwy 20, then over U.S. Hwy 20 to junction U.S. Hwy 14, then over NY Hwy 14 to junction Interstate Hwy 90, and return over the same route, (8) between junction NY Hwy 79 and U.S. Hwy 11 and junction NY Hwy 79 and Interstate Hwy 81, over NY Hwy 79, (9) between Buffalo and Rochester, NY, from Buffalo over NY Hwy 33 to junction Interstate Hwy 90, then over Interstate Hwy 90 to junction Interstate Hwy 490, then over Interstate Hwy 490 to Rochester, and return over the same route, (10) between junction Interstate Hwy 90 and Interstate Hwy 290 and junction NY Hwy 31 and Interstate Hwy 490, from junction Interstate Hwy 90 and Interstate Hwy 290, over Interstate Hwy 290 to junction NY Hwy 263, then over NY Hwy 263 to junction NY Hwy 78, then over NY Hwy 78 to junction NY Hwy 31, then over NY Hwy 31 to junction Interstate Hwy 490, and return over the same route, (11) between junction NY Hwy 31 and NY Hwy 31A near Medina, and junction NY Hwy 31A and NY Hwy 31 near Brockport, over NY Hwy 31A, (12) between Olean and Buffalo, NY, from Olean over NY Hwy 16 to junction NY Hwy 400 then over NY Hwy 400 to junction Interstate Hwy 90, then over Interstate Hwy 90 to junction Interstate Hwy 190, then over Interstate Hwy 190 to Buffalo, and return over the same route, (13) between Olean, NY, and junction NY Hwy 400 and Interstate Hwy 90, from Olean over NY Hwy 17 to junction U.S. Hwy 219, then over U.S. Hwy 219 to junction Interstate Hwy 90, then over Interstate Hwy 90 to junction NY Hwy 400 and return over the same route, (14) between Binghamton, NY, and Philadelphia, PA, from Binghamton over Interstate Hwy 81 to junction PA Hwy 9, then over PA Hwy 9 to junction Interstate Hwy 276, then over Interstate Hwy 276 to junction U.S. Hwy 422 to Philadelphia, and return over the same route, (15) between junction Interstate Hwy 81 and PA Hwy 9 and junction North Hampton Street and PA Hwy 9, from junction Interstate Hwy 81 and U.S. Hwy 9 over Interstate Hwy 81 to junction PA Hwy 115, then over PA Hwy 115 to junction PA Hwy 309, then over PA Hwy 309 to junction North Hampton Street, then over North Hampton Street to junction PA Hwy 9, and return over the same route, (16) between Binghamton and Utica, NY, (a) over NY Hwy 12, and (b) from Binghamton over NY Hwy 7 to Oneonta, then over NY Hwy 205 to junction NY Hwy 80, then over NY Hwy 80 to junction NY Hwy 28,

then over NY Hwy 28 to junction NY Hwy 5S, then over NY Hwy 5S to Utica, and return over the same route, (17) between Binghamton and Oneonta, NY, over Interstate Hwy 88, and (18) between Waverly and Oswego, NY, from Waverly over NY Hwy 34 to junction NY Hwy 104, to Oswego, and return over the same route, serving all intermediate points in routes (1) through (18) above, and serving as off-route points in route (1) above points in Tioga, Broome, Cortland, Onondaga, Oswego, and Jefferson Counties, NY, in route (2) above points in Onondaga and Oswego Counties, NY, in routes (3) and (4) above points in Monroe, Ontario, Seneca, Cayuga, Wayne, Onondaga, Madison, Oneida, and Herkimer Counties, NY, in route (5) above points in Chemung, Tompkins, Schuyler, and Cortland Counties, NY, in route (6) above points in Chemung, Schuyler, Yates, Seneca, and Ontario Counties, NY, in routes (7) and (8) above points in Ontario, Seneca, Schuyler, Tompkins, Tioga, and Broome Counties, NY, in routes (9), (10), and (11) above points in Erie, Niagara, Orleans, Genesee, and Monroe Counties, NY, in routes (12) and (13) above points in Erie, Cattagaugus, and Allegany Counties, NY, in routes (16) and (17) above points in Broome, Chenango, Delaware, Otsego, Madison, Herkimer, and Oneida Counties, NY, and in route (18) above points in Chemung, Tioga, Tompkins, Cayuga, Wayne, and Oswego Counties, NY, and serving points in Broome, Tioga, Chemung, Stueben, Allegany, Cattaraugus, Livingston, Delaware, Monroe, Rockland, Orange, and Sullivan Counties, NY, as off-route points in connection with applicant's otherwise authorized regular-route operations.

MC 35358 (Sub-51F) (Republication), filed December 4, 1979. Applicant: BERGER TRANSFER & STORAGE, INC., 3720 Macalaster Drive NE., Mineapolis, MN 55421. Representative: Andrew R. Clark, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting (1) *radios, phonographs, televisions, tape players, recorders and other such commodities as dealt in by Home Entertainment Centers, and (2) parts and accessories and components for the above described commodities,* between Minneapolis, MN, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Minneapolis, MN.)

**Note.**—This republication eliminates the facility restriction as published in **Federal Register** March 25, 1980.

MC 78228 (Sub-157F), filed February 20, 1980. Applicant: J MILLER EXPRESS, INC., 962 Greentree Road, Pittsburgh, PA 15220. Representative: Henry M. Wick Jr., 2310 Grant Bldg., Pittsburgh, PA 15219. Transporting (1) *iron and steel articles,* and (2) *materials, equipment and supplies* used in the manufacture of the commodities in (1) above between the facilities of Solar Steel, at Cleveland, OH, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Washington, DC, or Pittsburgh, PA.)

MC 106398 (Sub-1049F), filed January 11, 1980. Applicant: NATIONAL TRAILER CONVEY, INC., 705 South Elgin, Tulsa, OK 74120. Representative: Gayle Gibson (same address as applicant). Transporting *steel pipe and steel roofing,* from New Orleans, LA, and Houston, TX, to points in the United States (except AK and HI). (Hearing site: Portland, OR.)

MC 110098 (Sub-181F), filed February 22, 1980. Applicant: ZERO REFRIGERATED LINES, 1400 Ackerman Road, Box 20380, San Antonio, Texas 78220. Representative: T. W. Cothren (same address as applicant). Transporting *meats, meat products, meat by-products, and articles distributed by meat-packing houses,* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766 (except hides and commodities in bulk), from Kansas City, KS and points in IL, IN, IA, MN, NE, and SD, to points in ID, OR, UT, and WA. (Hearing site: Omaha, NE or Des Moines, IA.)

MC 110659 (Sub-31F), filed February 5, 1980. Applicant: COMMERCIAL CARRIERS, INC., 975 Virginia Street, West, Charleston, WV 25302. Representative: John M. Friedman, 2930 Putnam Ave., Hurricane, WV 25526. Transportating *malt beverages,* in containers, (a) from Newark, NJ, to Charleston and Huntington, WV, (b) from Eden, NC, and Milwaukee, WI, to Huntington, WV, (c) from Perry, GA, to Charleston, WV, (d) from Columbus, OH, and Williamsburg, VA, to points in Greenbrier County, OH, and (e) from points in Wood County, OH, to points in WV. (Hearing site: Charleston, WV.)

MC 113908 (Sub-501F), filed February 6, 1980. Applicant: ERICKSON TRANSPORT CORP., P.O. Box 10068 G.S., 2255 N. Packer Road, Springfield, MO 65804. Representative: B. B. Whitehead (same address as applicant). Transporting *chemicals,* in bulk, from Newport, TN to points in CA and AZ. (Hearing site: Kansas City, MO or Washington, DC.)

MC 113908 (Sub-503F), filed March 17, 1980. Applicant: ERICKSON TRANSPORT CORP., 2255 N. Packer Road, P.O. Box 10068 G.S., Springfield, MO 65804. Representative: Jim G. Erickson (same address as applicant). Transporting *alcohol and wine,* in bulk, from points in WA to Altus, AR. (Hearing site: Kansas City, MO or Washington, DC.)

MC 119099 (Sub-30F), filed February 25, 1980. Applicant: BJORKLUND TRUCKING, INC., First Ave. NE and 8th St., Buffalo, MN 55313. Representative: Val M. Higgins, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting *dried milk products,* from Howard Lake, MN, to points in DE, NC, and TN. (Hearing site: Minneapolis, MN.)

MC 119619 (Sub-147F), filed February 22, 1980. Applicant: DISTRIBUTORS SERVICE CO., a corporation, 2000 West 43rd St., Chicago, IL 60609. Representative: Arthur J. Piken, Queens Office Tower, 95–25 Queens Blvd., Rego Park, NY 11374. Transporting *meat, meat products and meat by-products and articles distributed by meat-packinghouses* as described in Sections A and C of Appendix I to the report in *Descriptions in Motor Carrier Certificates,* 61 M.C.C. 209 and 766, from the facilities of J.H. Routh Packing Co., at Castilia, OH to points in CT, DE, ME, MD, MA, NH, NJ, NY, PA, RI, VT, VA, WV, and DC. (Hearing site: Cleveland OH.)

MC 119689 (Sub-28F), filed February 19, 1980. Applicant: PEERLESS TRANSPORT CORP., 2701 Railroad St., Pittsburgh, PA 15222. Representative: Robert T. Hefferin (same address as applicant). Transporting (A) *fertilizers, fungicides, insecticides, plastic articles, and tree and weed killing compounds, and* (B) *materials, and equipment and supplies* used in the manufacture and distribution of commodities in (A) above between Danville, IL and points in MI, OH, and PA. (Hearing site: Pittsburgh, PA or Washington, DC.)

MC 119789 (Sub-681F), filed February 25, 1980. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). Transporting (1) *malt beverages* from points in Jefferson County, CO to points in AR, and (2) *empty used beverage containers* and *materials and supplies* used in and dealt by manufacturers of malt beverages, in the reverse direction. (Hearing site: Denver, CO.)

MC 119789 (Sub-682F), filed February 25, 1980. Applicant: CARAVAN REFRIGERATED CARGO, INC., P.O. Box 226188, Dallas, TX 75266. Representative: James K. Newbold, Jr. (same address as applicant). Transporting (1) *such commodities* as

are dealt in by grocery stores, drug stores and hardware stores, in containers, and (2) *materials and supplies* used in the manufacture of the commodities in (1) above (except commodities in bulk), between Dallas, TX, New York, NY, and points in NJ. (Hearing site: New York, NY.)

MC 119988 (Sub-222F), filed October 12, 1979. Applicant: GREAT WESTERN TRUCKING CO., INC., P.O. Box 1384, Lufkin, TX 75901. Representative: Hugh T. Matthews, 2340 Fidelity Union Tower, Dallas, TX 75201. Transporting *electric storage batteries, spent batteries,* and *materials and supplies* used in the manufacture and distribution of electric storage batteries (except commodities in bulk), between points in the United States (except AK and HI), restricted to the transportation of traffic originating at or destined to the facilities of General Battery Corporation, Yuasa General Battery Corporation, and Dixie Metals Corporation. (Hearing site: Dallas, TX.)

MC 120028 (Sub-18F), filed February 25, 1980. Applicant: CRAW CARTING, INC., 160 Despatch Drive, P.O. Box 267, East Rochester, NY 14445. Representative: Herbert M. Canter, 305 Montgomery St., Syracuse, NY 13202. Transporting (1) *Plastic articles* and (2) *Equipment, materials, and supplies* used in the manufacture and distribution of plastic articles, between points in Canandaigua, NY, on the one hand, and, on the other, points in DE, IA, IL, IN, KY, MA, MI, NJ, NY, OH, WV and WI, restricted (a) to the transportation of traffic originating at or destined to the facilities of Canandaigua Plastics Division of Voplex Corporation, and (b) in (1) and (2) above against the transportation of commodities in bulk.

MC 120098 (Sub-34F), filed June 4, 1979. Applicant: UINTAH FREIGHTWAYS, a corporation, 1030 South Redwood Rd., Salt Lake City, UT 84104. Representative: William S. Richards, P.O. Box 2465, Salt Lake City, UT 84110. Over regular routes, transporting *general commodities* (except those of unusual value, classes A and B explosives, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Salt Lake City, UT, and Albuquerque, NM, (1) from Salt Lake City over Interstate Hwy 15 to junction U.S. Hwy 89, then over U.S. Hwy 89 to junction U.S. Hwy 6, then over U.S. Hwy 6 to Grand Junction, CO, then over U.S. Hwy 50 to Montrose, CO, then over U.S. Hwy 550 to Farmington, NM, then over U.S. Hwy 64 to junction NM Hwy 44, then over NM Hwy 44 to junction U.S. Hwy 85, then over U.S. Hwy 85 to Albuquerque, and return over the same route, and (2) from Salt Lake City over Interstate Hwy 15 to junction U.S. Hwy 89, then over U.S. Hwy 89 to junction U.S. Hwy 6, then over U.S. Hwy 6 to junction U.S. Hwy 163, then over U.S. Hwy 163 to junction U.S. Hwy 666, then over U.S. Hwy 666 to Gallup, NM, then over U.S. Hwy 666 (Interstate Hwy 40), to Albuquerque, and return over the same route, serving Farmington, NM, as an intermediate point in route (1) above, and serving Shiprock, Grants, and Gallup, NM, and Crescent Junction and Price, UT, as intermediate points and Farmington, NM, as an off-route points in route (2) above. (Hearing site: Salt Lake City, UT, or Grand Junction, CO.)

MC 121568 (Sub-26F), filed January 14, 1980. Applicant: HUMBOLDT EXPRESS, INC., Hill Ave., P.O. Box 10096, Nashville, 37210. Representative: Walter Harwood, P.O. Box 15214, Nashville, TN 37215. Over regular routes, transporting *general commodities* (except those of unusual value, household goods as defined by the Commission, commodities in bulk, and those requiring special equipment), between Memphis, TN, and Oklahoma City, OK, over Interstate Hwy 40, serving all intermediate points, and serving as off route points, points in an area bounded by and on a line beginning at junction Interstate Hwy 40 and U.S. Hwy 64, and extending over U.S. Hwy 64 to Muskogee, OK, then over U.S. Hwy 69 to junction OK Hwy 51, then over OK Hwy 51 to Tulsa, OK, then over U.S. Hwy 66 to Oklahoma City, OK, then over U.S. Hwy 270 to junction U.S. Hwy 69 near McAlester, OK, then over U.S. Hwy 69 to junction Interstate Hwy 40, then over Interstate Hwy 40 to junction U.S. Hwy 64. Conditions: (1) Prior or coincidental conversion of applicant's certificates of registration in its lead docket and subs 1, 2, 3, 4, 6, 7, 8, and 9, to Certificates of Public Convenience and Necessity. (2) To the extent any certificate issued in this proceeding authorizes the transportation of classes A and B explosives, it shall be limited in point of time to a period expiring 5 years from the date of issuance of the certificate. (Hearing site: Memphis, TN, or Oklahoma City, OK.)

MC 123048 (Sub-478F), filed February 19, 1980. Applicant: DIAMOND TRANSPORTATION SYSTEM, INC., 5021 21st St., Racine, WI 53406. Representative: John L. Bruemmer, 121 West Doty St., Madison, WI 53703. Transporting (1) *equipment, attachments, accessories and parts* used in storage, handling and condition of grain, from Assumption, IL to points in the United States (except AK and HI), and (2) *materials, equipment and supplies* (except commodities in bulk) used in the manufacture or distribution of commodities in (1) above in the reverse direction. (Hearing site: Chicago, IL, or Washington, DC.)

MC 125708 (Sub-196F), filed February 19, 1980. Applicant: THUNDERBIRD MOTOR FREIGHT LINES, INC., 425 W. 152d St., East Chicago, IN 46312. Representative: Anthony C. Vance, 1307 Dolley Madison Blvd., McLean, VA 22101. Transporting *steel coils* from Marietta, GA, Tampa and Port Everglades, FL, Houston TX, and Chicago, IL, to points in NC, SC, TN, AL, VA, KY, GA, FL, IL, and TX. (Hearing site: Atlanta, GA, or Washington, DC.)

MC 125708 (Sub-197F), filed February 19, 1980. Applicant: THUNDERBIRD MOTOR FREIGHT LINES, INC., 425 W. 152d St., East Chicago, IN 46312. Representative: Anthony C. Vance, 1307 Dolley Madison Blvd., McLean, VA 22101. Transporting *metal articles* (1) from Ellsworth, MI, to points in the United States (except AK and HI) and (2) from Davenport, IA, and Chicago, IL, to Ellsworth, MI. (Hearing site: Lansing, MI, or Washington, DC.)

MC 128279 (Sub-40F), filed February 25, 1980. Applicant: ARROW FREIGHTWAYS, INC., 150 Woodward Rd, SE., P.O. Box 25125, Albuquerque, NM 87125. Representative: Olif Q. Boyd (same address as applicant). Transporting *gypsum wallboard* and *gypsum products,* from El Paso, TX, to points in AZ, CO, and NM. (Hearing site: Albuquerque, NM, or Phoenix, AZ.)

MC 135598 (Sub-41F), filed February 25, 1980. Applicant: SHARKEY TRANSPORTATION, INC., 3803 Dye Road, Quincy, IL 62301. Representative: Carl L. Steiner, 39 South LaSalle St., Chicago, Il 60603. Transporting *cleaning, scouring and washing compounds,* in containers, from Plano. IL, to Atlanta, GA, Jackson, MS, Ft. Madison, IA, Kansas City and St. Louis, MO, Cincinnati, Painesville and Fostoria, OH, Detroit, MI, Pittsburgh and Ft. Washington, PA, Oklahoma City, OK, Dallas, TX, Clifton, NJ, West Springfield, MA, Memphis, TN, and Birmingham, AL. (Hearing site: Chicago, IL.)

MC 138469 (Sub-222F), filed February 25, 1980. Applicant: DONCO CARRIERS, INC., 4720 S.W. 20th St., Oklahoma City, OK 73128. Representative: Jack H. Blanshan, 205 West Touhy Ave., Suite 200, Park Ridge, IL 60068. Transporting *cranberry products, fruit juices, and table sauces* (except in bulk), from the facilities of Ocean Spray Cranberries, Inc., at or near Sulphur Springs, TX, to points in AR, CO, KS, LA, MS, MO, NM, and OK, restricted to the transportation of traffic originating at the named origin

and destined to the indicated destinations. (Hearing site: Chicago, IL or Dallas, TX.)

MC 140628 (Sub-5F), filed February 25, 1980. Applicant: CHARLES R. PALS, d.b.a. PALS CARTAGE, 31 West 168th St., South Holland, IL 60473. Representative: Charles R. Pals (same address as applicant). Transporting *diapers,* between the facilities of Johnson & Johnson Baby Products at (a) Park Forest, IL, and (b) Indianapolis, IN. (Hearing site: Chicago, IL, or Washington, DC.)

MC 142449 (Sub-4F), filed June 14, 1979. Applicant: SPEEDWAY HAULERS, INC., P.O. Box 1463, South Bend, IN 46224. Representative: James L. Beattey, 130 East Washington Street, Suite 1000, Indianapolis, IN 46204. Transporting *general commodities* between Chicago, IL, and points in IN on and north of U.S. Hwy 40 (except Indianapolis), restricted to the transportation of traffic having a prior or subsequent movement by rail or water. (Hearing site: Indianapolis, IN.)

Note.—To the extent any certificate issued in this proceeding authorizes the transportation of classes A and B explosives, it shall be limited in point of time to a period expiring 5 years from the date of issuance of the certificate.

MC 144398 (Sub-6F), filed February 25, 1980. Applicant: WAYNE TRANSPORTS, INC., Box 366, Milaca, MN 56353. Representative: Val M. Higgins, 1000 First National Bank Bldg., Minneapolis, MN 55402. Transporting *liquefied petroleum gas,* from Greenwood and Geneva, NE, Clay Center, Conway and McPherson, KS, and Kearney, MO, to points in IA, MN, ND, and SD. (Hearing site: Minneapolis-St. Paul, MN.)

MC 144688 (Sub-43F), filed February 25, 1980. Applicant: READY TRUCKING, INC., 2717 Campbell Blvd., Ellenwood, GA 30049. Representative: Lavern R. Holdeman, 521 South 14th St., Suite 500, P.O. Box 81849, Lincoln, NE 68501. Transporting *office furniture,* and *parts, materials and supplies used in the manufacture, sale and distribution of office furniture* (except commodities in bulk), between Leeds, AL, and Henderson, TX, on the one hand, and, on the other, points in the United States (except AK and HI). (Hearing site: Atlanta, GA.)

MC 146519 (Sub-8F), filed February 21, 1980. Applicant: CALIANA MARKETING, INC., 2120 Prairieton Road, Terre Haute, IN 47802. Representative: Robert W. Loser II, 1101 Chamber of Commerce Bldg., Indianapolis, IN 46204. *Contract carrier,* transporting *dry corn products,* (except in bulk), from the facilities of Illinois Cereal Mills, Inc., at or near Paris, IL, to points in AL, FL, GA, MS, NC, SC, KY, and TN, under continuing contract(s) with Illinois Cereal Mills, Inc., of Paris, IL. (Hearing site: Chicago, IL, or Washington, DC.)

MC 147658 (Sub-4F), filed February 11, 1980. Applicant: R & W TRANSPORTATION, INC., Route 1, Repton, AL 36475. Representative: Gerald D. Colvin, Jr., 603 Frank Nelson Bldg., Birmingham, AL 35203. *Contract carrier,* transporting *lumber, lumber products and lumber byproducts* (1) from the facilities of T. R. Miller Mill Company at or near Brewton, AL, to points in IL, IN, TN, KY, MI, OH, MO, WI, and IA, under continuing contract(s) with T. R. Miller Mill Company, of Brewton, AL, and (2) from the facilities of Harrigan Lumber Company at or near Monroeville, AL, to points in AR, AL, GA, FL, MS, LA, TX, IL, IN, OH, MI, WI, MO, IA, TN, and KY, under continuing contract(s) with Harrigan Lumber Company, of Monroeville, AL. (Hearing site: Birmingham or Montgomery, AL.)

MC 147978 (Sub-4F), filed February 4, 1980. Applicant: SYSTEM REEFER SERVICE, INC., 4614 Lincoln Ave., Cypress, CA 90630. Representative: Charles E. Creager, 1329 PA Ave., P.O. Box 1417, Hagerstown, MD 21740. Transporting (1) *chains, cotter pins, hoisting equipment, trolleys, screws, washers, and abrasive wheels,* from York, PA, to points in CA, UT, OR, WA, NV, AZ, NM, CO, WY, ID, and MT; (2) *welding rods and wire,* from Bowling Green, KY, to points in CA, CO, OR, and WA; (3)(A) *foodstuffs and food treating compounds, chemicals and additives,* and (B) *commodities* the transportation of which is partially exempt from regulation under the provisions of Section 203(b)(6) of the Interstate Commerce Act, in mixed loads with the commodities named in (A) above, (a) between Baltimore, MD, and points in CA, and (b) from Baltimore, MD, to points in WA; (4) *cake decorations, icing, decorator heads and candles,* in mixed loads with foodstuffs and/or commodities the transportation of which would otherwise be partially exempt from regulation under the provisions of Section 203(b)(6) of the Interstate Commerce Act, between Baltimore, MD, and points in CA; (5) *cake decorations, icing, decorator heads and candles,* from East Hampton, MA, to points in CA; (6) *such commodities as are dealt in or used by manufacturers of power tools* (a) between Hampstead and Easton, MD, Raleigh, Tarboro and Fayetteville, NC, Lancaster, PA, and ports of entry on the international boundary line between the United States and Canada in MI and NY, on the one hand, and, on the other, points in the United States (except AK and HI), and (b) from Richmond, CA, to points in CA; (7) *such commodities* as are dealt in by manufacturers of household and electrical appliances, from Canton, OH, to points in WA, OR, ID, MT, WY, UT, NM, AZ, NV, CA, and CO; and (8) *chains, cotter pins, hoisting equipment, trolleys, screws, washers, iron and steel articles,* (a) from York, PA, and Cortland, NY, to points in CA, UT, OR, WA, NV, AZ, NM, CO, WY, ID, and MT, and (b) between Cortland, NY, and York, PA. The purpose of this application is to convert contract carrier authority to common carrier authority. Condition: Issuance of a certificate in this proceeding is subject to prior or coincidental cancellation of permits in MC 133097 Subs 4, 6, 8, 9, 11, 13, 21, and 22 F.(Hearing site: Los Angeles, CA.)

Note.—Dual operations are involved.

MC 148339 (Sub-3F), filed October 15, 1979, (Republication).Applicant: WILLIAM POTT & SON, INC., 5547 Cheviot Road, Cincinnati, OH 45239. Representative: James W. Muldoon, 50 West Broad Street, Columbus, OH 43215. Transporting *such commodities* as are dealt in or used by manufacturers of bedding or upholstery (except commodities in bulk), between Mason, OH, on the one hand, and, on the other, points in IN, IL, KY, MO, MI, MS, NC, OH, PA, TN, VA, and WV.

Note.—This republication broadens the territorial description as published February 26, 1980.

MC 150068 (Sub-1F), filed February 4, 1980. Applicant: A & M EXXON, 300 East Chestnut, Corydon, IN 47112. Representative: William H. Davis, 102 N. Capitol Ave., Corydon, IN 47112. Transporting *disabled, repossessed, and stolen motor vehicles,* between points in IL, IN, KY, and OH. (Hearing site: Louisville, KY, or Indianapolis, IN.)

MC 150128 (Sub-1F), filed February 25, 1980. Applicant: LOERTCO TRANSIT, INC., Route 6, Box 136, Lubbock, TX 79412. Representative: Thomas F. Sedberry, P.O. Box 2165, Austin, TX 78768. Transporting *brick, tile and concrete block,* (a) from points in Lubbock and Coleman Counties, TX, to points in AR, AZ, CA, LA, MS, NM, and OK, and (b) from points in AR, AZ, CA, LA, MS, NM, and OK to points in TX. (Hearing site: Fort Worth or Dallas, TX.)

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80-12128 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-6 (Sub-No. 64F)]

## Burlington Northern Inc. Abandonment Near Ellendale and Forbes in Dickey County, N. Dak.; Findings

Notice is hereby given pursuant to 49 U.S.C. 10903 that by a decision decided February 14, 1980, a finding, which is administratively final, was made by the Commission, Review Board Number 5, stating that, subject to the conditions for the protection of railway employees prescribed by the Commission in *Oregon Short Line Railroad Co.—Abandonment Goshen*, 360 I.C.C. 91 (1979), the present and future public convenience and necessity permit the abandonment by the Burlington Northern Inc. of its line between milepost 49.50 near Ellendale, ND, and milepost 62.97 at the end of the line near Forbes, ND, a distance of 13.47 miles, in Dickey County, ND. A certificate of abandonment will be issued to the Burlington Northern Inc. based on the above-described finding of abandonment, 30 days after publication of this notice, (May 22, 1980) unless within 30 days from the date of publication, the Commission further finds that:

(1) A financially responsible person (including a government entity) has offered financial assistance (in the form of a rail service continuation payment) to enable the rail service involved to be continued; and

(2) It is likely that such proffered assistance would:

(a) Cover the difference between the revenues which are attributable to such line of railroad and the avoidable cost of providing rail freight service on such line, together with a reasonable return on the value of such line, or

(b) Cover the acquisition cost of all or any portion of such line of railroad.

If the Commission so finds, the issuance of a certificate of abandonment will be postponed for such reasonable time, not to exceed 6 months, as is necessary to enable such person or entity to enter into a binding agreement, with the carrier seeking such abandonment, to provide such assistance or to purchase such line and to provide for the continued operation of rail services over such line. Upon notification to the Commission of the execution of such an assistance or acquisition and operating agreement, the Commission shall postpone the issuance of such a certificate for such period of time as such an agreement (including any extensions or modifications) is in effect. Information and procedures regarding the financial assistance for continued rail service or the acquisition of the involved rail line are contained in the Notice of the Commission entitled "Procedures for Pending Rail Abandonment Cases" published in the **Federal Register** on March 31, 1976, at 41 FR 13691, as amended by publication of May 10, 1978, at 43 FR 20072. All interested persons are advised to follow the instructions contained therein as well as the instructions contained in the above-referenced decision.

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80-12218 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

[Docket No. AB-6 (Sub-No. 61F)]

## Burlington Northern, Inc. Abandonment Near Funkley and Kelliher in Beltrami County, Minn.; Findings

Notice is hereby give pursuant to 49 U.S.C. 10903 that by a Certificate and Decision decided December 21, 1979, a finding, which is administratively final, was made by the Commission, Review Board Number 5, stating that, subject to the conditions for the protection of employees discussed in *Oregon Short Line R. Co.-Abandonment Goshen*, 360 I.C.C. 91 (1979), and the BN shall keep intact all the right-of-way underlying the track for 120 days from the decided date of the certificate and decision to permit any interested party to negotiate the acquisition for public use of all or any portion of the properties, the present and future public convenience and necessity permit the abandonment by the Burlington Northern, Inc. of its line of railroad from milepost 126.28 near Funkley, MN, to milepost 136.17 at the end of the line near Kelliher, MN, a distance of 9.89 miles in Beltrami County, MN. A certificate of public convenience and necessity permitting abandonment was issued to the Burlington Northern, Inc. Since the investigation has been completed, the requirement of § 1121.38(a) of the Regulations that publication of notice of abandonment decisions in the **Federal Register** be made only after such a decision becomes administratively final was waived.

Upon receipt by the carrier of an actual offer of financial assistance, the carrier shall make available to the offeror the records, accounts, appraisals, working papers, and other documents used in preparing Exhibit I (§ 1121.45 of the Regulations). Such documents shall be made available during regular business hours at a time and place mutually agreeable to the parties.

The offer must be filed and served on or before May 7, 1980. The offer, as filed, shall contain information required pursuant to § 1121.38(b)(2) and (3) of the Regulations. If no such offer is received, the certificate of public convenience and necessity authorizing abandonment shall become effective June 6, 1980.

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80-12105 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

[Ex Parte No. 311]

## Expedited Procedures for Recovery of Fuel Costs

Decided April 15, 1980.

In our decision of April 8, 1980, a 13.5 percent surcharge was authorized on all owner-operator traffic, and on all truckload traffic whether or not owner-operators were employed. We ordered that all owner-operators were to receive compensation at this level.

The weekly figures set forth in the appendix for transportation performed by owner-operators and for truckload traffic is 13.4 percent. Accordingly, we are authorizing that the 13.5-percent surcharge for this traffic remain in effect. All owner-operators are to receive compensation at the 13.5-percent level. No change will be made in the existing authorization of a 2.3-percent surcharge on less-than-truckload (LTL) traffic performed by carriers not utilizing owner-operators, the 5.0-percent surcharge for the bus carriers, nor the 1.3-percent surcharge for United States Parcel Service.

Notice shall be given to the general public by mailing a copy of this decision to the Governor of each State and to the Public Utilities Commissions or Boards of each State having jurisdiction over transportation, by depositing a copy in the Office of the Secretary, Interstate Commerce Commission, Washington, D.C., for public inspection, and by delivering a copy to the Director, Office of the Federal Register for publication therein.

It is ordered: This decision shall become effective Friday 12:01 a.m. April 18, 1980.

By the Commission, Chairman Gaskins, Vice Chairman Gresham, Commissioners Stafford, Clapp, Trantum and Alexis. Commissioner Stafford dissented in part with a separate expression. Commissioner Alexis absent and not participating.

**Agatha L. Mergenovich,**

*Secretary.*

Commissioner Stafford, dissenting in part:

I would limit the owner-operator/truckload surcharge to 13 percent.

**Appendix—*Fuel Surcharge***

*Base date and price per gallon (including tax)*

January 1, 1979 ..... 63.5¢

*Date of current price measurement and price per gallon (including tax)*

April 14, 1980 ..... 113.8

| | (1) From transportation performed by owner-operators [1] | (2) Other [2] | (3) Bus carrier | (4) UPS |
|---|---|---|---|---|
| Average percent: Fuel expenses (including taxes) of total revenue | 16.9 | 2.9 | 6.3 | 3.3 |
| Percent surcharge developed | 13.4 | 2.3 | 5.0 | [3]2.1 |
| Percent surcharged allowed | 13.5 | 2.3 | 5.0 | [4]1.3 |

[1] Apply to all truckload rated traffic.

[2] Including less-than-truckload traffic.

[3] The percentage surcharge developed for UPS is calculated by applying 81 percent of the percentage increase in the current price per gallon over the base price per gallon to the UPS average percent of fuel expense to revenue figure as of January 1, 1979 (3.3 percent).

[4] The percentage surcharge derived is reduced 0.8 percent to reflect fuel-related increases included in UPS rates.

[FR Doc. 80-12221 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

**[Ex Parte No. MC-43]**

## Lease and Interchange of Vehicles by Motor Carriers

Decided: April 11, 1980.

Country Wide Truck Service, Inc. (MC 138941) and R. F. Box, Inc., (MC 136989) (commonly controlled), have filed a petition for waiver of paragraph (c) of § 1057.12 of the Lease and Interchange of Vehicles Regulations (49 CFR 1057).

### Findings

1. In view of the fact that this Commission has no jurisdiction over motor carrier safety and all reference to safety has been excised from the above regulations, petitioners' request for waiver of safety inspection requirements is moot and will not be considered.

1. Petitioners are commonly controlled and jointly administer a common safety program.

2. Petitioners have acceptable fitness records.

3. Greater efficiency and economy would result with the waiver.

*It is ordered:* 1. The petition of Country Wide Truck Service, Inc., and R. F. Box, Inc., for waiver of paragraph 1057.12(c), is granted with respect to equipment leased between them.

By the Commission, Motor Carrier Leasing Board, Board Members Joel E. Burns, Robert S. Turkington, and W. F. Sibbald, Jr.

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80-12222 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

## Rail and Motor Carriers; Finance Applications

The following applications seek approval to consolidate, purchase, merge, lease operating rights and properties, or acquire control through ownership of stock, of rail carriers or motor carriers pursuant to Sections 11343 (formerly Section 5(2)) or 11349 (formerly Section 210a(b)) of the Interstate Commerce Act.

An original and one copy of protests against the granting of the requested authority must be filed with the Commission on or before May 22, 1980. Such protest shall comply with Special Rules 240(c) or 240(d) of the Commission's *General Rules of Practice* (49 CFR 1100.240) and shall include a concise statement of protestant's interest in the proceeding. A copy of the protest shall be served concurrently upon applicant's representative, or applicant, if no representative is named.

Each applicant states that approval of its application will not significantly affect the quality of the human environment nor involve a major regulatory action under the Energy Policy and Conservation Act of 1975.

**Agatha Mergenovich,**

*Secretary.*

### Captioned Summary of the Authority Sought for Publication in the "Federal Register"

MC-F-13916, filed January 31, 1979. Applicant: COLDWAY FOOD EXPRESS, INC., P.O. Box 747, State Route 29N, Sidney, OH 45365. Representative: Joseph M. Scanlan, 111 W. Washington, Chicago, IL 60602. Authority sought for purchase by Coldway Food Express, Inc., Route 29N, P.O. Box 747, Sidney, OH 45365 of the operating rights of Collins Transfer, Inc., 214 Pearl St., Sioux City, IA 51101 and for acquisition by John L. Maurer, 437 Pinehurst St., Sidney, OH 45365, William F. Crumpler, 307 N. Third St., Anna, OH 45302 and Joseph M. Scanlan, 111 W. Washington, Chicago, IL 60602 of the control of such rights through the purchase. Operating rights sought to be transferred: Over irregular routes, *Household goods, office furniture and equipment, and store fixtures,* between points and places in IA on the one hand, and points and places in SD, NE and IL, on the other.

*Household goods,* between Sioux City, IA, and points and places in IA within 150 miles of Sioux City, on the one hand, and points and places in MN within 150 miles of Sioux City, on the other. *Pianos, organs,* and *piano and organ benches and stools,* uncrated, from Sioux City, IA to points in Blue Earth, Brown, Cottonwood, Faribault, Jackson, Lincoln, Lyon, Martin, Urray, Nobels, Pipestone, Redwood, Rock and Watonwan Counties, MN; Antelope, Boone, Boyd, Burt, Butler, Cass, Cedar, Colfax, Cuming, Dakota, Dixon, Dodge, Douglas, Fillmore, Garfield, Greeley, Hall, Hamilton, Holt, Howard, Knox, Lancaster, Madison, Merrick, Nance, Otoe, Pierce, Platte, Polk, Saline, Sarpy, Saunders, Seward, Stanton, Thurston, Valley, Washington, Wayne, Wheeler, and York Counties, NE; and Aurora, Beadle, Bon Homme, Brookings, Charles Mix, Clay, Davison, Douglas, Gregory, Hanson, Hutchinson, Jerauld, Kingsbury, Lake, Lincoln, McCook, Miner, Minnehaha, Woody, Sanborn, Turner, Union, and Yankton Counties, SD, and *Traded-in, exchanged, or returned shipments* of the commodities described immediately above, from points in the above described destination territory to Sioux City, IA.

MC-F-14117F, filed on July 5, 1979, was previously published at 44 FR 55721 (September 27, 1979), and then republished through inadvertence at 45 FR 16580 (March 14, 1980). The publication of March 14, 1980, should be disregarded.

[FR Doc. 80-12220 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

## Long- and Short-Haul Applications for Relief (Formerly Fourth Section Applications)

April 17, 1980.

These applications for long-and-short-haul relief have been filed with the I.C.C.

Protests are due at the I.C.C. on or before May 7, 1980.

No. 43814, WESTERN TRUNK LINE COMMITTEE, Agent No. A-2760, on single empty freight trailers, new or used, moving within Southwestern Territory; and, between stations in Southwestern Territory and Western Trunk Line Territory as published in Supplement 36 to Western Trunk Line Committee, Agent's Freight Tariff ICC WTL 4931, effective May 12, 1980. Grounds for relief—motor carrier competition.

No. 43815. KARLANDER (AUSTRALIA) PTY., LIMITED, No. 7, on commodities in marine type trailers or

containers, from rail carrier terminals on the U.S. Atlantic and Gulf Coast to ports in Australia by way of ports on the west coast of the U.S., in its Freight Tariff ICC KRPU 303, effective May 14, 1980. Grounds for relief—water competition.

By the Commission.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 80-12217 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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[Docket No. AP-202 F]

## Montpelier & Barre Railroad Co.—Entire Line Abandonment—From Graniteville to Montpelier Junction in Washington County, Vt.; Findings

Notice is hereby given pursuant to 49 U.S.C. 10903 that by a decision decided February 6, 1980, a finding, which is administratively final, was made by the Commission, Review Board Number 5, stating that, subject to the conditions for the protection of railway employees prescribed by the Commission in Oregon Short Line Railroad Co.—Abandonment Goshen, 360 I.C.C. 91 (1979); provided that the Montpelier and Barre Railroad shall not sell, lease, exchange, or otherwise dispose of the right-of-way underlying the track, all bridges, and all culverts on the line for 120 days from April 11, 1980, to permit any state or local government agency or other interested party to negotiate the acquisition for public use of all or any portion of the right-of-way, the present and future public convenience and necessity permit the abandonment by the Montpelier and Barre Railroad Company of its entire line of railroad, which extends from Graniteville to Montpelier Junction, a distance of 14 miles, in Washington County, VT. Findings were also made that, if a certificate is issued, the following conditions regarding the Barre Depot shall be included: (a) M&B shall maintain the Depot for 180 days following issuance of a certificate, during which time it shall take reasonable steps to prevent alteration or deterioration of the Depot, and shall afford to any public agency or private organization the opportunity to acquire the station for public use; (b) If the 180 day period elapses, no one offers to acquire the station, and M&B plans to either demolish the Depot or sell it for use that would adversely affect its historic qualities, M&B must document the Depot pursuant to the standards of the Historic American Buildings Survey. The extent and nature of such documentation is to be developed in consultation with the Historic American Buildings Survey, and copies are to be provided to the Historic American Buildings Survey and the Vermont Division of Historic Preservation for inclusion in their respective archival collections; and (c) the M&B shall notify the Vermont Division of Historic Preservation of its plans for the Depot. If M&B sells the building, it shall include in the contract of sale a provision requiring the purchaser to notify the Division of Historic Preservation of its plans for the building. A certificate of abandoment will be issued to the Montpelier and Barre Railroad Company based on the above-described finding of abandonment, 30 days after publication of this notice (May 22, 1980), unless within 30 days from the date of the publication, the Commission further finds that:

(1) A financially responsible person (including a government entity) has offered financial assistance (in the form of a rail service continuation payment) to enable the rail service involved to be continued; and

(2) It is likely that such proffered assistance would:

(a) Cover the difference between the revenues which are attributable to such line of railroad and the avoidable cost of providing rail freight service on such line, together with a reasonable return on the value of such line, or

(b) Cover the acquisition cost of all or any portion of such line of railroad.

If the Commission so finds, the issuance of a certificate of abandonment will be postponed for such reasonable time, not to exceed 6 months, as is necessary to enable such person or entity to enter into a binding agreement, with the carrier seeking such abandonment, to provide such assistance or to purchase such line and to provide for the continued operation of rail services over such line. Upon notification to the Commission of the execution of such an assistance or acquisition and operating agreement, the Commission shall postpone the issuance of such a certificate for such period of time as such an agreement (including any extensions or modifications) is in effect. Information and procedures regarding the financial assistance for continued rail service or the acquisition of the involved rail line are contained in the Notice of the Commission entitled "Procedures for Pending Rail Abandonment Cases" published in the Federal Register on March 31, 1976, at 41 FR 13691, as amended by publication of May 10, 1978, at 43 FR 20072. All interested persons are advised to follow the instructions contained therein as well as the instructions contained in the above-referenced decision.

Agatha L. Mergenovich,

*Secretary.*

[FR Doc. 80-12219 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

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## Transportation of Government Traffic; Special Certificate Letter Notice(s)

The following letter notices request participation in a Special Certificate of Public Convenience and Necessity for the transportation of general commodities (except classes A and B explosives, radioactive materials, etiologic agents, shipments of secret materials, and weapons and ammunition which are designated sensitive by the United States Government), between points in the United States (including Alaska and Hawaii), restricted to the transportation of traffic handled for the United States Government or on behalf of the United States Government where the government contractor (consignee or consignor), is directly reimbursed by the government for the transportation costs, under the Commission's regulations (49 CFR 1062.4), pursuant to a general finding made in Ex Parte No. MC-107, *Government Traffic*, 131 M.C.C. 845 (1979).

An original and one copy of verified statement in opposition (limited to argument and evidence concerning applicant's fitness) may be filed with the Interstate Commerce Commission from the date of this publication. A copy must also be served upon applicant or its representative. Opposition to the applicant's participation will not operate to stay commencement of the proposed operation.

If applicant is not otherwise informed by the Commission, operations may commence the date of its notice in the Federal Register, subject to its tariff publication's effective date, or the filing of an effective tender pursuant to 49 U.S.C. 10721.

GT-119-80 (special certificate, Government traffic), filed March 24, 1980. Applicant: B-RIGHT TRUCKING CO., 492 Old State Route 7, Pottery Addition, Steubenville, OH 43952. Representative: A. Charles Tell, Baker & Hostetler, 100 East Broad Street, Suite 1800, Columbus, OH 43215. Government Agency involved: Department of Defense, and General Services Administration.

GT-120-80 (special certificate, Government traffic), filed March 24, 1980. Applicant: TOWER LINES, INC., P.O. Box 6010, Wheeling, WV 26003. Representative: George V. Thieroff, President (same address as applicant).

Government Agency involved: Departments of State, Treasury, Defense Justice, Interior, Agriculture, Commerce, Labor, Health, Education, and Welfare, Housing and Urban Development, Transportation, Energy, and General Services Administration.

GT–121–80 (special certificate, Government traffic), filed March 24, 1980. Applicant: ARCO AUTO CARRIERS, INC., 16 West 151 Shore Court, Burr Ridge, IL 60521. Representative: James Bouril, Vice President (same address as applicant). Government Agency involved: Department of Defense.

GT–122–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: MOSS TRUCKING CO., INC., 3027 North Tryon Street, Charlotte, NC 28213. Representative: Ernest S. Cox, P.O. Box 26125, Charlotte, NC 28213. Government Agency involved: Departments of Defense, Transportation, Agriculture, Commerce, Tennessee Valley Authority, and National Aeronautics and Space Administration.

GT–123–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: ALLAN D. GIBSON, 1915 Main Street, Eldorado, IL 62930. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. Government Agency involved: General Services Administration, Departments of Defense, Agriculture, Transportation, Energy, and Interior; National Railroad Passenger Service Corporation, Tennessee Valley Authority, National Aeronautics and Space Administration, United States Postal Service, and U.S. Government Printing Office.

GT–124–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: W.D.W. TRUCKING, INC., 2620 Southwest 66th Terrace, Miramar, FL 33023. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. Government Agency involved: General Services Administration, Departments of Defense, Agriculture, Transportation, Energy, and Interior; National Railroad Passenger Service Corporation, Tennessee Valley Authority, National Aeronautics and Space Administration, United States Postal Service, and U.S. Government Printing Office.

GT–125–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: SOUTHERN TRUCKING CORP., Box 7195, 1500 Orenda Avenue, Memphis, TN 38107. Representative: Diane Price, Traffic Manager, Route 6, Box 15, North Little Rock, AR 72118. Government Agency involved: Department of Defense, and General Services Administration.

GT–126–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: PITT COUNTY TRANSPORTATION CO., INC., P.O. Box 207, Farmville, NC 27828. Representative: Harry J. Jordan, Macdonald, & McInerny, P.C., suite 502, Solar Building, 1000 16th Street, NW., Washington, DC 20036. Government Agency involved: Department of Defense, and General Service Administration

GT–127–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: ACTION DELIVERY SERVICE, INC., 2401 West Marshall Drive, Grand Prairie, TX 75051. Representative: A. William Brackett, 1108 Contintenal Life Building, Fort Worth, TX 76102. Government Agency involved: Department of Defense.

GT–128–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: PETER HOLMAN TRUCKING, INC., P.O. Box 1090, Ft. Pierce, FL 33450. Representative: Dwight L. Koerber, Jr., 805 McLachlen Bank Building, 666 11th Street, NW., Washington, DC 20001. Government Agency involved: General Services Administration, Departments of Defense, Agriculture, Transportation, Energy, and Interior; National Railroad Passenger Service Corporation, Tennessee Valley Authority, National Aeronautics and Space Administration, U.S Postal Service, and U.S. Government Printing Office.

GT–129–80 (special certificate, Government Traffic), filed March 25, 1980. Applicant: LEMMON TRANSPORT CO., INC., P.O. Box 580, Marion, VA 24354. Representative: E. Stephen Heisley, 805 McLachlen Bank Building, 666 11th Street, NW., Washington, DC 20001. Government Agency involved: General Services Administration, Departments of Defense, Agriculture, Transportation, Energy, and Interior; National Railroad Passenger Service Corporation, Tennessee Valley Authority, National Aeronautics and Space Administration, U.S Postal Service, and U.S. Government Printing Office.

GT–130–80 (special certificate, Government traffic), filed March 27, 1980. Applicant: M&S TRANSPORT LINES, INC., P.O. 417, Sultana, CA 93666. Representative: Dwight L. Koerber, Jr., 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. Government Agency involved: General Services Administration, Departments of Defense, Agriculture, Transportation, Energy, and Interior; National Railroad Passenger Service Corporation, Tennessee Valley Authority, National Aeronautics and Space Administration, U.S. Postal Service, and U.S. Government Printing Office.

GT–131–80 (special certificate, Government traffic), filed March 27, 1980. Applicant: STARLING TRANSPORT LINES, INC., P.O. Box 1733, Ft. Pierce, FL 33450. Representative: Dwight L. Koerber, Jr., 805 McLachlen Bank Building, 666 11th Street NW., Washington, DC 20001. Government Agency involved: General Services Administration, Departments of Defense, Agriculture, Transportation, Energy, and Interior; National Railroad Passenger Service Corporation, Tennessee Valley Authority, National Aeronautics and Space Administration, U.S. Postal Service, and U.S. Government Printing Office.

GT–132–80 (special certificate, Government traffic), filed March 27, 1980. Applicant: ARMORED MOTOR SERVICE CORP., 160 Ewingville Road, Trenton, NJ 08638. Representative: Herbert Alan Dubin, Baskin and Sears, 818 Connecticut Avenue NW., Washington, DC 20006. Government Agency involved: General Service Administration, Departments of Agriculture, Treasury; and Federal Reserve System.

GT–133–80 (special certificate, Government traffic), filed March 27, 1980. Applicant: IDEAL TRUCK LINES, INC., 6785 East 50th Avenue, Commerce City, CO 80022. Representative: Carl J. Smith, General Traffic Manager (same address as applicant). Government Agency involved: General Services Administration, Departments of Treasury, Defense, and Agriculture.

GT–134–80 (special certificate, Government traffic), filed March 28, 1980. Applicant: J. W. PHILLIPS, INC., P.O. Box 18493, Oklahoma City, OK 73154. Representative: C. L. Phillips, Licensed Practitioner, room 248 Classen, Terrace Building, 1411 North Classen, Oklahoma City, OK 73106.Government Agency involved: Department of Defense.

GT–135–80 (Special certificate, Government traffic), filed March 28, 1980. Applicant: BROOKS ARMORED CAR SERVICE, INC., 13 East 35th Street, Wilmington, DE 19802. Representative: James F. Flint, 1250 Connecticut Avenue NW., Suite 600, Washington, DC 20036. Government Agency involved: Federal Reserve System.

GT–136–80 (special certificate, Government traffic), filed March 28, 1980. Applicant: GREENSTEIN

TRUCKING CO., 280 Northwest 12th Avenue, P.O. Box 608, Pompano Beach, FL 33061. Representative: Martin Sack, Jr., 1754 Gulf Life Tower, Jacksonville, FL 32207. Government Agency involved: U.S. Government Manual (1979–80 edition).

GT–137–80 (special certificate, Government traffic), filed March 28, 1980. Applicant: CRESSLER TRUCKING, INC., 691 Orrstown Road, Shippensburg, PA 17257. Representative: Edward G. Villalon, suite 1032, Pennsylvania Building, Pennsylvania Avenue and 13th Street NW., Washington, DC 20004. Government Agency involved: Department of Defense, and General Services Administration.

GT–138–80 (special certificate, Government traffic), filed March 28, 1980. Applicant: DITTO FREIGHT LINES, 1575 Industrial Avenue, San Jose, CA 95112. Representative: Daniel W. Baker, Handler, Baker, Greene & Taylor, P.C., 100 Pine Street, suite 2550, San Francisco, CA 94111. Government Agency involved: Department of Defense, and General Services Administration.

GT-139-80 (Special certificate, Government traffic), filed March 28, 1980. Applicant: PACIFIC STATES TRANSPORT, INC., 3328 East Valley Road, Renton, WA 98055. Representative: Henry C. Winters, 525 Evergreen Building, Renton, WA 98055. Government Agency involved: General Services Administration, Departments of Defense, Interior, and Agriculture.

GT-140-80 (Special certificate, Government traffic), filed March 28, 1980. Applicant: REDWING CARRIERS, INC., P.O. Box 426, Tampa, FL 33601. Representative: L. W. Fincher (same address as applicant). Government Agency involved: Defense Fuel Region Southeast.

GT-141-80 (Special certificate, Government traffic), filed March 28, 1980. Applicant: EXPLOSIVES CARRIER, INC., 8212 South Bryant, Route 8, Oklahoma City, OK 73129. Representative: James S. Cable, President (same address as applicant). Government Agency involved: Department of Defense, Federal Aviation Administration and General Services Administration Services.

GT-142-80 (Special certificate, Government traffic), filed March 24, 1980. Applicant: B & M EXPRESS, INC., 1900 South Portland, Oklahoma City, OK 73108. Representative: Leonard W. Mays, Jr., President, B & M Express, Inc., P.O. Box 82506, Oklahoma City, OK 73148. Government Agency involved: U.S. Government Manual (1979–80 edition).

GT-143-80 (Special certificate, Government traffic), filed March 24, 1980. Applicant: WESTPORT TRUCKING CO., 15580 South 169 Highway, Olathe, KS 66061. Representative: John T. Pruitt (same address as applicant). Government Agency involved: U.S. Government Manual (1979–80 edition).

GT-144-80 (Special certificate, Government traffic), filed March 24, 1980. Applicant: RED BALL MOTOR FREIGHT, INC., 3177 Irving Boulevard, Dallas, TX 75247. Representative: Jackie Hill (same address as applicant). Government Agency involved: U.S. Government Manual (1979–80 edition).

GT-145-80 (Special certificate, Government traffic), filed March 24, 1980. Applicant: R. W. SERVICE SYSTEM, INC., 20225 Goddard Road, Taylor, MI 48180. Representative: Martin J. Leavitt, Sullivan & Leavitt, P.C, 22375 Haggerty Road, P.O. Box 400, Northville, MI 48167. Government Agency involved: General Services Administration, U.S. Post Office, Departments of Defense, and Agriculture.

GT-146-80 (Special certificate, Government traffic), filed March 28, 1980. Applicant: HALL'S MOTOR TRANSIT CO., 6060 Carlisle Pike, Mechanicsburg, PA 17055. Representative: Edward W. Kelliher (same address as applicant). Government Agency involved: General Services Administration, Government Printing Office, Office of Personnel Management, Internal Revenue Service, Departments of Defense, Interior, and Agriculture.

GT-81-80 (Special certificate, Government traffic), filed March 20, 1980, and republished this issue to correctly set forth applicant's name and address as: ALBERTI VAN & STORAGE CO., INC., 18930 Gaithersburgh-Laytonsville Rd., Gaithersburg, MD 20760. Representative: Lauretta Alberti (same address as applicant). Government Agency involved: Department of Defense, and General Services Administration.

By the Commission.

**Agatha L. Mergenovich,**

*Secretary.*

[FR Doc. 80-12223 Filed 4-21-80; 8:45 am]

BILLING CODE 7035-01-M

## EQUAL EMPLOYMENT OPPORTUNITY COMMISSION

## DEPARTMENT OF LABOR

### Federal Contract Compliance Programs; Proposed Memorandum of Understanding

**AGENCIES:** Equal Employment Opportunity Commission and Department of Labor.

**ACTION:** Proposed notice.

**SUMMARY:** This document sets forth a proposed Memorandum of Understanding between the Equal Employment Opportunity Commission (EEOC) and the Office of Federal Contract Compliance Programs (OFCCP) of the Department of Labor (DOL). Both agencies have equal employment opportunity responsibilities and both wish to administer these responsibilities in a fashion that promotes efficiency and eliminates conflict, competition, duplication and inconsistency in the operation of their programs. This Memorandum of Understanding is designed to implement the mandate of Executive Order 12067.

**DATES:** Comments on the proposed Memorandum of Understanding must be received on or before June 23, 1980.

**ADDRESSES:** Comments may be sent to: Marie Wilson, Executive Officer, Executive Secretariat, Office of Policy Implementation, Room 4096 M, Equal Employment Opportunity Commission, 2401 "E" Street, N.W., Washington, D.C. 20506, and to: Director, Division of Program Policy, Office of Federal Contract Compliance Programs, Room C–3324, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210.

Copies of comments will be available for public inspection in the Library, EEOC, 2401 "E" Street, N.W., Washington, D.C. and Room C–3324, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. during normal business hours, from June 23, 1980, until such time as the two agencies adopt a final Memorandum.

**FOR FURTHER INFORMATION CONTACT:** Francesta E. Farmer, Director, Office of Interagency Coordination, Equal Employment Opportunity Commission, 2401 "E" Street, N.W., Room 2534, Washington, D.C. Area Code (202) 653–5490 or (202) 653–7443. Director, Division of Program Policy, Office of Federal Contract Compliance Programs, Room C–3324, U.S. Department of Labor, 200 Constitution Avenue, N.W., Washington, D.C. 20210 Area Code (202) 523–9426.

**SUPPLEMENTARY INFORMATION:**

When more than one government agency has power to regulate the same

subject matter there is the possibility of duplication and inconsistency in the use of public funds to achieve legitimate government goals. In the evolution of Federal equal employment opportunity (EEO) enforcement, a complex welter of statutes and regulations has enhanced the potential for such duplication. This fact was recognized by both the President and the Congress in Reorganization Plan No. 1 and Executive Order 12067.

Consistent and effective standards and procedures in this important area are clearly in the best interest of the public. Even though the Federal Government is often perceived as a single entity by those whom it regulates and serves, in reality the government necessarily implements related Federal policies through a number of separate agencies. In many areas artificial barriers may result. This Memorandum of Understanding seeks to eliminate or reduce such barriers to the extent possible and, as required by Executive Order 12067, to have the Federal Government function—in its dealings with citizens, beneficiaries, state and local governments, and regulated groups—as an efficient and coordinated entity.

Further, Executive Order 12067 specifically directs all Federal agencies to maximize their efforts to achieve the above goal, and directs the EEOC to provide leadership and coordination to this effort. A major step toward accomplishing the purposes of Executive Order 12067 is improving the coordination between the two chief EEO enforcement agencies: the EEOC which enforces Title VII of the Civil Rights Act of 1964, as amended, the Age Discrimination in Employment Act, and the Equal Pay Act; and OFCCP which enforces Executive Order 11246, as amended, Section 503 of the Rehabilitation Act of 1973, as amended, and Section 402 of the Vietnam Era Veterans' Readjustment Assistance Act of 1974.

Since the 1974 Memorandum of Understanding, the President and the Congress, through the issuance of Reorganization Plan No. 1 and Executive Order 12067, have issued a mandate for even greater coordination of government efforts in the implementation of antidiscrimination and affirmative action requirements. Thus, EEOC and DOL have reexamined the 1974 agreement and their experience thereunder, and are proposing a revised and more comprehensive Memorandum. The proposed Memorandum of Understanding is being published at this time for public comment in order that the final Memorandum of Understanding will reflect maximum public involvement in the preparation of the document, as required by Section I–305 of Executive Order 12067 and by Executive Order 12044.

The 1974 Memorandum of Understanding will remain in full force and effect until a revised Memorandum of Understanding is adopted and published in the **Federal Register.** The major provisions of the proposed Memorandum of Understanding may be summarized as follows:

1. The Memorandum of Understanding establishes improved procedures to ensure that employers and others are not subjected to duplicative and/or conflicting investigations or compliance reviews. Specifically, the Memorandum of Understanding requires that EEOC and OFCCP notify each other at specific stages in their case processing and compliance reviews and provide an opportunity to determine whether the notified agency contemplates or is then engaging in potentially duplicative proceedings.

2. Further, the Memorandum of Understanding recognizes that once a case is in process notification alone will not solve all problems and it thus establishes in Headquarters and each field office an ongoing consultative relationship between field personnel of EEOC and OFCCP by establishing a series of Compliance Coordination Committees which must meet at least quarterly and report on the results of their deliberations.

3. The existing Memorandum of Understanding provides that complaints filed with OFCCP are deemed charges filed with EEOC. OFCCP has traditionally investigated and resolved certain complaints, especially those of a systemic or class nature and will continue to do so. The proposed Memorandum provides that complaints filed with OFCCP within the jurisdiction of and referred to EEOC (e.g., Title VII) are deemed to be charges filed jointly with OFCCP and EEOC. Where OFCCP defers an investigation to EEOC, such complaints will be transmitted to EEOC.

Types of complaints normally retained by OFCCP for investigation include, *inter alia,* the following:

(a) Complaints against contractors in an OFCCP-targeted industry;

(b) Complaints against contractors where OFCCP has initiated a contract compliance review, or has planned a contract compliance review within 90 days of the complaint;

(c) Complaints cognizable under Executive Order 11246, but not under Title VII, such as: Third party complaints alleging systemic discrimination against unidentified victims; or complaints of deficiencies in a contractor's affirmative action plant or program;

(d) Complaints alleging retaliation for filing a complaint under EO 11246 or for assisting in a contract compliance review or complaint investigation.

After deciding to investigate a complaint, OFCCP may subsequently defer the complaint investigation to EEOC. Examples of circumstances where a subsequent deferral may occur include change in compliance review schedules or a finding that a complaint filed as a systemic complaint is in fact an individual complaint.

When OFCCP plans to investigate a complaint, OFCCP will notify EEOC of its receipt of the complaint by transmitting a copy to EEOC. EEOC will not open a charge file nor investigate such a complaint.

Where a complainant both files a charge with EEOC and a complaint with OFCCP which OFCCP plans to investigate, or where a previously deferred charge has not been resolved at the time of an OFCCP compliance review, the appropriate EEOC District Director and OFCCP Assistant Regional Administrator will determine which agency shall conduct the investigation.

This division of enforcement responsibilities will permit OFCCP to concentrate its efforts in areas of discrimination against and affirmative action for groups of employees, leaving EEOC free to address complaints of individual parties, as well as appropriate systemic discrimination complaints arising under Title VII. OFCCP, of course, will retain exclusive jurisdiction over complaints filed under section 503 of the Rehabilitation Act of 1973 and section 402 of the Vietnam Era Veterans Readjustment Assistance Act of 1974, while EEOC will retain exclusive jurisdiction over complaints filed under the Age Discrimination in Employment Act.

To protect the rights of charging parties, the Memorandum provides that complaints filed with OFCCP which are also within the jurisdiction of and referred to EEOC will be deemed filed with EEOC as of the date received by OFCCP. This will ensure full protection of rights during that period when complaints are forwarded from one agency to the other. This delineation of charge processing responsibilities in no way precludes the data-sharing between EEOC and OFCCP anticipated by Sections 1 and 2 of this proposed Memorandum of Understanding.

4. Finally, an interagency task group established by EEOC and OFCCP shall advise in the development of standards

and procedures for both agencies for matters such as targeting, data exchanges, analytical techniques, remedies and sanctions. These initiatives are supportive of the government's intention to enhance enforcement of antidiscrimination laws.

The Freedom of Information Act allows members of the general public to request certain data in the files of Federal government agencies, with certain exemptions. Because Title VII contains specific prohibitions against making certain information public, and because recent litigation in the case of *Chrysler Corp.* v. *Brown*, 99 S. Ct. 1705 (1979) leaves unresolved the exact scope of OFCCP's obligations in disclosing such data, this proposed Memorandum provides that whenever the agencies have data in their files which they have obtained from the other agency pursuant to this Memorandum of Understanding and they receive a request from a third party they will coordinate the response to such a request with the agency which initially compiled or collected the information. However, the proposed Memorandum of Understanding specifically exempts officials of state and local antidiscrimination agencies designated by EEOC as 706 agencies from the provisions of Section 5. This is accomplished by stating that the paragraph referring to requests is not applicable to any state or local agency designated as a 706 agency with whom EEOC has a current charge resolution contract and a work-sharing agreement. However, such state or local agencies cannot disclose any of the information initially compiled by OFCCP, to the public, without express written approval by the Director of OFCCP.

Specific mention of the state and local agencies is now considered necessary because of the increased emphasis on the statutory relationship between EEOC and the state and local agencies enforcing antidiscrimination legislation. Under Sections 706 and 709 of the Civil Rights Act of 1964, as amended, such agencies share enforcement authority for Title VII and EEOC has authority to enter into agreements with such agencies in order to assist EEOC in carrying out its mandate. The EEOC has devoted great attention in the last two years to developing closer and more effective working relationships with those agencies.

The charges of discrimination which are received by and which are in the jurisdiction of both EEOC and the state/local agencies under Section 706 are a part of the total Federal workload. The ability of EEOC to discharge its statutory responsibilities is directly related to the successful performance of these agencies. It is essential to Title VII enforcement and the effective functioning of this state/Federal compliance mechanism that these agencies have access to the data in EEOC's files without an arbitrary division of such data based upon its original source.

The Second Circuit Court of Appeals recently emphasized that, "Deference to state mechanisms for resolving discrimination complaints is an integral part of the enforcement process under Title VII." *Carey* v. *Gaslight Club*, 598 F. 2d 1253 (2d. Cir. 1979), cert. granted (—— U.S. ——). The Memorandum recognizes this statutory relationship, and includes these agencies as part of the coordinated enforcement process.

In addition, EEOC and OFCCP have considered the decision of the Supreme Court in *Chrysler, supra*, and have determined that such participation by the State agencies is consistent with this decision. Specifically, the Court remanded the case to determine whether certain disclosures are "authorized" by law. There is no such question in the case of state and local antidiscrimination agencies. EEOC is authorized in Section 706 and 709 of Title VII to enter into charge processing arrangements with such agencies, and those agencies are required to comply with the nondisclosure provision of Title VII, e.g., not to disclose any reporting forms prior to the institution of a proceeding under state or local law, not to disclose any other information contained in EEOC's charge file prior to the institution of a proceeding under Title VII, and not to make charges public. In the case of information initially compiled by OFCCP, and contained in EEOC files, the Memorandum provides that 706 agencies may publicly disclose such information only with the express written approval of the Director of OFCCP.

The Memorandum of Understanding limits participation by State agencies to those who have signed a work-sharing agreement agreeing to the safeguards required by Sections 706 and 709 of Title VII.

**Memorandum of Understanding**

This Memorandum of Understanding between the Office of Federal Contract Compliance Programs (OFCCP) and the Equal Employment Opportunity Commission (EEOC) is being implemented to further the objectives of Congress under Section 715 of Title VII of the Civil Rights Act of 1964, as amended by the Equal Employment Opportunity Act of 1972; of Executive Order 12067, 43 FR 28967 (June 30, 1978); and Section 6 of Reorganization Plan No. 1 of 1978 (43 FR 19807). These objectives are to develop and implement agreements, policies and practices designed to maximize effort, promote efficiency, and eliminate conflict, competition, duplication and inconsistency among the operations, functions and jurisdictions of the parties to the Memorandum.

The parties to this Memorandum agree as follows:

1. The OFCCP shall make available to the appropriate requesting official of the EEOC or his or her designee for inspection and copying and/or loan, any documents in its possession pertaining to the effective enforcement or administration of (a) Title VII of the Civil Rights Act of 1964, as amended; or (b) Reorganization Plan No. 1 of 1978 (43 FR 19807) and Executive Order 12067, 43 FR 28967, (June 30, 1978). All documents will be made available within ten days of such request. Disclosure of such material by EEOC shall be in accordance with para. 5 of this Agreement.

2.a. The EEOC shall make available to the appropriate requesting official of the OFCCP or his or her designee for inspection and copying and/or loan any documents pertaining to the enforcement and administration of Executive Order 11246; Section 402 of the Vietnam Era Veterans Readjustment Assistance Act; Section 503 of the Rehabilitation Act of 1973; and Executive Order 12067. All documents in its possession (or to which it has access through a work-sharing agreement as described in para. 5(b) of this Agreement) will be made available within ten days of such request.

b. Disclosure of such material by OFCCP shall be in accordance with para. 5 of this Agreement.

3. "Appropriate Requesting Officials" shall for the purpose of the Agreement, include the following officials, or their successors, or their designees:

a. For the EEOC:

1. The Chair.
2. The Executive Director.
3. The General Counsel.
4. Any Regional Attorney.
5. Assistant and Associate General Counsel.
6. Any District or Area Office Director.
7. Director, Office of Systemic Programs.
8. Director, Office of Interagency Coordination.
9. Director, Office of Field Services.
10. Director, Office of Policy Implementation.

b. For the OFCCP:

1. The Secretary or Under Secretary of Labor.
2. The Solicitor of Labor.
3. Assiatant Secretary for Employment Standards.

4. The Director or Deputy Director, OFCCP.
5. Associate Solicitor of Labor.
6. Any ESA Assistant Regional Administrator for OFCCP.
7. Any Area Office Director.
8. Any Regional Solicitor of Labor.
9. Any OFCCP Division Director.

4. Requests directed to a Headquarters Office of one agency from a field office of the other agency shall first be forwarded through the headquarters of the requesting agency. Responses to all requests for information shall be made to the official making such requests, or his/her designee.

5a. All requests by third parties for disclosure of information shall be coordinated with the agency which initially compiled or collected the information.

b. Subparagraph 5(a), above, is not applicable to requests for data in EEOC files made by any State or local agency designated as a 706 agency with whom EEOC has a current charge resolution contract and a work-sharing agreement containing provisions required by Sections 706 and 709 of Title VII of the Civil Rights Act of 1964, as amended. Provided, however, that any such agency shall not disclose any of the information, initially compiled by OFCCP, to the public without express written approval by the Director of OFCCP.

6. EEOC and OFCCP shall establish procedures for notification and consultation at various stages of their respective compliance activities in order to increase efficiency and ensure coordination and minimize duplication. Such procedures shall include:

a. Establishment of an ongoing Compliance Coordination Committee (CCC) which shall meet at least quarterly to review pending and future compliance plans, the selection of establishments for review, potential Commissioner Charges, and potential litigation, and to take such other steps as may be appropriate to increase effiency and eliminate competition and duplication. Such committees shall be established both in headquarters and in the field. In the field, the CCC shall be composed of the Assistant Regional Administrator for OFCCP and a representative of the EEOC in the region. At the conclusion of each quarterly meeting each field CCC shall forward to the Director, Office of Field Services, EEOC and the Director, Division of Program Operations, OFCCP, a report of the results of such meeting.

b. Contact by each agency at the commencement of and during a field investigation or compliance review where appropriate to obtain information in the possession of the agency on the employer being investigated.

c. Notification to OFCCP when EEOC has made a finding of cause and has determined that attempts at conciliation are unsuccessful and that no lawsuit will by filed by EEOC.

d. Consultation with the appropriate field office of OFCCP when an EEOC field office is contemplating recommending a Commissioner Charge or litigation, and coordination of its activities.

e. Consultation with the appropriate field office of EEOC when an OFCCP Regional Office is contemplating recommending the issuance of an administrative complaint and coordination of its activities.

7. Complaints filed with OFCCP within the jurisdiction of EEOC which OFCCP refers to EEOC shall be deemed charges filed jointly with EEOC. OFCCP shall promptly transmit all such charges to the appropriate EEOC Field Office. For the purpose of determining the timeliness of the charge under statutes administered by EEOC the date the matter was received by OFCCP shall be deemed to be the date it was received by EEOC.

8. OFCCP and EEOC seek to ensure consistent compliance and enforcement standards and procedures that will facilitate consistency of compliance determinations. The agencies also seek to make the most efficient use of their available resources through coordination. Accordingly, OFCCP and EEOC shall establish an interagency task group to advise in the development of standards and procedures for both agencies, including, but not limited to:

- Criteria and mechanisms for selecting industries and organizations for review and investigation;
- Procedures for routine exchanges of data, including, but not limited to, lists of proposed and completed compliance reviews, systemic, ELI and individual cases and conciliation agreements and settlements;
- Consistent analytical approaches to identifying and defining employment discrimination and determining appropriate remedies;
- Uniform training programs and training materials;
- Joint policy statements;
- Procedures for coordinated collection, sharing and analysis of data;
- Joint projects to develop consistent definitions and to share expertise, foster consistency, and reduce duplicative efforts in such areas as: analysis of employee selection procedures, labor market availability and use of employment statistics;
- Procedures to be utilized in obtaining compliance with OFCCP or EEOC requests for data and information, pursuant to investigations under either Title VII or Executive Order 11246.

9. EEOC and OFCCP shall conduct periodic reviews of the implementation of this agreement; on an ongoing basis.

This Memorandum of Understanding supersedes the agreement signed September 11, 1974.

Signed at Washington, D.C., this 17th day of April, 1980.

**Eleanor Holmes Norton,**
*Chair, Equal Employment Opportunity Commission.*

**F. Ray Marshall,**
*Secretary of Labor.*

**John N. Gentry,**
*Under Secretary of Labor.*

**Donald Elisburg,**
*Assistant Secretary of Labor.*

**Weldon J. Rougeau,**
*Director, Office of Federal Contract Compliance Programs.*

[FR Doc. 80-12404 Filed 4-21-80; 8:45 am]
BILLING CODE 4510-27-M

## NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

**[Notice (80-32)]**

### Space Science Steering Committee, Origins of Plasmas in the Earth's Neighborhood (Open) Ad Hoc Advisory Subcommittee

Pursuant to Section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), and after consultation with the Committee Management Secretariat, General Services Administration, NASA has determined that the establishment of an Ad Hoc Advisory Subcommittee for the evaluation of proposals for the Solar Terrestrial Program, Origins of Plasmas in the Earth's Neighborhood (Open), is in the public interest, in connection with the performance of duties imposed upon NASA by law. The Space Science Steering Committee, under which the Subcommittee will operate, is a NASA internal committee, composed wholly of Government employees.

The function of this Subcommittee will be to obtain the advice of the scientific community on proposals in the

specialized areas identified by the name of the Subcommittee.

**Russell Ritche,**

*Deputy Associate Administrator for External Relations.*

April 15, 1980.

[FR Doc. 80-12200 Filed 4-21-80; 8:45 am]

BILLING CODE 7510-01-M

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[Notice (80-33)]

### Space Science Steering Committee, International Comet Mission Ad Hoc Advisory Subcommittee

*Establishment*

Pursuant to Section 9(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), and after consultation with the Committee Management Secretariat, General Services Administration, NASA has determined that the establishment of an Ad Hoc Advisory Subcommittee for the evaluation of International Comet Mission proposals, is in the public interest, in connection with the performance of duties imposed upon NASA by law. The Space Science Steering Committee, under which the Subcommittee will operate, is a NASA internal committee, composed wholly of Government employees.

The function of this Subcommittee will be to obtain the advice of the scientific community on proposals in the specialized areas identified by the name of the Subcommittee.

**Russell Ritchie,**

*Deputy Associate Administration for External Relations.*

April 15, 1980.

[FR Doc 80-12201 Filed 4-21-80; 8:45 am]

BILLING CODE 7510-01-M

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## NATIONAL FOUNDATION ON THE ARTS AND THE HUMANITIES

### Federal Council on the Arts and the Humanities; Arts and Artifacts Indemnity Panel Advisory Committee; Meeting

April 17, 1980.

Pursuant to the provisions of the Federal Advisory Committee Act (Pub. L. 92-463, as amended) notice is hereby given that a meeting of the Arts and Artifacts Indemnity Panel of the Federal Council on the Arts and the Humanities will be held at the Columbia Plaza Office Building, 2401 E Street, N.W., Washington, D.C. 20506 in room 1422, from 9:00 a.m. to 5:00 p.m. on May 7, 1980.

The purpose of the meeting is to review applications for certificates of indemnity submitted to the Federal Council on the Arts and Humanities for exhibits beginning after July 1, 1980.

Because the proposed meeting will consider commercial and financial data and because it is important to keep values of objects, methods of transportation, and security measures confidential, pursuant to authority granted me by the Chairman's Delegation of Authority to Close Advisory Committee Meetings, dated April 16, 1978, I have determined that the meeting would fall within exemptions (4) and (9) of 5 U.S.C. 552b(c) and that it is essential to close the meeting to protect the free exchange of internal views and to avoid interference with operation of the Committee.

It is suggested that those desiring more specific information contact the Advisory Committee Management Officer, Mr. Stephen J. McCleary, 806 15th Street, N.W., Washington, D.C. 20506, or call (202) 724-0367.

**Stephen J. McCleary,**

*Advisory Committee Management Officer.*

[FR Doc. 80-12341 Filed 4-21-80; 8:45 am]

BILLING CODE 7536-01-M

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### Museum Panel (Challenge); Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Museum Panel to the National Council on the Arts will be held May 28, 1980 from 9:00 a.m.-5:00 p.m.; May 29, 1980 from 9:00 a.m.-5:00 p.m.; and May 30, 1980 from 9:00 a.m.-5:00 p.m. in Room 1422, Columbia Plaza Office Complex, 2401 E St., N.W., Washington, D.C.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and 9(b) of Section 552b of Title 5 United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.

Dated: April 17, 1980.

**John H. Clark,**

*Director, Office of Council and Panel Operations, National Endowment for the Arts.*

[FR Doc. 80-12314 Filed 4-21-80; 8:45 am]

BILLING CODE 7537-01-M

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### Museum Panel (Cooperative Programs; Wider Availability of Museums); Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Museum Panel (Cooperative Programs; Wider Availability of Museums) to the National Council on the Arts will be held May 12, 1980 from 9:00 a.m.-5:00 p.m. and May 13, 1980 from 9:00 a.m.-5:00 p.m. in Room 1426, Columbia Plaza Office Complex, 2401 E St., N.W., Washington, D.C.

This meeting is for the purpose of Panel review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and 9(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634-6070.

Dated: April 17, 1980.

**John H. Clark,**

*Director, Office of Council and Panel Operations, National Endowment for the Arts.*

[FR Doc. 80-12316 Filed 4-21-80; 8:45 am]

BILLING CODE 7537-01-M

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### Museum Panel (Special Exhibitions); Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), as amended, notice is hereby given that a meeting of the Museum Panel (Special Exhibitions) to the National Council on the Arts will be held May 14, 1980 from 9:00 a.m.-5:00 p.m.; May 15, 1980 from 9:00 a.m.-5:00 p.m.; May 16, 1980 from 9:00 a.m.-5:00 p.m. in Room 1426, Columbia Plaza Office Complex, 2401 E St., N.W., Washington, D.C.

This meeting is for the purpose of Panel review, discussion, evaluation,

and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c)(4), (6) and 9(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634–6070.

Dated: April 17, 1980.

**John H. Clark,**

*Director, Office of Council and Panel Operations, National Endowment for the Arts.*

[FR Doc. 80–12315 Filed 4–21–80; 8:45 am]

BILLING CODE 7537–01–M

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### National Council on the Arts; Meeting

Pursuant to Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92–463), notice is hereby given that a meeting of the National Council on the Arts will be held on Friday, May 9, 1980 from 9:00 a.m.–5:30 p.m. and Saturday, May 10, 1980 from 9:00 a.m.–5:30 p.m. at the Four Seasons Hotel, 2800 Pennsylvania Avenue, N.W., Georgetown, Washington, D.C.

A portion of this meeting will be open to the public on Friday, May 9, 1980 from 9:00 a.m.–5:00 p.m. and Saturday, May 10, 1980 from 9:00 a.m.–11:30 a.m. Topics for discussion will include Guidelines for Artists-in-Schools, Music (Solo Artists), and Special Projects Programs; review of the Museum Program; reports from the Policy/Planning, International, and National Council on the Arts/National Assembly of State Arts Agencies Committees; General discussion of future planning for the Endowment.

The remaining sessions of this meeting on Friday, May 9, 1980 from 5:00 p.m.–5:30 p.m. and Saturday, May 10, 1980 from 11:30 a.m.–5:30 p.m. are for the purpose of Council review, discussion, evaluation, and recommendation on applications for financial assistance under the National Foundation on the Arts and the Humanities Act of 1965, as amended, including discussion of information given in confidence to the agency by grant applicants. In accordance with the determination of the Chairman published in the **Federal Register** of February 13, 1980, these sessions will be closed to the public pursuant to subsections (c) (4), (6) and 9(b) of section 552b of Title 5, United States Code.

Further information with reference to this meeting can be obtained from Mr. John H. Clark, Advisory Committee Management Officer, National Endowment for the Arts, Washington, D.C. 20506, or call (202) 634–6070.

Dated: April 17, 1980.

**John H. Clark,**

*Director, Office of Council and Panel Operations, National Endowment for the Arts.*

[FR Doc. 80–12313 Filed 4–21–80; 8:45 am]

BILLING CODE 7537–01–M

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## SECURITIES AND EXCHANGE COMMISSION

**[File No. 500–1]**

### American Technical Resources, Inc.; Order of Suspension of Trading

April 16, 1980.

It appearing to the Securities and Exchange Commission that there has been recent unusual and unexplained market activity in the securities of American Technical Resources, Inc. that involved the raise in the price of ATR stock from $.20 to $1.25 per share between December 1979 and mid-March 1980, while there was no publicly available information which would have justified this market activity, the Commission is of the opinion that the public interest and the protection of investors require a summary suspension of trading in the securities of American Technical Resources, Inc.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, trading in such securities on a national securities exchange or otherwise is suspended, for the period from 2:00 pm on April 16, 1980 and terminating at midnight on April 25, 1980, unless sooner ordered by the Commission.

By the Commission.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 80–12309 Filed 4–21–80; 8:45 am]

BILLING CODE 8010–01–M

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**[File No. 500–1]**

### Bache Group, Inc.; Order of Termination of Suspension of Trading

April 1, 1980.

It appearing to the Securities and Exchange Commission that various disclosures have been made by Bache Group, Inc. with respect to the impact of recent developments in the commodities markets on the financial condition of Bache Group, Inc., the Commission is of the opinion that the public interest and the protection of investors require a termination of the summary suspension of trading in the securities of Bache Group, Inc. which the Commission ordered on March 27, 1980.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, that the termination of the suspension of trading of such securities will be effective at midnight on April 1, 1980.

By the Commission.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 80–12310 Filed 4–21–80; 8:45 am]

BILLING CODE 8010–01–M

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**[File No. 500–1]**

### Olympic Gas & Oil, Inc. and SNG & Oil Energy Co.; Order of Suspension of Trading

April 11, 1980.

It appearing to the Securities and Exchange Commission that: there are questions concerning the ownership of assets listed in the most recently published balance sheets of both companies; that certain real estate constituting the majority of the reported assets of both companies was never conveyed to such companies notwithstanding representations to the contrary contained in filings of these companies with the Commission; that questions have arisen with respect to the extent of gas, oil and mineral rights, if any, conveyed to Olympic Gas & Oil, Inc., the Commission is of the opinion that the public interest and the protection of investors require a summary suspension of trading in the securities of Olympic Gas & Oil, Inc. and SNG & Oil Energy Company.

Therefore, it is ordered, pursuant to Section 12(k) of the Securities Exchange Act of 1934, trading in such securities on a national securities exchange or otherwise is suspended, for the period from 10:00 a.m. on April 11, 1980 and terminating at midnight on April 20, 1980, unless sooner ordered by the Commission.

By the Commission.

**George A. Fitzsimmons,**

*Secretary.*

[FR Doc. 80–12199 Filed 4–21–80; 8:45 am]

BILLING CODE 8010–01–M

## SELECT COMMISSION ON IMMIGRATION AND REFUGEE POLICY

### Public Hearing, Albany, N.Y.

The Select Commission on Immigration and Refugee Policy will hold the eleventh of twelve regional hearings on:

Date: May 5, 1980.
Time: 9:00 a.m.–5:00 p.m. and 7:00 p.m.–9:00 p.m.
Place: The Roosevelt Room, Hearing Room C, Second Floor, Legislative Office Building, State Street—Albany, New York.

The Albany hearing will be chaired by Representative Hamilton Fish, Jr.

The major portion of this hearing will be devoted to testimony from invited witnesses addressing issues relating to inhibiting the employment of illegal aliens, refugee resettlement, visa processing and allocation, northern border crossings, and INS procedures.

There will be an Open Mike from 7:00–9:00 p.m. in the evening available to anyone wishing to address any immigration issue before the Commission.

The public is cordially invited to attend both the day and evening discussions.

Written statements will be accepted for a period of seven days following the hearing from people unable to appear in person.

The Select Commission on Immigration and Refugee Policy was created by Public Law to provide a comprehensive review of U.S. immigration laws, policies, and procedures. The regional hearings are being held to ensure that a wide range of views are heard and considered by the Commission. Other hearings are being held in Baltimore, Chicago, Denver, Los Angeles, Miami, New Orleans, New York, Phoenix, San Antonio, and San Francisco.

Members of the Commission include four Cabinet officers, eight members of Congress with four members selected from each Judiciary Committee, and four members appointed by the President.

Anyone wishing more information about the Albany hearing or about testifying at the evening session should contact: John Jones, Select Commission on Immigration and Refugee Policy, New Executive Office Building, Suite 2020, 726 Jackson Place, N.W., Washington, D.C. 20506, Telephone: 202–395–5615.

**Lawrence H. Fuchs,**

*Executive Director.*

[FR Doc. 80–12267 Filed 4–21–80; 8:45 am]

BILLING CODE 6820–AR–M

## SMALL BUSINESS ADMINISTRATION

[License No. 02/02–0395]

### E S One Capital Corp.; Application for a License To Operate as a Small Business Investment Company

Notice is hereby given that an application has been filed with the Small Business Administration pursuant to § 107.102 of the Regulations governing small business investment companies (13 CFR 107.102 (1980), under the name of E S One Capital Corporation (Applicant), for a license to operate as a Small Business Investment Company (SBIC) under the provisions of the Small Business Investment Act of 1958, as amended, and the Rules and Regulations promulgated thereunder.

The Applicant was incorporated under the laws of the State of Delaware and it will commence operations with a capitalization of $3,625,000, which amount is to be contributed by the parent company, Energy Search One N.V. (ESONV), a Netherlands Antilles corporation for 100% of the issued and outstanding stock of the Applicant. ESONV was incorporated on November 26, 1979 in Curacao for the purpose of investing in business enterprises in the United States. All capital ($14,691,500) was raised in a private offering outside of the United States to 59 European financial institutions, none of whom purchased as much as 10%. The operations of ESONV are under the supervision of its Board of Supervisory Directors consisting of five persons:

Hubert J. Hendrickx.
Thomas C. Kryzer.
Robert B. Stobaugh.
Harvey J. Wachtel.[1]
Harvey White.

The Applicant will have its place of business at 400 Madison Avenue, New York, New York 10017, and it intends to conduct operations primarily in the State of New York as well as other areas of the United States.

The Officers and Directors of the Applicant will be:

| Name | Title | Percent |
|---|---|---|
| Harvey Jack Wachtel, 765 Malabu, Lexington, KY 40502.. | ..... | ..... |
| | President and director. | ..... |
| Frank Clayton Schuller, 309 Walnut Street, Wellesley, MA 02181.. | Treasurer and director. | ..... |
| Donald Forrest MacLeod, 4 Little Brook Road, Rowayton, CT 06853. | Secretary and director. | ..... |
| Energy Search One N.V., c/o Curacao Corp. Co. NV., Handelskade No. 8, Curacao, Netherlands, Antilles.. | Sole stockholder ..... | 100 |

[1] Mr. Wachtel will be the President and a Director of the Applicant.

Matters involved in SBA's consideration of the Application include the general business reputation and character of the proposed owners and management, and the probability of successful operations of the Applicant under their management, including adequate profitability and financial soundness in accordance with the Act and SBA Regulations.

Notice is hereby given that any person may, not later than May 7, 1980, submit to SBA written comments on the proposed Applicant to the Deputy Associate Administrator for Finance and Investment, Small Business Administration, 1441 "L" Street, N.W., Washington, D.C. 20416.

A copy of this notice shall be published in a newspaper of general circulation in New York, New York.

(Catalog of Federal Domestic Assistance Program No. 59.011, Small Business Investment Companies)

Dated: April 11, 1980.

**Peter F. McNeish,**

*Deputy Associate Administer for Finance and Investment.*

[FR Doc. 80–12259 Filed 4–21–80; 8:45 am]

BILLING CODE 8025–01–M

### Region III Advisory Council; Public Meeting

The Small Business Administration Region III Advisory Council, located in the geographical area of Washington, D.C., will hold a public meeting at 10:00 a.m., Wednesday, May 14, 1980, in the Washington, D.C. District Office, located at 1030 15th Street, N.W., Suite 250, Washington, D.C., to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and other attending.

For further information, write or call Freddie M. Collins, District Director, U.S. Small Business Administration, 1030 15th Street, N.W., Suite 250, Washington, D.C. 20417—(202) 653–6965.

Dated: April 15, 1980.

**Michael B. Kraft,**

*Deputy Advocate for Advisory Councils.*

[FR Doc. 80–12260 Filed 4–21–80; 8:45 am]

BILLING CODE 8025–01–M

### Region IV Advisory Council; Public Meeting

The Small Business Administration Region IV Advisory Council, located in the geographical area of Birmingham, Alabama, will hold a public meeting at 9:30 a.m., Monday, May 12, 1980, at the South Twentieth Building, 908 South 20th Street, Room 202, (2nd, floor), Birmingham, Alabama, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call James C. Barksdale, District Director, U.S. Small Business Administration, 908 South 20th Street, Room 202, Birmingham, Alabama 35205—(205) 254–1341.

Dated: April 15, 1980.

**Michael B. Kraft,**

*Deputy Advocate for Advisory Councils.*

[FR Doc. 80-12261 Filed 4-21-80; 8:45 am]

BILLING CODE 8025-01-M

### Region V Advisory Council; Public Meeting

The Small Business Administration Region V Advisory Council, located in the geographical area of Detroit, Michigan, will hold a public meeting Friday, May 9, 1980 at the St. Regis Hotel, 3071 West Grand Boulevard, Detroit, Michigan. Registration will begin at 9:30 a.m. with the formal meeting commencing at 10:00 a.m., to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call Raymond L. Harshman, District Director, U.S. Small Business Administration, 515 Patrick V. McNamara Building, 477 Michigan Avenue, Detroit, Michigan 48228 (313) 226–7240.

Dated: April 15, 1980.

**Michael B. Kraft,**

*Deputy Advocate for Advisory Councils.*

[FR Doc. 80-12262 Filed 4-21-80; 8:45 am]

BILLING CODE 8025-01-M

### Region V Advisory Council; Public Meeting

The Small Business Administration Region V Advisory Council, located in the geographical area of Chicago, Illinois, will hold a public meeting at 11:00 a.m., Tuesday, May 6, 1980, at the Albany Bank and Trust Company, 3400 West Lawrence, Chicago, Illinois, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call John L. Smith, District Director, U.S. Small Business Administration, 219 South Dearborn Street, Chicago, Illinois 60604—(312) 353–4508.

Dated: April 15, 1980.

**Michael B. Kraft,**

*Deputy Advocate for Advisory Councils.*

[FR Doc. 80-12263 Filed 4-21-80; 8:45 am]

BILLING CODE 8025-01-M

### Region IX Advisory Council; Public Meeting

The Small Business Administration Region IX Advisory Council, located in the geographical area of Honolulu, Hawaii, will hold a public meeting at 9:00 a.m., Thursday, May 15, 1980, at the Ala Moana Americana Hotel, 410 Atkinson Drive, Plumeria Room, Honolulu, Hawaii, to discuss such business as may be presented by members, the staff of the U.S. Small Business Administration, and others attending.

For further information, write or call David K. Nakagawa, District Director, U.S. Small Business Administration, 300 Ala Moana Boulevard, Room 2213, Honolulu, Hawaii 96850—(808) 546–8950.

Dated: April 15, 1980.

**Michael B. Kraft,**

*Deputy Advocate for Advisory Councils.*

[FR Doc. 80-12264 Filed 4-21-80; 8:45 am]

BILLING CODE 8025-01-M

## DEPARTMENT OF STATE

### Office of the Secretary

**[Public Notice CM-8/289]**

### Advisory Committee on International Investment, Technology, and Development; Meeting

The Department of State will hold a meeting on May 5 of the Working Group on UN/OECD Investment Undertakings of the Advisory Committee on International Investment, Technology, and Development. The Working Group will meet from 9:30–12:30. The meeting will be held in Room 1406 of the State Department, 2201 C Street NW., Washington, D.C. 20520. The meeting will be open to the public.

The purpose of the meeting will be to discuss the work of the United Nations Inter-Governmental Working Group on a Code of Conduct.

Requests for further information on the meeting should be directed to Richard Kauzlarich, Department of State, Office of Investment Affairs, Bureau of Economic and Business Affairs, Washington, D.C. 20520. He may be reached by telephone on (area code 202) 632–2728.

Members of the public wishing to attend the meeting must contact Mr. Kauzlarich's office in order to arrange entrance to the State Department building.

The Chairman of the working group, will as time permits, entertain oral comments from members of the public attending the meeting.

Dated: April 11, 1980.

**Richard D. Kauzlarich,**

*Executive Secretary.*

[FR Doc. 80-12360 Filed 4-21-80; 8:45 am]

BILLING CODE 4710-07-M

**[Public Notice CM-8/290]**

### Shipping Coordinating Committee; Subcommittee on Safety of Life at Sea; Meeting

The Safety of Life at Sea Subcommittee will conduct an open meeting at 9:30 a.m. on Wednesday, May 7, 1980 in Room 3201 of the US Coast Guard Headquarters Building, 2100 2nd Street SW., Washington, D.C.

The purpose of the meeting is to finalize preparations for the 42nd Session of the Maritime Safety Committee (MSC) of the Intergovernmental Maritime Consultative Organization (IMCO) which is scheduled to meet May 19–23, 1980 in London. After discussions concerning the MSC, the results of the 42nd Session of the IMCO Legal Committee will be reviewed and the following agenda items for the 43rd Session not previously listed will be included:

Decision taken in the Group of Technical Experts relating to the list of substances to be included in any convention.

Treatment under the proposed convention of substances posing fire and explosion hazard.

Inclusion of packaged mass detonating explosives within the ambit of the proposed convention.

Issues of liability allocation and monetary limits raised in connection with Draft Alternatives II and IV.

The decision of the Committee to concentrate future work on Alternative II.

Progress of the ad hoc working group which is scheduled to meet in London, April 10–12 to revise the work of the Committee at the 42nd Session.

The agenda for future sessions of the Legal Committee.

For further information contact LCDR S. Delaney, US Coast Guard (G-LMI/34), 2100 Second Street SW., Washington, D.C. 20593. Telephone (202) 426-2280.

Dated: April 11, 1980.

**John Todd Stewart,**

*Chairman, Shipping Coordinating Committee.*

[FR Doc. 80-12361 Filed 4-21-80; 8:45 am]

BILLING CODE 4710-07-M

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**[Public Notice CM-8/288]**

## Study Group A of the U.S. Organization for the International Telegraph Telephone Consultative Committee (CCITT); Meeting

The Department of State announces that Study Group A of the U.S. Organization for the International Telegraph and Telephone Consultative Committee (CCITT) will meet on May 7, 1980 at 10:00 a.m. in Room A-110 of the Federal Communications Commission, 1229 20th Street, N.W., Washington, D.C. This Study Group deals with U.S. Government regulatory aspects of international telegraph and telephone operations and tariffs.

The Study Group will discuss international telecommunications questions relating to telegraph, telex, new record services, data transmission and leased channel services in order to develop U.S. positions to be taken at international CCITT meetings, and particularly at the upcoming June meeting of Study Group I in Montreal, Canada.

Members of the general public may attend the meeting and join in the discussion subject to instructions of the Chairman. Admittance of public members will be limited to the seating available.

Requests for further information should be directed to Arthur L. Freeman, State Department, Washington, D.C. 20520, telephone (202) 632-3405.

Dated: April 9, 1980.

**Arthur L. Freeman,**

*Director, Office of International Communications Policy.*

[FR Doc. 80-12359 Filed 4-21-80; 8:45 am]

BILLING CODE 4710-07-M

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## DEPARTMENT OF THE TREASURY

### Internal Revenue Service

### Performance Review Board

**AGENCY:** Internal Revenue Service, Treasury.

**ACTION:** Notice of change of the members of a Senior Executive Service Performance Review Board.

**DATE:** Performance Review Board effective July 1, 1979.

**FOR FURTHER INFORMATION CONTACT:** James W. House, RM:P:X, 1111 Constitution Avenue, N.W., Room 3335, Washington, D.C. 20224, Telephone No. 202-566-4633, (not a toll free number).

**SUPPLEMENTARY INFORMATION:** The members of the Internal Revenue Service's Senior Executive Service Performance Review Board which appeared in the **Federal Register** on August 31, 1979 (44FR51393) and October 16, 1979 (44FR59704) have been changed. The changes are as follows:

Donald J. Porter, Assistant Commissioner, Data Services (alternate member), replaces James I. Owens, Assistant Commissioner, Taxpayer Service and Returns Processing, as a regular member of the Board.

Russell E. Dyke, Assistant Commissioner, Planning and Research, is appointed to serve as an alternate member of the Board.

This document does not meet the criteria for significant regulations set forth in paragraph 8 of the Treasury Directive appearing in the **Federal Register** for Wednesday, November 8, 1978 (43FR52122).

**William E. Williams,**

*Deputy Commissioner.*

[FR Doc. 80-12256 Filed 4-21-80; 8:45 am]

BILLING CODE 4830-01-M

# Sunshine Act Meetings

Federal Register
Vol. 45, No. 79
Tuesday, April 22, 1980

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).

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### 1

**EQUAL EMPLOYMENT OPPORTUNITY COMMISSION.**

**TIME AND DATE:** 9:30 a.m. (Eastern time), Tuesday, April 22, 1980.

**PLACE:** Commission conference room, 5240, fifth floor, Columbia Plaza Office Building, 2401 E Street NW., Washington, D.C. 20506.

**STATUS:** Part will be open to the public and part will be closed to the public.

**MATTERS TO BE CONSIDERED:** Open to the public:

1. Freedom of Information Act No. 79–12–FOIA–449, concerning a request by a charging party for interoffice memoranda and notes compiled by Commission employees.
2. Freedom of Information Act No. 80–2–FOIA–97, concerning a request for Commission documents listing certain employers with charges pending against them.
3. Freedom of Information Act No. 80–1–FOIA–33, concerning a request by a respondent party for access to notes taken during a Fact Finding Conference.
4. Mission and Functions: Office of Administration.
5. Proposals for Revision of the Department of Labor's Interpretative Bulletin on Employee Benefit Plans.
6. Report on Commission Operations by the Executive Director.

Closed to the public:

Litigation Authorization; General Counsel Recommendations.

Note.—Any matter not discussed or concluded may be carried over to a later meeting.

**CONTACT PERSON FOR MORE INFORMATION:** Marie D. Wilson, Executive Officer, Executive Secretariat, at (202) 634–6748.

This Notice Issued April 15, 1980.

[S–794–80 Filed 4–18–80; 12:51 pm]

**BILLING CODE 6570–06–M**

### 2

**FEDERAL ENERGY REGULATORY COMMISSION.**

April 18, 1980.

**TIME AND DATE:** 10:00 a.m., April 25, 1980.

**PLACE:** 825 North Capitol Street, NE., Washington, D.C. 20426.

**STATUS:** Closed.

**MATTER TO BE CONSIDERED:** The agency's participation in a civil action.

**CONTACT PERSON FOR MORE INFORMATION:** Kenneth F. Plumb, Secretary, telephone (202) 357–8400.

The following members of the Commission voted to hold a closed meeting:

Chairman Curtis.
Commissioner Sheldon.
Commissioner Holden.
Commissioner Hall.

**Kenneth F. Plumb,**

*Secretary.*

[S–793–80 Filed 4–18–80; 10:56 am]

**BILLING CODE 6450–85–M**

### 3

**FEDERAL MARITIME COMMISSION.**

**"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:** 45 FR 26547, April 18, 1980.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:** 10 a.m., April 23, 1980.

**CHANGE IN THE MEETING:** Date of meeting changed from April 23, 1980 to April 24, 1980 at 10 a.m.

[S–798–80 Filed 4–18–80; 3:58 am]

**BILLING CODE 6730–01–M**

### 4

**FEDERAL RESERVE SYSTEM.**

**"FEDERAL REGISTER" CITATION OF PREVIOUS ANNOUNCEMENT:** Forwarded to Federal Register on April 15, 1980.

**PREVIOUSLY ANNOUNCED TIME AND DATE OF THE MEETING:** 10:30 a.m., Wednesday, April 23, 1980.

**CHANGES IN THE MEETING:** (1) Deletion of the following open item from the agenda:

Proposal to permit underwriting of credit-related home mortgage life insurance as a permissible activity for bank holding companies.

This matter will be rescheduled for an upcoming meeting.

(2) The time of the open meeting has been changed. The meeting will now be held at 11 a.m. on Wednesday, April 23, 1980.

**CONTACT PERSON FOR MORE INFORMATION:** Mr. Joseph R. Coyne, Assistant to the Board (202) 452–3204.

Dated: April 18, 1980.

**Theodore E. Allison,**

*Secretary of the Board.*

[S–795–80 Filed 4–18–80; 2:52 pm]

**BILLING CODE 6210–01–M**

### 5

**FEDERAL TRADE COMMISSION.**

**TIME AND DATE:** 2 p.m., Thursday, April 24, 1980.

**PLACE:** Room 532, (open); room 540 (closed), Federal Trade Commission Building, Sixth Street and Pennsylvania Avenue NW., Washington, D.C. 20580.

**STATUS:** Parts of this meeting will be open to the public. The rest of the meeting will be closed to the Public.

**MATTERS TO BE CONSIDERED:** Portions Open to Public:

(1) Oral Argument in Bristol-Myers Company, et al., Docket 8917.

Portions closed to the Public:

(2) Executive Session to discuss Oral Argument in Bristol-Myers Company, et al., Docket 8917.

**CONTACT PERSON FOR MORE INFORMATION:** Ira J. Furman, Office of Public Information (202) 523–3830; Recorded message: (202) 523–3806.

[S–796–80 Filed 4–18–80; 2:52 pm]

**BILLING CODE 6750–01–M**

### 6

**[NM–80–18]**

**NATIONAL TRANSPORTATION SAFETY BOARD.**

**TIME AND DATE:** 9 a.m., Tuesday, April 29, 1980.

**PLACE:** NTSB Board Room, National Transportation Safety Board, 800 Independence Avenue SW., Washington, D.C. 20594.

**STATUS:** The first four items are open to the public; the last item is closed under Exemption 10 of the Government in the Sunshine Act.

**MATTERS TO BE CONSIDERED:**

1. *Railroad Accident Report*—Derailment of Amtrak Train No. 4, the Southwest Limited, on the Atchison, Topeka, and Santa Fe Track at Lawrence, Kansas, October 2, 1979, and *Recommendations* to the Atchison, Topeka and Santa Fe, Amtrak, and the Federal Railroad Administration.
2. *Aircraft Accident Report*—Massey-Ferguson, Inc., Gates Learjet 25D, N137GL, Detroit, Michigan, January 19, 1979.
3. *Pipeline Accident Report*—Columbia Gas of Virginia, Inc., Explosion and Fire, Stanardsville, Virginia, October 24, 1979, and *Recommendation* to the American Gas Association.
4. *Proposed Special Study*—Pedestrian Awareness on Railroads.
5. *Opinion and Order*—Administrator v. Clausen, Dkt. SE–4401; disposition of the Administrator's appeal

**CONTACT PERSON FOR MORE INFORMATION:** Sharon Flemming 202–472–6022.

April 18, 1980.

[S–797–80 Filed 4–18–80; 3:02 pm]

**BILLING CODE 4910–58–M**

federal register

Tuesday
April 22, 1980

Part II

# Department of Health, Education, and Welfare

## Food and Drug Administration

## Classification of Microbiology or Immunology Devices; Development of General Provisions; Proposed Rules

**DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

**Food and Drug Administration**

**21 CFR Part 866**

**[Docket No. 78N-2113]**

## Classification of Microbiology or Immunology Devices; Development of General Provisions

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The agency is proposing general rules applicable to the classification of all microbiology or immunology devices. The Medical Device Amendments of 1976 require the Food and Drug Administration (FDA) to classify all medical devices intended for human use into three categories: class I, general controls; class II, performance standards; and class III, premarket approval. In the preamble to this proposal, FDA describes the development of the proposed regulations classifying individual microbiology or immunology devices, which are being published elsewhere in this issue of the **Federal Register**. The preamble also describes the activities of the Microbiology Device Classification Panel and the Immunology Device Classification Panel, FDA advisory committees that make recommendations to FDA concerning the classification of microbiology and immunology devices.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Device Classification System

The Medical Device Amendments of 1976 (Pub. L. 94-295) (hereinafter called the amendments) establish a comprehensive system for the regulation of medical devices intended for human use. One provision of the amendments, section 513 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360c) establishes three categories (classes) of devices, depending on the regulatory controls needed to provide reasonable assurance of their safety and effectiveness. The three categories are as follows: class I, general controls; class II, performance standards; and class III, premarket approval.

Most devices are not classified under section 513 of the act until after FDA has (1) received a recommendation from a device classification Panel (an FDA advisory committee); (2) published the Panel's recommendation for comment, along with a proposed regulation classifying the device; and (3) published a final regulation classifying the device. These steps must precede the classification of any device that was in commercial distribution before May 28, 1976 (the date of enactment of the amendments) and that was not previously regarded by FDA as a new drug under section 505 of the act (21 U.S.C. 355). A device that is first offered for commercial distribution after May 28, 1976, and that is substantially equivalent to a device classified under this scheme, is classified in the same class as the device to which it is substantially equivalent.

A device that FDA previously regarded as a new drug, or a newly offered device that is not substantially equivalent to a device that was in commercial distribution before the amendments, is classified by statute into class III. These two types of devices are classified into class III without any FDA rulemaking proceedings. The agency determines whether new devices are substantially equivalent to previously offered devices by means of the premarket notification procedure in section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807).

### Related Regulations

In the **Federal Register** of July 28, 1978 (43 FR 32988), the agency issued final regulations describing the procedures for classifying devices intended for human use. These regulations, which were proposed in the **Federal Register** of September 13, 1977 (42 FR 46028), supplement the agency's regulations in Part 14 (21 CFR Part 14) governing the use of advisory committees. The agency also issued interim device classification procedures in a notice published in the **Federal Register** of May 19, 1975 (40 FR 21848).

Microbiology and immunology devices are subject to labeling requirements in § 809.10 (21 CFR 809.10) for in vitro diagnostic products. As defined in § 809.3(a) (21 CFR 809.3(a)), in vitro diagnostic products are those reagents, instruments, and systems intended for use in the diagnosis of disease or in the determination of the state of health in order to cure, mitigate, treat, or prevent disease or its sequelae. These products are intended for use in the collection, preparation, and examination of specimens taken from the human body. Before the enactment of the amendments, FDA regarded in vitro diagnostic products as drugs or devices, or as combinations of drugs and devices. Since the enactment of the amendments, with their expanded definition of "device" in section 201(h) of the act (21 U.S.C. 321(h)), FDA regards in vitro diagnostic products as devices.

Certain in vitro diagnostic products are also biological products subject to section 351 of the Public Health Service Act (42 U.S.C. 262). However, FDA has not yet obtained the Panels' recommendations concerning the classification of microbiology and immunology devices that are licensed biological products. In the future, FDA will obtain the Panels' recommendations concerning the classification of these products and publish these recommendations and proposed regulations in the **Federal Register**. FDA will also publish a separate notice concerning the regulation of leukocyte typing serum, a product that is both a device and a licensed biological product and that is a valuable reagent for identifying suitable donors for organ transplants and platelet and leukocyte transfusions.

In addition, two devices that contain antibiotics (antimicrobial susceptibility test discs and antimicrobial susceptibility test powders) are subject to premarket approval regulations for antibiotics under section 507 of the act (21 U.S.C. 357). Section 520(1)(4) of the act (21 U.S.C. 360j(1)(4)) provides that if a class II device was subject to the requirements of section 507 on May 28, 1976 (the date of enactment of the amendments), these requirements shall continue to apply to the device until the effective date of a performance standard applicable to the device under section 514 of the act. Thus, devices that were then subject to the requirements of section 507 of the act continue to be subject to those requirements until the effective date of a performance standard for these devices.

### Activities of Panels

Anticipating enactment of the amendments, FDA established several advisory committees to make preliminary recommendations on device classification. The Microbiology Device Classification Panel and the Immunology Device Classification Panel were originally chartered on April 9,

1972, as the Microbiology and the Immunology Subcommittees of the Diagnostics Products Advisory Committee.

On August 10, 1976, the Subcommittees were rechartered as the Microbiology Device Classification Panel and the Immunology Device Classification Panel to reflect their new responsibilities under the amendments. The agency directed each Panel to reconsider its preamendments classification recommendations in light of the new requirements. In 1976 and 1977, the Panels reviewed all devices that FDA had referred to it to make certain that their recommendations were in accord with the amendments. On April 28, 1978, the Panels were again rechartered and became sections of the Immunology and Microbiology Devices Panel.

Throughout the Panel's deliberations, interested persons were given an opportunity to present their views, data, and other information concerning the classification of microbiology and immunology devices. The Panels also invited experts to testify and sought information on many devices from the published literature.

The Panels submitted to FDA preliminary reports of their recommendations. The reports included rosters of current and former Panel members and consultants and listed all meeting dates. The agency placed copies of the report in the office of the Hearing Clerk (HFA–305), Food and Drug Administration, and announced their availability to the public by notice published in the **Federal Register** of November 29, 1977 (42 FR 60792). Also available in the office of the Hearing Clerk are summary minutes from all Panel meetings, verbatim transcripts of meetings held after May 28, 1976 (the date of enactment of the amendments), and all references cited in individual microbiology and immunology device proposed classification regulations. Interested persons may review these documents in the office of the Hearing Clerk (address above).

### Relationship Between the Device Names in the Device Registration and Listing Codes and the Device Names in Classification Regulations

The agency is aware that manufacturers have become accustomed to identifying a device by its registration and listing classification name and three letter code for purposes of device listing. However, changes in the names and identifications of generic types of devices in the classification regulations are still being made in all panels for which final regulations have not been published. The agency believes that use of the present device registration and listing classification names in the regulations would complicate the agency's publication of the classification regulations unnecessarily. To aid a manufacturer in matching its device with the proper classification regulation, FDA has prepared an index of names of generic types of medical devices used in classification regulations. The index shows the device regulation and listing product code for each device reviewed by a classification panel and the corresponding name of the generic type of device and classification panel in which the device classification will be published in the **Federal Register.** The agency announced the availability of this index in the **Federal Register** of March 6, 1979 (44 FR 12269). If necessary, this index will be updated and the availability of the revised index will be reannounced in the **Federal Register.** FDA believes that because this index is available, it is unnecessary to include or cross-reference the present device registration and listing name and product code in each device in the classification regulations. In the future, following publication of most of the device classification regulations, the agency will revise and reissue the device regulation and listing product code so the device names to be used for registration and listing correspond to the device names in the final device classification regulations.

### List of Microbiology and Immunology Devices

In 1972 FDA surveyed device manufacturers to identify the devices for which classification regulations would be needed. Following this survey, FDA developed a list of microbiology and immunology devices. The Panels supplemented the list utilizing their members' knowledge of microbiology and immunology devices in use. Devices that were solely for experimental or investigational use or that were not generally available were not included.

FDA is proposing to establish a new Part 866 in Title 21 of the Code of Federal Regulations. Part 866 will consist of sections identifying each microbiology or immunology device with a brief narrative description and stating the classification of that device. A list of the microbiology and immunology devices appears elsewhere in this preamble.

### Individual Microbiology and Immunology Device Classification Regulations

Elsewhere in this issue of the **Federal Register,** FDA is issuing 88 individual proposed regulations to classify each microbiology device. The agency is proposing to classify 63 microbiology devices into class I (general controls) and 25 microbiology devices into class II (performance standards). The agency is also issuing 73 individual proposed regulations to classify each immunology device. The agency is proposing to classify 35 immunology devices into class I (general controls) and 38 immunology devices into class II (performance standards). The agency is not proposing to classify any microbiology or immunology devices into class III (premarket approval). FDA also is publishing the recommendations of the Panels regarding these devices as required by section 513(c)(2) and (d)(1) of the act (21 U.S.C. 360c(c)(2) and (d)(1)).

### Published Panel Recommendations

Each published Panel recommendation concerning a microbiology and immunology device includes the information described below.

1. *Identification.* Both the Panel recommendation and proposed FDA classification regulation include a brief narrative identification of the device. The identification statement is necessarily broad because it applies to a category or type of device rather than to a specific device. As explained in proposed § 864.1, any manufacturer of a newly offered device that files a premarket notification submission under section 510(k) of the act (21 U.S.C. 360(k)) and Part 807 of the regulations (21 CFR Part 807) cannot show merely that the device is accurately described by the section title and identification provisions of a classification regulation. Although a new device may be described accurately by the title and identification in a classification regulation, it is nevertheless in class III under section 513(f) of the act if it is not substantially equivalent to a preamendments device (or to a postamendments device that has already been reclassified from class III into class I or class II). It is not practical for FDA to publish an identification of each type of device that is so detailed as to anticipate every product feature that may be relevant in determining whether a new device is substantially equivalent to previous devices classified by the regulation. The agency believes that this problem was recognized in, and addressed by, the premarket notification procedures in section 510(k) of the act. Accordingly, any manufacturer who submits a premarket notification submission should state why the manufacturer believes the device is

substantially equivalent to other devices in commercial distribution, as required by § 807.87 (21 CFR 807.87), and whether the device is described in a classification regulation.

2. *Recommended classification.* Each Panel's recommendation describes whether the device is recommended for classification into class I (general controls) or class II (performance standards).

For each device recommended for classification into class I, the Panel considered whether the device should be exempt from any requirements under certain sections of the act: section 510 (21 U.S.C. 360, registration), section 519 (21 U.S.C. 360i, records and reports), and section 520(f) (21 U.S.C. 360j(f), good manufacturing practice requirements). Although the Panels did not recommend that any device be exempted at this time from section 519 of the act, the Microbiology Device Classification Panel did recommend that the manufacturers of six class I devices be exempted from the good manufacturing practice regulation in the manufacture of these devices. The Immunology Device Classification Panel recommended that manufacturers of two class I devices be exempted from the premarket notification requirements of section 510(k) of the act and Part 807 of the regulations (21 CFR Part 807). The agency's policy concerning these exemption recommendations is discussed below in the section of this proposal concerning "Exemptions for Class I Devices."

A Panel's recommendation that a device be classified into class II includes the Panel's recommended priority ("high," "medium," or "low") for establishing a performance standard for the device. As explained below in the section of this notice concerning "Priorities for Class II Devices," however, the agency is not proposing the establishment of FDA priorities at this time.

3. *Summary of reasons for recommendation.* The summary of reasons for the Panel's recommendation explains why the Panel believes that a particular device meets the statutory criteria for classification into class I or class II.

Except in those instances in which FDA's classification proposal differs from the Panel's recommendation, FDA is adopting the Panel's summary of reasons as the agency's statement of the reasons for issuing the regulations, as required by section 517(f) of the act (21 U.S.C. 360g(f)).

The Panels and FDA have not identified any device subject to these proposals as implants or as life-suppoting or life-sustaining devices.

4. *Summary of data on which the recommendation is based.* In many cases, the Panels based their recommendations on the Panel members' personal knowledge of, and clinical experience with, the devices under review. The Panels particularly relied upon clinical experience and judgment when considering a simple device that had been used extensively and was accepted widely before the amendments were enacted. The legislative history of the amendments makes clear that the term "data" has a special meaning in section 513(c)(2)(A) of the act, which requires that a panel's recommendation summarize the data upon which a recommendation is based. As used in that section, "data" refers not only to the results of scientific experiments, but also to less formal evidence, other scientific information or judgments of experts (House Committee on Interstate and Foreign Commerce, Medical Device Amendments of 1976, H.R. Rept. No. 94–853, 94th Congress, 2d Session 40 (1976)). The agency has determined that clinical experience and judgment is valid scientific evidence for classifying certain devices.

In many cases, FDA sought more data and information concerning the classification of a device than were cited by the Panels. References to these data and information are found in the "Proposed Classification" section of the preambles to individual microbiology and immunology device regulations. FDA is adopting, as the agency's statement of the basis for issuing the regulation under section 517(f) of the act, the Panel's summary of the data on which a recommendation to classify a device is based, together with any additional data and information cited in the preamble to the proposed classification regulation.

5. *Risks to health.* In identifying the risks to health presented by microbiology or immunology devices, the Panels recognized that few devices are completely free of risk. The Panels listed the risks they considered most significant, especially those that are unique to the individual device. In some cases, FDA has identified additional risks to health presented by a device. These additional risks are set out in the section of the preamble concerning the "Proposed Classification" of a particular device.

Because the classification recommendations and FDA regulations do not identify all risks to health presented by microbiology and immunology devices, future regulations establishing performance standards under section 514 of the act (21 U.S.C. 360d) or requiring premarket approval under section 515(b) of the act (21 U.S.C. 360e(b)) may identify additional risks to health to be addressed by FDA requirements.

**Proposed Classification**

Each proposed regulation to classify a microbiology or immunology device states whether FDA agrees with the Panel's recommendation, describes the agency's proposed classification of the device, and proposes a new section in Part 866 in which the device classification will be codified.

FDA cautions that the final classification of a device may differ from the proposal. Factors that may cause such a change include comments, the agency's reconsideration of existing data and information, and the agency's consideration of new data and information.

**Priorities for Class II Devices**

For a device that a Panel recommends be classified into class II, section 513(c)(2)(A) of the act requires that the Panel's recommendation include, to the extent practicable, a recommendation for the assignment of a priority for application to the device of a performance standard or premarket approval requirements. In developing its advice concerning priorities ("high," "medium," or "low") of devices recommended for classification into class II, the Panels compared the devices with other microbiology or immunology devices, based on information available to the Panel members concerning the relative importance of use of the device and the relative risks presented by the device. The Panels recommended assignment of a "high priority" only to those class II devices that the Panels believed should receive the agency's immediate attention.

FDA is not proposing at this time to establish priorities for development of performance standards for all class II devices. Section 513(d)(3) of the act authorizes, but does not require, establishment of these priorities. In the **Federal Register** of February 1, 1980 (45 FR 7493), FDA published a notice identifying which class II microbiology and immunology devices the agency found to warrant a high priority for the development of performance standards. At a later date, the agency will establish priorities for the development of standards for the remaining class II devices. All priorities established by the agency are based on the classification Panels' recommendations, availability resources, and other relevant factors.

The agency's priorities will be reflected in the agency's annual budget request and other publicly available documents and may be published in the **Federal Register.**

**Exemptions for Class I Devices**

Section 513 of the Federal Food, Drug, and Cosmetic Act (the act) provides that FDA may exempt a device recommended for classification into class I from a requirement under the following sections of the act: section 510 (21 U.S.C. 360, registration); section 519 (21 U.S.C. 360i, records and reports); and section 520(f) (21 U.S.C. 360j(f), good manufacturing practices).

Under section 510 of the act, a person "engaged in the manufacture, preparation, propagation, compounding or processing of * * * a device or devices" shall register with FDA (section 510(b) through (i)), file a list of devices (section 510(j)), and notify FDA at least 90 days before beginning commercial distribution of a device (section 510(k)). (See 21 CFR Part 807.) Section 510(g)(4) authorizes the agency to exempt a device from section 510 if it finds that compliance with that section is not necessary for the protection of the public health. In § 807.65 (21 CFR 807.65), FDA has exempted certain classes of persons from section 510. Several device classification panels have recommended that manufacturers of certain class I devices also be exempted from all or some of the requirements of section 510. The agency has determined that protection of the public health requires that manufacturers of medical devices, other than those already exempt under § 807.65, register and list their products with FDA to ensure that the agency can identify these manufacturers and their products and conduct necessary inspections.

The agency has determined, however, for certain devices, that it is not necessary for the protection of the public health that FDA receive premarket notification submissions. Thus, the agency is proposing to exempt certain devices from Subpart E of Part 807 of the regulations, which implements section 510(k). The agency does not, at this time, anticipate that premarket approval will be required for these devices. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice of new products within these generic types of devices.

Section 519 of the act authorizes FDA to issue regulations requiring device manufacturers, importers, and distributors to establish and maintain such records, make such reports, and provide such information as the agency may reasonably require to assure that devices are not adulterated or misbranded and to otherwise assure their safety and effectiveness. The records and reports requirements in several of FDA's present device regulations are authorized, wholly or in part, by section 519. The most extensive of these requirements are found in the device good manufacturing practice (GMP) regulation (21 CFR Part 820). In the future, FDA will publish other regulations under section 519, including regulations requiring reports to FDA of experience with medical devices. Until these regulations are issued, FDA believes that it cannot properly grant exemptions from them. In the future, whenever the agency proposes device regulations that include records and reports requirements, interested persons may submit comments requesting that certain classes of manufacturers or other persons be exempted from the requirements, and FDA will grant exemptions that are appropriate.

The only type of exemption from records and reports requirements that FDA is proposing now, in device classification regulations, is an exemption of certain manufacturers from most requirements of the device GMP regulation. As explained below, the exemption will not extend to two device GMP records requirements.

The device GMP regulation was published in final form in the **Federal Register** of July 21, 1978 (43 FR 31508). At the time of the Panel's recommendations, the GMP regulation had not yet been promulgated, and the agency had not yet developed criteria for exempting a class I device from GMP requirements. The agency has now decided that, if any of the following criteria is met, FDA will consider exempting from the GMP regulation a class I device that is not labeled or otherwise represented as sterile. the agency will not, however, exempt a device from § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The criteria are:

1. FDA has determined, based on adequate information about current practices in the manufacture of the device and about user experience with the device, that application of the GMP regulation is unlikely to improve the safety and effectiveness of the device.

2. FDA has determined that all possible defects relating to the safety and effectiveness of the device are readily detectable before use, either through visual examination by the user or routine testing before use, e.g., testing a clinical laboratory reagent with positive and negative controls.

3. FDA has determined that any defect in the device that is not readily detectable will not result in a device failure that could have an adverse effect on the patient or other user.

FDA has determined that no device that is labeled or otherwise represented as sterile will be exempted from the device GMP regulation. Such a device must be subject to the entire GMP regulation to ensure that manufacturers reduce adequately the bioburden (number of microorganisms) on the device and its components during the manufacturing process. This reduction is accomplished through adherence to a comprehensive quality assurance program as is required by the GMP regulation, with adequate environmental controls, trained personnel, appropriate maintenance and calibration of sterilization equipment, recordkeeping concerning lot sterility, strict packaging and labeling controls, and other quality assurance measures.

The agency also has determined that no exemption from the device GMP regulation will extend to § 820.180, with respect to general requirements concerning records, or § 820.198, with respect to complaint files. The agency believes that granting exemptions from these sections would not be in the public interest, and that compliance with these sections is not unduly burdensome for device manufacturers. To ensure that device manufacturers have adequate systems for complaint investigation and followup, all manufacturers are required to comply with the complaint file requirements of § 820.198. All device manufacturers also are required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

In general, FDA has not initiated proposals to exempt manufacturers of class I devices from requirements under section 510, 519, or 520(f), but has acted on the basis of exemption recommendations of the device classification panels. Manufacturers and other interested persons may submit comments on the appropriateness of exemptions of manufacturers of class I devices that are not the subject of panel exemption recommendations. FDA will consider granting exemptions from the requirement of premarket notification and from the GMP regulation (other than

§§ 820.180 and 820.198) according to the policies and criteria discussed above. Comments requesting additional exemptions should be supported by information showing that the exemption of manufacturers of a device from the premarket notification requirement or the GMP regulation (other than §§ 820.180 and 820.198), or both, is consistent with the policies and criteria discussed above.

### Guidelines for Preparing Petitions Requesting Exemption or Variance From the Device GMP Regulation for Devices Classified into Either Class I or Class II

FDA has prepared guidelines on the procedures that should be followed by persons who wish to submit petitions for exemption or variance from the device GMP regulation. These petitions may be submitted in accordance with provisions of section 520(f)(2) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)(2)). The agency announced the availability of the guidelines in a notice published in the **Federal Register** of Friday, January 18, 1980 (45 FR 3671).

### List of Microbiology and Immunology Devices

The following is a list of microbiology and immunology devices that shows the section in the Code of Federal Regulations under which the regulation classifying the device will be codified, the docket number of the proposed classification regulation, and the proposed classification of each device.

| Section | Device | Docket No. | Class |
|---|---|---|---|
| | **Subpart B—Diagnotic Devices** | | |
| | ..... | | |
| 866.1620 | Antimicrobial susceptibility test disc | 78N-2114 | II |
| 866.1640 | Antimicrobial susceptibility test powder | 78N-2115 | II |
| 866.1700 | Culture medium for antimicrobial susceptibility tests | 78N-2117 | II |
| | **Subpart C—Microbiology Devices** | | |
| 866.2050 | Staphylococcal typing bacteriophage | 78N-2118 | I |
| 866.2120 | Anaerobic chamber | 78N-2119 | I |
| 866.2160 | Coagulase plasma | 78N-2121 | II |
| 866.2170 | Automated colony counter | 78N-2122 | I |
| 866.2180 | Manual colony counter | 78N-2123 | I |
| 866.2300 | Multipurpose culture medium | 78N-2124 | I |
| 866.2320 | Differential culture medium | 78N-2125 | I |
| 866.2330 | Enriched culture medium | 78N-2126 | I |
| 866.2350 | Microbiological assay culture medium | 78N-2127 | I |
| 866.2360 | Selective culture medium | 78N-2128 | I |
| 866.2390 | Transport culture medium | 78N-2129 | I |
| 866.2410 | Culture medium for pathogenic *Neisseria* spp. | 78N-2130 | II |
| 866.2440 | Automated medium dispensing and stacking device | 78N-2131 | I |
| 866.2450 | Supplement for culture media | 78N-2132 | I |
| 866.2480 | Quality control kit for culture media | 78N-2133 | I |
| 866.2500 | Microtiter diluting and dispensing device | 78N-2134 | I |
| 866.2540 | Microbioligical Incubator | 78N-2135 | I |
| 866.2560 | Microbial growth monitor | 78N-2136 | I |
| 866.2580 | Gas-generating device | 78N-2137 | I |
| 866.2600 | Wood's fluorescent lamp | 78N-2138 | I |
| 866.2660 | Microorganism differentiation and identification device | 78N-2139 | I |
| 866.2850 | Automated zone reader | 78N-2140 | I |
| 866.2900 | Specimen collection and transport device | 78N-2141 | I |
| | **Subpart D—Serological Reagents** | | |
| 866.3010 | *Acinetobacter calcoaceticus* serological reagents | 78N-2282 | I |
| 866.3020 | Adenovirus serological reagents | 78N-2142 | I |
| 866.3935 | *Arizona* spp. serological reagents | 78N-2143 | I |
| 866.3040 | *Aspergillus* spp. serological reagents | 78N-2144 | I |
| 866.3060 | *Blastomyces dermatitidis* serological reagents | 78N-2145 | II |
| 866.3065 | *Bordetella* spp. serological reagents | 78N-2146 | I |
| 866.3085 | *Brucella* spp. serological reagents | 78N-2147 | II |
| 866.3110 | *Campylobacter* fetus serological reagents | 78N-2149 | I |
| 866.3120 | Chlamydia serological reagents | 78N-2150 | I |
| 866.3125 | *Citrobacter* spp. serological reagents | 78N-2151 | I |
| 866.3135 | *Coccidioides immitis* serological reagents | 78N-2152 | II |
| 866.3140 | *Corynebacterium* spp. serological reagents | 78N-2153 | I |
| 866.3145 | Coxsackievirus serological reagents | 78N-2154 | I |
| 866.3165 | *Cryptococcus neoformans* serological reagents | 78N-2156 | II |
| 866.3175 | Cytomegalovirus serological reagents | 78N-2157 | I |
| 866.3200 | *Echinococcus* spp. serological reagents | 78N-2158 | I |
| 866.3205 | Echovirus serological reagents | 78N-2159 | I |
| 866.3220 | *Entamoeba histolytica* serological reagents | 78N-2160 | II |
| 866.3235 | Epstein-Barr virus serological reagents | 78N-2162 | I |

| Section | Device | Docket No. | Class |
|---|---|---|---|
| | **Subpart D—Serological Reagents**—Continued | | |
| 866.3240 | Equine encephalomyelitis virus serological reagents | 78N-2163 | I |
| 866.3250 | *Erysipelothrix rhusiopathiae* serological reagents | 78N-2164 | I |
| 866.3255 | *Escherichia coli* serological reagents | 78N-2165 | I |
| 866.3270 | *Flavobacterium* spp. serological reagents | 78N-2166 | I |
| 866.3280 | *Francisella tularensis* serological reagents | 78N-2167 | II |
| 866.3300 | *Haemophilus* spp. serological reagents | 78N-2169 | I |
| 866.3305 | Herpes simplex virus serological reagents | 78N-2170 | II |
| 866.3320 | *Histoplasma capsulatum* serological reagents | 78N-2173 | II |
| 866.3330 | Influenza virus serological reagents | 78N-2174 | I |
| 866.3340 | *Klebsiella* spp. serological reagents | 78N-2175 | I |
| 866.3350 | *Leptospira* spp. serological reagents | 78N-2176 | II |
| 866.3355 | *Listeria* spp. serological reagents | 78N-2177 | I |
| 866.3360 | Lymphocytic choriomeningitis virus serological reagents | 78N-2178 | I |
| 866.3370 | *Mycobacterium tuberculosis* immunofluorescent reagents | 78N-2179 | I |
| 866.3375 | *Mycoplasma* spp. serological reagents | 78N-2180 | I |
| 866.3380 | Mumps virus serological reagents | 78N-2181 | I |
| 866.3390 | *Neisseria* spp. direct serological test reagents | 78N-2182 | II |
| 866.3400 | Parainfluenza virus serological reagents | 78N-2183 | I |
| 866.3405 | Poliovirus serological reagents | 78N-2184 | I |
| 866.3410 | *Proteus* spp. (Weil-Felix) serological reagents | 78N-2185 | I |
| 866.3415 | *Psuedomonas* spp. serological reagents | 78N-2186 | II |
| 866.3460 | Rabiesvirus immunofluorescent reagents | 78N-2187 | II |
| 866.3470 | Reovirus serological reagents | 78N-2188 | I |
| 866.3480 | Respiratory syncytial virus serological reagents | 78N-2189 | I |
| 866.3490 | Rhinovirus serological reagents | 78N-2190 | I |
| 866.3500 | Rickettsia serological reagents | 78N-2191 | I |
| 866.3510 | Rubella virus serological reagents | 78N-2192 | II |
| 866.3520 | Rubeola (measles) virus serological reagents | 78N-2193 | I |
| 866.3550 | *Salmonella* spp. serological reagents | 78N-2194 | II |
| 866.3600 | *Schistosoma* spp. serological reagents | 78N-2197 | I |
| 866.3630 | *Serratia* spp. serological reagents | 78N-2198 | I |
| 866.3660 | *Shigella* spp. serological reagents | 78N-2199 | II |
| 866.3680 | *Sporothrix schenckii* serological reagents | 78N-2200 | I |
| 866.3700 | *Staphylococcus* aureus serological reagents | 78N-2201 | I |
| 866.3720 | *Streptococcus* spp. Exoenzyme reagents | 78N-2202 | II |
| 866.3740 | *Streptococcus* spp. serological reagents | 78N-2203 | I |
| 866.3780 | *Toxoplasma gondii* serological reagents | 78N-2204 | II |
| 866.3820 | *Treponema pallidum* nontreponemal test reagents | 78N-2206 | II |
| 866.3830 | *Treponema pallidum* treponemal test reagents | 78N-2207 | II |
| 866.3850 | *Trichinella spiralis* serological reagents | 78N-2208 | I |
| 866.3870 | *Trypanosoma* spp. serological reagents | 78N-2209 | I |
| 866.3900 | Varicella-Zoster serological reagents | 78N-2210 | I |
| 866.3930 | *Vibrio cholerae* serological reagents | 78N-2211 | II |
| | **Subpart E—Immunology Laboratory Equipment and Reagents** | | |
| 866.4100 | Complement reagents | 78N-2212 | I |
| 866.4500 | Immunoelectrophoresis equipment | 78N-2213 | I |
| 866.4520 | Immunofluorometer equipment (includes U.V. immunologic test system). | 78N-2214 | I |
| 866.4540 | Immunonephelometer equipment (includes immunologic test system). | 78N-2215 | I |
| 866.4600 | Ouchterlony agar plate | 78N-2216 | I |
| 866.4800 | Radial immunodiffusion plate | 78N-2217 | I |
| 866.4830 | Rocket immunoelectrophoresis equipment | 78N-2218 | I |
| 866.4900 | Support gels | 78N-2219 | I |
| | **Subpart F—Immunological Test Systems** | | |
| 866.5040 | Albumin immunological test system | 78N-2220 | II |
| 866.5060 | Prealbumin immunological test system | 78N-2221 | I |
| 866.5065 | Human allotypic marker immunological test system | 78N-2222 | I |
| 866.5080 | Alpha-1-antichymotrypsin immunological test system | 78N-2223 | II |
| 866.5090 | Antimitochondrial antibody immunological test system | 78N-2224 | II |
| 866.5100 | Antinuclear antibody immunological test system | 78N-2225 | II |
| 866.5110 | Antiparietal antibody immunological test system | 78N-2226 | II |
| 866.5120 | Antismooth muscle antibody immunological test system | 78N-2227 | II |
| 866.5130 | Alpha-1-antitrypsin immunological test system | 78N-2228 | II |
| 866.5150 | Bence-Jones proteins immunological test system | 78N-2229 | II |
| 866.5160 | Beta globulin immunological test system | 78N-2284 | I |
| 866.5170 | Breast milk immunological test system | 78N-2230 | I |
| 866.5200 | Carbonic anhydrase B and C immunological test system | 78N-2231 | I |
| 866.5210 | Ceruloplasmin immunological test system | 78N-2232 | II |
| 866.5220 | Cohn fraction II immunological test system | 78N-2233 | I |
| 866.5230 | Colostrum immunological test system | 78N-2234 | I |
| 866.5240 | Complement components immunological test system | 78N-2235 | II |
| 866.5250 | Complement $C_1$ inhibitor (inactivator) immunological test system. | 78N-2236 | II |
| 866.5260 | Complement $C_{3b}$ inactivator immunological test system | 78N-2237 | II |
| 866.5270 | C-reactive protein immunological test system | 78N-2238 | II |
| 866.5320 | Properdin factor B immunological test system | 78N-2239 | II |
| 866.5330 | Factor XIII, A, S, immunological test system | 78N-2240 | I |
| 866.5340 | Ferritin immunological test system | 78N-2241 | II |

| Section | Device | Docket No. | Class |
|---|---|---|---|
| | **Subpart F—Immunological Test Systems**—Continued | | |
| 866.5350 | Fibrinopeptide A immunological test system | 78N-2242 | II |
| 866.5360 | Cohn fraction IV immunological test system | 78N-2243 | I |
| 866.5370 | Cohn fraction V immunological test system | 78N-2244 | I |
| 866.5380 | Free secretory component immunological test system | 78N-2245 | II |
| 866.5400 | Alpha globulin immunological test system | 78N-2246 | I |
| 866.5420 | Alpha-1-glycoproteins immunological test system | 78N-2247 | I |
| 866.5425 | Alpha-2-glycoproteins immunological test system | 78N-2248 | I |
| 866.5430 | Beta-2-glycoprotein I immunological test system | 78N-2249 | I |
| 866.5440 | Beta-2-glycoprotein III immunological test system | 78N-2250 | I |
| 866.5460 | Haptoglobin immunological test system | 78N-2251 | II |
| 866.5470 | Hemoglobin immunological test system | 78N-2252 | II |
| 866.5480 | Hemolytic immunological test system | 78N-2253 | II |
| 866.5490 | Hemopexin immunological test system | 78N-2254 | II |
| 866.5500 | Hypersensitivity pneumonitis immunological test system | 78N-2255 | II |
| 866.5510 | Immunoglobulins A, G, M, D, and E immunological test system. | 78N-2256 | II |
| 866.5520 | Immunoglobulin G (Fab fragment specific) immunological test system. | 78N-2257 | II |
| 866.5530 | Immunoglobulin G (Fc fragment specific) immunological test system. | 78N-2258 | II |
| 866.5540 | Immunoglobulin G (Fd fragment specific) immunological test system. | 78N-2283 | I |
| 866.5550 | Immunoglobulin (light chain specific) immunological test system. | 78N-2259 | II |
| 866.5560 | Lactic dehydrogenase immunological test system | 78N-2260 | I |
| 866.5570 | Lactoferrin immunological test system | 78N-2261 | I |
| 866.5580 | Alpha-1-lipoprotein immunological test system | 78N-2262 | II |
| 866.5590 | Lipoprotein X immunological test system | 78N-2263 | I |
| 866.5600 | Low-density lipoprotein immunological test system | 78N-2264 | II |
| 866.5620 | Alpha-2-macroglobulin immunological test system | 78N-2265 | II |
| 866.5630 | Beta-2-microglobulin immunological test system | 78N-2266 | II |
| 866.5640 | Infectious mononucleosis immunological test system | 78N-2267 | II |
| 866.5660 | Multiple autoantibodies immunological test system | 78N-2268 | II |
| 866.5680 | Myoglobin immunological test system | 78N-2269 | II |
| 866.5700 | Whole human plasma or serum immunological test system | 78N-2270 | I |
| 866.5715 | Plasminogen immunological test system | 78N-2271 | I |
| 866.5735 | Prothrombin immunological test system | 78N-2272 | I |
| 866.5750 | Radioallergosorbent (RAST) immunological test system | 78N-2273 | II |
| 866.5765 | Retinol-binding protein immunological test system | 78N-2274 | I |
| 866.5775 | Rheumatoid factor immunological test system | 78N-2275 | II |
| 866.5800 | Seminal fluid (sperm) immunological test system | 78N-2276 | I |
| 866.5820 | Systemic lupus erythematosus immunological test system | 78N-2277 | II |
| 866.5860 | Total spinal fluid immunological test system | 78N-2278 | I |
| 866.5870 | Thyroid autoantibody immunological test system | 78N-2279 | II |
| 866.5880 | Transferrin immunological test system | 78N-2280 | II |
| 866.5890 | Inter-alpha tryspan inhibitor immunological test system | 78N-2281 | I |

**Devices Considered by two or More Panels**

Many devices were reviewed by two or more device classification Panels. For these devices, FDA will publish each Panel's recommendations and a single proposed classification regulation. Several of the devices subject to proposals elsewhere in this issue of the **Federal Register** were reviewed by both the Microbiology Device Classification Panel and the Immunology Device Classification Panel. The following devices were considered by the Microbiology Device Classification Panel or the Immunology Device Classification Panel and by other Panels:

1. The Clinical Chemistry Device Classification Panel recommended that measurement of Bence-Jones proteins by immunochemical methods be classified into class II. The Immunology Device Classification Panel recommended that test systems for measurement of Bence-Jones proteins antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying Bence-Jones proteins immunological test systems into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

2. The Clinical Chemistry Device Classification Panel recommended that immunochemical methods for measurement of ceruloplasmin by indirect copper assay and phenylenediamine/EDTA (spectrophotometric) quantitative methods to measure copper be classified into class II. The Immunology Device Classification Panel recommended that ceruloplasmin, antigen, antiserum, control; ceruloplasmin, FITC, antigen, antiserum, control; and cruloplasmin rhodamine, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying immunological test systems for the measurement of ceruloplasmin into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

3. The Clinical Chemistry Device Classification Panel recommended that test systems for immunochemical measurement of thyroglobulin autoantibody be classified into class II. The Immunnology Device Classification Panel recommended that thyroglobulin, antigen, antiserum, control; thyroglobulin, FITC, antigen, antiserum, control; and thyroglobulin, rhodamine, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying thyroid autoantibody immunological test systems into class II and is publishing the two Panel's recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

4. The Clinical Chemistry Device Classification Panel recommended that measurement of transferrin by immunochemical methods be classified into class II. The immunology Device Classification Panel recommended that transferrin, antigen, antiserum, control; transferrin, FITC, antigen, antiserum, control; and transferrin, rhodamine, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying transferrin immunological test sytems into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the **Federal Register.**

5. The Clinical Chemistry Device Classification Panel recommended that measurement of ferritin by two-site solid-phase radioimmunoassay be classified into class II. The Immunology Device Classification Panel recommended that test systems for measurement of ferritin, antigen, antiserum, control be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying ferritin

immunology test systems into class II and is publishing the two Panels' recommendation in a proposal appearing elswhere in this issue of the Federal Register.

6. The Clinical Chemistry Device Classification Panel recommended that measurement of immunoglobulins A, G, M, D, and E by radioimmunoassay, immunodiffusion, immunoelectrophoresis or the nephelometric method be classified into class II. The Immunology Device Classification Panel recommended that measurement of immunoglobulins A, G, M, D, and E by methods such as immunodiffusion, immunoelectrophoresis, nephelometry or radioimmunoassay be classified into class II. FDA has determined that these devices are essentially the same. Therefore, the agency is proposing a single regulation classifying immunoglobulins A, G, M, D, and E immunological test systems into class II and is publishing the two Panels' recommendation in a proposal appearing elsewhere in this issue of the Federal Register.

The Immunology Device Classification Panel and the Clinical Chemistry Device Classification Panel made classification recommendations concerning the following devices:

Nonradioimmunoassay systems to detect human chorionic gonadatropin.

Radioimmunoassay systems to detect human chorionic gonadotropin.

Test systems to measure human placental lactogen.

Luteinizing hormone, antigen, antiserum, control.

Lysozyme, antigen, antiserum, control.

FDA is not at this time publishing the Immunology Device Classification Panel's recommendations to classify the devices listed above. The agency will publish these recommendations, and proposed classification regulations, when it publishes the recommendations of the Clinical Chemistry Device Classification Panel.

The Microbiology Device Classification Panel and the Toxicology Device Classification Panel made classification recommendations concerning the following devices:

Chromatography for bacterial identification.

Disc agar diffusion kits to determine serum levels of antibiotics.

FDA is not at this time publishing the Microbiology Device Classification Panel's recommendations to classify the devices listed above. The agency will publish these recommendations, and proposed classification regulations, when it publishes the recommendations of the Toxicology Device Classification Panel.

### Related Device Classification Regulations

The Microbiology Device Classification Panel or the Immunology Device Classification Panel made classification recommendations concerning the following devices that were published with the Hematology Device Classification Panel or the Pathology Device Classification Panel recommendations and the agency's proposed classification for these devices in the Federal Register of September 11, 1979 (44 FR 52950):

*Device and other panel*

Antithrombin III, antigen antiserum, control—Hematology.

Fibrinogen and fibrin-split products, antigen, antiserum, control—Hematology.

Stains, microbiologic, all—Pathology.

### Environmental Impact

The agency has determined pursuant to 21 CFR 25.24(b)(12) (proposed December 11, 1979, 44 FR 71742) that this proposed action is of a type that does not individually or cumulatively have a significant impact on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513 and 701d(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a)), and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposed that Chapter I of Title 21 of the Code of Federal Regulations be amended by adding new Part 866, Subpart A, to read as follows:

## PART 866—MICROBIOLOGY OR IMMUNOLOGY DEVICES

### Subpart A—General Provisions

Sec.

866.1 Scope.

**Authority:** Secs. 513 and 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c and 701(a)).

### Subpart A—General Provisions

**§ 866.1 Scope.**

(a) This part sets forth the classification of microbiology or immunology 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) The identification of a device in a regulation in this part is not a precise description of every device that is, or will be, subject to the regulation. A manufacturer who submits a premarket notification submission for a device under Part 807 cannot show merely that the device is accurately described by the section title and identification provision of a regulation in this part, but shall state why the device is substantially equivalent to other devices, as required by § 807.87.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m., Monday through Friday.

In accordance with Executive Order 12044, the economic effects of this proposal have been carefully analyzed, and it has been determined that the proposed rulemaking does not involve major economic consequences as defined by that order. A copy of the regulatory analysis assessment supporting this determination is on file with the Hearing Clerk, Food and Drug Administration.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11737 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2124]**

## Medical Devices; Classification of Antimicrobial Susceptibility Test Discs

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antimicrobial susceptibility test discs into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public

comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980 FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antimicrobial susceptibility test discs:

1. Identification: An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice. The Panel reviewed this generic type of device identified by the names "antimicrobial susceptibility test system" and "antimicrobial susceptibility test discs."

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that antimicrobial susceptibility test discs be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of accuracy, precision, potency, purity, and stability and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel recognizes the importance to the clinician of antimicrobial susceptibility tests in selecting the drug of choice for patients afflicted with diseases caused by infectious microbial pathogens. The Panel also observes that results obtained with antimicrobial susceptibility test discs may be influenced by the content and pH of the culture medium, the concentration of antimicrobial agents in the test system, the concentration of the bacterial inoculum, the temperature and atmosphere of incubation, and the variation of endpoint measurements. The Panel also observes that the susceptibility test disc is an integral component of disc-agar diffusion and disc-broth elution methods and that test results are significantly influenced by the purity, stability, and content (potency) of the antimicrobial agent contained in the disc. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, purity, potency, and stability. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard (Refs. 3 and 5).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, these devices and on the Panel's review of the literature, which disclosed variation in the manufacture of these devices regarding their identity, purity, potency, accuracy, and precision (Refs. 1, 2, and 4). Stubbs and Wicher (Ref. 1) evaluated an automated antimicrobial susceptibility test system using antimicrobial elution discs. Of 2,518 organisms examined, 651 (26 percent) showed discrepancies in response to one or more antibiotics when compared with the disc-agar diffusion method (Bauer-Kirby). Thornsberry, et al. (Ref. 2) noted that the problem of false susceptibility reports with these rapid systems usually results from the prolonged lag phase that may occur with subminimal inhibitory concentration of antimicrobial agent in certain drug/organism combinations. Rippere (Ref. 4) reported that different grades of paper used in the manufacture and assay of antibiotic diffusion discs have significant effects on the diffusion of antibiotics from the paper.

5. Risks to health: Inappropriate therapy: Failure of the device to perform satisfactorily may lead to inappropriate therapy which may place the patient at risk.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antimicrobial susceptibility test discs be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Antimicrobial susceptibility test systems that contain antibiotics are subject to premarket approval regulations for antibiotics under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) (Ref. 5). Section 520(1)(4) of the act (21 U.S.C. 360j(1)(4)) provides that if a class II device was subject to the requirements of section 507 on May 28, 1976 (the enactment date of the Medical Device Amendments), these requirements shall continue to apply to the device until the effective date of a performance standard applicable to the device under section 514 of the act. Thus, antimicrobial susceptibility test systems that were then subject to the requirements of section 507 of the act continue to be subject to these requirements until the effective date of a performance standard for these devices.

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Stubbs, K. G. and K. Wicher, "Laboratory Evaluation of an Automated Antimicrobial Susceptibility System," *American Journal of Clinical Pathology*, 68(6):769–777, 1977.

2. Thornsberry, C., T. L. Gavan, and E. H. Gerlach, coordinating editor J. C. Sherris, "New Developments in Antimicrobial Agent Susceptibility Testing," *Cumulative Techniques and Procedures in Clinical Microbiology (Cumitech), No. 6*, American Society for Microbiology, September 1977.

3. "Performance Standards for Antimicrobial Disc Susceptibility Tests," National Committee for Clinical Laboratory Standards, January 1976.

4. Rippere, R. A., "Effects of Paper on Performance of Antibiotic Impregnated Disks," *Journal of Pharmaceutical Sciences*, 67(3), 1978.

5. *Code of Federal Regulations*, Title 21, Part 460—Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease, Subpart A—Susceptibility Discs, pp. 694–706, 1979.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart B including § 866.1620, to read as follows:

### Subpart B—Antimicrobial Susceptibility Test Devices

**§ 866.1620 Antimicrobial susceptibility test disc.**

(a) *Identification.* An antimicrobial susceptibility test disc is a device that consists of antimicrobic-impregnated paper discs used to measure by a disc-agar diffusion technique or a disc-broth elution technique the in vitro susceptibility of most clinically important bacterial pathogens to antimicrobial agents. In the disc-agar diffusion technique, bacterial susceptibility is ascertained by directly measuring the magnitude of a zone of bacterial inhibition around the disc on an agar surface. The disc-broth elution technique is associated with an automated rapid susceptibility test system and employs a fluid medium in which susceptibility is ascertained by photometrically measuring changes in bacterial growth resulting when antimicrobial material is eluted from the disc into the fluid medium. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11738 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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### 21 CFR Part 866

**[Docket No. 78N–2115]**

## Medical Devices; Classification of Antimicrobial Susceptibility Test Powders

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antimicrobial susceptibility test powders into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antimicrobial susceptibility test powders:

1. Identification: An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the antimicrobial susceptibility test powder be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of identity, purity, potency, and stability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel recognizes the importance to the clinician of antimicrobial susceptibility tests in selecting the drug of choice for patients afflicted with diseases caused by infectious microbial pathogens. The Panel also observes that antimicrobial susceptibility tests are significantly influenced by the purity and strength of the antimicrobial agent. The Panel is aware of variations in the performance of these devices that may be caused by use of different manufacturing procedures and controls that affect their identity, purity, potency, and stability. The Panel believes that general controls would not provide sufficient control over the device's identity, purity, potency, and stability. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2). The Panel is aware of reference materials for the devices (Ref. 1).

5. Risks to health: Inappropriate therapy: Failure of the device to perform satisfactorily may lead to inappropriate therapy which may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antimicrobial susceptibility test powders be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

Antimicrobial susceptibility test powders that contain antibiotics are subject to premarket approval regulations for antibiotics under section 507 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 357) (Ref. 1). Section 520(1)(4) of the act (21 U.S.C. 360j(l)(4)) provides that if a class II device was subject to the requirements of section 507 on May 28, 1976 (the enactment date of the Medical Device Amendments), these requirements shall continue to apply to the device until the effective date of performance standard applicable to the device under section 514 of the act. Thus, antimicrobial susceptibility test powders that were then subject to the requirements of section 507 of the act continue to be subject to these

requirements until the effective date of a performance standard for these devices.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. *Code of Federal Regulations,* Title 21, Part 460—Antibiotic Drugs Intended for Use in Laboratory Diagnosis of Disease, Subpart B–Susceptibility Powders, pp. 706–721, 1979.

2. "Biological Tests and Assays: Antibiotics—Microbial Assays," *in United States Pharmacopeia,* XIX, pp. 595–600, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart B by adding new § 866.1640, to read as follows:

**§ 866.1640 Antimicrobial susceptibility test powder.**

(a) *Identification.* An antimicrobial susceptibility test powder is a device that consists of an antimicrobial drug powder packaged in vials in specified amounts and intended for use in clinical laboratories for determining in vitro susceptibility of bacterial pathogens to these therapeutic agents. Test results are used in the treatment of bacterial diseases to determine the antimicrobial agent of choice.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11739 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

**21 CFR Part 866**

**[Docket No. 78N–2117]**

## Medical Devices; Classification of Culture Media for Antimicrobial Susceptibility Tests

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying culture media for antimicrobial susceptibility tests into Class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980.

FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information conerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of culture media for antimicrobial susceptibility tests:

1. Identfication: A culture medium for antimicrobial susceptibility tests is a device that consists of any medium capable of supporting the growth of the majority of bacterial pathogens that require antimicrobial susceptibility tests. The medium is free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the culture medium for antimicrobial susceptibility tests be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, and reliability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel notes that culture media are an integral component of antimicrobial susceptibility testing and that reproducible test results are significantly influenced by several performance properties of the medium such as pH (measure of acidity) and cation (positively charged components) content. The Panel recommends that culture media for antimicrobial susceptibility testing be classified into class II (performance standards) to assure uniformity of these properties among manufacturers. The Panel members have noted significant variation in the manufacture of these products regarding their pH and cation content. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, and reliability. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1, 2, and 3). Barry (Ref. 1) states that there is unacceptable lot-to-lot variation in the manufacture of Mueller-Hinton agar (commonly used in susceptibility tests) and that in the future this medium should be replaced with a chemically defined medium. Barry (Ref. 2) indicates that the concentration of certain cations is critically important and that most Mueller-Hinton broth commercially available needs to be supplemented to obtain correct cation concentration. Barry (Ref. 2) also suggests that each batch of Mueller-Hinton medium should be checked for proper pH before use. Studies by Sherris, et al. (Ref. 3) have also demonstrated that Mueller-Hinton agar varies from lot to lot, whether the lot comes from the same manufacturer or from different manufacturers.

5. Risks to health: Inappropriate therapy: Failure of this device to perform satisfactorily may lead to inappropriate therapy which may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that culture media for antimicrobial susceptibility tests be classified into class II (performance standards). The agency believes that a performance

standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Barry, A. L., "The Role of NCCLS in the Standardization of Antimicrobic Susceptibility Techniques," *in* "Current Techniques for Antibiotic Susceptibility Testing," Balows, A. (ed.), pp. 47–53, 1974.

2. Barry, A. L., "Dilution Tests: General Considerations," *in* "The Antimicrobic Susceptibility Test: Principles and Practices," Lea and Febiger, Publishers, Philadelphia, pp. 61–75, 1976.

3. Sherris, J. C., C. Thornsberry, C. L. Aitken, and C. N. Baker, Abstract, *International Congress of Chemotherapy*, 9th Ed., Abstract No. M523, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart B by adding new § 866.1700, to read as follows:

**§ 866.1700 Culture medium for antimicrobial susceptibility tests.**

(a) *Identification.* A culture medium for antimicrobial susceptibility tests is a device that consists of any medium capable of supporting the growth of the majority of bacterial pathogens that require antimicrobial susceptibility tests. The medium is free of components known to be antagonistic to the common agents for which susceptibility tests are performed in the treatment of disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11740 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2118]**

## Medical Devices; Classification of Staphylococcal Typing Bacteriophages

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying staphylococcal typing bacteriophages into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of staphylococcal typing bacteriophages:

1. Identification: A staphylococcal typing bacteriophage is a device consisting of a bacterial virus used to identify pathogenic staphylococcal bacteria through use of this bacteria's susceptibility to cell destruction by the virus. Test results are used principally for the collection of epidemiological information.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that staphylococcal typing bacteriophages be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of pathogenic staphylococcal bacteria may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that staphylococcal typing bacteriophages be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2050, to read as follows:

### Subpart C—Microbiology Devices

**§ 866.2050 Staphylococcal typing bacteriophage.**

(a) *Identification.* A staphylococcal typing bacteriophage is a device consisting of a bacterial virus used to identify pathogenic staphylococcal bacteria through use of this bacteria's susceptibility to cell destruction by the virus. Test results are used principally for the collection of epidemiological information.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11741 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2119]**

## Medical Devices; Classification of Anaerobic Chambers

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying anaerobic chambers into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of anaerobic chambers:Q04

1. Identification: An anaerobic chamber is a device intended to maintain an anaerobic (oxygen free) environment that is used in the diagnosis of disease for the isolation and cultivation of anaerobic microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that anaerobic chambers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the anaerobic chamber be exempt from the good manufacturing practice regulation under section 520(f) of the act because the history of user experience with the device demonstrates that application of the entire GMP would not improve the quality (i.e., safety and efficacy) of the device. The Panel also recommends that the anaerobic chamber be exempt from premarket notification procedures under section 510(k) of the act because it is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that anaerobic chambers be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an anaerobic chamber be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning an anaerobic chamber. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of an anaerobic chamber be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. the agency believes, however, that manufacturers of an anaerobic chamber must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of an anaerobic chamber must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2120, to read as follows:

**§ 866.2120 Anaerobic chamber.**

(a) *Identification.* An anaerobic chamber is a device intended to maintain an anaerobic (oxygen free) environment that is used in the diagnosis of disease for the isolation and cultivation of anaerobic microorganisms.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11742 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2121]**

## Medical Devices; Classification of Coagulase Plasma

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying coagulase plasma into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of coagulase plasma:

1. Identification: Coagulase plasma is a device that consists of freeze-dried animal or human plasma that is used for performance of coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus *Staphylococcus* and provide epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that coagulase plasma be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of purity and stability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The chief sources of a staphylococcal infection are accessible human lesions, the respiratory tract, and the skin. Staphylococci can survive for a period of time outside the body in the air. The airborne infection potential is important in hospitals because a large proportion of the staff and patients carry antibiotic resistant staphylococci in the nose or throat or on the skin. Introduction of large quantities of airborne pathogenic staphylococci bacteria into newborn nurseries and surgical operating rooms may lead to serious clinical disease (e.g., abscesses in the organs). The coagulase test is a key test for differentiating the pathogenic (coagulase producing) strains of staphylococcal bacteria from the nonpathogenic strains. The Panel believes that general controls will not provide sufficient control over the device's purity and stability. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. 1). The literature review disclosed appreciable lot-to-lot variations in the purity and stability of coagulase plasmas which often lead to problems of false-positive and false-negative test results. Sperber and Tatini found that the source of supply of coagulase plasma is a factor in the occurrence of a false-positive test result (Ref. 1). These investigators also noted that the coagulation in the tube test seems to involve the conversion of fibrinogen to fibrin by the coagulase enzyme complex and the coagulase-reacting factor in the plasma. They noted that if the plasma in the tube test is to be standardized, attention should be given to assuring that adequate amounts of coagulase-reacting factor (the quantity varies with the source of the plasma) and optimal amounts of fibrinogen are present, and that procedures are used to minimize the influence of any inhibitory factors present in the plasma (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by pathogenic staphylococci. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of pathogenic staphylococci in a patient may contribute to epidemiological misinformation. Consequently, the risk relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that coagulase plasma be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls along are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seem by interested persons, from 9 a.m to 4 p.m., Monday through Friday.

1. Sperber, W. H., and S. R. Tatini, "Interpretation of the Tube Coagulases Test for Identification of Staphylococcus aureus," *Applied Microbiology*, pp. 502–505, April 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2160, to read as follows:

**§ 866.2160 Coagulase plasma.**

(a) *Identification.* Coagulase plasma is a device that consists of freeze-dried

animal or human plasma that is used for performance of coagulase tests primarily on staphylococcal bacteria. When reconstituted, the fluid plasma is clotted by the action of the enzyme coagulase which is produced by pathogenic staphylococci. Test results are used primarily as an aid in the diagnosis of disease caused by pathogenic bacteria belonging to the genus *Staphylococcus* and provides epidemiological information on disease caused by these microorganisms.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written coments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m and 4 p.m. Monday through Friday.

Dated March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11743 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2122]**

## Medical Devices; Classification of Automated Colony Counters

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated colony counters into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated colony counters:

1. Identification: An automated colony counter is a mechanical device used to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that automated colony counters be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the measurement of the degree of bacterial infection that may cause misdiagnosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classificaton

FDA agrees with the Panel recommendation and is proposing that automated colony counters be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2170, to read as follows:

**§ 866.2170 Automated colony counter.**

(a) *Identification.* An automated colony counter is a mechanical device used to determine the number of bacterial colonies present on a bacteriological culture medium contained in a petri plate. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11744 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2123]**

## Medical Devices; Classification of Manual Colony Counters

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying manual colony counters into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based

on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of manual colony counters:

1. Identification: A manual colony counter is a device that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

2. Recommended classification: Class I (general controls). The Panel recommends that manual colony counters be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification regulations under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that manual colony counters be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the manual colony counter be exempt from the good manufacturing practice regulation under section 520(f) of the act because all defects relating to the safety and effectiveness of the device are readily detectable prior to use. The Panel also recommends that the manual colony counter be exempt from premarket notification regulations under section 510(k) of the act because this is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that manual colony counters be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a manual colony counter be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification of submissions concerning a manual colony counter. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of a manual colony counter be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of a device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a manual colony counter must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a manual colony counter must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2180, to read as follows:

**§ 866.2180 Manual colony counter.**

(a) *Identification:* A manual colony counter is a device that consists of a printed grid system superimposed on an illuminated screen. Petri plates containing bacterial colonies to be counted are placed on the screen for better viewing and ease of counting. The number of colonies counted is used in the diagnosis of disease as a measure of the degree of bacterial infection.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11745 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2124]**

## Medical Devices; Classification of Multipurpose Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying multipurpose culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of the publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of multipurpose culture media:

1. Identification: A multipurpose culture medium is a device that consists primarily of liquid and/or solid biological materials used for the cultivation and identification of several types of microorganisms without the need of additional nutritional supplements. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that multipurpose culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media. The Panel believes, however, that lot-to-lot variations in product performance resulting from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that multipurpose culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2300, to read as follows:

**§ 866.2300 Multipurpose culture medium.**

(a) *Identification.* A multipurpose culture medium is a device that consists primarily of liquid and/or solid biological materials used for the cultivation and identification of several types of microorganisms without the need of additional nutritional supplements. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11746 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2125]**

## Medical Devices; Classification of Differential Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying differential culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of differential culture media:

1. Identification: A differential culture medium is a device that consists primarily of liquid and/or solid biological materials used

to cultivate and identify different types of microorganisms. The identification of these microorganisms is accomplished by the addition of a specific biochemical component(s) to the medium. Microorganisms are identified by a visible change (e.g., a color change) in a specific biochemical component(s) which indicates that specific metabolic reactions have occurred. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that differential culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media.

The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that differential culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2320, to read as follows:

**§ 866.2320 Differential culture medium.**

(a) *Identification.* A differential culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify different types of microorganisms. The identification of these microorganisms is accomplished by the addition of a specific biochemical component(s) to the medium. Microorganisms are identified by a visible change (e.g., a color change) in a specific biochemical component(s) which indicates that specific metabolic reactions have occurred. Test results aid in the diagnosis of disease and also provide epidemiological information on diseases caused by these microorganisms.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11747 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2126]**

## Medical Devices; Classification of Enriched Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying enriched culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of enriched culture media:

1. Identification: An enriched culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify fastidious microorganisms (having complex nutritional requirements). The device consists of a relatively simple basal medium enriched by the addition of such nutritional components as blood, blood serum, vitamins, and extracts of plant or animal tissues. The device is used in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that enriched culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media. The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedure can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowlege of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). In appropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological

misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that enriched culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2330, to read as follows:

**§ 866.2330 Enriched culture medium.**

(a) *Identification.* An enriched culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify fastidious microorganisms (having complex nutritional requirements). The device consists of a relatively simple basal medium enriched by the addition of such nutritional components as blood, blood serum, vitamins, and extracts of plant or animal tissues. The device is used in the diagnosis of disease caused by pathogenic microoganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 11748 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

## 21 CFR Part 866

**[Docket No. 78N–2127]**

## Medical Devices; Classification of Microbiological Assay Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microbiological assay culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microbiological assay culture media:

1. Identification: A microbiological assay culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate selected test microorganisms in order to identify and measure by microbiological procedures the presence and concentration of certain substances (e.g., amino acids, antimicrobial agents, vitamins) in a patient's serum. The presence and/or concentration of these substances is measured by their ability to promote or inhibit the growth of the test organism in the inoculated medium. Test results aid in the diagnosis of disease resulting from either deficient or excessive amounts of these substances in a patient's serum. Test results may also be used to monitor therapy, e.g., in the administration of certain antimicrobial drugs.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microbiological assay culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a disease state. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microbiological assay culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2350, to read as follows:

**§ 866.2350 Microbiological assay culture medium.**

(a) *Identification.* A microbiological assay culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate selected test microorganisms in order to identify and measure by microbiological procedures the presence and concentration of certain substances (e.g., amino acids, antimicrobial agents, vitamins) in a patient's serum. The presence and/or concentration of these substances is measured by their ability to promote or inhibit the growth of the test organism in the inoculated medium. Test results aid in the diagnosis of disease resulting from either deficient or excessive amounts of these substances in a patient's serum. Tests results may also be used to monitor therapy, e.g., in the administration of certain antimicrobial drugs.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11749 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2128]**

## Medical Devices; Classification of Selective Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying selective culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of selective culture media:

1. Identification: A selective culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify certain microorganisms. The device contains one or more components that suppress the growth of certain microorganisms while either promoting or not affecting the growth of other microorganisms. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reason for recommendation: The Panel recommends that selective culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these media. The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that selective culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2360, to read as follows:

**§ 866.2360 Selective culture medium.**

(a) *Identification.* A selective culture medium is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify certain microorganisms. The device contains one or more components that suppress the growth of certain microorganisms while either promoting or not affecting the growth of other microorganisms. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11750 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2129]**

## Medical Devices; Classification of Transport Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transport culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After

considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of transport culture media:

1. Identification: A transport culture medium is a device that consists of a semi-solid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that transport culture media be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in these products regarding their ability to maintain the viability of microorganisms. The Panel believes, however, that any variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that transport culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2390, to read as follows:

**§ 866.2390. Transport culture medium.**

(a) *Identification.* A transport culture medium is a device that consists of a semisolid, usually non-nutrient, medium that maintains the viability of suspected pathogens contained in patient specimens while in transit from the specimen collection area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11751 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

**21 CFR Part 866**

**[Docket No. 78N–2130]**

## Medical Devices; Classification of Culture Media for Pathogenic Neisseria Spp.

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying culture media for pathogenic *Neisseria* spp. into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of culture media for pathogenic *Neisseria* spp.:

1. Identification: A culture medium for pathogenic *Neisseria* spp. is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify pathogenic *Neisseria* spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria*, such as epidemic cerebrospinal meningitis, other meningoccoccal disease, and gonorrhea, and also provides epidemiological information on these diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for the recommendation: The Panel recommends that culture media for pathogenic *Neisseria* spp. be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of sensitivity, specificity and nutritional properties, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

*Neisseria meningitidis* is the prominent cause of epidemic cerebrospinal meningitis, an inflammation of brain and spinal cord membranes. Meningococcemia is a form of neural membrane disease involving the membranes which envelop the brain and spinal cord that may result from invasion of the bloodstream by *Neisseria meningitidis.* The resulting blood infection may cause massive hemorrhage near the kidneys accompanied by widespread blood coagulation within the blood vessels. If the above-described conditions are undetected and untreated, the outcome is usually fatal. Gonorrhea is a highly infectious veneral disease usually transmitted by sexual intercourse, but which also may be transmitted to a newborn by an infected mother. Gonorrhea caused by *Neisseria gonorrhoeae* is characterized by acute pus-producing inflammation of the urethra in men and inflammation of the cervix in women. Infection may also spread to the joints, resulting in a condition called gonococcal arthritis. The Panel observes that gonorrhea is epidemic in certain areas of the United States. Erradication of the disease is complicated by asymptomatic carriers who can be identified by use of diagnostic procedures that include an effective culture medium to identify *Neisseria gonorrhoeae* in patient specimens.

The Panel believes that general controls would not provide sufficient control over the device's sensitivity, specificity, and nutritional properties. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation of the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6). The Panel's literature review disclosed appreciable variation in the manufacture of this device regarding its sensitivity, specificity, and nutritional properties for *Neisseria* spp. cultivation and identification (Refs. 1 through 6). Isolation rates for Thayer-Martin medium, the most widely used medium, have been reported to range from 40 percent (Ref. 1) to 90 percent (Ref. 2). Brorson, et al. (Ref. 3) reported a proportion of gonococci which are inhibited by the effects of vancomycin, an antibiotic contained in Thayer-Martin media, thereby decreasing the sensitivity of the media. Jones and Talley (Ref. 4) observed that different commercial agars varied widely in their toxicity for *Neisseria gonorrhoeae.* Kousa, et al. (Ref. 5) observed differences in sensitivities between a gonococcal transport medium and Thayer-Martin medium. Knapp and Holmes (Ref. 6) reported that 39 percent of the isolates from nondisseminated gonococcal infections in Seattle, Washington, had nutritional requirements not provided for in cystine-trypticase agar media, thus pointing out the need for performance standards which would address the nutritional requirements of gonococci.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Neisseria* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of pathogenic *Neisseria* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that culture media for pathogenic *Neisseria* spp. be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Johnson, D. W., K. K. Holmes, P. A. Kvale, C. W. Halverson, and W. P. Hirsch, "An Evaluation of Gonorrhea Case Finding in the Chronically Infected Female," *American Journal of Epidemiology,* 90:438–448, 1969.

2. Caldwell, J. G., E. V. Price, G. J. Pazin, and C. E. Cornelius, III, "Sensitivity and Reproducibility of Thayer-Martin Culture Medium in Diagnosing Gonorrhea in Women," *American Journal of Obstetrics and Gynecology,* 109:463–468, 1971.

3. Brorson, J. E., I. Holmberg, B. Nygren, and S. Seeberg, "Vancomycin-Sensitive Strains of *Neisseria gonorrhoeae:* A Problem for the Diagnostic Laboratory," *British Journal of Venereal Disease,* 49:452–453, 1973.

4. Jones, R. T. and R. S. Talley, "Simplified Complete Medium for the Growth of *Neisseria gonorrhoeae,*" *Journal of Clinical Microbiology,* 5(1):9–14, 1977.

5. Kousa, M., O. V. Renkonen, U. Kiistala, and A. Lassus, "Transgrow (Clinicult) in the Laboratory Diagnosis of gonorrhea," *British Journal of Venereal Disease,* 49:450–451, 1973.

6. Knapp, J. S. and K. K. Holmes, "Disseminated Gonococcal Infections Caused by *Neisseria gonorrhoeae* with Unique Nutritional Requirements," *Journal of Infectious Diseases,* 132:204–208, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2410 to read as follows:

**§ 866.2410 Culture medium for pathogenic Neisseria spp.**

(a) *Identification.* A culture medium for pathogenic *Neisseria* spp. is a device that consists primarily of liquid and/or solid biological materials used to cultivate and identify, pathogenic *Neisseria* spp. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria,* such as epidemic cerebrospinal meningitis, other meningoccoccal disease, and gonorrhea, and also provides epidemiological information on this microorganism.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11752 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2131]**

## Medical Devices; Classification of Automated Medium Dispensing and Stacking Devices

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated medium dispensing and stacking devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated medium dispensing and stacking devices:

1. Identification: An automated medium dispensing and stacking device is a mechanical device used to dispense a microbiological culture medium into petri dishes followed by the mechanical stacking of the petri dishes. This device aids in the diagnosis of diesease.

2. Recommended classification: Class I (general controls). The Panel recommends that automated medium dispensing and stacking devices be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from the premarket notification regulations under section 510(k) of the act.

3. Summary of reasons for recommendation: The Panel recommends that automated medium dispensing and stacking devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that automated medium dispensing and stacking devices be exempt from the good manufacturing practice regulation under section 520(f) of the act because all defects relating to the safety and effectiveness of the device would be readily detectable before use. The Panel also recommends that automated medium dispensing and stacking devices be exempt from premarket notification regulations under section 510(k) of the act because this is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automated medium dispensing and stacking devices be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of an automated medium dispensing and stacking device be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification of submissions concerning an automated medium dispensing and stacking device. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of an automated medium dispensing and stacking device be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of an automated medium dispensing and stacking device must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of an automated medium dispensing and stacking device must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2440 as follows:

**§ 866.2440 Automated medium dispensing and stacking device.**

(a) *Identification.*—An automated medium dispensing and stacking device is a mechanical device used to dispense a microbiological culture medium into petri dishes followed by the mechanical stacking of the petri dishes. This device aids in the diagnosis of disease.

(b) *Classification.*—Class I (general controls). This device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820, with the exception of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11753 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

## 21 CFR Part 866

[Docket No. 78N-2132]

## Medical Devices; Classification of Supplements for Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying supplements for culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of supplements for culture media:

1. Identification: A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is used to enhance the growth of fastidious microorganisms (having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that supplements for culture media be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have observed lot-to-lot variation in the performance of these supplements. The Panel believes, however, that lot-to-lot variation in product performance resulting from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by human pathogens. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that supplements for culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(1))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2450, to read as follows:

**§ 866.2450 Supplement of culture media.**

(a) *Identification.* A supplement for culture media is a device, such as a vitamin or sugar mixture, that is added to a solid or liquid basal culture medium to produce a desired formulation and that is used to enhance the growth of fastidious microorganisms (having complex nutritional requirements). This device aids in the diagnosis of diseases caused by pathogenic microorganisms.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11754 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

## 21 CFR Part 866

[Docket No. 78N-2133]

## Medical Devices; Classification of Quality Control Kits for Culture Media

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying quality control kits for culture media into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of quality control kits for culture media:

1. Identification: A quality control kit for culture medium is a device that consists of paper discs, each impregnated with a specified, freeze-dried viable microorganism, used to determine if a given culture medium is able to support the growth of that microorganism(s). The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that quality control kits for culture media be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of this device to perform satisfactorily may lead to the use of faulty culture media for diagnostic purposes. Use of faulty culture media may result in failure to detect a suspected pathogen(s), thereby contributing to a misdiagnosis and inappropriate therapy. (b) Epidemiological misinformation: Failure of the device to detect the presence of a suspected pathogen(s) may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that quality control kits for culture media be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1). The Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2480, to read as follows:

**§ 866.2480 Quality control kit for culture media.**

(a) *Identification.* A quality control kit for culture media is a device that consists of paper discs, each impregnated with a specified, freeze-dried viable microorganism, used to determine if a given culture medium is able to suport the growth of that microorganism(s). The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 5, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11755 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2134]**

## Medical Devices; Classification of Microtiter Diluting and Dispensing Devices

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microtiter diluting and dispensing devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microtiter diluting and dispensing devices:

1. Identification: A microtiter diluting and dispensing device is a mechanical device used to dispense and/or serially dilute biological or chemical reagents in very small quantities for use in a variety of diagnostic procedures.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microtiter diluting and dispensing devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that microtiter diluting and dispensing devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority

delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2500, to read as follows:

**§ 866.2500 Microtiter diluting and dispensing device.**

(a) *Identification.* A microtiter diluting and dispensing device is a mechanical device used to dispense and/or serially dilute biological or chemical reagents in very small quantities for use in a variety of diagnostic procedures.

(b) *Classification.*, Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11756 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2135]**

## Medical Devices; Classification of Microbiological Incubators

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microbiological incubators into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microbiological incubators:

1. Identification: A microbiological incubator is a device with various chambers and/or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained for the cultivation of microorganisms. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that microbiological incubators be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that microbiological incubators be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that the microbiological incubators be exempt from good manufacturing practice regulations under section 520(f) of the act because all defects relating to the safety and effectiveness of the device would be readily detectable prior to use. The Panel also recommends that microbiological incubators be exempt from premarket notification regulations under section 510(k) of the act because this is a familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microbiological incubators be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of microbiological incubators be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning microbiological incubators. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of a microbiological incubator be exempt from the device good manufacturing practice (GMP) regulation under section 510(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a microbiological incubator must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and follow-up. The agency also believes that manufacturers of a microbiological incubator must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2540 as follows:

**§ 866.2540 Microbiological incubator.**

(a) *Identification.* A microbiological incubator is a device with various chambers and/or water-filled compartments in which controlled environmental conditions, particularly temperature, are maintained for the cultivation of microorganisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls). This device is exempt from premarket notification regulations in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198, with respect to complaint files.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11757 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2136]**

## Medical Devices; Classification of Microbial Growth Monitors

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Asministration (FDA) is issuing for public comment a proposed regulation classifying microbial growth monitors into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm, 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal eslewhere is this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of microbial growth monitors:

1. Identification: A microbial growth monitor is a device that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microbial growth monitors be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation of the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microbial growth monitors be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2560, to read as follows:

**§ 866.2560 Microbial growth monitor.**

(a) *Identification.* A microbial growth monitor is a device that measures the concentration of bacteria suspended in a liquid medium by measuring changes in light scattering properties, optical density, electrical impedance, or by making direct bacterial counts. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 11758 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2137]**

## Medical Devices; Classification of Gas-Generating Devices

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying gas-generating devices into class I (general controls). FDA is also publishing the recommendation of the

Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of gas-generating devices:

1. Identification: A gas-generating device is a device that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that gas-generating devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that gas-generating devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2580 as follows:

**§ 866.2580 Gas-generating device.**

(a) *Identification.* A gas-generating device is a device that produces predetermined amounts of selected gases to be used in a closed chamber in order to establish suitable atmospheric conditions for cultivation of microorganisms with special atmospheric requirements. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11759 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2138]**

## Medical Devices; Classification of Wood's Fluorescent Lamps

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Wood's fluorescent lamps into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Wood's fluorescent lamps:

1. Identification: A Wood's fluorescent lamp is a device used to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that Wood's fluorescent lamps be exempt from the good manufacturing practice regulation under section 520(f) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360j(f)) and from premarket notification under section 510(k) of the act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that Wood's fluorescent lamps be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that Wood's fluorescent lamps be exempt from the good manufacturing practice regulation under section 520(f) of the act because all defects relating to the safety and effectiveness of the device would be readily detectable prior to use. The Panel also recommends that this device be exempt from premarket notification regulations under section 510(k) of the act because it is a

familiar device that presents no hazards to health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Wood's fluorescent lamps be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a Wood's fluorescent lamp be exempt from section 510(k) of the act, FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning a Wood's fluorescent lamp. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

In response to the Panel's recommendation that manufacturers of a Wood's fluorescent lamp be exempt from the device good manufacturing practice (GMP) regulation under section 520(f) of the act, FDA is proposing that a manufacturer of this device be exempt, in the manufacture of the device, from all requirements in the GMP regulation except § 820.180 (21 CFR 820.180), with respect to general requirements concerning records, and § 820.198 (21 CFR 820.198), with respect to complaint files. Based on available information about current practices used in the manufacture of the device and user experience with the device, the agency has determined that application of the GMP regulation, other than §§ 820.180 and 820.198, is unlikely to improve the safety and effectiveness of the device. The agency believes, however, that manufacturers of a Wood's fluorescent lamp must still be required to comply with the complaint file requirements of § 820.198 to ensure that these manufacturers have adequate systems for complaint investigation and followup. The agency also believes that manufacturers of a Wood's fluorescent lamp must still be required to comply with the general requirements concerning records in § 820.180 to ensure that FDA has access to complaint files, can investigate device-related injury reports and complaints about product defects, may determine whether the manufacturer's corrective actions are adequate, and may determine whether the exemption from other sections of the GMP regulation is still appropriate.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2600, to read as follows:

#### § 866.2600 Wood's fluorescent lamp.

(a) *Identification.* A Wood's fluorescent lamp is a device used to detect fluorescent materials (e.g., fluorescein pigment produced by certain microorganisms) as an aid in the identification of these microorganisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807. The device also is exempt from the good manufacturing practice regulation in Part 820 with the exceptions of § 820.180, with respect to general requirements concerning records, and § 820.198 with respect to complaint files.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11760 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

## 21 CFR Part 866

**[Docket No. 78N–2139]**

## Medical Devices; Classification of Microorganism Differentiation and Identification Devices

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying microorganism differentiation and identification devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of microorganism differentiation and identification devices:

1. Identification: A microorganism differentiation and identification device is a device that consists of one or more components (e.g., differential culture media, biochemical reagents, and/or paper discs or paper strips impregnated with test reagents) that are usually contained in individual compartments and that are used to differentiate and identify selected microorganisms or groups or microorganisms. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that microorganism differentiation and identification devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that microorganism differentiation and identification devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2660 to read as follows:

**§ 866.2660 Microorganism differentiation and identification device.**

(a) *Identification.* A microorganism differentiation and identification device is a device that consists of one or more components (e.g., differential culture media, biochemical reagents, and/or paper discs or paper strips impregnated with test reagents) that are usually contained in individual compartments and that are used to differentiate and identify selected micro-organisms. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11761 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78–N–2140]**

## Medical Devices; Classification of Automated Zone Readers

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying automated zone readers into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of automated zone readers:

1. Identification: An automated zone reader is a mechanical device used to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that automated zone readers be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panal members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that automated zone readers be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2850, to read as follows:

**§ 866.2850 Automated zone reader.**

(a) *Identification.* An automated zone reader is a mechanical device used to measure zone diameters of microbial growth inhibition (or exhibition), such as those observed on the surface of certain culture media used in disc-agar diffusion antimicrobial susceptibility tests. The device aids in the diagnosis of disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket

number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11762 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2141]**

## Medical Devices; Classification of Specimen Collection and Transport Devices

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying specimen collection and transport devices into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of specimen collection and transport devices:

1. Identification: A specimen collection and transport device is a sterile specimen collecting chamber that preserves the viability of microorganisms during storage following collection and transport from the specimen collecting area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that specimen collection and transport devices be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by a human pathogen(s). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to preserve the viability of a suspected pathogen may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that specimen collection and transport devices be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart C by adding new § 866.2900, to read as follows:

**§ 866.2900 Specimen collection and transport device.**

(a) *Identification.* A specimen collection and transport device is a sterile specimen collecting chamber that preserves the viability of microorganisms during storage following collection and transport from the specimen collecting area to the laboratory. The device aids in the diagnosis of disease caused by pathogenic microorganisms and also provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11763 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2282]**

## Medical Devices; Classification of "Acinetobacter Calcoaceticus" Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Acinetobacter calcoaceticus* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Acinetobacter calcoaceticus* serological reagents:

1. Identification: *Acinetobacter calcoaceticus* serological reagents are devices that consist of *Acinretobacter calcoaceticus* antigens and antisera used to identify this bacterium from cultured isolates dervied from clinical specimens. The identification aids in the diagnosis of disease caused by the bacterium *Acinetobacter calcoaceticus* and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Acinetobacter calcoaceticus* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease cause by *Acinetobacter calcoaceticus*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

(b) Epidemiological misinformation: Failure of the device to detect the presence of *Acinetobacter calcoaceticus* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Acinetobacter calcoaceticus* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart D consisting of § 866.3010, to read as follows:

## Subpart D—Serological Reagents

**§ 866.3010 Acinetobacter calcoaceticus serological reagents.**

(a) *Identification. Acinetobacter calcoaceticus* serological reagents are devices that consist of *Acinetobacter calcoaceticus* antigens and antisera used to identify this bacterium from cultured isolates derived from clincial specimens. The identification aids in the diagnosis of disease caused by the bacterium *Acinetobacter calcoaceticus* and provides epidemiological information on disease caused by this microorganism. This organism becomes pathogenic in patients with burns or with immunologic deficiency, and infection can result in sepsis (blood poisoning).

(b) *Classification.* Class I (general controls.)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockvill, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 11764 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

**21 CFR Part 866**

**[Docket No. 78N–2142]**

## Medical Devices; Classification of Adenovirus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying adenovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of adenovirus serological reagents:

1. Identification: Adenovirus serological reagents are devices that consist of antigens and antisera that are used in serological tests to identify adenovirus antibodies in a patient's serum. Additionally, some of these reagents consist of adenovirus antisera conjugated with a fluorescent dye and are used to identify adenoviruses directly from clinical specimens. The identification aids in the diagnosis of diseases caused by adenovirus infections and provides epidemiological information on these diseases. Adenovirus infections may cause pharyngitis (inflammation of the throat),

acute respiratory diseases, and certain external diseases of the eye (e.g., conjunctivitis).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that adenovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The panel recognizes that a definitive diagnosis of adenovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for these diseases because there is a lack of available antiviral drug therapy. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the devices to detect the presence of adenoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that adenovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3020, to read as follows:

**§ 866.3020 Adenovirus serological reagents.**

(a) *Identification.* Adenovirus serological reagents are devices that consist of antigens and antisera that are used in serological tests to identify adenovirus antibodies in a patient's serum. Additionally, some of these reagents consist of adenovirus antisera conjugated with a fluorescent dye and are used to identify adenoviruses directly from clinical specimens. The identification aids in the diagnosis of diseases caused by adenoviruses and provides epidemiological information on these diseases. Adenovirus infections may cause pharyngitis (inflamation of the throat), acute respiratory diseases, and certain external diseases of the eye (e.g., conjunctivitis).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identifed with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11765 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2143]**

## Medical Devices; Classification of "Arizona" spp., Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Arizona* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comment, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Arizona* spp. serological reagents:

1. Identification: *Arizona* spp. serological reagents are devices that consist of antisera and antigens used to identify *Arizona* spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of desease caused by bacteria belonging to the genus *Arizona* and provides epidemiological information on diseases caused by these microorganisms. *Arizona* spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Arizona* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of these devices. The panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulations.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Arizona* spp., including gastroenteritis and blood poisoning. Inappropriate therapy based on

inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Arizona* spp. may contribute to epidemiological misinformation. Consequently the risk of incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs Proposes to amend Part 866 in Subpart D by adding new § 866.3935, to read as follows:

**§ 866.3935 Arizona spp. serological reagents.**

(a) *Identification. Arizona* spp. serological reagents are devices that consist of antisera and antigens used to identify *Arizona* spp. in cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Arizona* and provides epidemiological information on diseases caused by these microorganisms. *Arizona* spp. can cause gastroenteritis (food poisoning) and sepsis (blood poisoning).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11766 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

**21 CFR Part 866**

**[Docket No. 78N-2144]**

## Medical Devices; Classification of Aspergillus spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Aspergillus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Aspergillus* spp. serological reagents:

1. Identification: *Aspergillus* spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify *Aspergillus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genus *Aspergillus.* Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lesions in the skin, ear, eyeball cavity, nasal sinuses, lungs, and occasionally the bones.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Aspergillus* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of aspergillosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Aspergillus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3040, to read as follows:

**866.3040 Aspergillus spp. serological reagents.**

(a) *Identification. Aspergillus* spp. serological reagents are devices that consist of antigens and antisera used in various serological tests to identify *Aspergillus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of aspergillosis caused by fungi belonging to the genus *Aspergillus.* Aspergillosis is a disease marked by inflammatory granulomatous (tumor-like) lesions in the skin, ear, eyeball cavity, nasal sinuses, lungs, and occasionally the bones.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before

June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11767 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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## 21 CFR Part 866

**[Docket No. 78N-2145]**

## Medical Devices; Classification of "Blastomyces Dermatitidis" Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Blastomyces dermatitidis* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Blastomyces dermatitidis* serological reagents:

1. Identification: *Blastomyces dermatitidis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify the antibodies to *Blastomyces dermatitidis* in a patient's serum. The identification aids in the diagnosis of blastomycosis caused by the fungus *Blastomyces dermatitidis.* Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that *blastomyces dermatitidis* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1). The Panels' review of the literature disclosed appreciable variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of blastomycosis.

Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Blastomyces dermatitidis* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for the device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Volume 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–4–7, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3060, to read as follows:

**§ 866.3060 Blastomyces dermatitidis serological reagents.**

(a) *Identification. Blastomyces dermatitidis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify the antibodies to *Blastomyces dermatitidis* in a patient's serum. The identification aids in the diagnosis of blastomycosis caused by the fungus *Blastomyces dermatitidis.* Blastomycosis is a chronic granulomatous (tumor-like) disease, which may be limited to the skin or lung or may be widely disseminated in the body resulting in lesions of the bones, liver, spleen, and kidneys.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11768 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2146]

## Medical Devices; Classification of "Bordetella" spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Bordetella* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Bordetella* spp. serological reagents:

1. Identification: *Bordetella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify *Bordetella* spp. from cultured isolates and/or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Bordetella* and provides epidemiological information on these diseases. *Bordetella* spp. cause whooping cough and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Bordetella* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Bordetella* ssp. infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Bordetella* ssp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Bordetella* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3065, to read as follows:

**§ 866.3065 Bordetella spp. serological reagents.**

(a) *Identification. Bordetella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, used in serological tests to identify *Bordetella* spp. from cultured isolates and/or directly from clincial specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Bordetella* and provides epidemiological information on these diseases. *Bordetella* spp. cause whooping cough and other similarly contagious and acute respiratory infections characterized by pneumonitis (inflammation of the lungs).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing clerk (HFA-305), Food and Drug Administration, Rm 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11769 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2147]

## Medical Devices; Classification of "Brucella" spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Brucella* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Brucella* spp. immunofluorescent reagents which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all

devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Brucella* spp. serological reagents:

1. Identification: *Brucella* spp. serological reagents are devices that consist of antigens and antisera used for serological identification of *Brucella* spp. from cultured isolates derived from clinical specimens or to identify *Brucella* spp. antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Brucella* spp. directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis and treatment of brucellosis (e.g., undulant fever, Malta fever) caused by bacteria belonging to the genus *Brucella* and provides epidemiological information on diseases caused by these microorganisms.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Brucella* spp. serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Panel also recommends that *Brucella* spp. immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Brucella* spp. serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Brucellosis is characterized by an acute blood infection phase followed by a chronic stage which may extend over many years and may involve many tissues but primarily the reticuloendothelial system (liver, spleen, bone marrow, etc.). Serodiagnosis of brucellosis may be necessary when isolation of the infecting microorganism is not possible. A marked rise in *Brucella* agglutinins (antibodies) in a patient's serum is presumptive evidence of brucellosis. Positive agglutination tests using isolated colonies may also be presumptive evidence of brucellosis. Patients with chronic brucellosis will often have negative culture results for the microorganisms but will demonstrate a marked rise of *Brucella* spp. antibody in the serum. The patient's serum is tested against *Brucella* spp. serological reagents which are commercially available. These commercial antigens provide variable results (Ref. 1). Unpublished data from the Center for Disease Control (CDC) for calendar years 1971 through 1975 demonstrate the variability of these reagents intended to meet CDC specifications (Ref. 2). The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of *Brucella* spp. serological reagents (excluding immunofluorescent reagents) regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for the reagents (Ref. 3). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The Panel further recommends that *Brucella* spp. immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of brucellosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Brucella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation with respect to *Brucella* spp. serological reagents (excluding immunofluorescent reagents) and is proposing that the device be classified into class II.

However, FDA disagrees with the Panel recommendation with respect to *Brucella* spp. immunofluorescent reagents and is proposing that the device be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify these devices into class I and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depend appreciably on how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is also proposing that *Brucella* spp. immunofluorescent reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for the devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish standards to provide reasonable assurance of the safety and effectiveness of these devices.

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Hansler, W. J., Jr. and F. P. Koontz, "Brucella," in "Manual of Clinical

Microbiology," 2d Ed., Edited by Lennette, E. H., E. H. Spaulding, and J. P. Truant, *American Society for Microbiology*, Washington, DC, pp. 295–301, 1974.

2. Results of a Five Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

3. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Volume 1," 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare B1–5–7, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3085, to read as follows:

**§ 866.3085 Brucella spp. serological reagents.**

(a) *Identification. Brucella* spp. serological reagents are devices that consist of antigens and antisera used for serological identification of *Brucella* spp. from cultured isolates derived from clincial specimens of to identify *Brucella* spp. antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Brucella* spp. directly from clincial specimens and/or cultured isolates derived from clincial specimens. The identification aids in the diagnosis of brucellosis (e.g., undulant fever, Malta fever) casused by bacteria belonging to the genus *Brucella* and provides epidemiological information on disease caused by these microorganisms.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11770 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2149]**

## Medical Devices; Classification of "Campylobacter Fetus" Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Campylobacter fetus* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Campylobacter fetus* serological reagents:

1. Identification: *Campylobacter fetus* serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Campylobacter fetus* from clinical specimens and/or cultured isolates dervied from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Campylobacter* and provides epidemiological information on diseases caused by this micoorganism. *Campylobacter fetus* is a frequent cause of abortion in sheep and cattle and sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Campylobacter fetus* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurances of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Campylobacter fetus.* Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Campylobacter fetus* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Campylobacter fetus.* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1). The Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3110, to read as follows:

**§ 866.3110 Campylobacter fetus immunofluorescent reagents.**

(a) *Identification. Campylobacter fetus* serological reagents are devices that consists of antisera conjugated with a fluorescent dye used to identify *Campylobacter fetus* from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Campylobacter* and provides epidemiological information on diseases caused by this microorganism. *Campylobacter fetus* is a frequent cause of abortion in sheep and cattle and sometimes responsible for endocarditis (inflammation of certain membranes of the heart) and enteritis (inflammation of the intestines) in humans.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11771 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2150]**

## Medical Devices; Classification of Chlamydia Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and drug Administration (FDA) is issuing for public comment a proposed regulation classifying chlamydia serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of chlamydia serological reagents:

1. Identification: Chlamydia serological reagents are devices that consist of antigens and antisera used in serological tests to identify chlamydial antibodies in a patient's serum. Additionally, some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye, and are used to identify chlamydia directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* and provides epidemiological information on diseases caused by these microorganisms. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that chlamydia serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by chlamydia. In appropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of chlamydia may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that chlamydiae serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3120, to read as follows:

**§ 866.3120 Chlamydia serological reagents.**

(a) *Identification.* Chlamydia serological reagents are devices that consist of antigens and antisera used in serological tests to identify chlamydial antibodies in a patient's serum. Additionally, some of these reagents consist of chlamydia antisera conjugated with a fluorescent dye and are used to identify chlamydia directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Chlamydia* and provides epidemiological information on diseases caused by these microorganisms. Chlamydia are the causative agents of psittacosis (a form of pneumonia), lymphogranuloma venereum (a venereal disease), and trachoma (a chronic disease of the eye and eyelid).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four

copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11772 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2151]

## Medical Devices; Classification of "Citrobacter" spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Citrobacter* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Citrobacter* spp. serological reagents:

1. Identification: *Citrobacter* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Citrobacter* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Citrobacter* and provides epidemiological information on diseases caused by these microorganisms. *Citrobacter* spp. have occasionally been associated with urinary tract infections.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Citrobacter* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Citrobacter* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Citrobacter* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Citrobacter* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3125, to read as follows:

**§ 866.3125 Citrobacter spp. serological reagent.**

(a) *Identification. Citrobacter* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Citrobacter* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Citrobacter* and provides epidemiological information on diseases caused by these microorganisms. *Citrobacter* spp. have occasionally been associated with urinary tract infections.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11773 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2152]

## Medical Devices; Classification of "Coccidioides Immitis" Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Coccidioides immitis* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being

taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Coccidioides immitis* serological reagents:

1. Identification: *Coccidioides immitis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Coccidioides immitis* antibodies in a patient's serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genus *Coccidioides* and provides epidemiological information on diseases caused by this microorganism. An infection with *Coccidioides immitis* produces symptoms varying in severity from those accompanying the common cold to those of influenza.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that *Coccidioides immitis* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Because the diagnosis of coccidioidomycosis cannot always be confirmed by cultural isolation of the infecting organism or by histological examination, serological testing often provides the only rapid, though presumptive, evidence of infection. The clinical experience of the Panel revealed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications and evaluation methods for these reagents (Ref. 1). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard would provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of coccidioidomycosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Coccidioides immitis* antibodies may contribute to epidemiological misinformation. Consequently, the risk of incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Coccidioides immitis* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specificationa and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–8–10, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3135, to read as follows:

**§ 866.3135 Coccidioides immitis serological reagents.**

(a) *Identification. Coccidioides immitis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Coccioides immitis* antibodies in a patient's serum. The identification aids in the diagnosis of coccidioidomycosis caused by a fungus belonging to the genus *Coccidioides* and provides epidemiological information on disease caused by this microorganism. An infection with *Coccidioides immitis* produces symptoms varying in severity from those accompanying the common cold to those of influenza.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11774 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2153]**

## Medical Devices; Classification of "Corynebacterium" spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Corynebacterium* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panal, an FDA advisory committee, made the following recommendation regarding the classification of *Corynebacterium* spp. serological reagents:

1. Identification: *Corynebacterium* spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Corynebacterium* spp from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Corynebacterium* and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus *Corynebacterium diphtheriae,* causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin and are either nonpathogenic or have an uncertain pathogenic role.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Corynebacterium* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Corynebacterium* spp., principally human diphtheria. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Corynebacterium* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that *Corynebacterium* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3140, to read as follows:

**§866.3140 Corynebacterium spp. serological reagents.**

(a) *Identification. Corynebacterium* spp. serological reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Corynebacterium* spp. from clinical specimens. The identification aids in the diagnosis of disease cause by bacteria belonging to the genus *Corynebacterium* and provides epidemiological information on diseases caused by these microorganisms. The principal human pathogen of this genus *Corynebacterium diphtheriae,* causes diphtheria. However, many other types of corynebacteria form part of the normal flora of the human respiratory tract, other mucus membranes, and skin and are either nonpathogenic or have an uncertain role.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours or 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11775 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2154]**

## Medical Devices; Classification of Coxsackievirus Serological Reagents

**AGENCY:** Food and Drug Administation.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying coxsackievirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to required that the the device meet only general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written coments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulations. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the

classification of coxsackievirus serological reagents:

1. Identification: Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify coxsackievirus antibodies in a patient's serum. Additionally, some of these reagents consists of coxsackievirus antisera conjugated with a fluorescent dye, that are used to identify coxsackievirus from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat) and myopericarditis (inflammation of heart tissue).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that coxsackievirus serological reagents be classified class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that a definitive diagnosis of coxsackievirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for disease caused by coxsackieviruses (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemmination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulations.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the devices to detect the presence of coxsackieviruses may contribute to epidemiological misinformation. Consquently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that coxsackievirus seriological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3145, to read as follows:

**§ 866.3145 Coxsackievirus serological reagents.**

(a) *Identification.* Coxsackievirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify coxsackievirus antibodies in a patient's serum. Additonally, some of these reagents consist of coxsackievirus antisera conjugated with a fluorescent dye, that are used to identify coxsackievirus from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of coxsackievirus infections and provides epidemiological information on diseases caused by these viruses. Coxsackieviruses produce a variety of infections, including common colds, meningitis (inflammation of brain and spinal cord membranes), herpangina (brief fever accompanied by ulcerated lesions of the throat), and myopericarditis (inflammation of heart tissue).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11776 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

**21 CFR Part 866**

**[Docket No. 78N–2156]**

## Medical Devices; Classification of "Cryptococcus Neoformans" Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Cryptococcus neoformans* serological reagents into class II (performance standards). The FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Cryptococcus neoformans* immunofluorescent reagents which the Panel recommended be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of *Cryptococcus neoformans* serological reagents:

1. Identification: *Cryptococcus neoformans* serological reagents are devices that consist

of antigens and antisera used in serological tests to identify *Cryptococcus neoformans* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify *Cryptococcus neoformans* directly from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of *Cryptococcosis* and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Panel also recommends that *Cryptococcus neoformans* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendations: The Panel recommends that *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel notes that because of the serious nature of cryptococcosis, rapid diagnosis and treatment is necessary. Serological tests are often used for the diagnosis of this disease. Kaufman, et al. tested 24 commercial latex agglutination test kits (kits which utilize antigen coated latex suspensions from a single manufacturer). Fourteen kits were found unsatisfactory (Ref. 1). The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) with respect to their sensitivity, specificity, and titer. The Panel is aware of the ability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 2). The Panel further recommends that *Cryptococcus neoformans* immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in their sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1–3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of Cryptococcosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Cryptococcus neoformans* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation with respect to *Cryptococcus neoformans* serological reagents (excluding immunofluorescent reagents) and is proposing that the devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Cryptococcus neoformans* immunofluorescent reagents and is proposing that these immunofluorescent reagents be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify immunofluorescent reagents into class I (general controls) and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of antigens and immunofluorescent reagents depends appreciably upon how they are manufactured. The agency notes immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. The agency also is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 2). Therefore, the agency is proposing that *Cryptococcus neoformans* immunofluorescent reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for *Cryptococcus neoformans* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. Performance standards would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish standards to provide reasonable assurance of the safety and effectiveness of these devices.

## References

The following information has been placed in the Office of the Hearing Clerk (HFA–305), Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, and may be viewed by interested persons from 9 a.m. to 4 p.m. Monday through Friday.

1. Kaufman, L., G. Cowart, S. Blumer, A. Stine, and R. Wood, "Evaluation of a Commercial Latex Agglutination Test Kit for Cryptococcal Antigen," *Applied Microbiology*, 27(3):620–621, 1974.

2. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Volume I, 4th Ed.," Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–11–14, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3165 as follows:

### § 866.3165 Cryptococcus neoformans serological reagents.

(a) *Identification. Cryptococcus neoformans* serological reagents are devices that consist of antigens and antisera used in serological tests used to identify *Cryptococcus neoformans* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) and are used to identify *Cryptococcus neoformans* directly from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of Cryptococcosis and provides epidemiological information on this type of disease. Cryptococcosis infections are found most often as chronic meningitis (inflammation of brain membranes) and, if not treated, are usually fatal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written

comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11777 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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## 21 CFR Part 866

**[Docket No. 78N-2157]**

## Medical Devices; Classification of Cytomegalovirus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying cytomegalovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of cytomegalovirus serological reagents:

1. Identification: Cytomegalovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify cytomegalovirus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by cytomegaloviruses (principally cytomegalic inclusion disease) and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitis, and an infectious mononucleosis-like syndrome.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that cytomegalovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of cytomegalovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for these diseases (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer that results from manufacturing procedures can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of these devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of cytomegaloviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that cytomegalovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3175, to read as follows:

**§ 866.3175 Cytomegalovirus serological reagents.**

(a) *Identification.* Cytomegalovirus serological reagents are devices that consist of antigens used in serological tests to identify cytomegalovirus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by cytomegaloviruses (principally cytomegalic inclusion disease) and provides epidemiological information on these diseases. Cytomegalic inclusion disease is a generalized infection of infants and is caused by intrauterine or early postnatal infection with the virus. The disease may cause severe congenital abnormalities, such as microcephaly (abnormal smallness of the head), motor disability, and mental retardation. Cytomegalovirus infection has also been associated with acquired hemolytic anemia, acute and chronic hepatitus, and an infectious mononucleosis-like syndrome.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11778 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

21 CFR Part 866

[Docket No. 78N-2158]

## Medical Devices; Classification of Echinococcus spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Echinococcus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Echinococcus* spp. serological reagents:

1. Identification: *Echinococcus* spp. serological reagents are devices that consist of *Echinococcus* spp. antigens and antisera used in serological tests to identify *Echinococcus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genus *Echinococcus* and provides epidemiological information on this type of disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organism.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Echinococcus* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Serodiagnosis is most often the method of choice for identifying *Echinococcus* spp. infection.

The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagents sensitivity, specificity, and titer that results from manufacturing procedures can be adequately controlled by manufacturer's compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of these devices to perform satisfactorily may lead to anerror in the diagnosis of echinococcosis or may contribute to epidemiological misinformation. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Echinococcus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3200, to read as follows:

**§ 866.3200 Echinococcus spp. serological reagents.**

(a) *Identification. Echinococcus* spp. serological reagents are devices that consist of *Echinococcus* spp. antigens and antisera used in serological tests to identify *echinococcus* spp. antibodies in a patient's serum. The identification aids in the diagnosis of echinococcosis, caused by parasitic tapeworms belonging to the genus *Echinococcus* and provides epidemiological information of this type of disease. Echinococcosis is characterized by the development of cysts in the liver, lung, kidneys, and other organs formed by the larva of the infecting organism.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments shall be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11779 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2159]

## Medical Devices; Classification of Echovirus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying echovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health,

Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of echovirus serological reagents:

1. Identification: Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify echovirus antibodies in a patient's serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that echovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that a definitive diagnosis of echovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for these diseases (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices, and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of echoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that echovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3205, to read as follows:

**§ 866.3205 Echovirus serological reagents.**

(a) *Identification:* Echovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify echovirus antibodies in a patient's serum. Additionally, some of these reagents consist of echovirus antisera conjugated with a fluorescent dye used to identify echoviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of echovirus infections and provides epidemiological information on diseases caused by these viruses. Echoviruses cause illnesses such as meningitis (inflammation of the brain and spinal cord membranes), febrile illnesses (accompanied by fever) with or without rash, and the common cold.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11780 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2160]**

## Medical Devices; Classification of Entamoeba Histolytica Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rules.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Entamoeba histolytica* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Entamoeba histolytica* immunofluorescent reagents, which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440) Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Entamoeba histolytica* serological reagents:

1. Identification: *Entamoeba histolytica* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Entamoeba histolytica* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Entamoeba histolytica* directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic protozoan parasite *Entamoeba histolytica* and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Entamoeba histolytica* serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for the device be a medium priority. The Panel also recommends that *Entamoeba histolytica* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Entamoeba histolytica* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information.

Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Serological tests are useful in making a diagnosis when disease involving amebiasis and infections by other tissue-inhabiting parasites occur (Ref. 1). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer (Ref. 1).

The Panel further recommends that *Entamoeba histolytica* immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding the reagents' sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Entamoeba histolytica*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Entamoeba histolytica* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendations with respect to *Entamoeba histolytica* serological reagents (excluding immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Entamoeba histolytica* immunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify this device into class I (general controls) and has obtained additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depend appreciably upon how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is proposing that *Entamoeba histolytica* immunofluorescent reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for *Entamoeba histolytica* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. Performance standards would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

## References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Swartzwelder, J. C., "Clinical Parasitology: Introduction and General Methods," *Manual of Clinical Microbiology*, 2d Ed., Edited by Lenette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 577–581, 1974.

2. Results of a Five-Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare (unpublished).

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3220, to read as follows:

**§ 866.3220 Entamoeba histolytica serological reagents.**

(a) *Identification. Entamoeba histolytica* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Entamoeba histolytica* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Entamoeba histolytica* directly from clinical specimens. The identification aids in the diagnosis of amebiasis caused by the microscopic protozoan parasite *Entamoeba histolytica* and provides epidemiological information on diseases caused by this parasite. The parasite may invade the skin, liver, intestines, lungs, and diaphragm, causing disease conditions such as indolent ulcers, an amebic hepatitis, amebic dysentery, and pulmonary lesions.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be

submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11781 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2162]**

## Medical Devices; Classification of Epstein-Barr Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Epstein-Barr virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Epstein-Barr virus serological reagents:

1. Identification: Epstein-Barr virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify Epstein-Barr virus antibodies in a patient's serum. The identification aids in the diagnosis of Epstein-Barr virus infectious and provides epidemiological information on diseases caused by this virus. Epstein-Barr virus is thought to cause the infections mononucleosis and has been associated with Burkitt's lymphoma (a tumor of the jaw in African children and young adults) and postnasal carcinoma (cancer).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that Epstein-Barr virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that a positive diagnosis of Epstein-Barr virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for these diseases (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of Epstein-Barr virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Epstein-Barr virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3235, to read as follows:

**§ 866.3235 Epstein-Barr virus serological reagents.**

(a) *Identification.* Epstein-Barr virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify Epstein-Barr virus antibodies in a patient's serum. The identification aids in the diagnosis of Epstein-Barr virus infections and provides epidemiological information on diseases caused by this virus. Epstein-Barr virus is thought to cause infectious mononucelosis and has been associated with Burkitt's lymphoma (a tumor of the jaw in African children and young adults) and postnasal carcinoma (cancer).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11782 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2163]**

## Medical Devices; Classification of Equine Encephalomyelitis Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying equine encephalomyelitis virus serological reagents into class I (general controls). FDA is also publishing the recomendation of the Microbiology Device Classification Panel that the device be classified into

class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of equine encephalomyelitis virus serological reagents:

1. Identification: Equine encephalomyelitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify equine encephalitis virus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by equine encephalomyelitis viruses and provides epidemiological information on these viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects such as mosquitos and ticks and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that equine encephalomyelitis virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that diagnosis of diseases caused by equine encephalomyelitis viruses by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of equine encephalomyelitis viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that equine encephalomyelitis virus serological reagents be classified into class I (general controls) with no exemptions because the agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3240, to read as follows:

**§ 866.3240 Equine encephalomyelitis virus serological reagents.**

(a) *Identification.* Equine encephalomyelitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify equine encephalitis virus antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by equine encephalomyelitis viruses and provides epidemiological information on these viruses. Equine encephalomyelitis viruses are transmitted to humans by the bite of insects such as mosquitos and ticks and may cause encephalitis (inflammation of the brain), rash, acute arthritis, or hepatitis.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11783 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2164]**

## Medical Devices; Classification of Erysipelothrix Rhusiopathiae Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Erysipelothrix rhusiopathiae* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Erysipelothrix rhusiopathiae* serological reagents:

1. Identification: *Erysipelothrix rhusiopathiae* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Erysipelothrix rhusiopathiae* from cultured isolates derived from clinical speciments. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Erysipelothrix*. This organism is responsible for a variety of inflammation of the skin following skin abrasions from contact with fish, shellfish, or poultry.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Erysipelothrix rhusiopathiae* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivitry, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with lableing requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Erysipelothrix rhusiopathiae*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that *Erysipelothrix rhusiopathiae* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new §866.3250, to read as follows:

**§ 866.3250 Erysipelothrix rhusiopathiae serological reagents.**

(a) *Identification. Erysipelothrix rhusiopathiae* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Erysipelothrix rhusiopathiae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Erysipelothrix*. This organism is responsible for a variety of inflammations of the skin following skin abrasions from contact with fish, shellfish, or poultry.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11784 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2165]**

## Medical Devices; Classification of Escherichia Coli Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Escherichia coli* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Escherichia coli* serological reagents:

1. Identification: *Escherichia coli* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Escherichia coli* from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Escherichia coli* antisera conjugated with a fluorescent dye used to identify *Escherichia coli* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis and treatment of disease caused by this bacterium belonging to the genus *Escherichia* and provides epidemiological information on diseases caused by this microorganism. Although *Escherichia coli* constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually nonpathogenic, those strains which are pathogenic may cause urinary tract infections and/or epidemic diarrheal disease, especially in children.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Escherichia coli* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers'

compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Escherichia coli*. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Escherichia coli* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Escherichia coli* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3255, to read as follows:

**§ 866.3255 Escherichia coli serological reagents.**

(a) *Identification. Escherichia coli* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Escherichia coli* from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Escherichia coli* antisera conjugated with a fluorescent dye used to identify *Escherichia coli* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis and treatment of disease caused by this bacterium belonging to the genus *Escherichia* and provides epidemiological information on diseases caused by this microorganism. Although *Escherichia coli* constitutes the greater part of the microorganisms found in the intestinal tract in humans and is usually nonpathogenic, those strains which are pathogenic may cause urinary tract infections and/or epidemic diarrheal disease, especially in children.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11785 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2166]**

## Medical Devices; Classification of Flavobacterium spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Flavobacterium* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classificaton Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Flavobacterium* spp. serological reagents:

1. Identification: *Flavobacterium* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Flavobacterium* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Flavobacterium* and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. *Flavobacterium meningosepticum* is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and meningitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Flavobacterium* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Flavobacterium* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Flavobacterium* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that

*Flavobacterium* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3270, to read as follows:

**§ 866.3270 Flavobacterium spp. serological reagents.**

(a) *Identification. Flavobacterium* spp. serological reagents are devices that consist of antigents and antisera used in serological tests to identify *Flavobacterium* spp. from cultured isolates derived from clincial specimens. The identification aids in the diagnosis of disease caused by bacteria belinging to the genus *Flavobacterium* and provides epidemiological information on diseases caused by these microorganisms. Most members of this genus are found in soil and water and, under certain conditions, may become pathogenic to humans. *Flavobacterium meningosepticum* is highly virulent for the newborn, in whom it may cause epidemics of septicemia (blood poisoning) and menigitis (inflammation of the membranes of the brain) and is usually attributable to contaminated hospital equipment.

(b) *Classification.* Class I (general controls.)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11786 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

**21 CFR Part 866**

**[Docket No. 78N–2167]**

## Medical Devices; Classification of Francisella Tularensis Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Francisella tularensis* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Francisella tularensis* immunofluorescent reagents, which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Francisella tularensis* serological reagents:

1. Identification: *Francisella tularensis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Francisella tularensis* antibodies in a patient's serum and/or to identify *Francisella tularensis* in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Francisella tularensis* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of tularemia caused by *Francisella tularensis* and provides epidemiological information on this disease. Tularemia is a disease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Francisella tularensis* serological reagents (excluding into class II (performance standards) and that establishing a performance standard for this device be a low priority. The Panel also recommends that *Francisella tularensis* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Francisella tularensis* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel is aware of appreciable variation in the manufacture of *Francisella tularensis* serological reagents (excluding immunofluorescent reagents) regarding their sensitivity, specificity, and titer (Ref. 1). Sporadic cases of tularemia usually present difficult diagnostic problems because recovery of the organism in culture is often difficult. Diagnosis often depends on the outcome of serological tests. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The Panel is also aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 2). The Panel recommends that *Francisella tularensis* immunofluorescent reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture

of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of tularemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Francisella tularensis* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation with respect to *Francisella tularensis* serological reagents (excluding immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Francisella tularensis* immunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify this device into class I (general controls) and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depends appreciably upon how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is proposing that *Francisella tularensis* immunofluorescent reagents be classified into class II (performance standards). The agency believes that performance standards are necessary for *Francisella tularensis* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices (Ref. 2).

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jarnetz, E., J. L. Melnick, and E. A. Adelberg, "Review of Medical Microbiology," 12th Ed., Lange Medical publications, Los Altos, pp. 217–220, 1976.

2. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1–8–11, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3280, to read as follows:

**§ 866.3280 Francisella tularensis serological reagents.**

(a) *Identification. Francisella tularensis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Francisella tularensis* antibodies in a patients serum and/or to identify *Francisella tularensis* in cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Francisella tularensis* directly from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of tularemia cause by *Francisella tularensis* and provides epidemiological information on this disease. Tularemia is a disease principally of rodents, but may be transmitted to humans through handling of infected animals, animal products, or by the bites of fleas and ticks. The disease takes on several forms depending upon the site of infection, such as skin lesions, lymph node enlargements, or pulmonary infection.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11787 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2169]**

## Medical Devices; Classification of Haemophilus spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Haemophilus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation.

The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Haemophilus* spp. serological reagents:

1. Identification: *Haemophilus* spp. serological reagents are devices that consist of antigens and antisera Including antisera conjugated with a fluorescent dye, that are used in serological tests to identify *Haemophilus* from cultured isolates derived from clinical specimens and/or directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Haemophilus* and provides epidemiological information on diseases caused by these microorganisms. Diseases most often caused by *Haemophilus* spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Haemophilus* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Haemophilus* spp. Inappropriate thereapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Haemophilus* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Haemophilus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3300, to read as follows:

**§ 866.3300 Haemophilus spp. serological reagents.**

(a) *Identification: Haemophilus* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye, that are used in serological tests to identify *Haemophilus* spp. from cultured isolates derived from clinical specimens and/or directly from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Haemophilus* and provides epidemiological information on diseases caused by these microorganisms. Diseases most often caused by *Haemophilus* spp. include pneumonia, pharyngitis, sinusitis, vaginitis, chancroid venereal disease, and a contagious form of conjunctivitis (inflammation of eyelid membranes).

(b) *Classifaction.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11788 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2170]**

## Medical Devices; Classification of Herpes Simplex Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying herpes simplex virus serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of herpes simplex virus complement fixation test reagents which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of herpes simplex virus serological reagents:

1. Identification: Herpes simplex virus serological reagents are devices that consist of antigens and antisera used in various serological tests to identify herpes simplex virus antibodies in a patient's serum. Additionally, some of these reagents consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify herpers simplex virus directly from clincial specimens and/or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe form of encephalitis (inflammation of the brain).

2. Recommended classification: The Microbiology Device Classification Panel recommends that herpes simplex virus serological reagents (excluding complement fixation test reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Panel also recommends that herpes simplex virus complement fixation test reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that herpes simplex virus serological reagents (excluding complement fixation test reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Since the success of treatment of herpes simplex virus infection is determined by early diagnosis, a rapid means of diagnosis is strongly desired. Immunofluorescent procedures can produce rapid definitive determination of the virus in clinical materials. Virus neutralization tests and complement fixation are the most commonly used tests for detection of herpes simplex virus antibodies in a patient's serum. Gittzus and Rubin (Ref. 1) compared five commercial conjugates for herpes simplex virus and noted excessive nonspecific background fluorescent staining with one of the reagents. Cherry, et al. (Ref. 2) reported nonspecific staining from 12 sources of commercial conjugates due to impurity of the fluorescent dye preparations. Johnson, Beutner, and Holborow (Ref. 3) and Cherry and Reimer (Ref. 4) all warn of the variable performance of commercial conjugates and strongly advocate the need for standardization of these reagents. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard (Ref. 5). The Panel is also aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 6). The Panel further recommends that herpes simplex virus complement fixation test reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by herpes simplex virus. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presense of herpes simplex virus may contribute to epidemiological misinformation. Consequently, the risk, of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation with respect to herpes simplex virus serological reagents (excluding complement fixation test reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to herpes simplex virus complement fixation test reagents and is proposing that the devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify this device into class I and has sought additional data and documentation on the safety and effectiveness of this device. The agency has reviewed the available medical literature pertaining to herpes simplex virus complement fixation test reagents (Ref. 5). The agency notes that antigens for the complement fixation test and the antigens for the virus neutralization test are similar and are generally prepared from the same sources (Ref. 5). Consequently, the performance of complement fixation test reagents not only shares problems of variability common to the manufacturers of those other serological reagents described, but also exhibits a variability intrinsic to complement fixation reagents. Therefore, the agency is proposing that herpes simplex virus complement fixation reagents be classified into class II (performance standards).

The agency believes that performance standards are necessary for herpes simplex virus serological reagents cause general controls along are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficent information to establish a performance standard for these devices (Ref. 2).

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gittzus, J. G. and S. J. Rubin, "Clinical Evaluation of Commercial Conjugates for Direct Immunofluorescence of Herpes Simplex Virus," *Journal of Clinical Miorobiology*, 6(6): 574–577, 1977.

2. Cherry, W. B., R. M. McKinney, V. M. Emmel, J. T. Spillane, G. A. Hebert, and B. Pittman, "Evaluation of Commercial Fluorescein Isothiocvanates Used in Fluorescent Antibody Studies," *Stain Technology*, 44(4): 179–186, 1969.

3. Johnson, G. D., E. H. Beutner, and J. Holborow, "Development in Immunofluorescence: The Need for Standardization," *Journal of Clinical Pathology*, 20:720–723, 1967.

4. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials, 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin*, 48(6): 737–745, 1973.

5. Tokumara, T., "Herpesvirus," *in* "Diagnostic Procedures for Viral and Rickettsial Infections," 4th Ed., Edited by Lenette, E. H., and N. S. Schmidt, American Public Health Association, Inc., New York, pp. 641–676, 1969.

6. Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 2, 2d Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B–25, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3305, to read as follows:

### § 866.3305 Herpes simplex virus serological reagents.

(a) *Identification.* Herpes simplex virus serological reagents are devices that consist of antigens and antisera used in various serological tests to identify herpes simplex virus antibodies in a patient's serum. Additionally, some of these reagents consist of herpes simplex virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify herpes simplex virus directly from clinical specimens and/or tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by herpes simplex viruses and provides epidemiological information on these diseases. Herpes simplex viral infections range from common and mild lesions of the skin and mucous membranes to a severe

form of encephalitis (inflammation of the brain).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11789 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2173]**

## Medical Devices; Classification of Histoplasma Capsulatum Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Histoplasma capsulatum* serological Reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee made the following recommendation regarding the classification of *Histoplasma capsulatum* serological reagents:

1. Identification: *Histoplasma capsulatum* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Histoplasma capsulatum* antibodies in a patient's serum. Additionally, some of these reagents consist of *Histoplasma capsulatum* antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Histoplasma capsulatum* from clinical specimens and/or cultures isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genus *Histoplasma* and provides epidemiological information on diseases caused by this fungus. Histoplasmosis usually is a mild and often a symptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and organs.

2. Recommended classification: Class II. (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that *Histoplasma capsulatum* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Cherry and Reimer (Ref. 1) included fluorescent antibody reagents for *Histoplasma capsulatum* among several major immunofluorescent reagents requiring standardization. The need for standardization is seen in a study by Kaufman (Ref. 2), who described two *Histoplasma capsulatum* antigen serological reagents suitable for use in the complement fixation test (an alternative serological test). This investigator warns that interpretation of the test results using this device may be difficult because of the commonly observed cross-reactivity and nonspecificity of these two reagents. DiSalvo and Corbet (Ref. 3) reported false-positive histoplasmin latex agglutination reactions in specimens from patients who apparently did not have histoplasmosis, but had proven tuberculosis. These investigators suggested that the false-positive reactions observed were due, in part, to the limited specificity of the antigen reagents. Serological evidence is often the prime factor responsible for a definitive diagnosis of histoplasmosis because diagnosis cannot always be proven by cultural isolation or histologic examination. Moreover, the fluorescent antibody technique is frequently used for rapid screening of clinical materials to identify *Histoplasma capsulatum.* The Panel believes that general controls would not provide sufficient control over the device's accuracy, titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The clinical experience of the Panel and its familiarity with the literature have disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity and titer (Refs. 1, 2, and 3). The Panel is aware of the availability of reference materials, performance specifications and evaluation methods for these reagents (Ref. 4).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of histoplasmosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to identify *Histoplasma capsulatum* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Histoplasma capsulatum* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials, 4.

Diagnostic Immunofluorescence," *World Health Organization Bulletin*, 48:737–745, 1973.

2. Kaufman, L., "Serodiagnosis of Fungal Diseases," *in* "Manual of Clinical Microbiology," 2d Ed., edited by Lenette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 561–563, 1974.

3. DiSalvo, A. F. and D. S. Corbett, "Apparent False-Positive Histoplasmin Latex Agglutination Tests in Patients with Tuberculosis," *Journal of Clinical Microbiology*, 3(3):306–308, 1976.

4. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–15–18, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3320, to read as follows:

**§ 866.3320 Histoplasma capsulatum serological reagents.**

(a) *Identification. Histoplasma capsulatum* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Histoplasma capsulatum* antibodies in a patient's serum. Additionally, some of these reagents consist of *Histoplasma capsulatum* antisera conjugated with a fluorescent dye (Immunofluorescent reagents) used to identify *Histoplasma capsulatum* from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of histoplasmosis caused by this fungus belonging to the genus *Histoplasma* and provides epidemiological information on the diseases caused by this fungus. Histoplasmosis usually is a mild and often asymptomatic respiratory infection, but in a small number of infected individuals the lesions may spread to practically all tissues and organs.

(b) *Classification.* Class II (performance standards).

Interested persons may on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affiars.*

[FR Doc. 80–11790 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2174]**

## Medical Devices; Classification of Influenza Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying influenza virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of influenza virus serological reagents:

1. Identification: Influenza virus serological reagents are devices that consist of antigens and antisera and used in serological tests to identify influenza virus antibodies in a patient's serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that influenza virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of influenza virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for this disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of influenza virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of the infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that influenze virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3330, to read as follows:

**§ 866.3330 Influenza virus serological reagents.**

(a) *Identification.* Influenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify influenza antibodies in a patient's serum. The identification aids in the diagnosis of influenza (flu) and provides epidemiological information on influenza. Influenza is an acute respiratory tract disease, which is often epidemic.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11791 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2175]**

## Medical Devices; Classification of Klebsiella spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Klebsiella* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panal, an FDA advisory committee, made the following recommendation regarding the classification of *Klebsiella* spp. serological reagents:

1. Identification: *Klebsiella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify *Klebsiella* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of infections caused by bacteria belonging to the genus *Klebsiella* and provides epidemiological information on diseases caused by *Klebsiella* spp. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Klebsiella* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Klebsiella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Klebsiella* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3340 as follows:

**§ 866.3340 Klebsiella spp. serological reagents.**

(a) *Identification. Klebsiella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), that are used in serological tests to identify *Klebsiella* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of infections caused by bacteria belonging to the genus *Klebsiella* and provides epidemiological information on diseases caused by *Klebsiella* spp. These organisms can cause serious urinary tract and pulmonary infections, particularly in hospitalized patients.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 6, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11792 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N-2176]

## Medical Devices; Classification of Leptospira spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Leptospira* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Leptospira* spp. serological reagents:

1. Identification: *Leptospira* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Leptospira* spp. in a patient's serum and/or identification of *Leptospira* spp. from cultured isolates dervied from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify *Leptospira* spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genus *Leptospira* and provides epidemiological information on this disease. Leptospirosis infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that *Leptospira* spp. serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The clinical experience of the Panel members has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these devices (Ref. 1). The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of leptospirosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Leptospira* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the *Leptospira* spp. serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1-15, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3350, to read as follows:

**§ 866.3350 Leptospira spp. serological reagents.**

(a) *Identification. Leptospira* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify antibodies to *Leptospira* spp. in a patient's serum and/or identification of *Leptospira* spp. from cultured isolates derived from clinical specimens. Additionally, some of these antisera are conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify *Leptospira* spp. directly from clinical specimens. The identification aids in the diagnosis of leptospirosis caused by bacteria belonging to the genus *Leptospira* and provides epidemiological information on this disease. Leptospirosis infections range from mild fever-producing illnesses to severe liver and kidney involvement producing hemorrhage and dysfunction of these organs.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs*

[FR Doc. 80-11793 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

## 21 CFR Part 866

**[Docket No. 78N-2177]**

## Medical Devices; Classification of "Listeria" spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Listeria* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Listeria* spp. serological reagents:

1. Identification: *Listeria* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Listeria* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Listeria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Listeria* spp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus *Listeria*, and provides epidemiological information on diseases caused by these microorganisms. *Listeria monocytogenes*, the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for the infant before or after birth.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Listeria* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes that serological diagnosis of listeriosis is seldom performed because test results are often difficult to interpret. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of listeriosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Listeria* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and its proposing that *Listeria* ssp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3355, to read as follows:

**§ 866.3355 Listeria spp. serological reagents.**

(a) *Identification. Listeria* ssp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Listeria* ssp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Listeria* ssp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Listeria* ssp. directly from clinical specimens. The identification aids in the diagnosis of listeriosis, a disease caused by bacteria belonging to the genus *Listeria*, and provides epidemiological information on diseases caused by these micoorganisms. *Listeria monocytogenes*, the most common human pathogen of this genus, causes meningitis (inflammation of the brain membranes) and meningoencephalitis (inflammation of the brain and brain membranes) and is often fatal if untreated. A second form of human listeriosis is an intrauterine infection in pregnant women that results in a high mortality rate for infants before or after birth.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc 80-11794 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

## 21 CFR Part 866

**[Docket No. 78N-2178]**

## Medical Devices; Classification of Lymphocytic Choriomeningitis Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lymphocytic choriomeningitis virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lymphocytic choriomeningitis virus serological reagents:

1. Identification: Lymphocytic choriomeningitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify lymphocytic choriomeningitis virus antibodies in a patient's serum. The identification aids in the diagnosis of lymphocytic choriomeningitis virus infection and provides epidemiological information on diseases caused by this virus. Lymphocytic choriomeningitis virus usually causes a mild cerebral meningitis (inflammation of membranes that envelop the brain) and occasionally a mild pneumonia, but in rare instances may produce severe and even fatal illnesses due to complications from cerebral meningitis and pneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that lymphocytic choriomeningitis virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of lymphocytic choriomeningitis virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection of other individuals or communities. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the device.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of lymphocytic choriomeningitis virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lymphocytic choriomeningitis virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide a reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 is Subpart D by adding new § 866.3360, to read as follows:

### § 866.3360 Lymphocytic choriomeningitis virus serological reagents.

(a) *Identification.* Lymphocytic choriomeningitis virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify limphocytic choriomeningitis virus antibodies in a patient's serum. The identification aids in the diagnosis of lymphocytic choriomeningitis virus infection and provides epidemiological information on diseases caused by this virus. Lymphocytic choriomeningitis virus usually causes a mild cerebral meningitis (inflammation of membranes that envelop the brain) and occasionally a mild pneumonia, but in rare instances may produce severe and even fatal illnesses due to complications from cerebral meningitis and pneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11795 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2179]**

## Medical Devices; Classification of Mycobacterium Tuberculosis Immunofluorescent Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Mycobacterium tuberculosis* immunofluorescent reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30

days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Mycobacterium tuberculosis* immunofluorescent reagents:

1. Identification: *Mycobacterium tuberculosis* immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Mycobacterium tuberculosis* directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. *Mycobacterium tuberculosis* is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Mycobacterium tuberculosis* immunofluorescent reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of these devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of tuberculosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Mycobacterium tuberculosis* may contribute to epidemiological misinformation. Consequently, an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Mycobacterium tuberculosis* immunofluorescent reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3370, to read as follows:

**§ 866.3370 Mycobacterium tuberculosis immunofluorescent reagents.**

(a) *Identification: Mycobacterium tuberculosis* immunofluorescent reagents are devices that consist of antisera conjugated with a fluorescent dye used to identify *Mycobacterium tuberculosis* directly from clinical specimens. The identification aids in the diagnosis of tuberculosis and provides epidemiological information on this disease. *Mycobacterium tuberculosis* is the common causative organism in human tuberculosis, a chronic infectious disease characterized by formation of tubercles (small rounded nodules) and tissue necrosis (destruction), usually occurring in the lung.

(b) *Classification:* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857 written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11796 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2180]**

## Medical Devices; Classification of Mycoplasma spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Mycoplasma* spp. serologial reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Mycoplasma* spp. serological reagents:

1. Identification: *Mycoplasma* spp. serological reagents are devices that consist of antigens and antisera used is serological tests to identify *Mycoplasma* spp. antibodies

in a patient's serum. Additionally, some of these reagents consist of *Mycoplasma* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Mycoplasma* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Mycoplasma* and provides epidemiological information on diseases caused by these microorganisms. *Mycoplasma* spp. are associated with inflammatory conditions of the urinary and respiratory tracts, the genitals, and the mouth. The effects in humans of infection with *Mycoplasma pneumoniae* range from inapparent infection to mile or severe upper respiratory disease, ear infection, and bronchial pneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Mycoplasma* spp. serological reagents be classified into class I because the panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of *Mycoplasma* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Mycoplasma* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3375, to read as follows:

**§ 866.3375 Mycoplasma spp. serological reagents.**

(a) Identification: *Mycoplasma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Mycoplasma* spp. antibodies in a patient's serum. Additionally, some of these reagents consist of *Mycoplasma* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Mycoplasma* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Mycoplasma* and provides epidemiological information on diseases caused by these microorganisms. *Mycoplasma* spp. are associated with inflammatory conditions of the urinary and respiratory tracts, the genitals, and the mouth. The effects in humans of infection with *Mycoplasma pneumoniae* range from inapparent infection to mild or severe upper respiratory disease, ear infection, and bronchial pneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11797 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2181]**

## Medical Devices; Classification of Mumps Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying mumps virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of mumps virus serological reagents:

1. Identification: Mumps virus serological reagents consist of antigens and antisera used in serological tests to identify mumps virus antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used in serological tests to identify mumps viruses from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of mumps and provides epidemiological information on mumps. Mumps is an acute contagious disease, particularly in children, characterized by an enlargement of one or both of the parotid glands (glands situated near the ear), although other organs may also be involved.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that mumps virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of mumps virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes there is currently no

specific treatment for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of mumps viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that mumps virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3380, to read as follows:

**§ 866.3380 Mumps virus serological reagents.**

(a) *Identification.* Mumps virus serological reagents consist of antigens and antisera used in serological tests to identify mumps virus antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used in serological tests to identify mumps viruses from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of mumps and provides epidemiological information on mumps. Mumps is an acute contagious disease, particularly in children, characterized by an enlargement of one or both of the parotid glands (glands situated near the ear), although other organs may also be involved.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11798 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2182]**

## Medical Devices; Classification of Neisseria spp. Direct Serological Test Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Neisseria* spp. direct serological test reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Neisseria* spp. direct serological test reagents:

1. Identification: *Neisseria* spp. direct serological test reagents are devices that consist of antigens and antisera used in serological tests to identify *Neisseria* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of *Neisseria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) which may be used to detect the presence of *Neisseria* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria*, such as epidemic cerebrospinal meningitis, meningococcal disease, and gonorrhea, a venereal disease, and also provides epidemiological information on diseases caused by these microorganisms. The device does not include products for the detection of gonorrhea in humans by indirect methods, such as detection of antibodies or of oxidase produced by gonococcal organisms.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for these devices be a high priority.

3. Summary of reasons for the recommendation: The Panel recommends that *Neisseria* spp. direct serological test reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. There is a need for standardization since cross-reactions (lack of specificity) among *Neisseria* spp. and other unrelated bacteria are frequently encountered with immunofluorescent reagents as well as with other serological reagents (Refs. 1 and 2). Cherry and Reimer (Ref. 3) included fluorescent antibody reagents for *Neisseria gonorrhoeae* and *Neisseria meningitidis* among major immunofluorescent reagents requiring the highest priority for standardization. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience

of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer (Refs. 1, 2, and 3). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 4). *Neisseria meningitidis* is the prominent cause of epidemic cerebrospinal meningitis, an inflammation of the brain and spinal cord membranes. Meningococcemia is a form of membrane disease not involving the membranes which envelope the brain or spinal cord, that may result from invasion of the blood stream by *Neisseria meningitidis*. The resulting blood infection may cause massive hemorrhage near the kidneys accompanied by widespread blood coagulation within the blood vessels. If the above conditions are undetected and untreated, the outcome is usually fatal. Gonorrhea is a highly contagious venereal disease usually transmitted by sexual intercourse, but which may also be acquired by a newborn from the mother. *Neisseria gonorrhoeae* is characterized in men by acute pus producing inflammation of the urethra and in women by inflammation of the cervix. Infection may also spread to the joints resulting in a condition called gonococcal arthritis. Immunofluorescent microscopy is frequently used to detect *Neisseria* spp. in various body fluids such as cerebrospinal fluid and the synovial fluid in joint cavities.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Neisseria* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Neisseria* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Neisseria* spp. direct serological test reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

The proposed regulation would not apply to products for the detection of gonorrhea in humans by indirect methods, such as by detection of antibody or of oxidase produce by gonorrhea organisms. Such products were declared to be new drugs in a notice published in the **Federal Register** of January 29, 1974 (39 FR 3705). The products are now class III devices subject to premarket approval because the Medical Device Amendments of 1976 broadened the definition of device (21 U.S.C. 321(h)) and classified into class III those devices that FDA had previously declared to be new drugs (21 U.S.C. 360j(1)).

### References

1. Collin, B. W., *"Neisseria meningitidis* (Meningococcus)," *in* "Manual of Clinical Microbiology," 2d Ed., Edited by Lennette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 116–123, 1974.

2. Kellog, D. S., Jr. *"Neisseria gonorrhoeae* (Gonococcus)," *in* "Manual of Clinical Microbiology," 2d Ed., Edited by Lennette, E. H., E. H. Spaulding, and J. P. Truant, American Society for Microbiology, Washington, DC, pp. 124–129, 1974.

3. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Material, 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin*, 48:737–745, 1973.

4. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Volume 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B–111–12, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3390, to read as follows:

### § 866.3390 Neisseria spp. direct serological test reagents

(a) *Identification. Neisseria* spp. direct serological test reagents are devices that consist of antigens and antisera used in serological tests to identify *Neisseria* spp. from cultured isolates. Additionally, some of these reagents consist of *Neisseria* spp. antisera conjugated with a fluorescent dye (immunofluorescent reagents) which may be used to detect the presence of *Neisseria* spp. directly from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Neisseria*, such as epidemic cerebrospinal memingitis, meningococcal disease, and gonorrhea, a venereal disease, and also provides epidemiological information on diseases caused by these microorganisms. The device does not include products for the detection of gonorrhea in humans by indirect methods, such as detection of antibodies or of oxidase produced by gonococcal organisms.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affiars.*

[FR Doc. 80–11799 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2183]**

## Medical Devices; Classification of Parainfluenza Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying parainfluenza virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**
Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of parainfluenza virus serological reagents:

1. Identification: Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify parainfluenza virus antibodies in a patient's serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause many respriatory illnesses ranging from the common cold to pneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that parainfluenza virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of parainfluenza virus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the diseases cause by this virus (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of parainfluenza viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that parainfluenza virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3400, to read as follows:

**§ 866.3400 Parainfluenza virus serological reagents.**

(a) *Identification.* Parainfluenza virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify parainfluenza virus antibodies in a patient's serum. The identification aids in the diagnosis of parainfluenza virus infections and provides epidemiological information on diseases caused by these viruses. Parainfluenza viruses cause many respiratory illnesses ranging from the common cold to pneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**
*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11800 Filed 4–21–80; 8:45 am]
BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2184]**

## Medical Devices; Classification of Poliovirus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying poliovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**
Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of poliovirus serological reagents:

1. Identification: Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify poliovirus antibodies in a patient's serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis and provides epidemiological information on this disease. Poliomyelitis (polio) is an acute infectious disease, which in its serious form affects the central nervous system. Polio virus can destroy portions of the spinal cord motor neuronn, causing debilitating paralysis.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that poliovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of poliovirus infection by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: failure of the device to detect the presence of polioviruses, may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that poliovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3405, to read as follows:

**§ 866.3405 Poliovirus serological reagents.**

(a) *Identification.* Poliovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify poliovirus antibodies in a patient's serum. Additionally, some of these reagents consist of poliovirus antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify polioviruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of poliomyelitis and provides epidemiological information in this disease. Poliomyelitis (polio) is an acute infectious disease, which in its serious form affects the central nervous system.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11801 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2185]**

## Medical Devices; Classification of Proteus spp. (Weil-Felix) Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Proteus* spp. (Weil-Felix) serological reagents into class I (general controls). The FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Proteus* spp. (Weil-Felix) serological reagents:

1. Identification: *Proteus* spp. (Weil-Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium *Proteus vulgaris* used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to reckettsia (virus-like bacteria) in a patient's serum. Test results aid in the diagnosis of diseases caused by rickettsia, such a typhus fever and rocky mountain spotted fever, and provides epidemiological information on these diseases. The Panel reviewed this generic type of device identified by the name "*Proteus* spp. serological reagents."

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Proteus* spp. (Weil-Felix) serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases; such as typhus fever and rocky mountain spotted fever. Inappropriate therapy based on inaccurate diagnositc data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of rocky

mountain spotted fever and typhus fever may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Proteus* ssp. (Weil-Felix) serological reagents be classified into class I (general controls) and with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3410, to read as follows:

**§ 866.3410 Proteus spp. (Weil-Felix) serological reagents.**

(a) *Identification. Proteus* spp. (Weil—Felix) serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), derived from the bacterium *Proteus vulgaris* used in agglutination tests (a specific type of antigen-antibody reaction) for the detection of antibodies to rickettsia (virus-like bacteria) in a patient's serum. Test results aid in the diagnosis of disease caused by rickettsia, such as typhus fever and rocky mountain spotted fever, and provides epidemiological information on these diseases.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc 80-11802 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

**21 CFR Part 866**

**[Docket No. 78N–2186]**

## Medical Devices; Classification of Pseudomonas spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Pseudomonas* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Pseudomonas* spp. serological reagents:

1. Identification: *Pseudomonas* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identify *Pseudomonas* spp. from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Pseudomonas. Pseudomonas aeruginosa* is a major cause of hospital-acquired infections, and has been associated with urinary tract infections, eye infections, burn and wound infections, blood poisoning, abscesses, and meningitis (inflamation of brain membranes). *Pseudomonas pseudomallei* causes melioidosis, a chronic pneumonia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that *Pseudomonas* spp. serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer (Refs. 1, 2, and 3). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 4). Johnson, et al. (Ref. 1), Cherry, et al., and Moody (Ref. 2) warn of the lack of precision in testing performed with commercial immunofluorescent reagents and advocate the need for their standardization. Fox, et al. (Ref. 3) advise clinicians to test carefully the sensitivity and specificity of commercially produced reagents because of their observed variability. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disease caused by *Pseudomonas* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Pseudomonas* spp. serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency

also believes that there is sufficient information to establish a performance standard for these devices.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Johnson, G. D., E. H. Beutner, and E. J. Holborow, "Developments in Immunofluorescence: The Need for Standardization," *Journal of Clinical Pathology*, 20:720–723, 1967.

2. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials, 4. Diagnostic Immunofluoresence," *World Health Organiztion Bulletin*, 48(6):737–745, 1973.

3. Fox, H. A., et al., "Immunofluorescence in the Diagnosis of Acute Bacterial Meningitis: A Cooperative Evaluation of the Technique in a Clinical Laboratory Setting," *Pediatrics*, 43(1):44–49, 1969.

4. "Specification and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1–19, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3415, to read as follows:

**§ 866.3415 Pseudomonas spp. serological reagents.**

(a) *Identification. Pseudomonas* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used to identify *Pseudomonas* spp. from clinical specimens and/or from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Pseudomonas*. *Pseudomonas aeruginosa* is a major cause of hospital-acquired infections, and has been associated with urinary tract infections, eye infections, burn and wound infections, blood poisoning, absecesses, and meningitis (inflammation of brain membranes). *Pseudomonas pseudomallei* causes melioidosis, a chronic pneumonia.

(b) *Classification.* Class II (performance standards.)

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11803 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2187]**

## Medical Devices; Classification of Rabiesvirus Immunofluorescent Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rabiesvirus immunofluorescent reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rabiesvirus immunofluorescent reagents:

1. Identification: Rabiesvirus immunofluorescent reagents are devices that consist of rabiesvirus antisera conjugated with a fluorescent dye used to identify rabiesviruses in specimens taken from suspected rabid animals. The identification aids in the diagnosis of rabies in patients exposed by animal bite and provides epidemiological information on rabies. Rabies is an acute infectious disease of the central nervous system which, if undiagnosed, may be fatal. The disease is commonly transmitted to humans by a bite from a rabid animal.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that rabiesvirus immunofluorescent reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Therefore, it is extremely important to be able to demonstrate accurately whether rabiesviruses are present in an animal that has bitten someone. The fluorescent rabies antibody test makes possible a rapid diagnosis in cases of animal rabies. Cherry and Reimer (Ref. 1) included immunofluorescent reagents for rabiesviruses as high-priority reagents requiring standardization. The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods (Refs. 6 and 7) for the devices.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1–7).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of these devices to perform satisfactorily may lead to an error in the diagnosis of rabies. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

(b) Epidemiological misinformation: Failure of the device to detect the presence of rabiesviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that rabiesvirus immuofluorescent reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency also believes that there is sufficient information to establish a performance standard for these devices.

**References**

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Material, 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin*, 48(6):737–745, 1973.

2. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 2, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C1–2–6, 1974.

3. Johnson, H. N., "Rabiesvirus," *Diagnostic Procedures for Viral and Rickettsial Infections*, 4th Ed., edited by Lennette, E. H. and N. J. Schmidt, American Public Health Association, Inc., New York, pp. 312–353, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3460, to read as follows:

**§ 866.3460 Rabiesvirus immunofluorescent reagents.**

(a) *Identification.* Rabiesvirus immunofluorescent reagents are devices that consist of rabiesvirus antisera conjugated with a fluorescent dye used to identify rabiesviruses in specimens taken from suspected rabid animals. The identification aids in the diagnosis of rabies in patients exposed by animal bite and provides epidemiological information on rabies. Rabies is an acute infectious disease of the central nervous system which, if undiagnosed, may be fatal. The disease is commonly transmitted to humans by a bite from a rabid animal.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments, are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11804 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2188]**

## Medical Devices; Classification of Reovirus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying reovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of reovirus serological reagents:

1. Identification: Reovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify reovirus antibodies in a patient's serum. The identification aids in the diagnosis of reovirus infections and provides epidemiological information on diseases caused by these viruses. Reoviruses are thought to cause only mild respiratory and gastrointestinal illnesses.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that reovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of reovirus infections by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of reoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that reovirus serological reagents be

classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3470, to read as follows:

**§ 866.3470 Reovirus serological reagents.**

(a) *Identification.* Reovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify reovirus antibodies in a patient's serum. The identification aids in the diagnosis of reovirus infections and provides epidemiological information on diseases caused by these viruses. Reoviruses are thought to cause only mild respiratory and gastrointestinal illnesses.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11805 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2189]**

## Medical Devices; Classification of Respiratory Syncytial Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying respiratory syncytial virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of respiratory syncytial virus serological reagents:

1. Identification: Respiratory syncytial virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify respiratory syncytial virus antibodies in a patient's serum. Additionally, some of these reagents consist of respiratory syncytial virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify respiratory syncytial viruses from clinical specimens and/or from tissue culture isolates derived from clinical specimens. The identification aids in the diagnosis of respiratory syncytial virus infections and provides epidemiological information on diseases caused by these viruses. Respiratory syncytial viruses cause a number of respiratory tract infections, including the common cold, pharyngitis, and infantile bronchopneumonia.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that respiratory syncytial virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of respiratory syncytial virus infections by serological methods is often retrospective since the patient generally recovers (or succumbs) from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infections to other individuals or communities. The Panel has noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of respiratory syncytial viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that respiratory syncytial virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3480, to read as follows:

**§ 866.3480 Respiratory syncytial virus serological reagents.**

(a) *Identification.* Respiratory syncytial virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify respiratory syncytial virus antibodies in a patient's serum. Additionally, some of these reagents consists of respiratory syncytial virus antisera conjugated with a fluorescent dye (immunofluorescent reagents) and used to identify respiratory syncytial viruses from clinical specimens and/or from tissue culture isolates derived from clincial specimens. The identification

aids in the diagnosis of respiratory syncytial virus infections and provides epidemiological information on diseases caused by these viruses. Respiratory syncytial viruses cause a number of respiratory tract infections, including the common cold, pharyngitis, and infantile bronchopneumonia.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11806 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2190]**

## Medical Devices; Classification of Rhinovirus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rhinovirus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rhinovirus serological reagents:

1. Identification: Rhinovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rhinovirus antibodies in a patient's serum. The identification aids in the diagnosis of rhinovirus infections and provides epidemiological information on diseases caused by these viruses. Rhinoviruses cause common colds.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rhinovirus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of rhinovirus infections by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treatment for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of rhinoviruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rhinovirus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3490, to read as follows:

**§ 866.3490 Rhinovirus serological reagents.**

(a) *Identification.* Rhinovirus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rhinovirus antibodies in a patient's serum. The identification aids in the diagnosis of rhinovirus infections and provides epidemiological information on diseases caused by these viruses. Rhinoviruses cause common colds.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11807 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2191]**

## Medical Devices; Classification of Rickettsia Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rickettsia serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rickettsia serological reagents:

1. Identification: Rickettsia serological reagents are devices that consist of antigens and antisera used in serological tests to identify rickettsial antibodies in a patient's serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens as well as to detect rickettsial antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Rickettsiae* and provides epidemiological information on rickettsial diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rickettsia serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that serological testing for detection and quantitation of rickettsial antibodies is the method of choice for laboratory diagnosis of rickettsial diseases. The Panel also notes that because the prevalence of rickettsial diseases in the U.S. is low, these reagents are infrequently used. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of these reagents to perform satisfactorily may lead to an error in the diagnosis of diseases caused by rickettsial infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of rickettsia may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rickettsia serological reagents be classified into class I (general controls) with no exemptions. The agency believes that these controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3500, to read as follows:

### § 866.3500 Rickettsia serological reagents.

(a) *Identification.* Rickettsia serological reagents are devices that consist of antigens and antisera used in serological tests to identify rickettsial antibodies in a patient's serum. Additionally, some of these reagents consist of rickettsial antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify rickettsia directly from clinical specimens as well as to detect rickettsial antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Rickettsiae* and provides epidemiological information on rickettsial diseases. Rickettsia are generally transmitted by arthropods (e.g., ticks and mosquitoes) and produce infections in humans characterized by rash and fever (e.g., typhus fever, spotted fever, Q fever, and trench fever).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11808 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2192]**

## Medical Devices; Classification of Rubella Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubella virus serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based

on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubella virus serological reagents:

1. Identification: Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubella virus antibodies in a patient's serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns who had been infected with rubella virus in the uterus may be born with multiple congenital defects (rubella syndrome).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that rubella virus serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient or fetus at risk unnecessarily. There is no specific treatment for rubella infection unless the patient has laboratory-proven rubella and is a pregnant woman in first 10 weeks of pregnancy, in which case abortion may be considered to avoid birth of malformed infants. Laboratory-proven rubella in the first 10 weeks of pregnancy is usually associated with fetal infection. Serological testing for detection of rubella virus antibodies is the method of choice for laboratory diagnosis of rubella infections. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience of the Panel and its familiarity with the literature has disclosed appreciable variation in these tests regarding their sensitivity, specificity, and titer (Refs. 1 through 4). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for some of the reagents (Refs. 5 and 6). Lennette, Schmidt, and Magoffin (Ref. 1) compared the results obtained with four conventional tests used in the diagnosis of rubella virus infections and reported discrepant results. The hemagglutination inhibition (HI) test (one of the four tests mentioned above) is one of the most commonly used in the diagnosis of rubella. The reliability of the rubella test depends on the removal of nonspecific serum hemagglutination inhibitors from a patient's serum. Schmidt and Lennette (Ref. 2) reported false-negative false-positive reactions with all three of the methods used to remove nonspecific serum hemagglutination inhibitors from serum. Haukenes and Blom (Ref. 3) observed variable quality in different batches of dextran sulfate used in the dextran sulfate/calcium chloride method of the HI test. Data (unpublished) from the premarket testing program (1971–1975) at the Center for Disease Control (CDC) demonstrate the variability of these reagents when compared with CDC's performance requirements (Ref. 4).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of these devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by rubella virus. Inappropriate therapy based on inaccurate diagnostic data may place the patient or fetus at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of rubella virus may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the rubella virus serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Lennette, E. H., N. J. Schmidt, and R. L. Magoffin, "The Hemagglutination Inhibition Test for Rubella: A Comparison of Its Sensitivity to That of Neutralization, Complement Fixation, and Fluorescent Antibody Tests for Diagnosis of Infection and Determination of Immune Status," *Journal of Immunology*, 99:785–793, 1967.

2. Schmidt, N. J. and E. H. Lennette, "Variables in the Rubella Hemagglutination Inhibition Test System and Their Effect on Antigen and Antibody Titers," *Applied Microbiology*, 19:491–504, 1970.

3. Haukenes, G. and H. Blom, "False-Positive Rubella Virus Hemagglutination Inhibition Reaction: Occurrence and Disclosure," *Medical Microbiology and Immunology*, 161:99–106, 1975.

4. "Results of a Five Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products," Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare (unpublished).

5. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 2, 2d Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B–25, 1974.

6. Plotkin, S. A., "Rubella Virus," *in* "Diagnostic Procedures for Viral and Ricksettsial Infections," 4th Ed., edited by Lennette, E. H. and N. J. Schmidt, American Public Health Association, Inc., New York, pp. 364–413, 1969.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3510, to read as follows:

### § 866.3510 Rubella virus serological reagents.

(a) *Identification.* Rubella virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubella virus antibodies in a patient's serum. The identification aids in the diagnosis of rubella (German measles) or confirmation of a person's immune status from past infections or immunizations and provides epidemiological information on German measles. Newborns infected in the uterus with rubella virus may be born with multiple congenital defects (rubella syndrome).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before April 21, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11809 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2193]**

## Medical Devices; Classification of Rubeola (Measles) Virus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rubeola (measles) virus serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rubeola virus serological reagents:

1. Identification: Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubeola (measles) virus antibodies in a patient's serum. The identification aids in the diagnosis of measles and provides epidemiological information on measles. Measles is an acute, highly infectious disease, particularly in children, characterized by a confluent and blotchy rash.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rubeola virus serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of rubeola virus infections by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is no specific treatment at this time for the disease(s) (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of rubeola viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rubeola virus serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3520, to read as follows:

**§ 866.3520 Rubeola (measles) virus serological reagents.**

(a) *Identification.* Rubeola (measles) virus serological reagents are devices that consist of antigens and antisera used in serological tests to identify rubeola (measles) virus antibodies in a patient's serum. The identification aids in the diagnosis of measles and provides epidemiological information on measles. Measles is an acute, highly infectious disease, particularly in children, characterized by a confluent and blotchy rash.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administation, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m, Monday through Friday.

Dated: March 7, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11810 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2194]**

## Medical Devices; Classification of Salmonella spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Salmonella* ssp. serological reagents into class II (performance standard). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these

devices be classified into class II with the exception of *Salmonella* ssp. immunofluorescent reagents and *Salmonella* spp. antigens, both of which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910. 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classificaiton of Salmonella spp. serological reagents:

1. Identification: *Salmonella* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Salmonella* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to directly identify *Salmonella* spp. from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus *Salmonella* and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever ("enteric fever"), severe diarrhea, and cramps.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Salmonella* spp. serological reagents (antisera only) be classified into class II (performance standards) and that establishing a performance standard for this device be a medium priority. The Panel also recommends that *Salmonella* spp. immunofluorescent reagents and *Salmonella* spp. antigens be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Salmonella* spp. serological reagents (antisera only) be classified into class II because there is need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnositic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Evins, Linne, and Colvin (Ref. 1) evaluated *Salmonella* spp. antisera from six commercial producers. Center for Disease Control (CDC) methods and specifications were used. Results of this study showed that six antisera did not meet CDC performance specifications. Additional data (unpublished) from the CDC's premarket evaluation program for the calendar years 1971 through 1975 demonstrate the variability of these reagents intended to meet CDC specifications (Ref. 2). Forty-five different lots of commercial *Salmonella* somatic antisera were recently evaluated by the CDC, of which 20 percent were found unacceptable. CDC methods and specifications were used in this evaluation (Ref. 3). The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of *Salmonella* spp. antisera regarding their sensitivity, specificity, and titer (Refs. 1 through 4). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 4). The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel further recommends that *Salmonella* spp. antigens and immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in the sensitivity, specificity, and titer of these reagents resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which is the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1 through 11).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Salmonella* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Salmonella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the disseminiation of infections to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation with respect to *Salmonella* spp. serological reagents (excluding antigens and immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Salmonella* spp. antigens and *Salmonella* spp. immunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify these two groups of devices into class I and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to antigens and immunofluorescent reagents. The agency recognizes that the performance characteristics of *Salmonella* spp. serological reagents, including *Salmonella* spp. antigens and immunofluorescent reagents, depends appreciably on how they are manufactured. The agency notes that *Salmonella* spp. antigens and immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the serological reagents consisting of antisera discussed herein. Therefore, the agency is proposing that *Salmonella* spp. antigens and immunofluorescent reagents be classified into class II (performance standards).

The agency believes that a performance standard is necessary for *Salmonella* spp. serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices (Ref. 4).

## References

The following information has been placed in the office of the Hearing Clerk and may be seen by interested persons.

from 9 a.m. to 4 p.m., Monday through Friday.

1. Evins, G. M., L. L. Linne, and H. M. Colvin, "Evaluation of Commercial *Salmonella* O Polyvalent and Vi Antisera," *Journal of Clinical Microbiology*, 4:349–353, 1976.

2. Results of a Five Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

3. Evins, G. M., L. L. Linne, and H. M. Colvin, "Assessment of Availability and Efficacy of Commercial *Salmonella* Grouping Antisera," *Journal of Clinical Microbiology*, 8(4):360–368, 1978.

4. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Volume 1," 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B11–15–24, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3550, to read as follows:

**§ 866.3550 Salmonella spp. serological reagents.**

(a) *Identification. Salmonella* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Salmonella* spp. from cultured isolates derived from clinical specimens. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to directly identify *Salmonella* spp. from clinical specimens and/or cultured isolates derived from clinical specimens. The identification aids in the diagnosis of salmonellosis caused by bacteria belonging to the genus *Salmonella* and provides epidemiological information on this disease. Salmonellosis is characterized by high grade fever ("enteric fever"), severe diarrhea, and cramps.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: March 7, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11611 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2197]**

## Medical Devices; Classification of Schistosoma spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Schistosoma* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elswhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Schistosoma* spp. serological reagents:

1. Identification: *Schistosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Shistosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genus *Schistosoma*. Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer's itch), a skin disease marked by intense itching.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Schistosoma* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Serological testing is often the method of choice for the diagnosis of schistosomiasis. The Panel members have noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of these reagents to perform satisfactorily may lead to an error in the diagnosis of schistosomiasis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Schistosoma* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3600, to read as follows:

**§ 866.3600 Schistosoma spp. serological reagents.**

(a) *Identification. Schistosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Schistosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of schistosomiasis caused by parasitic flatworms of the genus *Schistosoma.* Schistosomiasis is characterized by a variety of acute and chronic infections. Acute infection is marked by fever, allergic symptoms, and diarrhea. Chronic effects are usually severe and are caused by fibrous degeneration of tissue around deposited eggs of the parasite in the liver, lungs, and central nervous system. Schistosomes can also cause schistosome dermatitis (e.g., swimmer's itch), a skin disease marked by intense itching.

(b) *Classification:* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11812 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2198]**

## Medical Devices; Classification of Serratia spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Serratia* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Serratia* spp. serological reagents:

1. Identification: *Serratia* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Serratia* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Serratia* and provides epidemiological information on these diseases. *Serratia* spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Serratia* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members have noted variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can adequately be controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Serratia* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Serratia* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Serratia* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a) , 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3630, to read as follows:

**§ 866.3630 Serratia spp. serological reagents.**

(a) *Identification. Serratia* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Serratia* spp. from cultured isolates. The identification aids in the diagnosis of disease cause by bacteria belonging to the genus *Serratia* and provides epidemiological information on these diseases. *Serratia* spp. are occasionally associated with gastroenteritis (food poisoning) and wound infections.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11813 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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21 CFR Part 866

[Docket No. 78N-2199]

## Medical Devices; Classification of Shigella spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Shigella* spp. serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Shigella* spp. serological reagents:

1. Identification: *Shigella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used in serological tests to identify *Shigella* spp. from cultured isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genus *Shigella* and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that *Shigella* spp. serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel recognizes certain serological groups of *Shigella* are more infectious than other groups. Consequently, serological identification of *Shigella* spp. isolates is particularly important for epidemiological information on *Shigella* spp. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard. The clinical experience of the Panel members has disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications and evaluation methods for these reagents (Ref. 1).

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of shigellosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Shigella* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Shigella* spp. serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

### References

The following information has been places in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B11-25-28, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3660, to read as follows:

**§ 866.3660 Shigella spp. serological reagents.**

(a) *Identification. Shigella* spp. serological reagents are devices that consist of antigens and antisera, including antisera conjugated with a fluorescent dye (immunofluorescent reagents), used in serological tests to identify *Shigella* spp. from cultural isolates. The identification aids in the diagnosis of shigellosis caused by bacteria belonging to the genus *Shigella* and provides epidemiological information on this disease. Shigellosis is characterized by abdominal pain, cramps, diarrhea, and fever.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11814 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2200]**

## Medical Devices; Classification of Sporothrix Schenckii Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Sporothrix schenckii* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Sporothrix schenckii* serological reagents:

1. Identification: *Sporothrix schenckii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Sporothrix schenckii* antibodies in a patient's serum. The identification aids in the diagnosis of sporothrichosis caused by a fungus belonging to the genus *Sporothrix* and provides epidemiological information on this disease. Sporothrichosis is a chronic tumorlike infection primarily of the skin.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Sporothrix schenckii* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel believes that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturer compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of sporothrichosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Sporothrix schenckii* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Sporothrix schenckii* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3680, to read as follows:

**§ 866.3680 Sporothrix schenckii serological reagents.**

(a) *Identification. Sporothrix schenckii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Sporothrix schenckii* antibodies in a patient's serum. The identification aids in the diagnosis of sporothrichosis caused by a fungus belonging to the genus *Sporothrix* and provides epidemiological information on this disease. Sporothrichosis is a chronic tumorlike infection primarily of the skin.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11815 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2201]**

## Medical Devices; Classification of Staphylococcus Aureus Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Staphylococcus aureus* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Staphylococcus aureus* serological reagents:

1. Identification: *Staphylococcus aureus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates derived from food sources. The identification aids in the diagnosis of disease caused by this bacteria belonging to the genus *Staphylococcus* and provides epidemiological information on these diseases. Certain strains of *Staphylococcus aureus* produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and causes destruction of the intestinal lining (gastroenteritis).

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Staphylococcus aureus* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of staphylococcal gastroenteritis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of enterotoxin producing *Staphylococcus aureus* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Staphylococcus aureus* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3700, to read as follows:

**§ 866.3700 Staphylococcus aureus serological reagents.**

(a) *Identification. Staphylococcus aureus* serological reagents are devices that consist of antigens and antisera used in serological tests to identify enterotoxin (toxin affecting the intestine) producing staphylococci from cultured isolates. The identification aids in the diagnosis of disease caused by this bacterium belonging to the genus *Staphylococcus* and provides epidemiological information on these diseases. Certain strains of *Staphylococcus aureus* produce an enterotoxin while growing in meat, dairy, or bakery products. After ingestion, this enterotoxin is absorbed in the gut and cause destruction of the intestinal lining (gastroenteritis).

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11816 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

## 21 CFR Part 866

**[Docket No. 78N–2202]**

## Medical Devices; Classification of Streptococcus spp. Exoenzyme Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Streptococcus* spp. exoenzyme reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Streptococcus* spp. exoenzyme reagents:

1. Identification: *Streptococcus* spp. exoenzyme reagents are devices used in serological tests to identify *Streptococcus* spp. exoenzyme antibodies in a patient's serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo ( an infection characterized

by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that *Streptococcus* spp. exoenzyme reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Many pathogenic streptococci produce and secrete several enzymes (antigens) which induce antibody responses. Serological tests are often used to detect increased levels of these antibodies as an aid in the diagnosis of streptococcal infection. The clinical experience of the Panel members and their familiarity with the literature has disclosed appreciable lot-to-lot variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer (Refs. 1, 2, and 3). Klein and Jones (Ref. 1) compared a multi-enzyme streptozyme test with three individual streptococcal exoenzyme tests, antistreptolysin O (ASO), antideoxyribonuclease B (ADN-B) and antihyaluronidase (AH) and observed that the multi-enzyme test is less sensitive for ADN-B than ASO antibodies. Klein and Jones also observed that the multi-enzyme streptozyme test is less sensitive for multiple antibodies ASO, ADN-B, and AH than are a combination of the conventional ASO, ADN-B, and AH tests. Golubjatnikov, et al. (Ref. 2) compared the streptococcal multi-enzyme test with the conventional ASO and ADN-B tests and observed a low rate of agreement among these tests. Golubjatnikov, et al. also suggested that the upper limits for normal ADN-B titers used by manufacturers of the ADB test kits are too low, indicating standards should be developed to provide normal ranges for the streptococcal enzyme tests. Hederstedt, et al. (Ref. 3) also compared the multi-enzyme test to the ADN-B and AH test and observed considerable discrepancies in the results. Hederstedt, et al. concluded that stricter control of lot-to-lot variations and standardization of the multi-enzyme test reagent is required. The Panel noted that an international standard for Antistreptolysin O has been established (Ref. 4) and could serve as the basis for a performance standard. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Streptococcus* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Streptococcus* spp. exoenzyme antibody may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the *Streptococcus* spp. exoenzyme reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls along are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

### References

The following information has been placed in the office of the Hearing Clerk and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Klein, G. C. and W. L. Jones, "Comparison of the Streptozyme Test with the Antistreptolysin O, Antideoxyribonuclease B, and Antihyaluronidase Tests," *Applied Microbiology*, 21:257–259, 1971.

2. Golubjatnikov, R., J. E. Koehler, and J. Buccowich, "Comparative Study of Antistreptolysin O, Antideoxyribonuclease B, and Multienzyme Tests in Streptococcal Infections," *Health Laboratory Science*, 14(4): 284–290, 1977.

3. Hederstedt, B., S. E. Holm, and T. Wadstrom, "Discrepancy Between Results of the Streptozyme Test and Those of the Antideoxyribonuclease B, and Antihualuronidase Tests," *Journal of clinical Microbiology*, 8:50–53, 1978.

4. Spaun, J., M. W. Bentzon, S.O. Larsen, and L. F. Hewitt, "International Standard for Antistreptolysin-O," *Bullentin of the World Health Organization*, 24:271–279, 1961.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3720, to read as follows:

**§ 866.3720 Streptococcus spp. exoenzyme reagents.**

(a) *Identification. Streptococcus* spp. exoenzyme reagents are devices used to identify *Streptococcus* spp. exoenzyme antibodies in a patient's serum. The identification aids in the diagnosis of disease caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, rheumatic fever, and kidney disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc 80–11817 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No 78N–2203]**

## Medical Devices; Classification of Streptococcus spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Streptococcus* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into Class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of this publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Streptococcus* spp. serological reagents:

1. Identification: *Streptococcus* spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, and with allergic-type reactions such as rheumatic fever, and kidney disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Streptococcus* spp. serological reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel has noted variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Streptococcus* spp. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Streptococcus* spp. may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that *Streptococcus* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3740, to read as follows:

**§ 866.3740 Streptococcus spp. serological reagents.**

(a) *Identification. Streptococcus* spp. serological reagents are devices that consist of antigens and antisera (excluding streptococcal exoenzyme reagents made from enzymes secreted by streptococci) used in serological tests to identify *Streptococcus* spp. from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of diseases caused by bacteria belonging to the genus *Streptococcus* and provides epidemiological information on these diseases. Pathogenic streptococci are associated with infections, such as sore throat, impetigo (an infection characterized by small pustules on the skin), urinary tract infections, and with allergic-type reactions, such as rheumatic fever, and kidney disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11818 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2204]**

## Medical Devices; Classification of Toxoplasma Gondii Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule..

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Toxoplasma gondii* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that these devices be classified into class II with the exception of *Toxoplasma gondii* immunofluorescent reagents which the Panel recommended be classified into class I (general controls). The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides

background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Toxoplasma gondii* serological reagents:

1. Identification: *Toxoplasma gondii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Toxoplasma gondii* antibodies in a patient's serum. Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Toxoplasma gondii* from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan *Toxoplasma gondii* and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

2. Recommended classification: The Microbiology Device Classification Panel recommends that *Toxoplasma gondii* serological reagents (excluding immunofluorescent reagents) be classified into class II (performance standards) and that establishing a performance standard for this device be a high priority. The Panel also recommends that *Toxoplasma gondii* immunofluorescent reagents be classified into class I (general controls) and that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Toxoplasma gondii* serological reagents (excluding immunofluorescent reagents) be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Serodiagnosis is often the method of choice for a definitive diagnosis of toxoplasmosis. The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable lot-to-lot variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 3). Remington (Ref. 1) tested the specificity of a number of commercial immunofluorescent reagents over a period of several years and observed appreciable variability. He advises laboratory personnel of the risk of obtaining false-positive and false-negative test results unless all commercial antisera are tested for specificity prior to use. Further, Remington strongly recommended that commercial antisera meet rigid standards of control for specificity and sensitivity. The Center for Disease Control (CDC) has performance specifications for commercial serological reagents and has been conducting voluntary premarket testing. Over a 6-year period only 49 percent of the products tested by CDC were found to be satisfactory (Ref. 3). Durham and Colvin (Ref. 2) report a decline in performance of immunofluorescent kits indicated by the decrease in the satisfactory incidence rate from 83.3 percent in 1973 to 31.6 percent in the first 6 months of 1977. The Panel believes that general controls would not provide sufficient control over the devices' titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectivenes of the devices and that there is sufficient information to establish a standard. The Panel further recommends that *Toxoplasma gondii* immunofluorescent reagents be classified into class I because the Panel believes general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel members noted variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedures can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases caused by *Toxoplasma gondii*. Inappropriate therapy based on inaccurate diagnositic data may place the patient at risk. False-positive daga may result in treatment with a drug that possesses undesirable side effects; false-negative data, when the patient is an infant or pregnant woman, may prevent necessary treatment and result in damage to the infant or fetus. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Toxoplasma gondii* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

## Proposed Classification

FDA agrees with the Panel recommendation with respect to *Toxoplasma gondii* serological reagents (excluding immunofluorescent reagents) and is proposing that these devices be classified into class II (performance standards). However, FDA disagrees with the Panel recommendation with respect to *Toxoplasma gondii* imunofluorescent reagents and is proposing that these devices be classified into class II (performance standards). The agency has reviewed the Panel recommendation to classify these devices into class I and has sought additional data and documentation on the safety and effectiveness of these devices. The agency has reviewed the available literature pertaining to immunofluorescent reagents. The agency recognizes that the performance characteristics of immunofluorescent reagents depends appreciably on how they are manufactured. The agency notes that immunofluorescent reagents are produced using essentially the same manufacturing procedures as those for the other serological reagents described herein. Therefore, the agency is proposing that *Toxoplasma gondii* immunofluorescent reagents be classified into class II (performance standards).

The agency believes that a performance standard is necessary for *Toxoplasma gondii* serological reagents because general controls alone are insufficient to control the risks to health presented by these devices. A performance standard would provide reasonable assurance of the safety and effectiveness of these devices. The agency also believes that there is sufficient information to establish a standard to provide reasonable assurance of the safety and effectiveness of these devices (Ref. 3).

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Remington, J. S., "Toxoplasmosis in the Adult," *Bulletin of the New York Academy of Medicine*, 50(2): 211–227, 1974.

2. Durham, T. M. and H. M. Colvin, "Premarket Evaluation of Commercial Toxoplasmosis Indirect Fluorescent Antibody Reagents," *Journal of Clinical Microbiology*, 7(3): 255–260, 1978.

3. *Specifications and Evaluation Methods for Immunological and Microbiological Reagents*, Volume 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, C–20–23, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3780, to read as follows:

### § 866.3780 Toxoplasma gondii serological reagents.

(a) *Identification. Toxoplasma gondii* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Toxoplasma gondii* antibodies in a patient's serum.

Additionally, some of these reagents consist of antisera conjugated with a fluorescent dye (immunofluorescent reagents) used to identify *Toxoplasma gondii* from clinical specimens. The identification aids in the diagnosis of toxoplasmosis caused by the parasitic protozoan *Toxoplasma gondii* and provides epidemiological information on this disease. Congenital toxoplasmosis is characterized by lesions of the central nervous system, which if undetected and untreated may lead to brain defects, blindness, and death of an unborn fetus. The disease is characterized in children by inflammation of the brain and spinal cord.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

William F. Randolph,

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11819 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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21 CFR Part 866

[Docket No. 78N–2206]

## Medical Devices; Classification of Treponema Pallidum Nontreponemal Test Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Treponema pallidum* nontreponemal test reagents into class II (performance standard). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. The actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of *Treponema pallidum* nontreponemal test reagents:

1. Identification: *Treponema pallidum* nontreponemal test reagents are devices that consist of antigens and antisera, which are derived from nontreponemal sources (sources not directly associated with treponemal organisms), and other control reagents (standardized reagents with which test results are compared) used to identify reagin, an antibody-like agent, which is produced from the reaction of treponemal microorganisms with certain body tissues. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus *Trenponema* and provides epidemiological information on syphilis. Syphilis is a contagious veneral disease which can lead to many structural and skin-related lesions. It is transmitted by direct sexual contact or to a newborn by an infected mother (congenital syphilis).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that *Treponema pallidum* nontreponemal test reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possiblilty that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel observes that serological testing is presently the only available method for diagnosis of syphilis. The Center for Disease Control (CDC) has performance specifications and reference materials for nontreponemal test reagents. Since 1971 CDC has operated a premarket evaluation program for the voluntary testing of commercially available in vitro diagnostic products, including nontreponemal test reagents for syphilis. The results of the first 5 years (1971 through 1975) of testing demonstrates the variability of these reagents intended to meet CDC specifications (Ref. 1). Black (Ref. 2) reported significantly different sensitivities among three nontreponemal tests when compared to the fluorescent treponemal antibody absorption test (FTA–ABS, a definitive test for syphilis). The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of these reagents with respect to their sensitivity, specificity, and titer (Refs. 1 and 2). The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 3). The causative bacterium is not capable of being cultivated by usual laboratory procedures. Diagnosis based on detection of reagin is regarded as presumptive for syphilis. The Panel believes that general controls would not provide sufficient control over the devices' titer sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of devices and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of syphilis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Treponema pallidum* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Treponema pallidum* nontreponemal test reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance for these devices.

1. Results of a Five Year (1971–1975) Premarket Evaluation Program for

Commercial Microbiology Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

2. Black, D. A., P. E. Ray, and B. L. Therrell, "Quantitative Evaluation of the Reagin Screen Test," *Journal of Clinical Microbiology*, pp. 16–18, July 1976.

3. *Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Vol. 1*, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, BIII–5, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3820, to read as follows:

**§ 866.3820 Treponema pallidum nontreponemal test reagents.**

(a) *Identification. Treponema pallidum* nontreponemal test reagents are devices that consist of antigens derived from nontreponemal sources (sources not directly associated with treponemal organisms) and control sera (standardized sera with which test results are compared) used in serological tests to identify reagin, an antibody-like agent, which is produced from the reaction of treponeme microorganisms with body tissues. The identification aids in the diagnosis of syphilis caused by microorganisms belonging to the genus *Treponema* and provides epidemiological information on syphilis.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m. Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11820 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

**21 CFR Part 866**

**[Docket No. 78N–2207]**

## Medical Devices; Classification of Treponema Pallidum Treponemal Test Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Treponema pallidum* treponemal test reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Treponema pallidum* treponemal test reagents:

1. Identification: *Treponema pallidum* treponemal test reagents are devices that consist of the antigens, antisera and all control reagents (standardized reagents with which tests results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA–ABS), the *Treponema pallidum* immobilization test (T.P.I.), and other treponemal tests used to identify treponemal antibodies (antibodies induced directly from infecting treponemal organisms) in a patient's serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the genus *Treponema* and provides epidemiological information on syphilis. Syphilis is a contagious venereal disease which can lead to many structural and skin-related lesions. It is transmitted either by direct sexual contact or to a newborn by an infected mother (congenital syphilis).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for Panel recommendation: The Panel recommends that *Treponema pallidum* treponemal test reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Procedures for evaluating the fluorescein-labeled anti-human globulin (antibody to human antibody labeled with fluorescein) for the FTA–ABS test have been established (Ref. 1). Hardy (Ref. 2) and Hunter (Ref. 3) have indicated that variation occurs in anti-human conjugate preparations that could affect test results. Cherry, et al. (Ref. 4) examined the purity of commercial preparations from 12 sources of fluorescein isothiocyanate (a fluorescent dye) used for the FTA–ABS test and observed that the purity was highly variable. Scales, Jacobs, and Skaggs reported undesirable immunological specificity in commercial conjugates (Ref. 5). Cherry and Reimer included anti-human globulins as major immunofluorescent reagents requiring a high priority for standardization (Ref. 6). CDC has performance specifications and reference materials for treponemal test reagents. Since 1971, CDC has operated a premarket evaluation program for the voluntary testing of commercially available diagnostic products, including treponemal test reagents. The results of the first 5 years (1971 through 1975) of testing demonstrate the variability of these reagents, some of which do not meet CDC specifications (Ref. 7).

The causative bacterium is not cultivatable by usual laboratory procedures. Diagnosis based on detection of treponemal antibodies is regarded as definitive for syphilis.

The clinical experience of the Panel members and their familiarity with the literature have disclosed appreciable variation in the manufacture of these reagents as to their sensitivity, specificity, and titer (Refs. 2 through 7).

The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel is aware of

the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 8).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 8).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the devices to perform satisfactorily may lead to an error in the diagnosis of syphilis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Treponema pallidum* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that the *Treponema pallidum* treponemal test reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectiveness of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. *Manual of Tests for Syphilis*, U.S. Department of Health, Education, and Welfare, Public Health Service, National Communicable Disease Center, Venereal Disease Program, Atlanta, GA, Pub. No. 411, 1969.

2. Hardy, P. H. and E. E. Nell, "Characteristics of Fluorescein Labelled Antiglobulin Preparations That May Affect the Fluorescent Treponemal Antibody-Absorption Test," *American Journal of Clinical Pathology*, 56:181–186, 1971.

3. Hunter, E. F., J. F. Smith, J. S. Lewis, B. E. McGrew, and J. D. Schmale, "Immunochemical Parameters of Some Commerical Conjugates for the Fluorescent Treponemal Antibody-Absorption Test," *Infection and Immunity*, 5:858–862, 1972.

4. Cherry, W. B., R. M. McKinney, V. M. Emmel, J. T. Spillane, G. A. Hebert, and B. Pittman, "Evaluation of Commercial Fluorescein Isothiocynates Used in Fluorescent Antibody Studies," *Stain Technology*, 44(4):179–186, 1969.

5. Scales, R. W., N. F. Jacobs, Jr., and R. Skaggs, "Use of Immunoglobulin Coupled to Agarose Beads for Examining the Specificity of Conjugates," *Journal of Clinical Microbiology*, 2(4):292–295, 1975.

6. Cherry, W. B. and C. B. Reimer, "Standardization of Diagnostic Materials, 4. Diagnostic Immunofluorescence," *World Health Organization Bulletin*, 48:737–745, 1973.

7. Results of a Five-Year (1971–1975) Premarket Evaluation Program for Commercial Microbiological Diagnostic Products, Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, (unpublished).

8. *Specifications and Evaluation Methods for Immunological and Microbiological Reagents, Vol. 1*, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, BIII–1–11, 1974.

Therefore, under the Federal Food, Drug, Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))] and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3830, to read as follows:

**§ 866.3830 Treponema pallidum treponemal test reagents.**

(a) *Identification. Treponema pallidum* treponemal test reagents are devices that consist of antigens, antisera and all control reagents (standardized reagents with which tests results are compared) which are derived from treponemal sources and that are used in the fluorescent treponemal antibody absorption test (FTA–ABS), the *Treponema pallidum* immobilization test (T.P.I.), and other treponemal tests used to identify treponemal antibodies (antibodies induced directly from infecting treponemal organisms) in a patient's serum. The identification aids in the diagnosis of syphilis caused by bacteria belonging to the *Treponema* and provides epidemiological information on syphilis. Syphilis is a contagious veneral disease which can lead to many structural and skin-related lesions. It is transmitted either by direct sexual contact or to a newborn by an infected mother (congenital syphilis).

(b) *Classification:* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the hearding of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11821 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2208]**

## Medical Devices; Classification of Trichinella Spiralis Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Trichinella spiralis* serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Trichinella spiralis* serological reagents:

1. Identification: *Trichinella spiralis* serological reagents are devices that consist

of antigens and antisera used in serological tests to identify *Trichinella spiralis* antibodies in a patient's serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus *Trichinella* and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Trichinella spiralis* serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel notes variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of trichinosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Trichinella spiralis* may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Trichinella spiralis* serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3850, to read as follows:

**§ 866.3850 Trichinella spiralis serological reagents.**

(a) *Identification. Trichinella spiralis* serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Trichinella spiralis* antibodies in a patient's serum. The identification aids in the diagnosis of trichinosis caused by parasitic roundworms belonging to the genus *Trichinella* and provides epidemiological information on trichinosis. Trichinosis is caused by ingestion of undercooked, infested meat, especially pork, and characterized by fever, muscle weakness, and diarrhea.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11822 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2209]**

## Medical Devices; Classification of Trypanosoma spp. Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Trypanosoma* spp. serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification *Trypanosoma* spp. serological reagents:

1. Indentification: *Trypanosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Trypanosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus *Trypanosoma.* Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that *Trypanosoma* spp. serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. Serological testing is often the preferred method for diagnosis of trypanosomiasis. The Panel notes variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device

to perform satisfactorily may lead to an error in the diagnosis of trypanosomiasis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Trypanosoma* spp. serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3870, to read as follows:

**§ 866.3870 Trypanosoma spp. serological reagents.**

(a) *Identification. Trypanosoma* spp. serological reagents are devices that consist of antigens and antisera used in serological tests to identify *Trypanosoma* spp. antibodies in a patient's serum. The identification aids in the diagnosis of trypanosomiasis, a disease caused by parasitic protozoans belonging to the genus *Trypanosoma.* Trypanosomiasis in adults is a chronic disease characterized by fever, chills, headache, and vomiting. Central nervous system involvement produces typical sleeping sickness syndrome: physical exhaustion, inability to eat, tissue wasting, and eventual death. Chagas disease, an acute form of trypanosomiasis in children, most seriously affects the central nervous system and heart muscle.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11823 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2210]**

## Medical Devices; Classification of Varicella-Zoster Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying varicella-zoster serological reagents into class I (general controls). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of varicella-zoster serological reagents:

1. Identification: Varicella-zoster serological reagents are devices that consist of antigens and antisera used in serological tests to identify varicella-zoster antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that varicella-zoster serological reagents be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recognizes that a definitive diagnosis of varicella-zoster infection by serological methods is often retrospective since the patient generally recovers from the illness before the serodiagnosis can be made. The Panel also notes that there is currently no specific treament for the disease (i.e., there is a lack of available antiviral drug therapy). Consequently, the risk of an incorrect diagnosis relates primarily to the dissemination of infection to other individuals or communities. The Panel notes variation in the manufacture of these reagents as to their sensitivity, specificity, and titer. The Panel believes, however, that any variation in reagent sensitivity, specificity, and titer resulting from manufacturing procedure can be adequately controlled by manufacturers' compliance with labeling requirements and the good manufacturing practice regulation.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the devices and on a history of satisfactory performance of the devices.

5. Risks to health: Epidemiological misinformation: Failure of the device to detect the presence of varicella-zoster viruses may contribute to epidemiological misinformation. Consequently, the risk of an incorrect diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that varicella-zoster serological reagents be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs

proposes to amend Part 866 in Subpart D by adding new § 866.3900, to read as follows:

**§ 866.3900 Varicella-zoster serological reagents.**

(a) *Identification.* Varicella-zoster serological reagents are devices that consist of antigens and antisera used in serological tests to identify varicella-zoster antibodies in a patient's serum. The identification aids in the diagnosis of diseases caused by varicella-zoster viruses and provides epidemiological information on these diseases. Varicella (chicken pox) is a mild, highly infectious disease, chiefly of children. Zoster (shingles) is the recurrent form of the disease, occurring in adults who were previously infected with varicella-zoster viruses. Zoster is the response (characterized by a rash) of the partially immune host to a reactivation of varicella viruses present in latent form in the patient's body.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11824 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**[21 CFR Part 866]**

**[Docket No. 78N–2211]**

## Medical Devices; Classification of Vibrio Cholerae Serological Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying *Vibrio cholerae* serological reagents into class II (performance standards). FDA is also publishing the recommendation of the Microbiology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Thomas M. Tsakeris, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information cond-cerning the development of the proposed regulation. The Microbiology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of *Vibrio cholerae serological reagents:*

1. Identification: *Vibrio cholerae* serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to schock, renal failure, cardiovascular collapse, and death.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that *Vibrio cholerae* serological reagents be classified into class II because there is a need for a performance standard that prescribes for these devices acceptable ranges of titer, sensitivity, and specificity and thereby minimizes the possibility that the devices may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Serological (agglutination) tests are often used to differentiate *Vibrio cholerae* from noncholera vibrios obtained from cultured isolates. The clinical experience of the Panel members has disclosed appreciable variation in the manufacture of these reagents regarding their sensitivity, specificity, and titer. The Panel believes that general controls would not provide sufficient control over the device's titer, sensitivity, and specificity: The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard. The Panel is aware of the availability of reference materials, performance specifications, and evaluation methods for these reagents (Ref. 1).

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Ref. 1).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of cholera. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk. (b) Epidemiological misinformation: Failure of the device to detect the presence of *Vibrio cholerae* may contribute to epidemiological misinformation. Consequently, the risk of an incorrct diagnosis relates to the dissemination of infection to other individuals or communities.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that *Vibrio cholerae* serological reagents be classified into class II (performance standards). The agency believes that a performance standard is necessary for these devices because general controls alone are insufficient to control the risks to health presented by the devices. A performance standard would provide reasonable assurance of the safety and effectivenes of the devices. The agency believes that there is sufficient information to establish a performance standard for these devices.

### References

The following information has been placed in the office of the Hearing Clerk (address above), and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. "Specifications and Evaluation Methods for Immunological and Microbiological Reagents," Vol. 1, 4th Ed., Center for Disease Control, Public Health Service, Department of Health, Education, and Welfare, B1–29–30, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the

Commissioner of Food and Drugs proposes to amend Part 866 in Subpart D by adding new § 866.3930, to read as follows:

**§ 866.3930 Vibrio cholerae serological reagents.**

(a) *Identification. Vibrio cholerae* serological reagents are devices that are used in the agglutination (an antigen-antibody clumping reaction) test to identify *Vibrio cholerae* from cultured isolates derived from clinical specimens. The identification aids in the diagnosis of cholera caused by the bacterium *Vibrio cholerae* and provides epidemiological information on cholera. Cholera is an acute infectious disease characterized by severe diarrhea with extreme fluid and electrolyte (salts) depletion, and by vomiting, muscle cramps, and prostration. If untreated, the severe dehydration may lead to shock, renal failure, cardiovascular collapse, and death.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11825 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2212]**

## Medical Devices; Classification of Complement Reagents

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement reagents into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of complement reagents:

1. Identification: A complement reagent is a device that consists of naturally occurring serum protein from any warm-blooded animal (such as guinea pigs) that may be included as a component part of serological test kits used in the diagnosis of disease.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempt from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that complement reagents be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that complement reagents be exempt from premarket notification procedures under section 510(k) of the act because the Panel believes that premarket notification is not necessary for the protection of the public health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement reagents be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a complement reagent be exempt from section 510(k) of the act (21 U.S.C. 360), FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning a complement reagent. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart E and adding new § 866.4100, to read as follows:

### Subpart E—Immunology Laboratory Equipment and Reagents

**§ 866.4100 Complement reagent.**

(a) *Identification.* A complement reagent is a device that consists of naturally occurring serum protein from any warm-blooded animal (such as guinea pigs) that may be included as a component part of serological test kits used in the diagnosis of disease.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11826 Filed 4-21-80; 8:45 am]

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## 21 CFR Part 866

**[Docket No. 78N-2213]**

## Medical Devices; Classification of Immunoelectrophoresis Equipment

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoelectrophoresis equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATE:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of this publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoelectrophoresis equipment:

1. Identification: Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

2. Recommended classfication: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that immunoelectrophoresis equipment for clinical use be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoelectrophoresis equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4500, to read as follows:

**§ 866.4500 Immunoelectrophoresis equipment.**

(a) *Identification.* Immunoelectrophoresis equipment for clinical use with its electrical power supply is a device used for separating protein molecules. Immunoelectrophoresis is a procedure in which a complex protein mixture is placed in an agar gel and the various proteins are separated on the basis of their relative mobilities in an agar gel under the influence of an electric current. The separated proteins are then permitted to diffuse through the agar toward a multispecific antiserum, allowing precipitation and visualization of the separate complexes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11827 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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## 21 CFR Part 866

**[Docket No. 78N-2214]**

## Medical Devices; Classification of Immunofluorometer Equipment

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunofluorometer equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation.

The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunofluorometer equipment:

1. Identification: Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that immunofluorometer equipment be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunofluorometer equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4520, to read as follows:

**§ 866.4520 Immunofluorometer equipment.**

(a) *Identification.* Immunofluorometer equipment for clinical use with its electrical power supply is a device used to measure the fluorescence of fluorochrome-labeled antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light is passed through a solution in which a fluorochrome has been selectively attached to serum protein antibody molecules in suspension. The amount of light emitted by the fluorochrome label is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the fluorescence value and is used to measure the concentration of antigen-antibody complexes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11828 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2215]**

## Medical Devices; Classification of Immunonephelometer Equipment

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunonephelometer equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunonephelometer equipment:

1. Identification: Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody complexes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that immunonephelometer equipment be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunonephelometer equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4540, to read as follows:

**§ 866.4540 Immunonephelometer equipment.**

(a) *Identification.* Immunonephelometer equipment for clinical use with its electrical power supply is a device that measures light scattering from antigen-antibody complexes. The concentration of these complexes may be measured by means of reflected light. A beam of light passed through a solution is scattered by the particles in suspension. The amount of light is detected by a photodetector, which converts light energy into electrical energy. The amount of electrical energy registers on a readout system such as a digital voltmeter or a recording chart. This electrical readout is called the light-scattering value and is used to measure the concentration of antigen-antibody complexes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affiars.*

[FR Doc. 80–11829 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2216]**

## Medical Devices; Classification of Ouchterlony Agar Plates

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Ouchterlony agar plates into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Ouchterlony agar plates:

1. Identification: An Ouchterlony agar plates for clinical use is a device that containing and agar gel used to examine antigen-antibody reactions In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that Ouchterlony agar plates be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. Although care must be taken during manufacture to ensure that the plates are level, the Panel notes that these plates are extremely simple devices that perform satisfactorily during normal use.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Ouchterlony agar plates be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drug proposes to amend Part 866 in Subpart D by adding new § 866.4600, to read as follows:

**§ 866.4600 Ouchterlony agar plate.**

(a) *Identification:* An Ouchterlony agar plate for clinical use is a device containing an agar gel used to examine antigen-antibody reactions. In immunodiffusion, antibodies and antigens migrate toward each other through gel which originally contained neither of these reagents. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and is immobilized.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857 written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11830 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2217]**

## Medical Devices; Classification of Radial Immunodiffusion Plates

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radial immunodiffusion plates into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of radial immunodiffusion plates:

1. Identification: A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.

2. Recommended classification: Class I (general controls). The Panel recommends that this device be exempted from premarket notification under section 510(k) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(k)).

3. Summary of reasons for recommendation: The Panel recommends that radial immunodiffusion plates be classified into class I because general controls are sufficient to provide reasonable assurance of the safety and effectiveness of these devices. The Panel recommends that radial immunodiffusion plates be exempt from premarket notification under section 510(k) of the act because the Panel believes that premarket notification is not necessary for the protection of the public health.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device. The Panel members note that this is a simple plastic dish.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that radial immunodiffusion plates be classified into class I (general controls). The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

In response to the Panel's recommendation that manufacturers of a radial immunodiffusion plate be exempt from section 510(k) of the act (21 U.S.C. 360), FDA agrees with the Panel and is proposing that the manufacturer of this device be exempt from premarket notification under section 510(k) of the act and Subpart E of Part 807 of the regulations. The agency has determined that it is not necessary for the protection of the public health that FDA receive premarket notification submissions concerning a radial immunodiffusion plate. The agency does not at this time anticipate that premarket approval will be required for this device. The agency believes that the semiannual updating of device listing under section 510(j)(2) will provide FDA with adequate notice concerning new products within this generic type of device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4800, to read as follows:

**§ 866.4800 Radial immunodiffusion plate.**

(a) *Identification.* A radial immunodiffusion plate for clinical use is a device that consists of a plastic plate to which agar gel containing antiserum is added. In radial immunodiffusion, antigens migrate through gel which originally contains specific antibodies. As the reagents come in contact with each other, they combine to form a precipitate that is trapped in the gel matrix and immobilized.

(b) *Classification.* Class I (general controls). The device is exempt from the premarket notification procedures in Subpart E of Part 807 of this chapter.

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11831 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2218]**

## Medical Devices; Classification of Rocket Immunoelectrophoresis Equipment

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rocket immunoelectrophoresis equipment into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna R. Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757

Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rocket immunoelectrophoresis equipment:

1. Identification: Rocket immunoelectrophoresis equipment for clinical use is a device used to perform a specific test on proteins by using a procedure called rocket immunoelectrophoresis. In this procedure, an electric current causes the protein in a solution to migrate through agar gel containing specific antisera. The protein precipitates with the antisera in a rocket-shaped pattern, giving the name to the device. The height of the peak (or the area under the peak) is proportional to the concentration of the protein.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that rocket immunoelectrophoresis equipment be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that rocket immunoelectrophoresis equipment be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4830, to read as follows:

**§ 866.4830 Rocket immunoelectrophoresis equipment.**

(a) *Identification.* Rocket immunoelectrophoresis equipment for clinical use is a device used to perform a specific test on proteins by using a procedure called rocket immunoelectrophoresis. In this procedure, an electric current causes the protein in solution to migrate through agar gel containing specific antisera. The protein precipitates with the antisera in a rocket-shaped pattern, giving the name to the device. The height of the peak (or the area under the peak) is proportional to the concentration of the protein.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11832 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2219]**

## Medical Devices; Classification of Support Gels

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying support gels into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of support gels:

1. Identification: A support gel for clinical use is a device that consists of an agar or agarose preparation that is used while measuring various kinds of, or parts of, protein molecules by various immunochemical techniques, such as immunoelectrophoresis, immunodiffusion, or chromatography.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that support gels be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that support gels be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart E by adding new § 866.4900, to read as follows:

**§ 866.4900 Support gel.**

(a) *Identification:* A support gel for clinical use is a device that consists of an agar or agarose preparation that is used while measuring various kinds of, or parts of, protein molecules by various

immunochemical techniques, such as immunoelectrophoresis, immunodiffusion, or chromatography.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11833 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2220]**

## Medical Devices; Classification of Albumin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying albumin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation with respect to the classification of albumin immunological test systems:

1. Identification: An albumin immunological test system is a device that consists of a the reagents used to measure by immunochemical techniques the albumin (a plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the albumin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Albumin levels may be reduced in nephrosis (kidney disease), proteinuria (protein in urine), protein-losing enteropathies (diseases of the small bowel), gastroenteropathis (diseases of the stomach and small intestine), rheumatoid arthritis, and viral hepatitis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 5).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of kidney and intestinal diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that albumin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Earle, D. P., "Abnormal Albumins," *in* "Cecil-Loeb Textbook of Medicine," 12th ed., edited by Beeson, P. B. and W. McDermott, W. B. Saunders Co., Philadelphia, pp. 1194–1195, 1967.

2. Keyser, J. W. and M. Cawson, "A Serum Reference Standard for Automated Total Protein and Albumin Procedures, "*Clinical Chemistry*, 18:335, 1970.

3. Murayama, M., "The Structure of Serum Albumin," *in* "Serum Proteins and the Dysproteinemias," edited by F. W. Sunderman, and F. W. Sunderman, Jr., J. B. Lippincott Co., Philadelphia, pp. 1–4, 1964.

4. Meinke, W. W., Standard Reference Materials for Clinical Measurements, *Analytical Chemistry*, 43:28A–47A, 1971.

5. Peters, T. J., "Serum Albumin" *in* "The Plasma Proteins, Structure, Function and Genetic Control," Vol. 1, 2d Ed., Edited by F. W. Pittman, Academic Press, New York, pp. 133–181, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 by adding new Subpart F and new § 866.5040, to read as follows:

### Subpart F—Immunological Test Systems

**§ 866.5040 Albumin immunological test system.**

(a) *Identification.* An albumin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the albumin (plasma protein) in serum and other body fluids. Measurement of albumin aids in the diagnosis of kidney and intestinal diseases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers

Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11834 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2221]**

## Medical Devices; Classification of Prealbumin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prealbumin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of prealbumin immunological test systems:

1. Identification: A prealbumin immunological test system is a device that consist of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient's nutritional status.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the prealbumin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that prealbumin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5060, to read as follows:

**§ 866.5060 Prealbumin immunological test system.**

(a) *Identification:* A prealbumin immunological test system is a device that consist of the reagents used to measure by immunochemical techniques the prealbumin (a plasma protein) in serum and other body fluids. Measurement of prealbumin levels in serum may aid in the assessment of the patient's nutritional status.

(b) *Classification:* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11835 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2222]**

## Medical Devices; Classification of Human Allotypic Marker Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying human allotypic marker immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna R. Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of human allotypic marker immunological test systems:

1. Identification: A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochemical techniques the inherited human protein allotypic markers (such as Gm2 and Km allotypes) in serum, saliva, and other biological fluids. The identification may be used while studying population genetics.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the human allotypic marker immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that human allotypic marker immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5065, to read as follows:

**§ 866.5065 Human allotypic marker immunological test system.**

(a) *Identification.* A human allotypic marker immunological test system is a device that consists of the reagents used to identify by immunochemical techniques the inherited human protein allotypic markers (such as Gm2 and Km allotypes) in serum, saliva, and other biological fluids. The identification may be used while studying population genetics.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11836 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2223]**

## Medical Devices; Classification of Alpha-1-Antichymotrypsin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-antichymotrypsin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha-1-antichymotrypsin immunological test systems:

1. Identification: An alpha-1-antichymotrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-antichymotrypsin (a protein) in serum, tissues, and body fluids. Alpha-1-antichymotrypsin helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standards for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-1-antichymotrypsin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Alpha-1-antichymotrypsin is a naturally occurring protein in human serum and semen (Refs. 1, 2, and 3). Alpha-1-antichymotrypsin is one of five known inhibitors of enzymes that break down proteins. The exact function of alpha-1-antichymotryposin is still to be determined. Nevertheless, it is involved in the protection of tissues against proteolytic (protein-splitting) enzymes released during infection (Refs. 4 through 6). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of unexplained tissue damage due to infections. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-antichymotrypsin

immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

**References**

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Schelp, F. P., P. Migasena, P. Pongpaew, W. H. P. Schreurs, and V. Supawan, "Serum Proteinase Inhibitors and Other Serum Proteins in Protein-energy Malnutrition," *British Journal of Nutrition*, 38:31–38, 1977.

2. Orjasaeter, H., "Study of Substances Related to Carcinoembryonic Antigens CEA–NCA and Association With Alpha-1-Antichymotrypsin," *Acta Pathologica Microbiology Scandinavia*, Section C, 84:235–244, 1976.

3. Schill, W. B., "Quantitative Determination of High Molecular Weight Serum Proteinase Inhibitors in Human Semen," *Andrologia* 8(4):359–364, 1976.

4. Heimburger, N., H. Haupt, and H. G. Schwick, "Proteinase Inhibitors of Human Plasma," Proceedings of the International Research Conference on Proteinase Inhibitors, Edited by Futz, H., H. Tschesche, and Walter de Gryter, Munich, November 4 through 6, 1970, Berlin, New York, 1971.

5. Kosaka, S. and M. Tazawa "Alpha-1-Antichymotrypsin in Rheumatoid Arthritis," *Tohoku Journal of Experimental Medicine*, 119:369–375, 1976.

6. Ohlsson, K. and U. Akesson, "Alpha-1-Antichymotrypsin Interaction With Cationic Proteins from Granulocytes," *Clinica Chimica Acta* 73:285–291, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5080, to read as follows:

**§ 866.5080 Alpha-1-antichymotrypsin immunological test system.**

(a) *Identification.* An alpha-1-antichymotrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-antichymotrypsin (a protein) in serum, tissues, and body fluids. Alpha-1-antichymotrypsin helps protect tissues against proteolytic (protein-splitting) enzymes released during infection.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11837 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2224]**

## Medical Devices; Classification of Antimitochondrial Antibody Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antimitochondrial antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antimitochondrial antibody immunological test systems:

1. Identification: An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body's own tissue), such as primary biliary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the antimitochondrial antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. These tests are useful in the evaluation of patients in whom primary biliary cirrhosis, chronic active hepatitis, and other diseases produce a spectrum of autoantibodies. These antibodies are multi-specific and will react with components of cells from many species. Antimitochondrial antibodies may belong to any of the immunoglobulin classes IgM, IgG, or IgA. Immunological test procedures that are used to detect antimitochondrial antibodies include complement fixation, passive agglutination, radioimmunoassay, and immunofluorescence assay. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical

experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of primary biliary cirrhosis, chronic active hepatitis, and other diseases producing a spectrum of autoantibodies. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antimitochondrial antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necesary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Aho, K., I. Rostedt, and N. E. Saris, "Reactivity of Various Anticardiolipin Antibodies With Intact Mitochondria," *Clinical and Experimental Immunology*, 14(4):573–579, 1973.

2. Candeias, J. A. N., F. Antonacio, H. Sette, and L. C. da Silva, "Occurrence of Hepatitis-Assoicated Antigen (HAA) Subdeterminates ad and ay in Blood Donors, Acute and Chronic Liver Disease," *Review Institute Medicine Tropical*, Sao Paulo, Brazil, 16(4):226–231, 1974.

3. Glynn, L. E., "Immunopathology of Liver Disease," *Progress in Liver Diseases*, 5:311–325, 1976.

4. Hilton, A. M., B. E. Boues, P. J. Smith, J. Sharpe, and I. W. Dymock, "Liver Disease in Patients with Joint Symptoms," *Annals of Rheumatic Diseases*, 33(6):540–547, 1974.

5. Sherlock, S. "Primary Biliary Cirrhosis," *Progress in Liver Diseases*, 5:559–574, 1976.

6. Steigmann, F., D. Dourdourekas, N. Shobassay, S. B. V. Vittal, P. B. Szanto, U. Khin, H. Ainis, M. Telischi, "Humoral Response in Patients With Liver Disease," *American Journal of Gastroenterology*, 61(5):349–355, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5090, to read as follows:

**§ 866.5090 Antimitochondrial antibody immunological test system.**

(a) *Identification.* An antimitochondrial antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antimitochondrial antibodies in human serum. The measurements aid in the diagnosis of diseases that produce a spectrum of autoantibodies (antibodies produced against the body's own tissue), such as primary billiary cirrhosis (degeneration of liver tissue) and chronic active hepatitis (inflammation of the liver).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11838 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2225]**

## Medical Devices; Classification of Antinuclear Antibody Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antinuclear antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antinuclear antibody immunological test systems:

1. Identification: An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins) in serum or body fluids. The measurements aid in the diagnosis of systemic lupus erythematosus, a multisystem autoimmune disease (a disease in which antibodies attack the victim's own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjogren's syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the antinuclear antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. This test is useful in diagnosing systemic lupus erythematosus. Absence of systemic lupus

erythematosus antinuclear antibody may exclude diagnosing this condition. However, a positive test result has been associated with a large number of disorders, such as rheumatoid arthritis and Sjogren's syndrome. It should be noted that the antinuclear antibody may be positive in normal individuals (Refs. 1 through 3). Latex test procedures have been shown to be less sensitive than indirect immunofluorescent methods (Ref. 4). A variety of nuclear antigens react with systemic lupus erythematosus sera, such as DNA (deoxyribonucleic acid) both native and denatured, and nucleoproteins (proteins associated with DNA) such as histones (small alkaline proteins). The use of immunofluorescent (antibodies chemically combined with fluorescent dye) methods has led to recognition of a variety of patterns of fluorescent staining of the nucleus that have diagnostic significance. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of autoimmune diseases. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antinuclear antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Casals, S. P., G. J. Friou, and P. O. Teague, "Specific Nuclear Reaction Pattern of Antibody to DNA in Lupus Erythematosus Sera," *Journal of Laboratory and Clinical Medicine*, 62: 625–631, 1963.

2. Gonzalez, E. N. and N. F. Rothfield, "Immunoglobulin Class and Pattern of Nuclear Fluorescence in Systemic Lupus Erythematosus," *New England Journal of Medicine*, 274: 1333–1338, 1966.

3. Rothfield, N. F. and B. D. Stollar, "The Relation of Immunoglobulin Class, Pattern of Anti-Nuclear Antibody, and Complement-Fixing Antibodies to DNA in Sera from Patients with Systemic Lupus Erythematosus," *Journal of Clinical Investigation*, 46:1785–1794, 1967.

4. Chapman, J. C., "Lupus Erythematosus Latex Tests Compared with the Immunofluorescence Method for Antinuclear Factor," *American Journal of Medical Technology*, 42(5): 126–129, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5100, to read as follows:

**§ 866.5100 Antinuclear antibody immunological test system.**

(a) *Identification:* An antinuclear antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and tissues that react with cellular nuclear constituents (molecules present in the nucleus of a cell, such as ribonucleic acid, deoxyribonucleic acid, or nuclear proteins) in serum or body fluids. The measurements aid in the diagnosis of systemic lupus erythematosus, a multisystem autoimmune disease (a disease in which antibodies attack the victim's own tissues), hepatitis (a liver disease), rheumatoid arthritis, Sjogren's syndrome (arthritis with inflammation of the eye, eyelid, and salivary glands), and systemic sclerosis (chronic hardening and shrinking of many body tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11839 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2226]**

## Medical Devices; Classification of Antiparietal Antibody Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antiparietal antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antiparietal antibody immunological test systems:

1. Identification: An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in human serum and body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin B12 to be absorbed by the body. The measurements aid in the diagnosis of vitamin B12 deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the antiparietal antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The antiparietal antibody immunological test system measurements aid in the diagnosis of pernicious anemia (malabsorption of vitamin B12), atrophic gastritis (inflammation of the stomach) and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies that attack its own tissues). Immunofluorescent (using antibodies chemically combined with fluorescent dye) assay is the method chosen by most clinical laboratories for measuring antiparietal antibodies. Parietal cell antibodies are present in 90 percent of patients with pernicious anemia, and to a lesser degree in patients with such other conditions as thyroiditis (inflammation of thyroid gland), Sjogren's syndrome (inflammation of the eye), atrophic gastritis, and gastric ulcer. Parietal cell antibodies also occur in a low percentage of normal persons. Levels increase with advancing age, and elevated levels are more common in women. For these reasons, additional tests are usually needed to interpret the significance of antiparietal antibody levels. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of pernicious anemia and atrophic gastritis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antiparietal antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bigazzi, P. E. and N. R. Rose, "Tests for Antibodies to Tissues Specific Antigens," *in* "Manual of Clinical Immunology," Edited by Noel R. Rose and Herman Friedman, published by the American Society for Microbiology, Washington, DC, pp. 682–691. 1976.

2. Goldberg, L. S. and H. H. Fudenberg, "The Autoimmune Aspects of Pernicious Anemia," *American Journal of Medicine*, 46:489–494, 1969.

3. Bernhadt, H. L. L. Burkett, M. L. Fields, and J. Killian, "The Diagnostic Significance of the Parietal Cell Immunofluorescent Test," *Annals of Internal Medicine*, 63:635–641, 1965.

4. Strickland, R. G., S. Baurn, L. A. E. Ashworth, and K. B. Taylor, "A Correlative Study of Immunological Phenomenon in Pernicious Anemia," *Clinical and Experimental Immunology*, 8:25–36, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5110, to read as follows:

**§ 866.5110 Antiparietal antibody immunological test system.**

(a) *Identification.* An antiparietal antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific antibody for gastric parietal cells in human serum and body fluids. Gastric parietal cells are those cells located in the stomach that produce a protein that enables vitamin $B_{12}$ to be absorbed by the body. The measurements aid in the diagnosis of vitamin $B_{12}$ deficiency (or pernicious anemia), atrophic gastritis (inflammation of the stomach), and autoimmune connective tissue diseases (diseases resulting when the body produces antibodies against its own tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11840 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2227]**

## Medical Devices; Classification of Antismooth Muscle Antibody Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying antismooth muscle antibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of antismooth muscle antibody immunological test systems:

1. Identification: An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the antismooth muscle antibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The measurements aid in the diagnosis of chronic hepatitis and autoimmune connective tissue diseases that produce a spectrum of autoantibodies against a variety of antigens (Refs. 1 through 4).The antibodies belong mainly to the IgG class of immunoglobulins, but can also be found in the IgM (high molecular weight immunoglobulin) class. Methods that have been used to detect antismooth muscle antibodies include complement fixation, passive hemagglutination, gel diffusion, counter immunoelectrophoresis, radioimmunoassay, and immunofluorescent assay. Significant numbers of apparently normal individuals will also demonstrate antismooth muscle antibody. Consequently, for the definite diagnosis of a given disorder, additional, more specific tests are needed to interpret the significance of the test results. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: (a) Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of chronic hepatitis and primary biliary cirrhosis (liver diseases). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that antismooth muscle antibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the Office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Doniach, D., I. M. Roitt, J. G. Walker, and S. Sherlock, "Tissue Antibodies in Primary Biliary Cirrhosis, Active Chronic (Lupoid) Hepatitis, Cryptogenic Cirrhosis, and other Liver Diseases and Their Clinical Implications," *Clinical and Experimental Immunology*, 1:237–262, 1966.

2. Johnson, G. D., E. J. Holborow, and L. E. Glynn, "Antibody to Smooth Muscle In Patients with Liver Disease," *Lancet*, 2:878–879, 1965.

3. Whitehouse, J. M. A. and E. J. Holborow, "Smooth Muscle Antibody in Malignant Disease," *British Medical Journal*, 4:511–513, 1971.

4. Whittingham, S., J. Irwin, I. R. McKay, and M. Smalley, "Smooth Muscle Autoantibody in "Autoimmune" Hepatitis," *Gastroenterology*, 51:499–505, 1966.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5120, to read as follows:

**§ 866.5120 Antismooth muscle antibody immunological test system.**

(a) *Identification.* An antismooth muscle antibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the antismooth muscle antibodies (antibodies to nonstriated, involuntary muscle) in serum. The measurements aid in the diagnosis of chronic hepatitis (inflammation of the liver) and autoimmune connective tissue diseases (diseases resulting from antibodies produced against the body's own tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11841 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2228]**

## Medical Devices; Classification of Alpha-1-Antitrypsin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-antitrypsin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device.

After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 30910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha-1-antitrypsin immunological test systems:

1. Identification: An alpha-1-antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-antitrypsin (a plasma protein) in serum, tissue, and other body fluids. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha-1-antitrypsin deficiency has been associated with pulmonary emphysema.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Reasons for recommendation: The Panel recommends that the alpha-1-antitrypsin immunological test system be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Alpha-1-antitrypsin (AAT) deficiency has been associated with pulmonary emphysema and cirrhosis of the liver in infants and adults. Serum deficiency of AAT is noted in the following diseases: chronic obstructive disease (an asthma-like condition) in adults, juvenile and adult cirrhosis of the liver, neonatal hepatitis (inflammation of the liver in the very young), and hepatocellular carcinoma (cancer of the liver) (Refs. 1 through 4). AAT levels have been reported to be increased in lung cancer. Further studies are required to determine if the serum level is a reflection of tumor growth in patients with cancer (Refs. 1 and 3). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy. Failure of the device to perform satisfactorily may lead to an error in the diagnosis of alpha-1-antitrypsin deficiency and associated disorders, such as pulmonary emphysema (enlargement of small air spaces of the lung) and cirrhosis (degeneration of the liver). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-antitrypsin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Harris, C. C., A. Primacke, and M. H. Cohen, "Elevated Alpha-1-Antitrypsin Serum Levels in Lung Cancer Patients," *Cancer* 34:280–281, 1974.

2. Falk, G. A. and J. P. Smith, "Chronic Bronchitis: A Seldom Noted Manifestation of Homozygous Alpha–1–Antitrypsin Deficiency," *Chest*, 60: 166–169, 1971.

3. Tuttle, W. C., and R. K. Jones "Fluorescent Antibody Studies of Alpha–1–Antitrypsin in Adult Human Lung," *American Journal of Clinical Pathology*, 64:477–482, 1975.

4. Lieberman, J., R. M. Silton, C. M. Agliozzo and J. McMahon, "Hepatocellular Carcinoma and Intermediate Alpha–1–Antitrypsin Deficiency (MZ Phenotype)," *American Journal of Clinical Pathology*, 64:304–310, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs, proposes to amend Part 866 in Subpart F by adding new § 866.5130, to read as follows:

**§ 866.5130 Alpha–1–antitrypsin immunological test system.**

(a) *Identification.* An alpha–1–antitrypsin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha–1–antitrypsin (a plasma protein) in serum, tissue, and other body fluids. The measurements aid in the diagnosis of several conditions including juvenile and adult cirrhosis of the liver. In addition, alpha–1–antitrypsin deficiency has been associated with pulmonary emphysema.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regading this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11842 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2229]**

## Medical Devices; Classification of Bence-Jones Proteins Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Bence-Jones proteins immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into

class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Bence-Jones proteins immunological test systems:

1. Identification: A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and serum. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in a patient's plasma and urine, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleem and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

2. Recommended Classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the Bence-Jones proteins immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Bence-Jones proteins are monoclonal light chain proteins. They are made and secreted by plasma cells in association with malignant immunoproliferative disorders (cancer of the antibody-producing tissue cells). They are circulated in plasma, are broken down by the kidney, and are excreted in the urine. Although Bence-Jones proteins are found most often in patients with multiple myeloma, they may be present in a variety of disorders, such as Waldenstrom's macroglobulinemia and lymphocytic neoplasms (lymphomas and leukemia). Bence-Jones proteins are readily detected by immunochemical methods (immunoelectrophoresis and immunodiffusion) in both serum and urine specimens.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of multiple myeloma or other lymphoproliferative disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Bence-Jones proteins immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Deegan, M. J., "Bence-Jones Proteins: Nature, Metabolism, Detection, and Significance," *Annals of Clinical and Laboratory Science* 6(1):38–46, 1976.

2. Perry, M. C. and R. A. Kyle, "The Clinical Significance of Bence-Jones Proteinuria," *Mayo Clinic Proceedings* 50(5):234–238, 1975.

3. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(1):17–23, 1976.

4. Solomon, A. "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(2):91–98, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5150, to read as follows:

### § 866.5150 Bence-Jones proteins immunological test system.

(a) *Identification.* A Bence-Jones proteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Bence-Jones proteins in urine and serum. Immunoglobulin molecules normally consist of pairs of polypeptide chains (subunits) of unequal size (light chains and heavy chains) bound together by several disulfide bridges. In some cancerous conditions, there is a proliferation of one plasma cell (antibody-producing cell) with excess production of light chains of one specific kind (monoclonal light chains). These free homogeneous light chains not associated with an immunoglobulin molecule can be found in a patient's plasma and urine, and have been called Bence-Jones proteins. Measurement of Bence-Jones proteins and determination that they are monoclonal aid in the diagnosis of multiple myeloma (malignant proliferation of plasma cells), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins by spleen and bone marrow cells), leukemia (cancer of the blood-forming organs), and lymphoma (cancer of the lymphoid tissue).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be

identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11843 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2284]**

## Medical Devices; Classification of Beta Globulin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta globulin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of beta globulin immunological test systems:

1. Identification: A beta globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids. Beta globulin proteins include beta lipoprotein, transferrin, glycoproteins, and complement and are rarely associated with specific pathological disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the beta globulin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that beta globulin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5160, to read as follows:

**§ 866.5160 Beta globulin immunological test system.**

(a) *Identification.* A beta globulin immunological test system is a device that consists of reagents used to measure by immunochemical techniques beta globulins (serum protein) in serum and other body fluids. Beta globulin proteins include beta lipoprotein, transferrin, glycoproteins, and complement and are rarely associated with specific pathologic disorders.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11844 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2230]**

## Medical Devices; Classification of Breast Milk Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying breast milk immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation

regarding the classification of breast milk immunological test systems:

1. Identification: A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the breast milk immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that breast milk immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5170, to read as follows:

**§ 866.5170 Breast milk immunological test system.**

(a) *Identification.* A breast milk immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the breast milk proteins.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 11845 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2231]**

## Medical Devices; Classification of Carbonic Anhydrase B and C Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying carbonic anhydrase B and C immunological test systesm into class I (general controls). FDA is also publishing the recomendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of carbonic anhydrase B and C immunological test systems:

1. Identification: A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific carbonic anhydrase protein molecules in human serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the carbonic anhydrase B and C immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that carbonic anhydrase B and C immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5200, to read as follows:

**§ 866.5200 Carbonic anhydrase B and C immunological test system.**

(a) *Identification.* A carbonic anhydrase B and C immunological test system is a device that consists of the reagents used to measure by immunochemical techniques specific carbonic anhydrase protein molecules in human serum and other body fluids. Measurements of carbonic anhydrase B and C aid in the diagnosis of abnormal hemoglobin metabolism.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments

may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs*

[FR Doc. 80-11846 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2232]**

## Medical Devices; Classification of Ceruloplasmin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ceruloplasmin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ceruloplasmin immunological test systems:

1. Identification: A ceruloplasmin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the ceruloplasmin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. A decrease in serum ceruloplasmin to less than 20 milligrams per deciliter is almost always observed in Wilson's disease, a genetic disease characterized by toxi deposits of copper in the tissues (Ref. 1). Accumulations of copper may affect brain function, or the liver may be exclusively involved. When the brain is involved, central nervous system dysfunction such as tremor and incoordination may occur. In the hepatic (liver) form of the disease, neurologic signs are often minor or absent. Diagnosis of asymptomatic patients is possible, and preventive therapy is effective in delaying and perhaps preventing the appearance of symptoms. Occasionally, asymptomatic patients exhibit normal ceruloplasmin concentrations, and this may introduce diagnostic difficulty. A recent Center for Disease Control (CDC) proficiency survey (Ref. 2) has shown that commercially available antisera gave variable immunological test results. For this reason, CDC recommended the standardization of reagents for these tests. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of Wilson's disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ceruloplasmin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Sternleib, I., "Present Status of Diagnosis and Prophylaxis of Asymptomatic Patients with Wilson's disease," *in* "Diseases of the Liver and the Biliary Tract," Edited by C. M. Levy, Karger, Basel, Switzerland, pp. 137-142, 1976.

2. Center for Disease Control, "Proficiency Testing Summary Analysis," *in* "Diagnostic Immunology," U.S. Department of Health, Education, and Welfare, Public Health Service, Atlanta, GA, April 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5210, to read as follows:

**§ 866.5210 Ceruloplasmin immunological test system.**

(a) *Identification.* A ceruloplasmin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ceruloplasmin (copper-transporting serum protein) in serum, body fluids, or tissues. Measurements of ceruloplasmin aid in the diagnosis of copper metabolism disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11847 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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## 21 CFR Part 866

**[Docket No. 78N-2233]**

## Medical Devices; Classification of Cohn Fraction II Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Cohn fraction II immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of Cohn fraction II immunological test systems.

1. Identification: A Cohn fraction II immunological test system is a device that consists of reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominately of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques. Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the Cohn fraction II immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Cohn fraction II immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5220, to read as follows:

**§ 866.5220 Cohn fraction II immunological test system.**

(a) *Identification.* A Cohn fraction II immunological test system is a device that consists of the reagents that contain or are used to measure that fraction of plasma containing protein gamma globulins, predominately of the IgG class. The device may be used as a coprecipitant in radioimmunoassay methods, as raw material for the purification of IgG subclasses, and to reduce nonspecific adsorption of plasma proteins in immunoassay techniques. Measurement of these proteins aids in the diagnosis of any disease concerned with abnormal levels of IgG gamma globulins such as agammaglobulinemia or multiple myeloma.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11848 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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## 21 CFR Part 866

**[Docket No. 78N-2234]**

## Medical Devices; Classification of Colostrum Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying colostrim immunological test systems into class I (general controls). FDA is also publishing the recommendation of the immunology device classification panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the medical device amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Eduction, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of

the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of colostrum immunological test systems:

1. Identification: A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the colostrum immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that colostrum immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5230, to read as follows:

**§ 866.5230 Colostrum immunological test system.**

(a) *Identification.* A colostrum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the specific proteins in colostrum. Colostrum is a substance excreted by the mammary glands during pregnancy and until production of breast milk begins 1 to 5 days after childbirth.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11849 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2235]**

## Medical Devices; Classification of Complement Components Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement components immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of complement components immunological test systems:

1. Identification: A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components Clq, Clr, Cls, C2, C3, C4, C5, C6, C7, C8, and C9 in serum, biological fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurement of these proteins aid in the diagnosis of immunologic disorders, especially deficiencies of complement components.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the complement components immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate thereapy that places the patient at risk unnecessarily. The literature emphasizes the importance of detecting complement component deficiencies (Refs. 2 through 6). Collection and storage of serum samples for functional serological testing with antigen-antibody complexes and immunochemical (electrophoretic) complement assays present special problems because of lability of some complement components (Ref. 1). A variety of complement deficiencies may be transmitted as hereditary defects (Refs. 2 through 6). Deficiencies of C1, C2, and C4 are associated mainly with diseases resembling systemic lupus erythematosus (SLE), a multisystem autoimmune disease (a condition in which antibodies formed against the body's own tissues react with and injure these tissues), and other connective tissue disorders. In addition, patients may have increased susceptibility to infection. Some patients may not be clinically affected. Complement component C3 deficiency has been associated with markedly increased susceptibility to infection with encapsulated bacteria. Complement mediated functions such as hemolytic activity (destruction of red cells), opsonization (coating of infectious agents with antibody), and bactericidal activities are also reduced. Deficiencies of complement components C5, C6, C7, C8, and C9 may also be associated with increased suceptibility to infections in which bacterial lysis (disruption of the bacterial cells) is important in the elimination of the organism.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases resembling systemic lupus erythematosus (SLE). Additionally, complement mediated functions may be reduced leading to increased susceptibility to infections. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement components immunological test systems be classified into Class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Stites, D. P., "Laboratory Methods for Detection of Antigens and Antibodies," *in* "Basic and Clinical Immunology," Edited by Fudenberg, H. H., D. P. Stities, J. L. Caldwell, and J. V. Wells, Lange Medical Publications, Los Altos, CA, p. 311, 1976.

2. Alper, C. A. and F. S. Rosen, "Genetics of the Complement System," *in* "Advances in Human Genetics," Edited by Harris, H. and K. Hirschhorn, Plenum Press, New York, 7: 141–188, 1976.

3. Kehoe, J. M., "Complement Function and Disorders," *Pediatric Annals*, 5(6):397–404, 1976.

4. Ruddy, S., I. Gigli, and K. F. Austen, "The Complement System of Man," *New England Journal of Medicine*, 287:489–495, 545–549, 592–596, 642–646, 1972.

5. Jersild, C. P. Rubinstein and N. K. Day, "The HLA System and Inherited Deficiencies of the Complement System," *Transplant Review*, 32:43–71, 1976.

6. Alper, C. A. and F. S. Rosen, "Genetic Aspects of the Complement System," *Advances in Immunology*, 14:251–290, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5240, to read as follows:

**§ 866.5240 Complement components immunological test system.**

(a) *Identification.* A complement components immunological test system is a device that consists of the reagents used to measure by immunochemical techniques complement components C1q, C1r, C1s, C2, C3, C4, C5, C6, C7, C18, and C9 in serum, biological fluids, and tissues. Complement is a group of serum proteins which destroy infectious agents. Measurement of these proteins data in the diagnosis of immunologic disorders, especially those associated with deficiencies of complement components.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11850 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2236]**

## Medical Devices; Classification of Complement $C_1$ Inhibitor (Inactivator) Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement $C_1$ inhibitor (inactivator) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to ensure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of complement $C_1$ inhibitor (inactivator) immunological test systems:

1. Identification: A complement $C_1$ inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement $C_1$ inhibitor (a plasma protein) in serum. Complement $C_1$ inhibitor occurs normally in plasma and blocks the action of the $C_1$ component of complement ( a group of serum proteins which destroy infectious agents). Measurement of complement $C_1$ inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the complement $C_1$ inhibitor (inactivator) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may

generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hereditary angioneurotic edema. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement $C_1$ inhibitor (inactivator) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Alper, C. A. and F. S. Rosen, "Genetics of the Complement System" *in* "Advances in Human Genetics," Editors: H. Harris and K. Hirschorn, Plenum Press, NY, pp. 141–188, 1976.

2. Ruddy, S., I. Gigli, and K. F. Austen, "The Complement System of Man," *New England Journal of Medicine*, 287:489–495, 545–549, 592–596, 642–646, 1972.

3. Donaldson, V. H. and F. S. Rosen, "Hereditary Angioneurotic Edema, A Clinical Survey," *Pediatrics*, 37:1017–1027, 1966.

4. Donaldson, V. H. and R. R. Evans, "A Biochemical Abnormality in Hereditary Angioneurotic Edema: Absence of Serum Inhibitor of $C_1$-Esterase," *American Journal of Medicine*, 35:37–44, 1963.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5250, to read as follows:

**§ 866.5250 Complement $C_1$ Inhibitor (Inactivator) Immunological Test System.**

(a) *Identification.* A complement $C_1$ inhibitor (inactivator) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement $C_1$ inhibitor (a plasma protein) in serum. Complement $C_1$ inhibitor occurs normally in plasma and blocks the action of the $C_1$ component of complement (a group of serum proteins which destroy infectious agents). Measurement of complement $C_1$ inhibitor aids in the diagnosis of hereditary angioneurotic edema (increased blood vessel permeability causing swelling of tissues) and a rare form of angioedema associated with lymphoma (lymph node cancer).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Asssociate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11851 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2237]**

## Medical Devices; Classification of Complement $C_{3b}$ Inactivator Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying complement $C_{3b}$ inactivator immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of complement $C_{3b}$ inactivator immunological test systems:

1. Identification: A complement $C_{3b}$ inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement $C_{3b}$ inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement $C_{3b}$ inactivator aids in the diagnosis of inherited antibody dysfunction.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the complement $C_{3b}$ inactivator immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecesarily. Complement $C_{3b}$ inactivator

blocks the activity of $C_{3b}$, an inhibitor of the alternative pathway of the classic system of activation of complement. A single patient with inherited $C_{3b}$ inactivator deficiency has been described (Ref. 2). The patient's serum is deficient in complement-mediated functions, such as hemolytic activity against sensitized sheep red cells, and antibody resistance to infectious disease. As a result, the patient has had a continuous history of life-threatening bacterial infections. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of complement $C_{3b}$ inactivator deficiency. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that complement $C_{3b}$ inactivator immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kehoe, J. M., "Complement Function and Disorders," *Pediatric Annals*, 5(6):397–404, 1976.

2. Alper, C. A. and F. S. Rosen, "Genetics of the Complement System" *in* "Advances in Human Genetics," Edited by Harris, H. and K. Hirschhorn, Plenum Press, New York, pp. 141–188, 1976.

3. Agnnello, V., "Complement Deficiency States," *Medicine* (Baltimore), 57(1):1–23, 1978.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5260, to read as follows:

**§ 866.5260 Complement $C_{3b}$ inactivator immunological test system.**

(1) *Identification:* A complement $C_{3b}$ inactivator immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the complement $C_{3b}$ inactivator (a plasma protein) in serum. Complement is a group of serum proteins that destroy infectious agents. Measurement of complement $C_{3b}$ inactivator aids in the diagnosis of inherited antibody dysfunction.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11852 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2238]**

## Medical Devices; Classification of C-Reactive Protein Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying C-reactive protein immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of C-reactive protein immunological test systems:

1. Identification: A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum, plasma, and body fluids. Measurements of C-reactive protein aids in evaluation of the amount of injury to body tissues.

2. Recommended classification: Class II (performance standards). The Panel recommends that the C-reactive protein immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. C-reactive protein is not an antibody, but elevated levels appear nonspecifically in a wide variety of inflammatory, necrotic (tissue-destructive), and infective conditions. It is an important index to general tissue injury. It is also noted in moderate-to-advanced carcinoma (cancer) where tissue wastage has occurred. C-reactive protein determination aids in the evaluation of acute infection and tissue damage from conditions such as tuberculosis, rheumatic fever, and coronary occlusion. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes

that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel member's personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of a variety of inflammatory, necrotic, and infective conditions. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that C-reactive protein immunoligical test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls by themselves are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Carnevali, G. and E. Delprete, "Comparative Evaluation Between the Precipitation Test, Latex Test, and the Radial Immunodiffusion Test for Determination of C-reactive Protein." *Quaderni Sclavo di Diagnostica Clinical Medicine*, 87(1):120–128, 1976.

2. Claus, D. R., A. P. Osmand and H. Gewurz, "Radioimmunoassay of Human C-Reactive Protein and Levels in Normal Sera," *Journal of Laboratory and Clinical Medicine*, 87(1):120–128, 1976.

3. Nilsson, L., "Comparative Testing of Precipitation Methods for Quantitation of C-Reactive Protein in Blood Serum," *Acta Pathologica Microbiologica Scandinavica*, 73:129–144, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5270, to read as follows:

**§ 866.5270 C-reactive protein immunological test system.**

(a) *Identification.* A C-reactive protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the C-reactive protein in serum, plasma, and body fluids. Measurements of C-reactive protein aids in evaluation of the amount of injury to body tissues.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11853 Filed 4–21–80; 8:45 am]

BILING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2239]**

## Medical Devices; Classification of Properdin Factor B Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying properdin factor B immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of properdin factor B immunological test systems:

1. Identification: A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunochemical techniques properdin factor B in serum and body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B aids in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermititis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the properdin factor B immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Complement is a group of about 20 different proteins that are activated by antibodies that have reacted with their

corresponding antigen (that substance that caused the antibodies to be produced by the body). The classical pathway of complement activation begins with components $C_1$, $C_2$, $C_3$, and $C_4$, and ends with components $C_5$, $C_6$, $C_7$, $C_8$, and $C_9$, which cause the lysis (destruction) of cells that are foreign to the body, e.g., bacteria. The alternative to the classical pathway of complement activation does not require antibodies or the first few components of complement, $C_1$, $C_2$, and $C_4$, for activation. Certain components of bacterial cell walls and similar substances can cause the activation of complement beginning with component $C_3$ in combination with properdin factor B. In this situation, $C_3$ and properdin factor B are deposited on bacterial cells or body tissues (in the case of malfunctions of the immunologic system). The activation of the alternate pathway of complement activation can be detected in patient serum by a depression in the amount of properdin factor B, $C_3$, and the other final complement components concomitant with normal values of $C_4$ and the primary complement components. The measurement of the contribution of the alternate pathway of complement activation to a disease process may aid in the diagnosis of several kidney and skin diseases, as well as rheumatoid arthritis, sickle cell anemia, and gram-negative bacterial infections.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of immunologic disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that properdin factor B immunological test systems be classfied into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Cooper, N. R., "The Complement System" *in* "Basic and Clinical Immunology," Lange Medical Publications, Edited by H. H. Fudenberg, D. P. Stities, J. L. Caldwell, and J. V. Wells, Los Altos, CA, pp. 58–69, 1976.

2. Götze, O. and H. J. Mueller-Eberhard, "The Alternative Pathway of Complement Activation," *Advances in Immunology*, 24:1–35, 1976.

3. Tucker, E. S., "The Role of Complement and Other Biochemical Mediators in Immunologic Disease" *in* "Immunopathology, Clinical Laboratory Concepts and Methods," Little, Brown and Co., Boston, pp. 104–131, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5340, to read as follows:

**§ 866.5320 Properdin factor B immunological test system.**

(a) *Identification.* A properdin factor B immunological test system is a device that consists of the reagents used to measure by immunological techniques properdin factor B in serum and body fluids. The deposition of properdin factor B in body tissues or a corresponding depression in the amount of properdin factor B in serum and body fluids is evidence of the involvement of the alternative to the classical pathway of activation of complement (a group of plasma proteins which cause the destruction of cells which are foreign to the body). Measurement of properdin factor B adds in the diagnosis of several kidney diseases, e.g., chronic glomerulonephritis (inflammation of the glomeruli of the kidney), lupus nephritis (kidney disease associated with a multisystem autoimmune disease, systemic lupus erythematosus), as well as several skin diseases, e.g., dermititis herpetiformis (presence of vesicles on the skin that burn and itch), and pemphigus vulgaris (large vesicles on the skin). Other diseases in which the alternate pathway of complement activation has been implicated include rheumatoid arthritis, sickle cell anemia, and gram-negative bacteremia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11854 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2240]**

## Medical Devices; Classification of Factor XIII, A, S, Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying factor XIII, A, S, immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register**.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the

development of the proposed regulation. The immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of factor XIII, A, S, immunological test systems:

1. Identification: A factor XIII, A, S, immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the factor XIII (a blood-clotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis of certain bleeding disorders resulting from a deficiency of this factor.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the factor XIII, A, S, immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device. Absence of coagulation factor XIII is rare and results in bleeding disorders and problems in wound healing. Congenital deficiencies are inherited, but acquired deficiencies occur in liver disorders and in the presence of circulating inhibitors.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Factor XIII, A, S, immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5330, to read as follows:

**§ 866.5330 Factor XIII, A, S, immunological test system.**

(1) *Identification:* A factor XIII, A, S, immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the factor XIII (a blood-clotting factor), in platelets (A) or serum (S). Measurements of factor XIII, A, S, aid in the diagnosis and treatment of certain bleeding disorders resulting from a deficiency of this factor.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11855 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2241]**

## Medical Devices; Classification of Ferritin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying ferritin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of ferritin immunological test systems:

1. Identification: A ferritin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ferritin (an iron-storing protein) in serum and body fluids. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the ferritin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Ferritin is the major iron-storage protein of the body. Several different molecular forms are found in all tissues of the body. Large amounts of ferritin are found in the red-blood-cell forming organs (liver, spleen, and bone marrow). Very small amounts have been demonstrated as a normal constitutent of plasma or serum. In clinical disorders of iron imbalance, the levels of plasma ferritin may reflect the levels of iron stored in the body. Elevated levels of serum ferritin have been found in liver disease and in increased red cell turnover (Ref. 6). In iron deficiency anemia, low levels of plasma ferritin have been found. However, the usefulness of the serum ferritin test may be limited when a deficiency coexists with inflammatory or malignant conditions, because ferritin levels in serum may be within the normal range. Under these conditions, caution must be observed in the interpretation of the results. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical

experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of diseases affecting the iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that ferritin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jacobs, A. and M. Worwood, "Ferritin in Serum: Clinical and Biochemical Implications," *New England Journal of Medicine*, 292:951–956, 1975.

2. Wands, J. R. et al., "Normal Serum Ferritin Concentrations in Precirrhotic Hemochromatosis," *New England Journal of Medicine*, 294:302–305, 1976.

3. Crosby, W. H., "Serum Ferritin Fails to Indicate Hemochromatosis—Nothing Gold Can Stay," *New England Journal of Medicine*, 294:333–334, 1976.

4. Crosby, W. H., "Normal Serum Ferritin in Precirrhotic Hemochromatosis," *New England Journal of Medicine*, 296(19):1116, 1977.

5. Fairbanks, V. F. and E. Beutler, "Iron Metabolism," *in hematology*, 2d Ed., Edited by Williams, W., E. Butler, A. Erslev, and R. W. Rundles, McGraw Hill, pp. 168–177, 1977.

6. Lipschitz, D. A., J. D. Cook, and C. A. Finch, "A Clinical Evaluation of Serum Ferritin as an Index of Iron Stores," *New England Journal of Medicine*, 290(22):1213–1216, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5340, to read as follows:

**§ 866.5340 Ferritin immunological test system.**

(a) *Identification.* A ferritin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the ferritin (an ironstoring protein) in serum and body fluids. Measurements of ferritin aid in the diagnosis of diseases affecting iron metabolism, such as hemochromatosis (iron overload) and iron deficiency anemia.

(b) *Classification.* Class II (performance standards).

Interested perons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11856 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2242]**

## Medical Devices; Classification of Fibrinopeptide A Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying fibrinopeptide A immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fibrinopeptide A immunological test systems:

1. Identification: A fibrinopeptide A immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the fibrinopeptide A (a blood-clotting factor) in plasma and body fluids. Measurement of fibrinopeptide A may aid in the diagnosis and treatment of certain blood-clotting disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the fibrinopeptide A immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, specificity, sensitivity, and stability, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Fibrinogen is essential for the formation of blood clots because it is the substance from which the clot is formed. The enzyme thrombin converts fibrinogen into fibrinopeptide A, fibrinopeptide B, and the fibrin monomer, which combine chemically with other fibrin molecules to form a blood clot. Measurement of fibrinopeptide A can be used as a tool for studying thrombin activity in vitro. Significantly increased levels of fibrinopeptide A have been seen in patients with venous thrombosis (blood clot) and/or pulmonary embolism (clot in lung). Following heparin therapy (administration of the anticoagulant heparin, intravenously), levels of fibrinopeptide A have been shown to decline, indicating that measurement of fibrinopeptide A may be useful to monitor

clotting therapy. Fibrinogen and fibrinogen derivatives containing fibrinopeptide A have been shown to cross-react in immunochemical assays, and therefor fibrinopeptide A must be extracted before assay. The Panel believes that general controls will not provide sufficient control over the device's accuracy, precision, sensitivity, specificity, and stability. The Panel believes that a performance standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of blood-clotting disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that fibrinopeptide A immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons from 9 a.m. to 4 p.m., Monday through Friday.

1. Gerrits, W. B. J., O. T. N. Flier, and J. van der Meer, "Fibrinopeptide A Immunoreactivity in Human Plasma," *Thrombosis Research*, 5(2):197–212, 1974.

2. Nossel, H., V. P. Butler, R. E. Canfield, I. Yudelman, M. Kalliope Spanondis, and T. Soland, "Potential Use of Fibrinopeptide A Measurement in the Diagnosis and Management of Thrombosis," *Thrombosis et Diathesis Haemorrhagica*, 33(3):426–434, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5350, to read as follows:

**§ 866.5350 Fibrinopeptide A immunological test system.**

(a) *Identification.* A fibrinopeptide A immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the fibrinopeptide A (a blood-clotting factor) in plasma and body fluids. Measurement of fibrinopeptide A may aid in the diagnosis and treatment of certain blood-clotting disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11857 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2243]**

## Medical Devices; Classification of Cohn Fraction IV Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Cohn fraction IV immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the Office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFA–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of Cohn fraction IV immunological test systems:

1. Identification: A Cohn fraction IV immunological test system is a device that consists of or measures that fraction of plasma proteins, predominantly *alpha-* and *beta*-globulins, used as a raw material for the production of pure *alpha-* or *beta*-globulins. Measurement of specific *alpha-* or *beta*-globulins aids in the diagnois of many diseases, such as Wilson's disease (an inherited disease affecting the liver and brain), Tangier's disease (absence of Alpha-1-lipoprotein), malnutrition, iron deficiency anemia, red blood cell disorders and kidney disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the Cohn fraction IV immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is produced by a simple process, i.e., fractional precipitation of plasma proteins with ethanol at low temperature and moderately low pH (hydrogen-ion concentration).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Cohn fraction IV immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5360, to read as follows:

**§ 886.5360 Cohn fraction IV immunological test system.**

(a) *Identification.* A Cohn fraction IV immunological test system is a device that consists of or measures that fraction of plasma proteins, predominantly *alpha-* and *beta-*globulins, used as a raw material for production of pure *alpha-* or *beta-*globulins. Measurement of specific *alpha-* or *beta-*globulins aids in the diagnosis of many diseases, such as Wilson's disease (an inherited disease affecting the liver and brain), Tangier's disease (absence of alpha-1-lipoprotein), malnutrition, iron-deficiency anemia, red blood cell disorders and kidney disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11858 Filed 4–21–80: 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2244]**

## Medical Devices; Classification of Cohn Fraction V Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying Cohn Fraction V immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFA–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of fraction V immunological test systems:

1. Identification: A Cohn fraction V immunological test system is a device that consists of or measures that fraction of plasma containing predominantly albumin (a plasma protein). This test aids in the diagnosis of diseases where albumin levels may be depressed, e.g., nephrosis (disease of the kidney), proteinuria (protein in the urine), gastroenteropathy (disease of the stomach and small intestine), rheumatoid arthritis, and viral hepatitis.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the Cohn fraction V immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. The device is produced by a simple process, i.e., fractional precipitation of plasma proteins with ethanol at low temperature and low pH (hydrogen-ion concentration).

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that Cohn fraction V immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5370, to read as follows:

**§ 866.5370 Cohn fraction V immunological test system.**

(a) *Identification.* A Cohn fraction V immunological test system is a device that consists of or measures that fraction of plasma containing predominantly albumin (a plasma protein). This test aids in the diagnosis of diseases where albumin levels may be depressed, e.g., nephrosis (disease of the kidney), proteinuria (protein in the urine), gastroenteropathy (disease of he stomach and small intestine), rheumatoid arthritis, and viral hepatitis.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (JFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11859 Filed 4–21–80: 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2245]**

## Medical Devices; Classification of Free Secretory Component Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying free secretory component immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal became effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Depatment of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of free secretory component immunological test systems:

1. Identification: A free secretory component immunological test system is a device that consists of the reagents used to measure by immunochemical techniques free secretory component (normally a portion of the secretory IgA antibody molecule) in human body fluids. Measurement of free secretory component (protein molecules) aids in the diagnosis of persons with repetitive lung infections and other hypogammaglobulinemic conditions (low antibody levels).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the free secretory component immunological test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurement of free secretory component aids in the evaluation of patients in whom recurrent pulmonary infections or other hypogammaglobulinemic conditions produce a spectrum of infectious diseases. Several studies (Refs. 1 and 3) have shown that there is a high degree of correlation between elevated levels of free secretory component at mucosal surfaces and disease, such as recurrent pulmonary infections. Free secretory component has been detected using radioimmunoassay. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of persons with recurrent pulmonary infections. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

## Proposed Classification

FDA agrees with the Panel recommendation and is proposing that free secretory component immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Strober, W., et al., "Secretory Component Deficiency, a Disorder of the IgA Immune System," *The New England Journal of Medicine,* 294(7) :351–356, 1976.

2. Tourville, D. R., R. H. Adler, J. Bienenstock, T. B. Tomasi, Jr., "The Human Secretory Immunoglobulin System: Immunohistological Localization of Gamma A, Secretory "Piece," and Lactoferrin in Normal Human Tissues," *Journal of Experimental Medicine,* 129:411–429, 1969.

3. Tomasi, T. B., Jr. and J. Bienenstock "Secretory Immunoglobins," *Advances in Immunology,* 9:1–96, 1968.

4. Eidelman, S., "Some Immunological Factors in Small Intestine Disease," *The American Journal of Clinical Nutrition,* 21(9):1110–1114, 1968.

5. O'Reilly, R. J., L. Lee, and B. G. Welch, "Secretory IgA Antibody Responses to *Neisseria gonorrhoeae* in the Genital Secretions of Infected Females," *The Journal of Infectious Diseases,* 133(2):113–125, 1976.

6. Bull, D. M., and T. B. Tomasi, "Deficiency of Immunoglobulin A in Intestinal Disease," *Gastroenterology,* 54(2):313–320, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5380, to read as follows:

**§ 866.5380 Free secretory component immunological test system.**

(a) *Identification:* A free secretory component immunological test system is a device that consists of the reagents used to measure by immunochemical techniques free secretory component (normally a portion of the secretory IgA antibody molecule) in human body fluids. Measurement of free secretory component (protein molecules) aids in the diagnosis of persons with repetitive lung infections and other hypogammaglobulinemic conditions (low antibody levels).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 11860 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

**21 CFR Part 866**

**[Docket No. 78N-2246]**

## Medical Devices; Classification of Alpha Globulin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha globulin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha globulin immunological test systems:

1. Identification: An alpha globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha globulin (a serum protein) in serum and other body fluids. Measurements of alpha globulin may aid in the diagnosis of inflammatory lesions, infections, severe burns, and a variety of other conditions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the alpha globulin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. A decrease in alpha globulin occurs in conditions in which other serum mucoproteins are diminished, but this is not always demonstrable. An increase may occur in conditions characterized by an increase in alpha-2-globulin, such as inflammatory lesions, infections, severe burns, myocardial infarction (heart disease), extensive malignancy, rheumatoid arthritis, and other conditions.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha globulin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5400, to read as follows:

**§ 866.5400 Alpha globulin immunological test system.**

(a) *Identification.* An alpha globulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha globulin (a serum protein) in serum and other body fluids. Measurement of alpha globulin may aid in the diagnosis of inflammatory lesions, infections, servere burns, and a variety of other conditions.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11861 Filed 4-21-80; 8:45 am]

**BILLING CODE 4110-03-M**

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**21 CFR Part 866**

**[Docket No. 78N-2247]**

## Medical Devices; Classification of Alpha-1-Glycoproteins Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-glycoproteins immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFA-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of alpha-1-glycoproteins immunological test systems:

1. Identification: An alpha-1-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-glycoproteins (a group of plasma proteins found in the alpha-1 group when subjected to electrophoresis) in serum and other body fluids. Measurement of specific alpha-1-glycoproteins may aid in the diagnosis of collagen (connective tissue) disorders, tuberculosis, infections, extensive malignancy, and diabetes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-1-glycoproteins immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-glycoproteins immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficent to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5420, to read as follows:

**§ 866.5420 Alpha-1-glycoproteins immunological test system.**

(a) *Identification.* An alpha-1-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques alpha-1-glycoproteins (a group of plasma proteins found in the alpha-1 group when subjected to electrophoresis) in serum and other body fluids. Measurement of specific alpha-1-glycoproteins may aid in the diagnosis of collagen (connective tissue) disorders, tuberculosis, infections, extensive malignancy, and diabetes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11862 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2248]**

## Medical Devices; Classification of Alpha-2-Glycoproteins Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-2-glycoproteins immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of alpha-2-glycoproteins immunological test systems:

1. Identification: An alpha-2-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-glycoproteins (a group of plasma proteins found in the alpha-2 group when subjected to electrophoresis) in serum and other body fluids. Measurement of alpha-2-glycoproteins aids in the diagnosis of some cancers and genetically-inherited deficiencies of these plasma proteins.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-2-glycoprotein immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-2-glycoproteins immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5425, to read as follows:

**§ 866.5425 Alpha-2-glycoproteins immunological test system.**

(a) *Identification.* An alpha-2-glycoproteins immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-glycoproteins (a group of plasma proteins found in the alpha-2 group when subjected to electrophoresis) in serum and other body fluids. Measurement of alpha-2-glycoproteins aids in the diagnosis of some cancers and genetically-inherited deficiencies of these plasma proteins.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11863 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2249]**

## Medical Devices; Classification of Beta-2-Glycoprotein I Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta-2-glycoprotein I immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of beta-2-glycoprotein I immunological test systems:

1. Identification: A beta-2-glycoprotein I immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein I (a serum protein) in serum and other body fliuds. Measurement of beta-2-glycoprotein I aids in the diagnosis of an inherited deficiency of this serum protein.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the beta-2-glycoprotein I immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that beta-2-glycoprotein I immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5430, to read as follows:

**§ 866.5430 Beta-2-glycoprotein I immunological test system.**

(a) *Identification.* A beta-2-glycoprotein I immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein I (a serum protein) in serum and other body fliuds. Measurement of beta-2-glycoprotein I aids in the diagnosis of an inherited deficiency of this serum protein.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11864 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2250]**

## Medical Devices; Classification of Beta-2-Glycoprotein III Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta-2-glycoprotein III immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of beta-2-glycoprotein III immunological test systems:

1. Identification: A beta-2-glycoprotein III immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein III (a serum protein) in serum and other body fluids. Measurement of beta-2-glycoprotein III aids in the diagnosis of an inherited deficiency of this serum protein and a variety of other conditions.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the beta-2-glycoprotein III immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device. An increase in serum glycoproteins occurs in various acute and chronic conditions, e.g., malignant neoplasm (cancer), collagen disease (wasting disease), tuberculosis, diabetes mellitus, gout, and liver disease. However, the nonspecificity of increased serum glycoproteins has limited its usefulness in clinical diagnosis.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that beta-2-glycoprotein III immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5440, to read as follows:

**§ 866.5440 Beta-2-glycoprotein III immunological test system.**

(a) *Identification.* A beta-2-glycoprotein III immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the beta-2-glycoprotein III (a serum protein) in serum and other body fluids. Measurement of beta-2-glycoprotein III aids in the diagnosis of an inherited deficiency of this serum protein and a variety of other conditions.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11865 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2251]**

## Medical Devices; Classification of Haptoglobin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying haptoglobin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of haptoglobin immunological test systems:

1. Identification: A haptoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the haptoglobin (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the haptoglobin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Haptoglobins are a group of closely related glycoproteins (proteins with a covalently attached carbohydrate group) that bind to the protein portions of hemoglobin. Haptoglobins are inherited (genetically controlled) serum glycoproteins. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of the data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to Health: Misdiagnosis and inappropriate therapy: Failure of the device

to perform satisfactorily may lead to an error in the diagnosis of the cause of red blood cell hemolysis and kidney. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that haptoglobin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (HFA–305) (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Atwater, J. and A. J. Erslev, "Haptoglobin Assay" *in* "Hematology," Edited by W. J. Williams et al., McGraw Hill, New York, pp. 1384–1386, 1972.

2. Bacchus, H., "Serum Glycoproteins and Malignant Neoplastic Disorders," CRC Critical Reviews in Clinical Laboratory Sciences, pp. 333–362, December 1977.

3. Davidson, I. and D. Nelson, "The Blood" *in* "Clinical Diagnosis by Laboratory Methods," Edited by Davidson, J. Henry and W. B. Saunders, 15th Ed., Philadelphia, Pa., p. 186, 1974.

4. Ramakers, J. M. and H. J. H. Kreutzer, "Turbidimetric Determination of Haptoglobin," *Journal of Clinical Chemistry and Clinical Biochemistry*, 14(8):407–410, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5460, to read as follows:

**§ 866.5460 Haptoglobin immunological test system.**

(a) *Identification.* A haptoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the haptoglobin (a protein that binds hemoglobin, the oxygen-carrying pigment in red blood cells) in serum. Measurement of haptoglobin may aid in the diagnosis of hemolytic diseases (diseases in which the red blood cells rupture and release hemoglobin) related to the formation of hemoglobin-haptoglobin complexes and certain kidney diseases.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11866 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2252]**

## Medical Devices; Classification of Hemoglobin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hemoglobin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Springs, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:** .

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hemoglobin immunological test systems:

1. Identification: A hemoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the different types of free hemoglobin (the oxygen-carrying pigment in red blood cells) in blood, urine, plasma, or other biological fluids. Measurement of free hemoglobin aids in the diagnosis of patients with various hematologic disorders, such as sickle cell anemia, Fanconi's anemia (a rare inherited disease), aplastic anemia (bone marrow does not produce enough blood cells), and leukemia (cancer of the blood-forming organs).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that hemoglobin immunological test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The red blood cells of normal adult blood contain a mixture of three structurally different hemoglobin (Hb) molecules. Increased or decreased amounts of one or more of the hemoglobins are found in some hematologic diseases, and the measurement of hemoglobins, e.g., Ao, A1, A2, Fo, S, C, has important diagnostic applications. Increased levels of Hb–Fo are often found in patients with Fanconi's anemia, aplastic anemia, sickle cell anemia, and leukemia (cancer of bloodforming organs). The precent of Hb–A2 is increased in patients with beta-thalassemia trait (a hereditary hemolytic anemia caused by diminished synthesis of the beta-polypeptide chain of hemoglobin) and decreased in individuals with hereditary persistence of fetal hemoglobin (a form of hemoglobin constituting 50 percent of fetal hemoglobin, but found in small amounts in adults) (Ref. 1). Radioimmunoassy is the preferred method for measuring the various hemoglobins. The device may be used for prenatal diagnosis of hemoglobinopathies (a hemolytic disorder characterized by hemoglobin abnormality)

and for microanalysis of blood samples for legal purposes such as paternity determinations or evidence of involvement in a crime. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hematologic disorders such as anemia or luekemia. Inapproriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hemoglobin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for the device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Garver, F. A. et al., "Specific Radioimmunochemical Identification and Quantitation of Hemoglobins A2 and F," *American Journal of Hematology*, 1:459–469, 1976.

2. Rowley, P. T. et al., "Sickle Hemoglobin: A Specific Radioimmunoassay," *Blood*, 43(4):607–611, 1974.

3. Boerma, F. W. and T. H. J. Huisman, "Serologic Investigations of Human Hemoglobins, II. Antibodies Produced by Isolated Human Hemoglobin Types With Known Structural Differences," *Journal of Laboratory and Clinical Medicine*, 63(2):264–278, 1964.

4. Goodman, M. and D. H. Campbell, "Differences in Antigenic Specificity of Human Normal Adult, Fetal, and Sickle Cell Anemia Hemoglobin," *Blood*, 8:422–433, 1953.

Therefore, under the Federal Food, Drug, and Cosmetic Act secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5470, to read as follows:

**§ 866.5470 Hemoglobin immunological test system.**

(a) *Identification.* A hemoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the different types of free hemoglobin (the oxygen-carrying pigment in red blood cells) in blood, urine, plasma, or other biological fluids. Measurements of free hemoglobin aids in the diagnosis of patients with various hematologic disorders, such as sickle cell anemia, Fanconi's anemia (a rare inherited disease), aplastic anemia (bone marrow does not produce enough blood cells), and leukemia (cancer of the blood-forming organs).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11867 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2253]**

## Medical Devices; Classification of Hemolytic Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hemolytic immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hemolytic immunological test systems:

1. Identification: A hemolytic immunological test system is a device that consists of the reagents used to measure by immunochemical techniques immunoglobulins and $C_3$ (the third component of complement) attached to the surface of a patient's red blood cells. Measurement of immunoglobulins and $C_3$ on the surface of red blood cells aids in the diagnosis of hemolytic transfusion reactions (red cell destruction that results from a patient's receiving blood from a noncompatible donor), hemolytic disease of the newborn (destruction of the red blood cells of an Rh+ fetus of an RH− mother), immune drug-induced hemolytic anemia, such as a reaction to penicillin, as well as many autoimmune hemoytic anemias (destruction of red cells by the body's own antibodies) associated with chronic lymphocytic leukemia (cancer of the white blood cells), lymphoma (cancer of lymphoid tissues), systemic lupus erythematosus (a multisystem autoimmune disease), or paroxysmal nocturnal hemoglobinuria (hemoglobin in the urine).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the hemolytic immunological test system be classified into class II (performance

standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, specificity, sensitivity, and stability and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. When a patient has antibodies present in his/her system that react with some component on the surface of his/her own red blood cells, these antibodies attach to the surface of the red blood cell. If there is enough antibody on the red blood cell that can fix complement (plasma proteins that cause destruction of red cells and bacteria), components of complement including $C_3$ (the third complement component) also attach to the red cells. The presence of large amounts of complement on the surface of a red blood cell may cause the destruction of the red blood cell. Differential diagnosis of the many hemolytic anemias depends upon whether either or both immunoglobulin or $C_3$ are present on the red cell surface, and upon the temperature at which these substances can be detected. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4). Properdin factor B is a protein derived by enzyme activity from a component of the complement system. The properdin is a group of proteins involved in resistance to infection and is similar to, but distinct from, complement. The properdin hemolytic system has been implicated in instances of the human disease known as paroxysmal nocturnal hemoglobinuria (hemoglobin in urine). Measurement of complement components $C_3$ and $C_4$ and of Properdin Factor B gives an estimate of the contribution which the alternative pathway of complement activation rather than the classical complement activation system may have in a given disease process. This determination is useful in evaluation of anemias, chronic glomerulonephritis (inflammation of the glomeruli of the kidney), and certain other disorders of inflammation and infection. (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hemotologic disorders and some disorders of inflammation and infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hemolytic immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gotze, O. and H. J. Muller-Eberhard, "The Alternative Pathway of Complement Activation," *Advances in Immunology, 24:1–35, 1976.*

2. Tucker, E. S., "The Role of Complement and Other Biochemical Mediators in Immunologic Disease," *in* "Immunopathology-Clinical Laboratory Concepts and Methods," Edited by R. H. Nakamura, Little, Brown and Co., pp. 104–131, 1974.

3. Shulman, N. R., "Analyses of Drug Antibodies with Autoimmune Implications," *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Brecher, Grune and Stratton pp. 31–46, 1975.

4. Petz, L. D. and G. Garratty, "Laboratory Correlations in Immune Hemolytic Anemias," *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and B. Brecher, Grune and Stratton, pp. 139–153, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5480, to read as follows:

**§ 866.5480 Hemolytic immunological test system.**

(a) *Identification.* A hemolytic immunological test system is a device that consist of the reagents used to measure by immunochemical techniques immunoglobulines and $C_3$ (the third component of complement) attached to the surface of a patient's red blood cells. Measurement of immunoglobulins and $C_3$ on the surface of red blood cells aids in the diagnosis of hemolytic transfusion reactions (red cell destruction that results from a patient's receiving blood from a noncompatible donor), hemolytic disease of the newborn (destruction of the red blood cells of an Rh+ fetus of an Rh− mother), immune drug-induced hemolytic anemia, such as a reaction to penicillin, as well as maney autoimmune hemolytic anemias (destruction of red cells by the body's own antibodies) associated with chronic lymphocytic leukemia (cancer of the white blood cells), lymphoma (cancer of lymphoid tissues), systemic lupus erythematosus (a multisystem autoimmune disease), or paroxysmal nocturnal hemoglobinuria (hemoglobin in the urine).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11868 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2254]**

## Medical Devices; Classification of Hemopexin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hemopexin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30

days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hemopexin immunological test systems:

1. Identification: a hemopexin immunological test system is a device that consists of the reagents used to measure by immunchemical techniques the hemopexin (a serum protein that binds heme, a component of hemoglobin) in serum. Measurement of hemopexin aids in the diagnosis of various hematologic disorders, such as hemolytic anemia (anemia due to shortened in vivo survival of mature red blood cells and inability of the bone marrow to compensate for their decreased life span) and sickle cell anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the hemopexin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unneccessarily. Hemopexin is a glycoprotein synthesized in the liver; its major function is the binding of heme (a component of hemoglobin). Serum hemopexin levels are decreased in conditions of intravascular hemolysis (internal bleeding) and anemias such as thallasemia major, sickle cell, and pernicious anemia (diseases affecting functioning of red blood cells). Increased levels of hemopexin have been reported in patients with inflammatory conditions and various types of cancer. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based. The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hematologic disorders such as hemolytic anemia, intravascular hemolysis, or sickel cell anemia. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hemopexin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Bacchus, H., "Serum Glycoproteins and Malignant Neoplastic Disorders," *CRC Critical Reviews in Clinical Laboratory Sciences*, p. 356, Dec. 1977.

2. Wintrobe, M. et al., "Clinical Hematology," 7th Ed. Lea and Febringer, Publishers, Philadelphia, Pa., p. 730, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5490, to read as follows:

**§ 866.5490 Hemopexin immunological test system.**

(a) *Identification.* A hemopexin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the hemopexin (a serum protein that binds heme, a component of hemoglobin) in serum. Measurement of hemopexin aids in the diagnosis of various hematologic disorders, such as hemolytic anemia (anemia due to shortened in vivo survival of mature red blood cells and inability of the bone marrow to compensate for their decreased life span) and sickle cell anemia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11869 Filed 4–21–80; 8:45 am]

**BILLING CODE 4110–03–M**

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**21 CFR Part 866**

**[Docket No. 78N–2255]**

## Medical Devices; Classification of Hypersensitivity Pneumonitis Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying hypersensitivity pneumonitis immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After Considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of hypersensitivity pneumonitis immunological test systems:

1. Identification: A hypersensitivity pneumonitis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin antibodies which react specifically with organic dust derived from fungal or animal protein sources. When these antibodies react with such dusts in the lung, immune complexes precipitate and trigger an inflammatory reaction (hypersensitivity pneumonitis). Measurement of these immunoglobulin G antibodies aid in the diagnosis of hypersensitivity pneumonitis and other allergic respiratory disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the hypersensitivity pneumonitis immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Hypersensitivity pneumonitis is an allergic respiratory disorder. The precipitating antibodies which cause the condition may be formed against organic dusts derived from fungal or animal proteins. Regardless of the inciting organic dust, the clinical symptoms remain essentially the same: cough, shortness of breath, fever, and chills. Immunofluorescent studies of human lung biopsy specimens of affected persons have provided histological evidence of IgG, IgM, and complement (immune complexes) as well as an intense infiltration of inflammatory cells in the alveolar (blood gas exchange) area of the lung. The immunologic diagnosis of extrinsic allergic alveolitis (inflammation of the lungs) is based on the detection of immune complexes present in the alveolar area of the lung. Hypersensitivity pneumonitis and other pulmonary diseases with immunological features must be distinguished from bronchial asthma for correct treatment. The causal antibodies may be detected by various methods, including skin tests, agar gel diffusion, indirect immunofluorescence, or rocket electrophoresis. The Panel believes the general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will profile reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of hypersensitivity pneumonitis (an allergic respiration disorder). Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that hypersensitivity pneumonitis immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Pepys, J., "Pulmonary Hypersensitivity Disease due to Inhaled Organic Antigens," *Annals of Internal Medicine, 64:943–948, 1966.*

2. Ghose, T., P. Landrigan, R. Killeen, and J. Dill, "Immunopathological Studies in Patients With Farmer's Lung," *Clinical Allergy,* 4:119–129, 1974.

3. Wenzel, F. J., D. A. Emanuel, and B. R. Lawton, "Pneumonitis due to Micromonospora Vulgaris (Farmer's Lung," *American Review of Respiratory Diseases,* 95:652–655, 1967.

4. Pepys, J. and P. A. Jenkins, "Precipitin (FLH) Test in Farmer's Lung," *Thorax,* 20:21–35, 1965.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5500, to read as follows:

**§ 866.5500 Hypersensitivity pneumonitis immunological test system.**

(a) *Identification.* A hypersensitivity pneumonitis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulin antibodies which react specifically with organic dust derived from fungal or animal protein sources. When these antibodies react with such dusts in the lung, immune complexes precipitate and trigger an inflammatory reaction (hypersensitivity pneumonitis). Measurement of these immunoglobulin G antibodies aid in the diagnosis of hyper-sensitivity pneumonitis and other allergic respiratory disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11870 Filed 2–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2256]**

## Medical Devices; Classification of Immunoglobulins A, G, M, D, and E Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulins A, G, M, D, and E immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a

device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulins A, G, M, D, and E immunological test systems.

1. Identification: An immunoglobulins A, G, M, D, and E immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulins A, G, M, D, and E (serum antibodies) in serum. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that immunoglobulins A, G, M, D, and E immunological test systems be classified into class II because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, precision, specificity, sensitivity, and stability, and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, specificity, sensitivity, and stability. The Panel believes that a standard will provide a reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a review of the literature (Refs. 1 through 8). Scientists have established through repetitious testing of the same persons that normal persons vary as much as plus or minus 11 percent in levels of immunoglobulins A, G, M, D, and E; and the expected or inherent laboratory precision variability for this test system has been estimated at plus or minus 6 percent (Ref. 5). Three separate evaluations of the accuracy and sensitivity of five manufacturers' immunoglobulin test kits (using 12 serum specimens) revealed variations of 100 percent in the expected test results (Refs. 1 through 3). The Panel noted that the Internation Union of Immunological Societies under the World Health Organization is developing standards for the various immunoglobulins. (Ref. 8).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of the ability of the body to resist infectious agents and in the diagnosis of abnormal protein metabolism. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglobulins A, G, M, D, and E immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Berne, B. H., "Differing Methodology and Equations Used in Quantitating Immunoglobulins by Radial Immunodiffusion—a Comparative Evaluation of Reported and Commercial Techniques," *Clinical Chemistry*, 20(1): 61–69, 1974.

2. Center for Disease Control, "Proficiency Testing Summary Analysis, Diagnostic Immunology," U.S. Department of Health, Education, and Welfare, Public Health Service, Atlanta, GA, April 1978.

3. Davis, N. C. and M. Ho, "Quantitation of Immunoglobulins" *in* "Manual of Clinical Immunology," Edited by N. R. Rose and H. Friedman, ASM, Washington, DC, pp. 4–16, 1976.

4. Fahey, J. L. and E. M. McKelvey, "Quantitative Determination of Serum Immunoglobulins in Antibody-Agar Plates," *The Journal of Immunology*, 94:84–90, 1965.

5. Gilliland, B. C. and M. Mannik, "Immunologic Quantitation of Proteins in Serum, Urine, and Other Body Fluids," *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Brecher, Grune and Stratton, New York, pp. 13–30, 1975.

6. Heremans, J. F. and P. L. Masson, "Specific Analysis of Immunoglobulins: Techniques and Clinical Values," *Clinical Chemistry*, 19:294–300, 1973.

7. Hosty, T. A., M. Hollenbeck, and S. Shane, "Intercomparison of Results Obtained with Five Commercial Diffusion Plates Supplied for Quantitation of Immunoglobulins," *Clinical Chemistry*, 19:524–526, 1973.

8. Rowe, D. S., B. Grab, and S. G. Anderson, "An International Reference Preparation for Human Serum Immunoglobulins G, A, and M: Content of Immunoglobulins by Weight," *Bulletin of the World Health Organization* 46:67–79, 1972.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5510, to read as follows:

**§ 866.5510 Immunoglobulins A, G, M, D, and E immunological test system.**

(a) *Identification.* An immunoglobulins A, G, M, D, and E immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the immunoglobulins A, G, M, D, and E (serum antibodies) in serum. Measurement of these immunoglobulins aids in the diagnosis of abnormal protein metabolism and the body's lack of ability to resist infectious agents.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11871 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

## 21 CFR Part 866

**[Docket No. 78N-2257]**

## Medical Devices; Classification of Immunoglobulin G (Fab Fragment Specific) Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin G (Fab fragment specific) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin G (Fab fragment specific) immunological test systems:

1. Identification: An immunoglobulin G (Fab fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fab antigen-binding fragment resulting from breakdown of immunoglobulin G antibodies in urine, serum, and other biological fluids. Measurement of Fab fragments of immunoglobulin G aids in the diagnosis of lymphoproliferative disorders, such as multiple myeloma (tumor of bone marrow cells), Waldenstrom's macroglobulinemia (increased immunoglobulin production by the spleen and bone marrow cells), and lymphoma (tumor of the lymphoid tissues).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglobulin G (Fab fragment specific) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Immunoglobulin G can be broken down into many different fragments, depending on where the break takes place in the molecule, e.g., heavy chains, light chains, Fc fragments, or Fab fragments. Fab is the antigen-binding fragment resulting from the enzymatic breakdown of immunoglobulin G antibodies. This fragment can be detected in urine or serum, usually by immunoelectrophoresis. The presence of monoclonal (homogeneous) immunoglobulin in either serum or urine is presumptive evidence for the diagnosis of lymphoproliferative disorders, e.g., multiple myeloma, Waldenstrom's macroglobulinemia and lymphoma. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Penal believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of lymphoproliferative disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglobulin G (Fab fragment specific) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gilliand, B. C. and M. Mannik, "Immunologic Quantitation of Proteins in Serum, Urine and other Body Fluids" *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Breecher, Grune and Stratton, New York pp. 13-30, 1975.

2. Solomon, A, "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(1):17-23, 1976.

3. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine,* 294(2):91-98, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5520, to read as follows:

### § 866.5520 Immunoglobulin G (Fab fragment specific) immunological test system.

(a) *Identification.* An immunoglobulin G (Fab fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fab antigen-binding fragment resulting from breakdown of immunoglobulin G antibodies in urine, serum, and other biological fluids. Measurement of Fab fragments of immunoglobulin G aids in the diagnosis of lymphoproliferative disorders, such as multiple myeloma (tumor of bone marrow cells), Waldenstrom's macroglobulinemia (increased immunoglobulin production by the spleen and bone marrow cells), and lymphoma (tumor of the lymphoid tissues).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be indentified with the Hearing Clerk Docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11872 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2258]**

## Medical Devices; Classification of Immunoglobulin G (FC Fragment Specific) Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin G (Fc fragment specific) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlumudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin G (Fc fragment specific) immunological test systems:

1. Identification: An immunoglobulin G (Fc fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fc (carbohydrate containing) fragment of immunoglobulin G (resulting from breakdown of immunoglobulin G antibodies) in urine, serum, and other biological fluids. Measurement of immunoglobulin G Fc fragments aids in the diagnosis of plasma cell antibody-forming abnormalities, e.g., gamma heavy chain disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglobulin G (Fc fragment specific) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Immunoglobulin G can be broken down into many different fragments, depending on where the break takes place in the molecule, e.g., heavy chains, light chains, Fab or Fc fragments. Immunochemical analysis has demonstrated the presence of gamma globulin and gamma globulin fragments in the urine of normal individuals. The immunoglobulin G Fc (carbohydrate containing) fragment may account for 15 percent of the gamma globulin present in normal urine. Gamma heavy chain disease is a relatively rare form of plasma cell abnormality characterized by the elaboration of excessive quantities of Fc fragments of IgG. Measurement of the Fc fragment of IgG requires specific and sensitive immunochemical techniques to show that it is not Bence-Jones proteins (a form of light chain fragment of immunoglobulin G excreted in the urine of myeloma patients) or any other light chain fragment. Gamma heavy chain disease resembles lymphoma with a patient having a marked susceptibility to infection. Survival from time of onset of symptoms has ranged from a few months to a few years (Refs. 1 and 2). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health. Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of gamma heavy chain disease or other plasma cell abnormalities. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglobulin G (Fc fragment specific) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Deegan, M. J., "Bence Jones Proteins: Nature, Metabolism, Detection, and Significance," *Annals of Clinical and Laboratory Science,* 6(1):38–46, 1976.

2. Osserman, E., "Plasma Cell Dyscrasias," *in* "Textbook of Medicine," Edited by P. Beeson and W. McDermott, 14th Ed., W. B. Saunders & Co., Philadelphia, PA., pp. 1548–1549, 1975.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5530, to read as follows:

**§ 866.5530 Immunoglobulin G (Fc fragment specific) immunological test system.**

(a) *Identification.* An immunoglobulin G (Fc fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the Fc (carbohydrate containing) fragment of immunoglobulin G (resulting from breakdown of immunoglobulin G antibodies) in urine, serum, and other

biological fluids. Measurement of immunoglobulin G Fc fragments aids in the diagnosis of plasma cell antibody-forming abnormalities, e.g., gamma heavy chain disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11873 Filed 4–18–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2283]**

## Medical Devices; Classification of Immunoglobulin G (Fd Fragment Specific) Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin G (Fd fragment specific) immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immumology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 Days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin G (Fd fragment specific) immunological test systems:

1. Identification: An immunoglobulin G (Fd fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the amino terminal (antigen-binding) end (Fd fragment) of the heavy chain (a subunit) of the immunoglobulin antibody molecule. Measurement of immumoglobulin G Fd fragments aids in the diagnosis of plasma antibody-forming cell abnormalities.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglubulin G (Fd fragment specific) immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that immunoglubulin G (Fd fragment specific) immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5540, to read as follows:

**§ 866.5540 Immunoglobulin G (Fd fragment specific immunological test system.**

(a) *Identification.* An immunoglobulin G (Fd fragment specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the amino terminal (antigen-binding) end (Fd fragment) of the heavy chain (a subunit) of the immunoglobulin antibody molecule. Measurement of immunoglobulin G Fd fragments aids in the diagnosis of plasma antibody-forming cell abnormalities.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11874 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2259]**

## Medical Devices; Classification of Immunoglobulin (Light Chain Specific) Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying immunoglobulin (light chain specific) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

## Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of immunoglobulin (light chain specific) immunological test systems:

1. Identification. An immunoglobulin (light chain specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques both kappa and lambda types of light chain portions of immunoglobulin molecules in serum, body fluids, and tissues. In some diseases states, an excess of light chains is produced by the antibody-forming cells. These free light chains, unassociated with gamma globulin molecules, can be found in a patient's body fluids and tissues. Measurements of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.

2. Recommended classification: Class II (performance standards). The Panel recommended that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the immunoglobulin (light chain specific) immunological test system immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unneccessarily. Immunoglobulin molecules normally consist of four polypeptide chains of unequal size (heavy chains and light chains) bound together by several disulfide bridges. A light chain consists of two regions, a variable region that varies with each antigen which simulates immunoglobulin synthesis, and a constant region which is characteristic of a light chain. There are two types of constant regions present in light chains, kappa and lambda.

Normally, an individual possesses a heterogeneous population of kappa and lambda light chains throughout all five classes of immunoglobulins. The urine of normal persons contains free light chains unassociated with gamma globulin molecules. Up to 50 mg of light chains may be excreted daily. Elevated levels of heterogeneous free light chains may be excreted in the urine of patients with connective tissue disease, such as rheumatoid arthritis or systemic lupus erythematosus. Free light chains of restricted heterogeneity have also been observed in urine specimens from patients with lymphocytic neoplasms. In some cancerous conditions there is a proliferation of one antibody-forming cell with excess production of light chains of one specific kind (monoclonal or homogeneous light chains).

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of multiple myeloma and other lymphoproliferative disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

## Proposed Classification

The agency agrees with the Panel recommendation and is proposing that immunoglobulin (light chain specific) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by this device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

## References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gilliland, B. and M. Mannik, "Immunologic Quantititation of Proteins in Serum, Urine, and Other Body Fluids" *in* "Laboratory Diagnosis of Immunologic Disorders," Edited by G. N. Vyas, D. P. Stites, and G. Brecher, Grune and Stratton Publishing Co., New York, pp. 13–30, 1975.

2. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine*, 294(1):17–23, 1976.

3. Solomon, A., "Bence-Jones Proteins and Light Chains of Immunoglobulins," *New England Journal of Medicine*, 294(2):91–98, 1976.

4. Deegan, M. J., "Bence-Jones Proteins Nature, Metabolism, Detection and Significance," *Annals of Clinical and Laboratory Science*, 6(1):38–46, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5550, to read as follows:

**§ 866.5550 Immunoglobulin (light chain specific) immunological test system.**

(a) *Identification.* An immunoglobulin (light chain specific) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques both kappa and lambda types of light chain portions of immunoglobulin molecules in serum, body fluids, and tissues. In some disease states, an excess of light chains are produced by the antibody-forming cells. These free light chains, unassociated with gamma globulin molecules, can be found in a patient's body fluids and tissues. Measurement of the various amounts of the different types of light chains aids in the diagnosis of multiple myeloma (cancer of antibody-forming cells), lymphocytic neoplasms (cancer of lymphoid tissue), Waldenstrom's macroglobulinemia (increased production of large immunoglobulins), and connective tissue diseases such as rheumatoid arthritis or systemic lupus erythematosus.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11875 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2260]**

## Medical Devices; Classification of Lactic Dehydrogenase Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lactic dehydrogenase immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. the effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lactic dehydrogenase immunological test systems:

1. Identification: A lactic dehydrogenase immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the activity of the lactic dehydrogenase enzyme in serum. Increased levels of lactic dehydrogenase are found in a variety of conditions, including megaloblastic anemia (decrease in the number of mature red blood cells), myocardial infarction (heart disease), and some forms of leukemia (cancer of the blood-forming organs). However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that lactic dehydrogenase immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lactic dehydrogenase immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5560, to read as follows:

**§ 866.5560 Lactic dehydrogenase immunological test system.**

(a) *Identification.* A lactic dehydrogenase immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the activity of the lactic dehydrogenase enzyme in serum. Increased levels of lactic dehydrogenase are found in a variety of conditions, including megaloblastic anemia (decrease in the number of mature red blood cells), myocardial infarction (heart disease), and some forms of leukemia (cancer of the blood-forming organs). However, the diagnostic usefulness of this device is limited because of the many conditions known to cause increased lactic dehydrogenase levels.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11876 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2261]**

## Medical Devices; Classification of Lactoferrin Immunological Test Systems

**AGENCY:** Food and Drug Administation.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lactoferrin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of

Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classifiction Panel, an FDA advisory committee, made the following recommendation regarding the classification of lactoferrin immunological test systems:

1. Identification: A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, human milk, body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

2. Recommendation classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the lactoferrin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based it recommendation on the Panel member's personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that lactoferrin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5570, to read as follows:

**§ 866.5570 Lactoferrin immunological test system.**

(a) *Identification.* A lactoferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the lactoferrin (an iron-binding protein with the ability to inhibit the growth of bacteria) in serum, human milk, body fluids, and tissues. Measurement of lactoferrin may aid in the diagnosis of an inherited deficiency of this protein.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be indentified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11877 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2262]**

## Medical Devices; Classification of Alpha-1-Lipoprotein Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-1-lipoprotein immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of alpha-1-lipoprotein immunological test systems:

1. Identification: An alpha-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-lipoprotein (high-density lipoprotein) in serum or plasma. Measurement of alpha-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the alpha-1-lipoprotein immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Tangier disease is a genetic disorder consisting of a complete or nearly complete absence of plasma alpha-1-lipoprotein. Its predominant clinical features include hypocholesterolemia (low levels of cholesterol), increased levels of serum triglycerides (neutral fats synthesized from carbohydrates for storage in animal adipose cells), tonsils of unusual size and discoloration, and sometimes hepatosplenomegaly (enlarged liver and spleen). Kocen et al. (Ref. 1) has also reported a patient with neurological abnormalities. Alpha-1-lipoprotein can be measured immunochemically by immunoelectrophoresis. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of Tangier disease. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-1-lipoprotein immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Kocen, R. S., J. K. Lloyd, P. T. Lascelles, A. S. Fosbrooke, and D. Williams, "Familial Alpha-lipoprotein Deficiency (Tangier Disease) with Neurological Abnormalities," *Lancet*, Vol. I:1341–1345, 1967.

2. Frederickson, D. S., "Inheritance of High Density Lipoprotein Deficiency (Tangier Disease)," *Journal of Clinical Investigation*, 43(2):228–236, 1964.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5580, to read as follows:

**§ 866.5580 Alpha-1-lipoprotein immunological test system.**

(a) *Identification.* An alpha-1-lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-1-lipoprotein (high-density lipoprotein) in serum of plasma. Measurement of alpha-1-lipoprotein may aid in the diagnosis of Tangier disease (a hereditary disorder of fat metabolism).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11878 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2263]**

## Medical Devices; Classification of Lipoprotein X Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying lipoprotein X immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of lipoprotein X immunological test systems:

1. Identification: A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the lipoprotein X immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that lipoprotein X immunological test systems be classified into class I (general controls) with no exemption. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5590, to read as follows:

**§ 866.5590 Lipoprotein X immunological test system.**

(a) *Identification.* A lipoprotein X immunological test system is a device that consists of the reagents used to measure by immunochemical techniques lipoprotein X (a high-density lipoprotein) in serum and other body fluids. Measurement of lipoprotein X aids in the diagnosis of obstructive liver disease.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be

submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11879 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2264]**

## Medical devices; Classification of Low-Density Lipoprotein Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying low-density lipoprotein immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of low-density lipoprotein immunological test systems:

1. Identification: A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the low-density lipoprotein immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. These tests are useful in the evaluation of patients in whom cholesterol levels are being monitored. Low-density lipoproteins function to transport cholesterol and fatty acids. Low-density lipoprotein measurement is an effective means of identifying patients, particularly the young, who may be at high risk of cardiovascular disease. Disorders of lipid (fat) metabolism in body tissues may also be detected by this device (Refs. 1 through 3). The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with the device and upon a review of the literature (Refs. 1, 2, and 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of disorders of fat metabolism or of heart disease in young persons. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that low-density lipoprotein immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Fredrickson, D. S., R. I. Levy, and R. S. Lees, "Fat Transport in Lipoproteins—an Integrated Approach to Mechanisms and Disorders," *New England Journal of Medicine,* 276:34-44, 94-103, 148-156, 215-225, 273-281, 1967.

2. Fisher, W. R., and D. H. Truitt, "The Common Hyperlipoproteinemias. An Understanding of Disease Mechanisms and Their Control," *Annals of Internal Medicine,* 85:497-508, 1976.

3. Fredrickson, D. S. and R. S. Lees, "A System for Phenotyping Hyperlipoproteinemia," *Circulation,* 31:321-327, 1965.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5600, to read as follows:

**§ 866.5600 Low-density lipoprotein immunological test system.**

(a) *Identification.*—A low-density lipoprotein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the low-density lipoprotein in serum and other body fluids. Measurement of low-density lipoprotein in serum may aid in the diagnosis of disorders of lipid (fat) metabolism and help to identify young persons at risk from cardiovascular diseases.

(b) *Classification.*—Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading

of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11880 Filed 4-21-80 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2265]**

## Medical Devices; Classification of Alpha-2-macroglobulin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed Rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying alpha-2-macroglobulin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA-305), Food and Drug Administration, Rm. 4-65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK-440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301-427-7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of alpha-2-macroglobulin immunological test systems:

1. Identification: An alpha-2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-macroglobulin (a serum protein) in plasma. Measurement of alpha-2-macroglobulin may aid in the diagnosis of blood clotting or clot lysis disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that alpha-2-macroglobulin immunological test systems be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Alpha-2-macroglobulin is a normally occurring glycoprotein (carbohydrate-containing protein) in the plasma of humans. Studies indicate one of the functions of the functions of alpha-2-macroglobulin may be binding and removal of proteolytic enzymes from the body (Ref. 1). The Panel assumes that alpha-2-macroglobulin functions in the body as protection against autodigestion (Ref. 1). However, Steins and Mehl (Ref. 2) believe alpha-2-macroglobulin's physiologic role is related more to blood clotting or clot lysis than to any interaction with proteolytic enzymes. the levels of alpha-2-macroglobulin do not increase during the infection (Ref. 3), nor do they increase in systemic sclerosis (wasting of nerve cells) (Ref. 4). In contrast, alpha-2-macroglobulin concentration increases in chronic progressive polyarthritis (rheumatism) (Ref. 1), diabetes mellitus, and in patients with kidney disease (Ref. 2). Van Oss, et al., (Ref. 5) report that immunochemical tests may detect alpha-2-macroglobulin in urine of patients suffering from kidney disease. In reality, physical and chemical tests show only smaller fragments of the proteins present in the urine. It may be assumed that proteins undergo enzymatic breakdown as they pass from the kidney into the urine. Immunochemical methods cannot discriminate between a given protein and its subunits (breakdown).

Subunits of various serum proteins can occur under normal and pathological conditions. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, these devices and upon a review of the literature (Refs. 1 through 5).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of various disorders, including blood disorders, kidney disease, and chronic rheumatism. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that alpha-2-macroglobulin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for the device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Jakab, L., T. Pozsonsyi, and J. Feher, "Serum Glycoproteins in Autoimmune Diseases, *Acta Medica Academiae Scientiarum Hungaricae, Tomus,* 33(2):161-169, 1976.

2. Steines, W. J. and J. W. Mehl, "The Elevation of Alpha-2-macroglobulin and Trypsin-binding Activity in Nephrosis," *Journal of Laboratory and Clinical Medicine* 67(4):559-565, 1966.

3. Schelp, F. P., P. Migasena, P. Pongpaew, W. H. P. Schreurs, and V. Supawan, "Serum Proteinase Inhibitors and Other Serum Proteins in Protein-Energy Malnutrition," *British Journal of Nutrition* 38:31-39, 1977.

4. Husson, J. M., A. LeGo, R. Engler, M. P. Ollier, J. N. Fiessinger, E. Housset, and L. Hartman, "Immunochemical Study on Serum Proteins in Systemic Sclerosis," *Biomedicine* 26:182-187, 1977.

5. Van Oss, C. J., M. K. Hawking, and P. M. Bronson, "A Comparison Between Immunochemical and Physical Chemical Analyses of the Molelcular Size of Urinary Proteins," *Biochemical Medicine* 7:466-472, 1973.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540-546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5620, to read as follows:

**§ 866.5620 Alpah-2-macroglobulin immunological test system.**

(a) *Identification.* An alpha-2-macroglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the alpha-2-macroglobulin (a serum protein) in plasma. Measurement of alpha-2-macroglobulin may aid in the diagnosis of blood-clotting or clot lysis disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the hearing of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11881 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2266]**

## Medical Devices; Classification of Beta–2–Microglobulin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying beta–2–microglobulin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of beta–2–microglobulin immunological test systems:

1. Identification: A beta–2–microglobulin immunological test system is device that consists of the reagents used to measure by immunochemical techniques the beta–2–microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of beta–2–microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a low priority.

3. Summary of reasons for recommendation: The Panel recommends that the beta–2–microglobulin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Beta–2–microglobulin is a small molecular weight serum protein and is associated with human cell surface antigens. It is present in low concentrations in normal serum, urine, spinal fluid, colostrum (human milk protein), and amniotic fluid. Serum levels have been shown to increase with age, and levels are consistently higher in females than in males. They are also increased in synovial (joint) fluid of patients with active rheumatoid arthritis and in saliva of patients with Sjogren's syndrome (a type of disease of the cornea of the eye) (Ref. 1). It appears that beta–2–microglobulin is eliminated by the kidney, and levels may be used to monitor renal tubular deficiency. Teasdale et al. (Ref. 2) have concluded that serum levels of beta–2–microglobulin are increased in cancer patients, but note that the biological significance of these findings is subject to debate.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 and 2).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of rheumatoid arthritis, Sjogrens syndrome, and kidney disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that beta-2-microglobulin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Fye, K., H. Moutsopoulos, and N. Talal, "Rheumatoid Diseases," *in* "Basic and Clinical Immunology," Edited by Fudenberg, H. H., D. P. Stites, J. L. Caldwell, and J. V. Wells, Lange Medical Publications, Los Altos, p. 374, 1976.

2. Teasdale, C., A. M. Mander, R. Fifield, J. W. Keyser, R. G. Newcombe, and L. E. Hughes, "Serum beta-2-Microglobulin in Controls and Cancer Patients," *Clinica Chimica Acta* 78: 135–143, 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5630, to read as follows:

**§ 866.5630 Beta-2-microglobulin immunological test system.**

(a) *Identification.* A beta-2-microglobulin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques beta-2-microglobulin (a protein molecule) in serum, urine, and other body fluids. Measurement of beta-2-microglobulin aids in the diagnosis of patients with active rheumatoid arthritis and kidney disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11882 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2267]**

## Medical Devices; Classification of infectious Mononucleosis Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying infectious mononucleosis immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Siver spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. the Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of infectious mononucleosis immunological test systems:

1. Identification: An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques infectious mononucleosis antibodies in serum, plasma, and body fluids. Measurments of infectious mononucleosis antibodies aid in the diagnosis of infectious mononucleosis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the infectious mononucleosis immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specifity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Infectious mononucleosis is an acute and self-limiting disease occurring most frequently in the young adult. The Epstein-Barr virus, which is responsible for the disease, is most often detected indirectly with various immunochemical techniques. Between 50 and 90 percent of patients with infectious mononucleosis develop heterophile antibodies (antibodies which will cause the red blood cells of several different animals, e.g., sheep, horse, and cow, to agglutinate or clump together). The agglutination of sheep or horse red cells is the common method used for the detection of this heterophilic infectious nononucleosis antibody. Heterophile antibodies may also appear during serum sickness (an allergic reaction following a large injection of foreign serum), or they may be present in normal individuals. Positive identification of the heterophile antibodies of infectious mononucleosis can be made by a differential adsorption of the patient's serum with beef red cells and guinea pig kidney before testing for agglutination of sheep or horse red blood cells. Antibodies of infectious mononucleosis are adsorbed by beef red cells, but not by guinea pig kidney; serum sickness agglutinins are adsorbed by both; and normal serum heterophile antibodies are adsorbed by guinea pig kidney, but not usually by beef red blood cells. It is important to diagnose infectious mononucleosis correctly because the symptoms, particularly fever and enlargement of the lymph glands, are very similar to those of lymphatic and monocytic leukemia. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability and specificity. the Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: the Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of infectious mononucleosis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that infectious mononucleosis immunological test systems be classified into II (performance standards). The agency believes that a performance is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Gerber, P., J. Whang-Peng, and J. H. Monroe, "Transformation and Chromosome Changes Induced by Epstein-Barr Virus in Normal Human Leukocyte Cultures," Proceedings of National Academy of Science, U.S.A., 63: 740–747, 1969.

2. Paul, J. R. and W. W. Bunnell "The Presence of Heterophile Antibodies *in*

Infectious Mononucleosis," *The American Journal of Medical Science*, 183:90–104, 1932.

3. Lee, C. L., I. Davidsohn and R. Slaby, "Horse Agglutinins in Infectious Mononucleosis," *The American Journal of Clinical Pathology*, 49:3–11, 1968.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371 (a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5640, to read as follows:

**§ 866.5640 Infectious mononucleosis immunoligical test system.**

(a) *Identification.* An infectious mononucleosis immunological test system is a device that consists of the reagents used to measure by immunochemical techniques infectious mononucleosis antibodies in serum, plasma, and body fluids. Measurements of infectious mononucleosis antibodies aid in the diagnosis of infectious monoucleosis.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11883 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2268]**

## Medical Devices; Classification of Multiple Autoantibodies Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying multiple autoantibodies immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the Federal Register.

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the Federal Register provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of multiple autoantibodies immunological test systems:

1. Identification: A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in human serum and other biological fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (diseases produced when the body's own tissues are injured by autoantibodies).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the multiple autoantibodies immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The device aids in the evaluation of patients in whom systemic lupus erythematosus (a multisystem autoimmune disease) or one of several other autoimmune connective tissue diseases produce a spectrum of autoantibodies (antibodies produced against patient's own tissues) against a variety of tissues. These multiple antibodies are not specific and will react with the antigenic components of cells from many species. Multiple autoantibodies may belong to any of the immunoglobulin classes (IgA, IgD, IgE, IgG, and IgM). Immunological procedures that have been used to detect multiple autoantibodies include: complement fixation, passive hemagglutination, passive agglutination, gel diffusion, counter immunoelectrophoresis, radioimmunoassays, and immunofluorescence assays. A significant number of apparently normal individuals also demonstrate autoantibodies in their serum. Consequently, for the definite diagnosis of a given autoimmune disorder, additional immunological tests are needed to interpret the significance of detecting multiple antoantibodies in serum. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which The recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 5).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of autoimmune disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that multiple autoantibodies immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Moake, J. L. and D. R. Schultz, "Hemolytic Anemia Associated with Multiple Autoantibodies and Low Serum Complement," *American Journal of Medicine*, 58(3) :431–437, 1975.

2. Notman, D. D., N. Kurata, and E. M. Tan, "Profiles of Antinuclear Antibodies in Systemic Rheumatic Disease," *Annals of Internal Medicine*, 83:464–469, 1975.

3. Shaller, J., C. Kupfer and R. J. Wedgwood, "Iridocyclitis in Juvenile Rheumatoid Arthritis," *Pediatrics*, 44:92–100, 1969.

4. Tan, E. M. and H. G. Kunkel, "Characteristics of a Soluble Nuclear Antigen Precipitating with Sera of Patients with Systemic Lupus Erythematosus," *Journal of Immunology*, 96:464–471, 1966.

5. Sharp, G. C., W. S. Irvin, R. L. LaRogue, C. Velez, V. Daly, A. D. Kaiser and H. R. Holman, "Association of Autoantibodies to Different Nuclear Antigens with Clinical Patterns of Rheumatic Disease and Responsiveness to Therapy," *The Journal of Clinical Investigation*, 50:350–359, 1971.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5660, to read as follows:

**§ 866.5660 Multiple autoantibodies immunological test system.**

(a) *Identification.* A multiple autoantibodies immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) in human serum and other biological fluids. Measurement of multiple autoantibodies aids in the diagnosis of autoimmune disorders (diseases produced when the body's own tissues are injured by autoantibodies).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11884 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2269]**

## Medical Devices; Classification of Myoglobin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying myoglobin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comment to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of myoglobin immunological test systems:

1. Identification: A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of patients with renal or heart disease.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the myoglobin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, this device.

5. Risks to health: None identified.

### Proposed Classification

FDA disagrees with the Panel recommendation that this device be classified into class I (general controls) and is proposing that myoglobin immunological test systems be classified into class II (performance standards). The agency has reviewed the Panel recommendation and has sought other information and data describing the measurement of myoglobin in patients suffering from heart attacks. Myoglobin is a protein synthesized by cardiac and skeletal muscle tissue. The snythesis of myoglobin and resulting myoglobinemia (myoglobin protein in urine) has been found to correlate with myocardial infarction (heart attact), skeletal muscle damage, circulatory collapse, and severe renal disease (Refs. 1 through 5). The agency notes that reliance on the diagnostic information derived from use of this device, if inaccurate, could result in a situation that may be hazardous to the patient's health. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the device's accuracy, precision, sensitivity, stability, and specificity. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency also believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Miyoshi, K., S. Saito, H. Kawai, A. Kondo, M. Iwasa, T. Hayashi, and M. Yagita, "Radioimmunoassay for Human Myoglobin: Methods and Results in Patients with Skeletal Muscle or Myocardial Disorders," *Journal Laboratory and Clinical Medicine*, 92(3):341–352, Sept. 1978.

2. Reichlin, M., J. P. Visco, F. J. Klocke, "Radioimmunoassay for Human Myoglobin. Initial Experience in Patients with Coronary Heart Disease," *Circulation*, 57(1):52–56, Jan. 1978.

3. Stone, M. J., M. R. Waterman, D. Harimoto, G. Murray, N. Willson, M. R. Platt, G. Blomqvist, J. T. Willerson, "Serum Myoglobin Level as Diagnostic Test in Patients with Acute Myocardial Infarction," *British Heart Journal*, 39(4):375–380, Apr. 1977.

4. Kagen, L., S. Scheidt, A. Butt, "Serum Myoglobin in Myocardial Infarction: the Staccato Phenomenon: Is acute Myocardial Infarction in Man and Intermittent Event?" *The American Journal of Medicine*, 62(1):86–92, Jan. 1977.

5. Donald, T. G., M. J. Cloonan, C. Neale, D. E. L. Wilcken, "Excretion of Myoglobin in Urine after Acute Myocardial Infarction," *British Heart Journal*, 39(1):29–34, Jan. 1977.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5680, to read as follows:

**§ 866.5680 Myoglobin immunological test system.**

(a) *Identification.* A myoglobin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the myoglobin (an oxygen storage protein found in muscle) in serum and other body fluids. Measurement of myoglobin aids in the rapid diagnosis of patients with renal or heart disease.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11885 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2270]**

## Medical Devices; Classification of Whole Human Plasma or Serum Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying whole human plasma or serum immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of whole human plasma or serum immunological test systems:

1. Identification: A whole human plasma or serum immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the proteins in human plasma or serum. Measurements of proteins in human plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the whole human plasma or serum immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. A summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device. The immunochemical techniques that have been used include gel diffusion, immunoelectrophoresis, crossed-immunoelectrophoresis, counterimmunoelectrophoresis, radioimmunoassays or immunofluorescence assays.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that whole human plasma or serum immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5700, to read as follows:

**§ 866.5700 Whole human plasma or serum immunological test system.**

(a) *Identification.* A whole human plasma or serum immunological test system is a device that consists of reagents used to measure by immunochemical techniques the proteins in human serum or plasma. Measurements of proteins in human plasma or serum aid in the diagnosis of any disease concerned with abnormal levels of plasma or serum proteins, e.g., agammaglobulinemia, allergies, multiple myeloma, rheumatoid vasculitis, or hereditary angioneurotic edema.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing

Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11886 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

## 21 CFR Part 866

**[Docket No. 78N–2271]**

## Medical Devices; Classification of Plasminogen Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying plasminogen immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a defice into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of plasminogen immunological test systems:

1. Identification: A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the plasminogen immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that plasminogen immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5715, to read as follows:

**§ 866.5715 Plasminogen immunological test system.**

(a) *Identification.* A plasminogen immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the plasminogen (an inactive substance from which plasmin, a blood-clotting factor, is formed) in serum, body fluids, and tissues. Measurement of plasminogen levels may aid in the diagnosis of fibrinolytic (blood-clotting) disorders.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11887 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

## 21 CFR Part 866

**[Docket No. 78N–2272]**

## Medical Devices; Classification of Prothrombin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying prothrombin immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:**

Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of prothrombin immunological test systems:

1. Identification: A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of patients with blood-clotting disorders.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the prothrombin immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of this device.

5. Risks to health: None identified.

**Proposed Classification**

FDA agrees with a the Panel recommendation and is proposing that prothrombin immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5735, to read as follows:

**§ 866.5735 Prothrombin immunological test system.**

(a) *Identification.* A prothrombin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the prothrombin (clotting factor II) in serum. Measurements of the amount of antigenically competent (ability to react with protein antibodies) prothrombin aid in the diagnosis of patients with bloodclotting disorder.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11888 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2273]**

## Medical Devices; Classification of Radioallergosorbent (Rast) Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying radioallergosorbent (RAST) immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that 78–1873 the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of radioallergosorbent (RAST) immunological test systems:

1. Identification: A radioallergosorbent immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodites which cause an allergic reaction) specific for a given allergen. Measurement of specific allergen antibodies may aid in the diagnosis of asthma, allergies, and other pulmonary disorders.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the radioallergosorbent (RAST) immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. The radioallergosorbent tests (RAST) were developed to detect the antibodies (IgE class) specific for particular organic dust allergens (Ref. 1). These tests are useful in the diagnosis of patients in whom an immediate allergic reaction to more than one organic dust allergen results in bronchial asthma symptoms. Antibodies may be directed against organic dusts derived from plant, fungal, or animal protein sources.

However, clinical allergy is caused by IgE-allergen complexes located in the tissues rather than circulating in body fluids. Both radioallergoabsorbent tests and passive tranfer tests only indicate the presence or absence of the particular IgE antibody in serum. A provocative test (a test which acutally provokes the allergic tissues with an allergen) is the most reliable method for determining the causative agent of an allergy. Pulmonary provocation tests are easy to perform and interpret, but many other provocation tests for other types of allergies are more demanding with regard to both equipment and experience.

In one study, the use of the radioallegosorbent test as a supplement to a carefully collected case history and critically evaluated skin tests made the performance of provocative tests superfluous in 82 percent of patients studied (Ref. 1). The Panel believes

that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literaute (Refs. 1 through 3).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the identification of the causative agent in asthma, allergies, and other pulmonary disorders. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that radioallergosorbent (RAST) immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Aas, K. and S. G. O. Johansson, "The Radioallergosorbent Test in the In Vitro Diagnosis of Multiple Reaginic Allergy," *Journal of Allergy and Clinical Immunology*, 48:134–142, 1971.

2. Wide, L., H. Bennich, and S. G. O. Johansson, "Diagnosis of Allergy by an In Vitro Test for Allergen Antibodies," *Lancet*, 2:1105–1107, 1967.

3. Gleich, G. J. and R. T. Jones "Measurement of IgE Antibodies by the Radioallergosorbent Test. I. Technical Considerations in the Performance of the Test," *Journal of Allergy and Clinical Immunology, 55:334–345, 1975.*

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5750, to read as follows:

**§ 866.5750 Radioallergosorbent (RAST) immunological test system.**

(a) *Identification.* A radioallergosorbent immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the allergen antibodies (antibodies which cause an allergic reaction) specific for a given allergen. Measurement of specific allergen antibodies may aid in the diagnosis of asthma, allergies, and other pulmonary disorders.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11889 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2274]**

## Medical Devices; Classification of Retinol-Binding Protein Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying retinol-binding protein immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of retinol-binding protein immunological test systems:

1. Identification: A retinol-binding protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques retinol-binding protein that binds and transports vitamin A in serum and urine. Measurement of this protein may aid in the diagnosis of kidney disease and in monitoring patients with kidney transplants.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the retinol-binding protein immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that retinol-binding protein immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs

proposes to amend Part 866 in Subpart F by adding new § 866.5765, to read as follows:

**§ 866.5765 Retinol-binding protein immunological test system.**

(a) *Identification.* A retinol-binding protein immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the retinol-binding protein that binds and transports vitamin A in serum and urine. Measurement of this protein may aid in the diagnosis of kidney disease and in monitoring patients with kidney transplants.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980 submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11890 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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**21 CFR Part 866**

**[Docket No. 78N–2275]**

## Medical Devices; Classification of Rheumatoid Factor Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying rheumatoid factor immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immuology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of rheumatoid factor immunological test systems:

1. Identification: A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in human serum, body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the rheumatoid factor immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Measurements of rheumatoid factor aid in the diagnosis of rheumatoid arthritis and other chronic inflammatory diseases, such as tuberculosis and leprosy. Rheumatoid factor present in patients with vasculitis (inflammation of veins) and rashes, particularly when limited to the legs, may be indicative of cancer of the lymphoid system. Immunochemical test procedures which have been used to detect rheumatoid factor antibodies include slide latex agglutination, latex tube dilution, and aggregated precipitin tests. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 6).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of rheumatoid arthritis. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that rheumatoid factor immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Allen, J. C. and H. G. Kunkel, "Hidden Rheumatoid Factors with Specificity for Native Gammaglobulins," *Arthritis and Rheumatism*, 9:758–768, 1966.

2. Edelman, G. M., H. G. Kinkel, and E. C. Franklin, "Interaction of the Rheumatoid Factor with Antigen Antibody Complexes and Aggregated Gammaglobulin," *Journal of Experimental Medicine*, 108:105–120, 1958.

3. Singer, J. M. and C. M. Plotz, "The Latex-Fixation Test-I Application to the Serologic Diagnosis of Rheumatoid Arthritis," *American Journal of Medicine*, 21:888–892, 1956.

4. Waller, M. V. and J. H. Vaughan, "Use of Anti-Rh Sera for Demonstrating Agglutination Activating Factor in Rheumatoid Arthritis," *Proceedings of the Society of Expermental Biology and Medicine*, 92:198–200, 1956.

5. Ziff, M., "The Agglutination Reaction in Rheumatoid Arthritis," *Journal of Chronic Disease*, 5:644–667, 1957.

6. Winchester, R., *Tests for Detection of the Rheumatoid Factors," in* "Manual of Clinical Immunology," edited by Noel R. Rose and Herman Friedman, American Society for Microbiology, Washington, DC, pp. 665–675, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513,

701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5775, to read as follows:

**§ 866.5775 Rheumatoid factor immunological test system.**

(a) *Identification.* A rheumatoid factor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the rheumatoid factor (antibodies to immunoglobulins) in human serum, body fluids, and tissues. Measurement of rheumatoid factor may aid in the diagnosis of rheumatoid arthritis.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11891 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2276]**

## Medical Devices; Classification of Seminal Fluid (Sperm) Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying seminal fluid (sperm) immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. the Immunology Device Classification Panel, and FDA advisory committee, made the following recommendation regarding the classification of seminal fluid (sperm) immunological test systems:

1. Identification: A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results can be used as court evidence in alleged instances of rape and other sex-related crimes.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the seminal fluid (sperm) immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that seminal fluid (sperm) immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5800, to read as follows:

**§ 866.5800 Seminal fluid (sperm) immunological test system.**

(a) *Identification.* A seminal fluid (sperm) immunological test system is a device that consists of the reagents used for legal purposes to identify and differentiate animal and human semen. The test results can be used as court evidence in alleged instances of rape and other sex-related crimes.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11892 Filed 4-27-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2277]**

## Medical Devices; Classification of Systemic Lupus Erythematosus Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying systemic lupus erythematosus immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These

actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of systemic lupus erythematosus immunological test systems:

1. Identification: A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a high priority.

3. Summary of reasons for recommendation: The Panel recommends that the systemic lupus erythematosus immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily.

Antibodies directed against certain defined nuclear antigens are more specific for SLE than for other connective tissue disorders. High titers of antibodies that react with double-stranded deoxyribonucleic acid (DNA) appear mainly in active SLE, although they have been found occasionally in patients with other diseases such as rheumatoid arthritis, juvenile rheumatoid arthritis, and chronic active hepatitis. The increase or decrease in the amount of antidouble-stranded DNA antibodies usually reflect disease activity or remission, respectively, and thus may be used to monitor SLE disease activity. Immunological test systems used to detect these antibodies may include gel diffusion, complement fixation, passive hemagglutination, latex or bentonite agglutination, counter immunoelectrophoresis, or radioimmunodiffusion.

An anti-Sm antibody (an antibody reacting with an acidic glycoprotein found in the cellular nucleus) is also highly specific for SLE, but is found in only about 20 percent of SLE patients.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature. (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of systemic lupus erythematosus. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that SLE immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Casals, S. P., G. J. Friou, and P. O. Teague, "Specific Nuclear Reaction Pattern of Antibody to DNA in Lupus Erythematosus Sera," *Journal of Laboratory and Clinical Medicine*, 62:625–631, 1963.

2. Gonzalez, E. N. and N. F. Rothfield, "Immunoglobulin Class and Pattern of Nuclear Fluorescence in Systemic Lupus Erythematosus," *New England Journal of Medicine*, 274:1333–1338, 1966.

3. Rothfield, N. F. and B. D. Stollar, "The Relation of Immunoglobulin Class, Pattern of Anti-nuclear Antibody and Complement-fixing Antibodies to DNA in Sera From Patients with Systemic Lupus Erythematosus," *Journal of Clinical Investigation*, 46:1785–1794, 1967.

4. Chapman, J. C., "Lupus Erythematosus Latex Tests Compared with the Immunofluorescence Method for Antinuclear Factor," *American Journal of Medical Technology*, 42(5):126–129, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5820, to read as follows:

**§ 866.5820 Systemic lupus erythematosus immunological test system.**

(a) *Identification.* A systemic lupus erythematosus (SLE) immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoimmune antibodies in serum and body fluids that react with cellular nuclear double-stranded deoxyribonucleic acid (DNA) or other nuclear constituents that are specifically diagnostic of SLE. Measurement of nuclear double-stranded DNA antibodies aids in the diagnosis of systemic lupus erythematosus (a multisystem autoimmune disease in which tissues are attacked by the person's own antibodies).

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11893 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N-2278]

## Medical Devices; Classification of Total Spinal Fluid Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying total spinal fluid immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FUTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION**

### Panel Recommendation

A proposal elswhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of total spinal fluid immunological test systems:

1. Identification: A total spinal fluid immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of inflamation of the central nervous system.

2. Recommended classification: Class I (general controls). the Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that the total spinal fluid immunological test system be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of date on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that total spinal fluid immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5860, to read as follows:

**§ 866.5860 Total spinal fluid immunological test system.**

(a) *Identification.* A total spinal fluid immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the total protein in cerebrospinal fluid. Measurement of spinal fluid proteins may aid in the diagnosis of inflammation of the central nervous system.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11894 Filed 4–21–80: 8:45 am]

BILLING CODE 4110–03–M

21 CFR Part 866

[Docket No. 78N-2279]

## Medical Devices; Classification of Thyroid Autoantibody Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying thyroid autoantibody immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure the safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. the Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of thyroid autoantibody immunological test systems:

1. Identification: A thyroid autoantibody immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) to thyroid tissues. Measurement of thyroid autoantibodies may aid in the diagnosis of certain thyroid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic

goiter (enlargement of thyroid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the thyroid autoantibody immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specificity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Detection and measurement of thyroid antibodies aid in distinguishing Hashimoto's disease (chronic lymphocytic thyroiditis) from nontoxic goiter, Grave's disease, and several types of cancer of the thyroid. Immunochemical techniques used for the detection and measurement of thyroid autoantibodies include the following: sheep cell hemagglutination, latex agglutination, bentonite agglutination, complement fixation, immunofluorescence, and cytotoxicity assays. Low levels of thyroid autoantibodies have also been found in patients with pernicious anemia (reduced hemoglobin due to inability of the body to absorb vitamin $B_{12}$), atrophic gastritis (long-lasting inflammation of the stomach with atrophy of the mucous membrane and glands), and other disorders. About 80 percent of cases with thyrotoxicosis (a disease condition resulting from overactivity of the thyroid gland) also have increased thyroid autoantibody levels (Refs. 1 through 4). Because false-positive results are common with immunochemical techniques, diagnosis of Hashimoto's disease should be confirmed histologically by a needle biopsy. The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1 through 4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an eror in the differentiation of chronic lymphocytic thyroiditis (Hashimoto's Disease) from nontoxic goiter (Grave's disease), and several types of cancer of the thyroid. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that thyroid autoantibody immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard will provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

### References

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Amino, N., S. R. Hagen, N. Yamada and S. Refetoff, "Measurement of Circulating Thyroid Microsomal Antibodies by the Tanned Red Cell Haemagglutination Technique: Its Usefulness in the Diagnosis of Autoimmune Thyroid Diseases," *Clinical Endocrinology*, 5(2):115–125, 1976.

2. Pinchera, A., et al., "Studies on the Nature of Thyroid Antigens Involved in Thyroid Autoimmune Disorders," *in* "Thyroid Research," edited by J. Robbins et al., *Excerpta. Medica.*, Amsterdam, 1976. pp. 395–398.

3. Perrin, J. and M. A. bubel, "Assessment of a Haemagglutination Test for Thyroid Microsomal Antibody," *Medical Laboratory Technology*, 31(3):205–211, 1974.

4. Rose, N. R., "Endocrine Diseases" *in* "Basic and Clinical Immunology," edited by H. M. Fudenberg, D. P. Stites, J. L. Caldwell, and J. Vivian Wells, Lange Medical Publications, Los Altos, Calif. 554–563, 1976.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5870, to read as follows:

**§ 866.5870 Thyroid autoantibody immunological test system.**

(a) *Identification.* A thyroid autoantibody immunologioal test system is a device that consists of the reagents used to measure by immunochemical techniques the autoantibodies (antibodies produced against the body's own tissues) to thyroid tissues. Measurement of thyroid autoantibodies may aid in the diagnosis of certain thryoid disorders, such as Hashimoto's disease (chronic lymphocytic thyroiditis), nontoxic goiter (enlargement of thryoid gland), Grave's disease (enlargement of the thyroid gland with protrusion of the eyeballs), and cancer of the thyroid.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11895 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

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## 21 CFR Part 866

**[Docket No. 78N–2280]**

## Medical Devices; Classification of Transferrin Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying transferrin immunological test systems into class II (performance standards). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class II. The effect of classifying a device into class II is to provide for the future development of one or more performance standards to assure safety and effectiveness of the device. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

**Panel Recommendation**

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of transferrin immunological test systems:

1. Identification: A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders such as iron deficiency anemia.

2. Recommended classification: Class II (performance standards). The Panel recommends that establishing a performance standard for this device be a medium priority.

3. Summary of reasons for recommendation: The Panel recommends that the transferrin immunological test system be classified into class II (performance standards) because there is a need for a performance standard that prescribes for this device acceptable ranges of accuracy, stability, precision, sensitivity, and specifity and thereby minimizes the possibility that the device may generate inaccurate diagnostic information. Reliance upon inaccurate diagnostic information could result in inappropriate therapy that places the patient at risk unnecessarily. Transferrin is a glycoprotein (carbohydrate-containing protein) synthesized mainly in the liver. Transferrin functions in iron binding and transport and is the most important pathway by which iron gains access to the red blood cell-forming organs. Normally, most of the iron found in the circulatory system (blood and plasma) is bound to transferrin. The ratio of serum iron level to plasma transferrin level (percent saturation) varies from disease to disease. An increase in the saturation of transferrin can occur in conditions of decreased circulating protein (liver disease), blockage of hemoglobin synthesis, iron overload, and acute blood loss. A decrease in the saturation of transferrin is present in iron deficiency eenemia, malignant tumors, and late pregnancy. Measurement of transferrin levels also aids in evaluation of red blood cell disorders and infections.

The Panel believes that general controls would not provide sufficient control over the device's accuracy, precision, sensitivity, stability, and specificity. The Panel believes that a performance standard will provide reasonable assurance of the safety and effectiveness of the device and that there is sufficient information to establish a standard.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and upon a review of the literature (Refs. 1–4).

5. Risks to health: Misdiagnosis and inappropriate therapy: Failure of the device to perform satisfactorily may lead to an error in the diagnosis of anemia, malnutrition, acute inflammation, and infection. Inappropriate therapy based on inaccurate diagnostic data may place the patient at risk.

**Proposed Classification**

FDA agrees with the Panel recommendation and is proposing that the transferrin immunological test systems be classified into class II (performance standards). The agency believes that a performance standard is necessary for this device because general controls alone are insufficient to control the risks to health presented by the device. A performance standard would provide reasonable assurance of the safety and effectiveness of the device. The agency believes that there is sufficient information to establish a performance standard for this device.

**References**

The following information has been placed in the office of the Hearing Clerk (address above) and may be seen by interested persons, from 9 a.m. to 4 p.m., Monday through Friday.

1. Henry, J. B., "Clinical Diagnosis by Laboratory Methods," 15th Ed., W. B. Saunders Co., Philadelphia, pp. 652–656, 1975.

2. Ingenbleek, Y., H. van den Schrieck, P. de Nayer, and M. de. Visscher, "Albumin, Transferrin and the Thyroxine-Binding Prealbumin/Retinol-Binding Protein (TBPA–RBP) Complex in Assessment of Malnutrition" *Clinica Chimica Acta,* 63:61–67, 1975.

3. Tietz, N. W., "Fundamentals of Clinical Chemistry," 2d Ed., W. B. Saunders Co, Philadelphia, pp. 926–928, 1976.

4. Wintrobe, N. M. and G. R. Lee, "Iron Deficiency Anemia and other Hypochromic Microcytic Anemias," *in* "Harrison's Principles of Internal Medicine," 7th Ed., McGraw-Hill, New York, pp. 1581–1585, 1974.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in Subpart F by adding new § 866.5880, to read as follows:

**§ 866.5880 Transferrin immunological test system.**

(a) *Identification.* A transferrin immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the transferrin (an iron-binding and transporting serum protein) in serum, plasma, and body fluids. Measurement of transferrin levels aids in the diagnosis of malnutrition, acute inflammation, infection, and red blood cell disorders such as iron deficiency anemia.

(b) *Classification.* Class II (performance standards).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of any comments are to be submitted, except that individuals may submit one copy. Comments are to be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80-11896 Filed 4-27-80; 8:45 am]

BILLING CODE 4110-03-M

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**21 CFR Part 866**

**[Docket No. 78N-2281]**

## Medical Devices; Classification of Inter-Alpha Trypsin Inhibitor Immunological Test Systems

**AGENCY:** Food and Drug Administration.

**ACTION:** Proposed rule.

**SUMMARY:** The Food and Drug Administration (FDA) is issuing for public comment a proposed regulation classifying inter-alpha trypsin inhibitor immunological test systems into class I (general controls). FDA is also publishing the recommendation of the Immunology Device Classification Panel that the device be classified into class I. The effect of classifying a device into class I is to require that the device meet only the general controls applicable to all devices. After considering public comments, FDA will issue a final regulation classifying the device. These actions are being taken under the Medical Device Amendments of 1976.

**DATES:** Comments by June 23, 1980. FDA proposes that the final regulation based on this proposal become effective 30 days after the date of its publication in the **Federal Register.**

**ADDRESS:** Written comments to the office of the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857.

**FOR FURTHER INFORMATION CONTACT:** Srikrishna Vadlamudi, Bureau of Medical Devices (HFK–440), Food and Drug Administration, Department of

Health, Education, and Welfare, 8757 Georgia Ave., Silver Spring, MD 20910, 301–427–7550.

**SUPPLEMENTARY INFORMATION:**

### Panel Recommendation

A proposal elsewhere in this issue of the **Federal Register** provides background information concerning the development of the proposed regulation. The Immunology Device Classification Panel, an FDA advisory committee, made the following recommendation regarding the classification of inter-alpha trypsin inhibitor immunological test systems:

1. Identification: An inter-alpha trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immuno-chemical techniques the inter-alpha trypsin inhibitor (a protein) in serum and body fluids. Measurement of inter-alpha trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

2. Recommended classification: Class I (general controls). The Panel recommends that there be no exemptions.

3. Summary of reasons for recommendation: The Panel recommends that inter-alpha trypsin inhibitor immunological test systems be classified into class I because the Panel believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

4. Summary of data on which the recommendation is based: The Panel based its recommendation on the Panel members' personal knowledge of, and clinical experience with, the device and on a history of satisfactory performance of the device.

5. Risks to health: None identified.

### Proposed Classification

FDA agrees with the Panel recommendation and is proposing that inter-alpha trypsin inhibitor immunological test systems be classified into class I (general controls) with no exemptions. The agency believes that general controls are sufficient to provide reasonable assurance of the safety and effectiveness of the device.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 513, 701(a), 52 Stat. 1055, 90 Stat. 540–546 (21 U.S.C. 360c, 371(a))) and under authority delegated to him (21 CFR 5.1), the Commissioner of Food and Drugs proposes to amend Part 866 in subpart F by adding new § 866.5896, to read as follows:

**§ 866.5890 Inter-alpha trypsin inhibitor immunological test system.**

(a) *Identification.* An inter-alpha trypsin inhibitor immunological test system is a device that consists of the reagents used to measure by immunochemical techniques the inter-alpha trypsin inhibitor (a protein) in serum and body fluids. Measurement of inter-alpha trypsin inhibitor may aid in the diagnosis of acute bacterial infection and inflammation.

(b) *Classification.* Class I (general controls).

Interested persons may, on or before June 23, 1980, submit to the Hearing Clerk (HFA–305), Food and Drug Administration, Rm. 4–65, 5600 Fishers Lane, Rockville, MD 20857, written comments regarding this proposal. Four copies of all comments shall be submitted, except that individuals may submit single copies of comments, and shall be identified with the Hearing Clerk docket number found in brackets in the heading of this document. Received comments may be seen in the above office between the hours of 9 a.m. and 4 p.m., Monday through Friday.

Dated: April 2, 1980.

**William F. Randolph,**

*Acting Associate Commissioner for Regulatory Affairs.*

[FR Doc. 80–11897 Filed 4–21–80; 8:45 am]

BILLING CODE 4110–03–M

federal register

Tuesday
April 22, 1980

Part III

# Office of Management and Budget

## Cost Principles for Grants to State and Local Governments

## OFFICE OF MANAGEMENT AND BUDGET

[Circular 74-4]

### Cost Principles for Grants to State and Local Governments

**AGENCY:** Office of Management and Budget.

**SUMMARY:** This notice advises that Circular 74-4 has been revised by modifying Attachment B, "Standards for Selected Items of Cost." The revision affects the rules dealing with travel costs of chief executives and members of governing bodies, and the costs of office space used in federally assisted programs. The revision was recommended by State and local officials, Federal grantmaking agencies, the General Accounting Office, and various associations.

The first change recognizes travel costs that are specifically related to federally assisted programs. It requires approval of such costs by the agency.

The second change recognizes the costs of space in publicly owned buildings. It does this by permitting internal "rental rates," or equivalent systems, to be used in allocating the cost of space. If approved by a grantor agency, rates would include depreciation, interest, operation, maintenance and other allowable costs. The total cost of space would not be allowed to exceed the rental cost of comparable space in the same locality.

The change also revises the provisions dealing with interest and other costs of financing, for consistency with the revision on rental costs. It continues the policy of not permitting amortization of the cost of buildings constructed originally with Federal funds.

**EFFECTIVE DATE:** This revision becomes effective upon issuance.

**FOR FURTHER INFORMATION CONTACT:** John J. Lordon, Chief, Financial Management Branch, Office of Management and Budget, Washington, D.C. 20503; (202) 395-6823.

**SUPPLEMENTARY INFORMATION:** On September 5, 1979, a notice was published in the **Federal Register** (44 FR 51921) to amend Circular 74-4 with regard to travel costs. Interested persons were invited to submit written comments. About 35 comments were received from Federal agencies, State and local governments, associations, and other interested parties. Most comments supported the change. Several suggested clarifying the provision on Federal approval of travel costs, and this has been clarified.

On June 28, 1979, a notice was published in the **Federal Register** (44 FR 37707) to amend Circular 74-4 with regard to rental costs. Interested persons were invited to submit written comments. About 60 comments were received from Members of Congress, Federal agencies, State and local governments, colleges and universities, associations, and other interested parties. The comments were considered in developing these final regulations. The more significant comments received, and OMB's responses to them, are discussed below.

*Comment.* Several respondents recommended deleting the phrase "new or newly occupied," in order to permit the new policy to apply to all existing buildings.

*Response.* Existing buildings of State and local government were constructed in the face of a Federal policy that limited recognition of their costs when occupied by federally assisted programs. To apply the new rules to old buildings would appear to provide a windfall recovery to these governments. Further, we were concerned that applying the new rules to all buildings would drive up the overhead costs of federally assisted programs. Applying them only to new buildings, on the other hand, may be expected to hold down overhead costs, since some governments may now convert from expensive leased space to government-owned buildings.

*Comment.* Several respondents recommended extension of the proposed policy to automatic data processing facilities and equipment. A few respondents recommended covering "all" capital investment.

*Response.* The proposal relating to buildings has been under consideration for some time. It was studied extensively by OMB, the General Accounting Office, and others, and considerable analysis went into its formulation. Suggestions for extending the proposal to other classes of assets would have to be examined with equal care. This has not yet been done, and we are reluctant to further delay issuance of this revision. Accordingly, no change is being made at this time with respect to the recognition of costs for automatic data processing equipment, or other classes of assets.

*Comment.* Some respondents found the terminology "rental rate" confusing; others found it inapplicable to a number of governments.

*Response.* We agreed that the term "rental rate" needed clarification. As presented here, State and local governments may use the rental rate systems that so many of them have in place, or they may choose alternative methods that will result in equivalent costs for the use of space.

**John J. Lordan,**

*Chief, Financial Management Branch.*

### Circular 74-4.—Cost Principles for Grants to State and Local Governments

Circular 74-4 is revised by modifying Attachment B, as follows:

"B.28. *Travel.*" (Add the following sentence at the end of the paragraph.)

"Notwithstanding the provisions of paragraphs D.6. and 8., travel costs of officials covered by those paragraphs, when specifically related to grant programs, are allowable with the prior approval of a grantor agency.

"C.2.a. *Rental cost.* The rental cost of space in a privately owned building is allowable. Similar costs for publicly owned buildings newly occupied on or after October 1, 1980, are allowable where "rental rate" systems, or equivalent systems that adequately reflect actual costs, are employed. Such charges must be determined on the basis of actual cost (including depreciation based on the useful life of the building, interest paid or accrued, operation and maintenance, and other allowable costs). Where these costs are included in rental charges, they may not be charged elsewhere. No costs will be included for purchases or construction that were originally financed by the Federal Government.

"D.7. *Interest and other financial costs.* Interest on borrowings (however represented), bond discounts, cost of financing and refinancing operations, and legal and professional fees paid in connection therewith, are unallowable except when authorized by Federal legislation and except as provided for in paragraph C.2.a. of this Attachment."

[FR Doc. 80-12194 Filed 4-21-80; 8:45 am]

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federal register

Tuesday
April 22, 1980

Part IV

# Environmental Protection Agency

## Interim Cleanup Standards for Inactive Uranium Processing Sites

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 192**

**[FRL 1469-8]**

## Interim Cleanup Standards for Inactive Uranium Processing Sites

**AGENCY:** Environmental Protection Agency.

**ACTION:** Interim standards.

**SUMMARY:** The Environmental Protection Agency (EPA) is issuing interim standards for cleanup of open lands and buildings contaminated with residual radioactive materials (mainly tailings) from inactive uranium processing sites. These standards are also being published simultaneously as proposed standards upon which public comment is being solicited. (See Proposed Cleanup Standards in the Proposed Rules section of the **Federal Register**.)

EPA has developed these standards pursuant to Section 275(a) of the Atomic Energy Act, as added by Section 206(a) of Pub. L. 95-604, the Uranium Mill Tailings Radiation Control Act of 1978. Pub. L. 95-604 requires the Department of Energy (DOE) to conduct remedial actions for designated inactive uranium processing sites in accordance with standards promulgated by EPA. Buildings and land contaminated with tailings pose a continuing threat to public health. Some of these buildings have been found to have radiation levels which are highly dangerous to anyone exposed to them for long times. Pub. L. 95-604 precludes undertaking remedial action before EPA has promulgated standards. Therefore, we have decided to promulgate interim standards for cleanup of these open lands and buildings, to permit DOE to take remedial actions under Pub. L. 95-604 to alleviate these problems.

**DATES:** Effective date: April 22, 1980. Comment date: Comments should be received on or before June 23, 1980.

**ADDRESS:** Comments should be submitted to Docket No. A-79-25, which is located in the Environmental Protection Agency, Central Docket Section, Room 2903B, 401 M Street, SW., Washington, D.C. 20460. The Draft Environmental Impact Statement may be examined at the Central Docket Section. Shortly, after we propose disposal standards for inactive processing sites, single copies of the Draft Environmental Impact Statement may be obtained by writing to the address given below.

**FOR FURTHER INFORMATION CONTACT:** Dr. Stanley Lichtman, Criteria and Standards Division (ANR-460), Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460; telephone number 703-557-8927.

**SUPPLEMENTARY INFORMATION:** Pursuant to Section 275(a) of the Atomic Energy Act, as added by Section 206(a) of Pub. L. 95-604, the Uranium Mill Tailings Radiation Control Act of 1978, EPA has developed standards for the cleanup of open lands and buildings contaminated with uranium mill tailings from inactive processing sites. Pub. L. 95-604 requires the Department of Energy to conduct remedial actions for designated inactive uranium processing sites in accordance with standards promulgated by EPA. (Section 108(a)(1), 42 U.S.C. Section 7915(a)(1)). However, Pub. L. 95-604 precludes undertaking remedial actions before such standards are promulgated.

Lands and buildings contaminated with uranium mill tailings pose risks to public health. The greatest hazard from tailings on open lands is increased levels of radon decay products in buildings. When radon decay products are inhaled, they increase the chance of lung cancer. Exposure to direct gamma radiation and contamination of drinking water and food may also occur.

Tailings usually only pose significant risk to people who are exposed for a long time. However, some homes and other buildings have been found in which the radon decay product concentration is quite dangerous. There are such buildings, for example, in Salt Lake City, and in Canonsburg, Pennsylvania. Several buildings in Salt Lake City are immediately adjacent to a tailings pile, or have tailings in, under, or around them. In some of these, indoor radon decay product concentrations exceed the average occupational concentration limit for uranium miners (0.3 WL).[1] Included among these is a fire station in Salt Lake City, where substantially elevated levels have been measured even when mechanical ventilation is used. In Canonsburg, an industrial park is now located on an inactive processing site. Eight buildings leased to commercial tenants are located directly over heavily contaminated land. Measurements during working hours show that all buildings have substantially elevated indoor radon decay product concentrations, with the highest average daytime level being 0.4 WL. These levels are dangerous and will continue. To allow DOE to begin remedial action under Pub. L. 95-604 to alleviate these hazards, we have decided to promulgate these immediately effective interim cleanup standards.

Studies of indoor background radioactivity in Grand Junction (Colorado), New York State, and New Jersey show that at least 10 percent of houses with basements exceed the interim standard's remedial action level of 0.015 WL. Because of this, we believe it would often be impossible to try to reduce levels for houses affected by tailings significantly below 0.015 WL by removing the tailings. Thus, it is unlikely that the final standards will be set at a level significantly more stringent than the interim action level of 0.015 WL, and remedial actions performed under the interim standard will not have to be redone. Furthermore, although we have not formally solicited public comments on the interim standards, the Nuclear Regulatory Commission and the Department of Energy have been consulted. For these reasons, we believe issuing immediately effective interim cleanup standards is justified.

A statement of the research, analysis, and other available information in support of this interim standard is contained in the preamble to the proposed standards published elsewhere in the **Federal Register** today. Additional background material may be found in the Draft Environmental Impact Statement being made available in Docket No. A-79-25, which is located at the address given above, and in other information contained in that docket. We invite written comments on these interim standards, and they remain subject to modification in response to such comments and to views expressed orally at public hearings (see below).

In addition to the procedures we followed prior to promulgating these interim cleanup standards, we are conducting the required public review process for promulgating final standards. In the Proposed Rules section of today's **Federal Register**, we are proposing for comment the cleanup standards for inactive uranium processing sites. They are identical to the interim cleanup standards which are being made effective immediately. Furthermore, EPA intends to hold public hearings on these proposed cleanup standards and on proposed standards for the disposal of tailings from inactive sites. The disposal standards will be proposed for public comment soon, and the Draft Environmental Impact Statement for both proposed standards will be made generally available at that

[1] A working level (WL) is any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha rays with a total energy of 130 billion electron volts. The working level expresses a concentration of radioactivity in the air, not how much radiation a person receives.

time. Therefore, before these proposed cleanup and disposal standards become final, members of the public will have the opportunity to comment in writing, and to present data, views, and arguments at a public hearing.

Note.—The costs and benefits of these standards are discussed in the Draft Environmental Impact Statement. However, neither our issuance of interim cleanup standards nor the remainder of our program to set remedial action standards for Pub. L. 95-604 require preparation of an economic analysis under Executive Order 12044. We expect the costs of the remedial action program in any calendar year to be less than the $100 million criterion EPA has established (44 FR 30988-30998, May 29, 1979) for requiring an economic analysis.

Dated: April 14, 1980.

**Douglas M. Costle,**

*Administrator.*

Part 192 is added to Title 40 of the Code of Federal Regulations as follows:

## PART 192—ENVIRONMENTAL PROTECTION STANDARDS FOR URANIUM MILL TAILINGS

**Subpart A—[Reserved]**

**Subpart B—Environmental Standards for Cleanup of Open Lands and Buildings Contaminated with Residual Radioactive Materials From Inactive Uranium Processing Sites**

Sec.

192.10 Applicability.
192.11 Definitions.
192.12 Standards.
192.13 Effective date.

**Subpart C—Exceptions**

192.20 Criteria for exceptions.
192.21 Remedial actions for exceptional circumstances.
Table A [Reserved]
Table B.

Authority: Sec. 275, Atomic Energy Act of 1954, (42 U.S.C. 2022), as amended by the Uranium Mill Tailings Radiation Control Act of 1978, Pub. L. 95-604.

### Subpart A—[Reserved]

### Subpart B—Environmental Standards for Cleanup of Open Lands and Buildings Contaminated with Residual Radioactive Materials From Inactive Uranium Processing Sites

#### § 192.10 Applicability.

This subpart applies to open lands and buildings which are part of any processing site designated by the Secretary of Energy under Pub. L. 95-604, Section 102. Section 101 of Pub. L. 95-604, states that "processing site" means—

(a) Any site, including the mill, containing residual radioactive materials at which all or substantially all of the uranium was produced for sale to any Federal agency prior to January 1, 1971 under a contract with any Federal agency, except in the case of a site at or near Slick Rock, Colorado, unless—

(1) Such site was owned or controlled as of January 1, 1978, or is thereafter owned or controlled, by any Federal agency, or

(2) A license (issued by the (Nuclear Regulatory) Commission or its predecessor agency under the Atomic Energy Act of 1954 or by a State as permitted under section 274 of such Act) for the production at such site of any uranium or thorium product derived from ores is in effect on January 1, 1978, or is issued or renewed after such date; and

(b) Any other real property or improvement thereon which—

(1) Is in the vicinity of such site, and

(2) Is determined by the Secretary, in consultation with the Commission, to be contaminated with residual radioactive materials derived from such site.

Any ownership or control of an area by a Federal agency which is acquired pursuant to a cooperative agreement under this title shall not be treated as ownership or control by such agency for purposes of paragraph (a)(1) of this section. A license for the production of any uranium product from residual radioactive materials shall not be treated as a license for production from ores within the meaning of paragraph (a)(2) of this section if such production is in accordance with section 108(b).

#### § 192.11 Definitions.

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as defined in Title I of the Uranium Mill Tailings Radiation Control Act of 1978.

(b) *Remedial action* means any action performed under Section 108 of the Uranium Mill Tailings Radiation Control Act of 1978.

(c) *Open land* means any surface or subsurface land which is not a disposal site and is not covered by a building.

(d) *Working Level (WL)* means any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts.

(e) *Dose equivalent* means absorbed dose multiplied by appropriate factors to account for differences in biological effectiveness due to the type and energy of the radiation and other factors. The unit of dose equivalent is the "rem."

(f) *Curie (Ci)* means the amount of radioactive material which produces 37 billion nuclear transformations per second. One picocurie (pCi) = $10^{-12}$ Ci.

#### § 192.12 Standards.

Remedial actions shall be conducted so as to provide reasonable assurance that—

(a) The average concentration of radium-226 attributable to residual radioactive material from any designated processing site in any 5 cm thickness of soils or other materials on open land within 1 foot of the surface, or in any 15 cm thickness below 1 foot, shall not exceed 5 pCi/gm.

(b) The levels of radioactivity in any occupied or occupiable building shall not exceed either of the values specified in Table B because of residual radioactive materials from any designated processing site.

(c) The cumulative lifetime radiation dose equivalent to any organ of the body of a maximally exposed individual resulting from the presence of residual radioactive materials or byproduct materials shall not exceed the maximum dose equivalent which could occur from radium-226 and its decay products under paragraphs (a) and (b) of this section.

#### § 192.13 Effective date.

The standards of this subpart shall be effective April 22, 1980.

### Subpart C—Exceptions

#### § 192.20 Criteria for exceptions.

Exceptions to the standards may be justifiable under any of the following circumstances:

(a) Public health or safety would be unavoidably endangered in attempting to meet one or more of the requirements of Subpart A or Subpart B of this part.

(b) The goal of environmental protection would be better served by not satisfying cleanup requirements for open land, § 192.12(a) or the corresponding part of § 192.12(c). To justify an exception to these requirements there should be a clearly unfavorable imbalance between the environmental harm and the environmental and health benefits which would result from implementing the standard. The likelihood and extent of current and future human presence at the site may be considered in evaluating these benefits.

(c) The estimated costs of remedial actions to comply with the cleanup requirements for buildings, § 192.12(b) or the corresponding part of § 192.12(c), are unreasonably high relative to the benefits. Factors which may be considered in this judgment include the period of occupancy, the radiation levels in the most frequently occupied areas, and the residual useful lifetime of the building. This criterion can only be used

when the values in Table B are only slightly exceeded.

(d) There is no known remedial action to meet one or more of the requirements of Subpart A or Subpart B of this part. Destruction and condemnation of buildings are not considered remedial actions for this purpose.

**§ 192.21 Remedial actions for exceptional circumstances.**

Section 108 of Pub. L. 95–604 requires the Secretary of Energy to select and perform remedial actions with the concurrence of the Nuclear Regulatory Commission and the full participation of any State which pays part of the cost, and in consultation, as appropriate, with affected Indian tribes and the Secretary of the Interior. Under exceptional circumstances satisfying one or more of the conditions 192.20 (a), (b), (c), and (d), the Department of Energy may select and perform remedial actions, according to the procedures of Sec. 108, which come as close to meeting the standard to which the exception applies as is reasonable under the exceptional circumstances. In doing so, the Department of Energy shall inform any private owners and occupants of affected properties and request their comments on the selected remedial actions. The Department of Energy shall provide any such comments to the parties involved in implementing Sec. 108 of Pub. L. 95–604. The Department of Energy shall also inform the Environmental Protection Agency of remedial actions for exceptional circumstances under Subpart C of this rule.

**Table A.—[*Reserved*]**

**Table B**

| | |
|---|---|
| Average annual indoor radon decay product concentration—including background (WL) | 0.015 |
| Indoor gamma radiation—above background (milliroentgen per hour | 0.02 |

[FR Doc. 80-12305 Filed 4-21-80; 8:45 am]

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federal register

Tuesday
April 22, 1980

Part V

# Environmental Protection Agency

## Proposed Cleanup Standards For Inactive Uranium Processing Sites

**ENVIRONMENTAL PROTECTION AGENCY**

**40 CFR Part 192**

**[FRL 1454-8]**

## Proposed Cleanup Standards for Inactive Uranium Processing Sites; Invitation for Comment

**AGENCY:** U.S. Environmental Protection Agency.

**ACTION:** Proposed cleanup standards.

**SUMMARY:** The Environmental Protection Agency (EPA) is publishing for comment proposed environmental standards for the cleanup of open lands and buildings contaminated with residual radioactive materials (mainly tailings) from inactive uranium processing sites. These standards are being made immediately effective on an interim basis. (See Interim Standards published in the Final Rules section of the **Federal Register**.) EPA has developed these standards pursuant to Section 275(a) of the Atomic Energy Act, as added by Section 206(a) of Pub. L. 95-604. Title I of Pub. L. 95-604 requires the Department of Energy to conduct remedial actions for designated inactive uranium processing sites in accordance with standards promulgated by EPA.

The proposed cleanup standards require that remedial actions lower the concentration of radium in contaminated soil below specified levels. Limits are also proposed on the radon decay product concentration and gamma radiation in occupied or occupiable buildings affected by tailings.

Additional background material is given in a Draft Environmental Impact Statement which EPA is entering in the Docket simultaneously with this notice. In addition to this request for written comments, the Agency will shortly publish for comment proposed standards for the disposal of tailings from inactive processing sites. Shortly thereafter, we will announce the time and place of hearings at which interested persons may present comments on the proposed cleanup and disposal standards.

**DATE:** Comments should be received on or before June 23, 1980.

**ADDRESS:** Comments should be submitted to Docket No. A-79-25, which is located in the Environmental Protection Agency, Central Docket Section, Room 2903B, 401 M Street, S.W., Washington, D.C. 20460. Shortly, after we propose final disposal standards for inactive sites, single copies of the Draft Environmental Impact Statement may be obtained by writing to the address given below.

**FOR FURTHER INFORMATION CONTACT:** Dr. Stanley Lichtman, Criteria & Standards Division (ANR-460), Office of Radiation Programs, U.S. Environmental Protection Agency, Washington, D.C. 20460; telephone number 703-557-8927.

**SUPPLEMENTARY INFORMATION:**

### I. Introduction

The proposed cleanup standards are part of the standards EPA is developing at the direction of Congress for remedial actions to protect public health, safety, and the environment from uranium mill tailings from inactive processing sites. There are two major parts of the remedial actions: cleanup and disposal. The cleanup process reduces the potential health consequences of tailings which have been dispersed from their original location on a tailings pile, or used in construction. Disposal is the operation which places the tailings themselves in a condition which will be safe for a long time. The disposal site may be at the original location of the tailings, or a new one.

This notice announces proposal of cleanup standards (Subpart B) for the inactive processing sites covered under Title I of Pub. L. 95-604, and solicits public comment on these standards. They are also being made immediately effective as interim standards for the remedial action program authorized by Title I, pending completion of the public comment and hearing process contemplated by Pub. L. 95-604. We are continuing to develop standards for disposal of tailings from inactive processing sites (Subpart A), and standards for tailings at active sites. We expect to propose disposal standards for inactive processing sites shortly, and to solicit public comments at that time. After they are published, we will hold hearings covering the proposed cleanup and disposal standards for inactive sites.

In order to carry out our responsibility under Pub. L. 95-604 to set generally applicable standards for uranium mill tailings, we have examined their potential public health and environmental impacts. This examination established the radiological and nonradiological characteristics of tailings which require control.

Tailings are hazardous primarily because: (1) Breathing radon and its decay products exposes the lungs to alpha particles; (2) the body may be exposed to gamma rays; (3) radioactive materials and nonradioactive toxic elements from tailings may be swallowed with food and water. The radiation hazard from tailings lasts for many thousands of years, and nonradioactive toxic elements persist indefinitely. The longevity of these hazards played a major role in determining the proposed standards.

The most commonly used unit of exposure to radon decay products is working level months (WLM).[1] Gamma radiation doses are usually expressed in units of rads.[2]

Although the available data are consistent with many models, we believe that a linear, nonthreshold dose-effect relationship is a reasonable model for deriving estimates of risk to the general public. This model assumes that any radiation dose presents some risk to humans and that the risk is directly proportional to the damage demonstrated at higher doses. We recognize, however, that the data preclude neither a threshold for some types of radiation below which there is no damage to people, nor the possibility that low doses may do more damage to some people than the linear model implies.

The main danger from breathing radon decay products is induction of lung cancer by alpha radiation. Gamma rays, while less harmful per rad than alpha radiation, can also cause cancers, teratogenesis, and genetic damage. Our health risk estimates are based on our review of epidemiological studies conducted in the United States and other countries of underground miners of uranium and other metals who have been exposed to radon decay products, and on two reports, "The Effects on Population of Exposure to Low Levels of Ionizing Radiation" (1972) and "Health Effects of Alpha Emitting Particles in the Respiratory Tract" (1976) by the Advisory Committee on the Biological Effects of Ionizing radiation of the National Academy of Sciences (the BEIR Committee). Information in the report of

[1] A working level (WL) is any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts. The working level expresses a concentration of radioactivity in the air, not how much radiation a person receives. One WLM means exposure to 1 WL for 170 hours, the number of working hours in a month, based on a 40-hour working week.

[2] A rad measures the energy absorbed per unit mass; one rad is 100 ergs absorbed per gram. A rad is more fundamentally related to biological damage than a WLM, but it is convenient to state radon decay product exposure in WLM's because most of the data on their health effects comes from studies of uranium miners and is stated in WLM's. However, miners breathe more as they work than people breathe on the average. Allowing for this, one can show (see EPA 520/4-78-013, July 1979) that continuous exposure to 1 WL for an average person corresponds to 27 WLM in a year. One WLM is roughly equivalent to 0.5 rad to the lung.

the United Nations Scientific Committee on the Effects of Atomic Radiation entitled "Sources and Effects of Ionizing Radiation" (1977) was also considered. Details of our risk estimates are provided in "Indoor Radiation Exposure Due to Radium-226 in Florida Phosphate Lands" (EPA 520/4-78-013) and in the Draft Environmental Impact Statement (EIS).

Data from studies of underground miners lead to uncertain risk estimates when extrapolated to the general population. Nevertheless, we believe they provide a sufficient basis for public health standards. Data from many exposed groups are available as a basis for gamma ray exposure standards. Summaries of our risk estimates (using both the "relative" and "absolute" risk models) for exposure to radon decay products and to gamma radiation are given in Table 1. The assumptions of these models and the applicability and basis for the estimates are discussed in the EIS.

Generally it is not possible to remove all the risk to people exposed to radiation or any other dangerous substance. To help us decide how much we should attempt to reduce the risk, we considered the longevity, efficacy, and costs of remedial action methods for uranium mill tailings as well as the level of risk. We also considered benefits and costs which are not easily quantified, such as equity, and administrative difficulties. Finally, we considered the overall implementation costs and benefits of alternative standards to determine those which are most reasonable.

EPA's mandate is to set standards which apply to any site and method of control. The law gives other agencies of Government the authority to decide how these standards will be satisfied at particular locations. Therefore, our analyses of technology, costs, risk, and other pertinent factors emphasize the general characteristics of uranium mill tailings and their control.

The information, reasoning, and judgments which lead us to issue these particular proposed cleanup standards for inactive uranium processing sites are summarized below. Additional background information is contained in the Draft Environmental Impact Statement which is on file in the Docket and will be available for distribution shortly.

**Table 1(A).**—*Estimated Risk of Fatal Lung Cancer Due to Radon Decay Products* [1] (for 0.01 Working Level and Lifetime Exposure 75 percent of the Time]

| | Estimated risk | |
|---|---|---|
| | Relative | Absolute |
| Percent of the exposed who will die of lung cancer caused by the exposure [2] | 1 | 0.5 |
| Years of life lost per fatality [3] | 15 | 25 |

**Table 1(B).**—*Estimated Risk of Fatal Cancer Due to Exposure of the Whole Body to Gamma Radiation* [1] (for Lifetime Exposure at 100 mrad per Year)

| | Estimated risk | |
|---|---|---|
| | Relative | Absolute |
| Percent of the exposed who will die of cancer caused by the exposure [2] | 0.5 | 0.8 |
| Years of life lost per fatality [3] | 14 | 23 |

[1] Estimated lifetime risk of fatal cancer caused by the indicated rate of radiation exposure over an average lifetime (70.7 years).

[2] The percentage for higher or lower radiation levels changes in proportion, except for very high levels. Exposure over less than 70.7 years gives smaller risks; however, the expected effect of an exposure depends on the recipient's age at the time, so the risk is not strictly proportional to the exposure time.

[3] Another measure of harm is "average days of life lost per exposed person." This is gotten by multiplying the two numbers in each vertical column. For example, the estimated Relative Risk in Part A of the Table is (0.01)G3×15 years=55 average days of life lost per exposed person.

## II. Cleanup of Open Lands and Buildings [3]

Uranimum mill tailings from inactive sites have been spread by wind, water, and people to nearby and distant locations. Therefore, standards for cleanup of tailings must address the following situations:

(1) Tailings have spread different distances from different piles, occur at various depths in the soil, and are mixed with various materials. The standard must specify the quantity or concentration of tailings which requires cleanup.

(2) Radionuclides leak into the soil under the piles. If these piles are removed, the maximum allowable residual level of radioactivity in the subsoil must be specified.

(3) Tailings that have been used as landfill or in building materials, or have accumulated around a structure are particularly hazardous. Building interiors have limited airflow and radon decay product concentrations in them may be many times the outdoor levels. Thus, the standard must specify the maximum allowable radon decay product concentration in buildings. The cleanup standard for open land must consider the possibility of future building on the land.

Before Pub. L. 95-604 was enacted, EPA and the predecessors of DOE (the Atomic Energy Commission and the Energy Research and Development Administration) conducted surveys to identify places where tailings from inactive processing sites had been used in construction, and to determine the extent of contamination of open lands. Since then, additional measurements have been made by Federal, State, and local authorities, and are continuing as part of the program authorized by Title I of Pub. L. 95-604.

### *Proposed Cleanup Standards for Open Lands*

The greatest hazard from tailings on open lands is increased levels of radon decay products in buildings. Exposure to direct gamma radiation and contamination of drinking water and food may also occur, but generally will be of less concern.

The radon decay product concentration in an existing or future building will depend on the radium concentration in the soil under or adjacent to it. However, so many other factors affect the indoor radon decay product concentration that a useful correlation with the radium in soil is difficult to establish. Under some condtions, radium concentrations as low as 1-5 pCi/gm in natural or contaminated soil can produce indoor radon decay product concentration exceeding 0.01 WL. Common natural soils have radium concentrations near the lower end of this range. Therefore, where indoor radon decay product concentrations are only slightly elevated, radon sources other than tailings may often be the dominant causes, and removing the tailings may do little good.

[3] Under Title I of Pub. L. 95-604, the Department of Energy may designate as a "processing site" eligible for remedial actions:

"(A) any site, including the mill, containing residual radioactive materials at which all or substantially all of the uranium was produced for sale to any Federal agency * * *

(B) any other real property or improvement thereon which—

(i) is in the vicinity of such site, and

(ii) is determined by the Secretary, in consultation with the (Nuclear Regulatory Commission, to be contaminated with residual radioactive materials derived from such site."

Therefore, remedial actions may be needed for the tailings or other residual radioactive materials stored at an inactive mill, as well as for buildings or lands, on or off the original mill site, which are affected by radioactive materials derived from the mill. The land portion of a "designated processing site," i.e., all but the buildings, may consist of two parts: The disposal site, if the tailings are to be permanently kept at the site, and the remaining land. We will use the term "open land" for any land (surface and subsurface) which is not a disposal site and is not covered by a building. After the remedial actions are completed, all parts of a designated "processing site" except buildings must satisfy either the standards for disposal or the standards for open lands.

Natural or contaminated soils which have 5 pCi of radium per gram of soil for several feet down can also give exposure rates from gamma radiation[4] of about 80 mR/yr. The exposure rates are proportional to the concentration of radium, and decrease as the layer of radium-containing material becomes thinner, or is covered over by other materials. Therefore, cleanup standards for open land must take account of both the level of radium concentration and the thickness of the contaminated layer.

Locating contaminated soils with concentrations less than 5 pCi/gm would require extensive surveys and lengthy measurement procedures. Increasingly large land areas would need to be stripped in order to lower the radioactivity much below 5 pCi/gm. Doing this would provide very little gain in health protection, since such slightly contaminated soils are usually thin layers containing little total radium. Therefore, in order to keep sampling costs within reason, and to avoid having to clean large areas which contain little radioactivity, the proposed standard requires that for any open land contaminated with tailings, the average radium concentration shall not be more than 5 pCi/gm after cleanup. The contamination which remains after such cleanup will have less than 5 times the radon release of average soils. It could also cause a gamma radiation dose of less than 80 millirad per year to a person who spends 100 percent of the time outdoors on the site. These levels of radon emission and gamma radiation are within the variations that occur in undisturbed land areas. We believe that the actual radon and gamma ray levels after cleanup will usually be much less than the maximum possible under these standards.

For contaminated material located more than 1 foot beneath the surface of open land, our proposed standard requires cleanup if the average radium concentration over any 15 cm thickness is greater than 5 pCi/gm. Practical measurement instruments could not find buried material of this concentration in any thinner layer. We expect this standard for buried material will mostly apply to defining the edges of buried tailings deposits, because the radium concentration in tailings is usually much higher than 5 pCi/gm.

Surveys at inactive processing sites indicate that it should cost little more to implement the proposed cleanup standard than one permitting residual contamination levels 2 to 4 times higher. The proposed cleanup standard is EPA's judgment of the most stringent uniform cleanup condition that may reasonably be required for all the inactive mill sites.

We expect that the rules developed to implement this standard will relate the concentration of radium in soil to other conveniently measured quantities. We also expect that appropriate sampling techniques will be established to locate and identify tailings material, to determine its concentration of radium, and to verify compliance with the standard. Any such rules must insure that the standard is not met by dispersing the material to achieve a lower concentration.

*Proposed Cleanup Standards for Indoor Radon Decay Product Concentration*

Even normal levels of indoor radon decay product concentrations are harmful. We believe that Congress intended that people should not have to bear an unreasonable increase in this risk because of tailings.

A standard should have the following characteristics:

1. Unambiguous. It should be clear whether or not a situation meets the standard.
2. Risk-related. It should limit the harm done to people.
3. Cost-related. The cost should be related to the amount of injury prevented.
4. Practical. It must be possible to accomplish the requirements in a reasonable time with the techniques and personnel available.

We considered expressing the cleanup standard for indoor radon decay products in terms of the

1. Quantity or concentration of tailings near the building;
2. Gamma radiation level in the building;
3. Amount by which the indoor radon decay product concentration exceeds the level is would be if no tailings were present in or near the building;
4. Amount by which the indoor radon decay product concentration exceeds what the average level in similar buildings in the areas would be if there were no tailings in the region;
5. Radon decay product concentration in the building.

Alternatives 1 and 2 are not strongly risk-related or cost-related because there is no known way to deduce the indoor radon decay product concentration from them.

Alternative 3 is impractical because there is no known way to determine what the indoor radon decay product concentration would be if no tailings were present in or near a building except by removing all the tailings. Thus, under this alternative, one would have to perform the remedial action in order to determine if the building was eligible for remedial action.

Alternative 4 is impractical and ambiguous because it will be too difficult to establish which buildings that are not affected by tailings are "similar" to a given building that is affected. This is because indoor radon concentrations vary significantly with building location, design, materials, and patterns of use. The reasons for these variations are not well understood.

Alternative 5 is unambiguous, practical, cost-related, and directly related to the total risk to people living in the building. We have thus chosen to base our standard on it.

We believe that the proposed remedial action level of 0.015 WL (including background) for occupied or occupiable buildings is the most protective level that can be justified for the Pub. L. 95–604 remedial action program. It is about the same as that applied to homes and schools over the last seven years in the Grand Junction remedial action program, because the action level there was 0.01 WL above an "average" background value taken as 0.007 WL. Experience in the Grand Junction program indicates that it is usually technically and financially practical to lower concentrations greater than 0.017 WL when the high working levels are due to residual radioactive materials from uranium processing sites. 0.017 WL is practically indistinguishable from our level of 0.015 WL. In some situations, a lower action level might be justified. However, since studies of normal houses with basements in Grand Junction, New York State, and New Jersey indicate that at least 10 percent are above 0.015 WL, it would often be fruitless to try to reduce levels significantly below 0.015 WL, it would often be fruitless to try to reduce levels significantly below 0.015 WL by removing tailings.

Although indoor radon decay product levels much higher than 0.015 WL can occur without the presence of uranium mill tailings, these proposed cleanup standards are explicitly for remedial actions at sites designated under Pub. L. 95–604.[5] Pub. L. 95–604 is clearly directed at potential health problems due to tailings, and not to similar hazards from other causes. The proposed cleanup standard therefore applies only when there is reason to believe that the

[4] The roentgen (R) is a unit measuring the electrical charge that gamma rays release in air. A milliroentgen (mR) is one thousandth of a roentgen. Exposing body tissue to 1 mR of gamma radiation produces a dose of approximately 1 mrad.

[5] In particular, the remedial action standard should not necessarily be taken as an appropriate design goal for indoor radon decay product concentration in new housing.

allowable level is exceeded because of uranium mill tailings from a designated site. If the allowable level is still exceeded after all apparent tailings have been removed or otherwise prevented from affecting the interior of the building, then the standard does not require further remedial measures.

*Proposed Cleanup Standards for Indoor Gamma Radiation*

The proposed standard for indoor radon decay product concentration is based on the hazard from breathing air containing these products. Tailings also emit gamma radiation, however, which can penetrate the body from the outside. We expect the indoor radon decay product concentration standards will usually be met by removing tailings from the building, and that this will eliminate any indoor gamma radiation problem. For some buildings, however, engineering problems may make it impractical to lower the indoor radon decay product concentration by completely removing tailings. Alternate methods, such as air cleaning, improving ventilation, or applying sealants to the walls and floors are available. If these are used, standards will be needed to limit gamma radiation exposure of the occupants.

It will often be possible to meet the radon decay product standards without removing the tailings. Removal is the remedial method we wish to encourage, however, because it is a permanent solution. To do this we have chosen a proposed action level for gamma radiation (0.02 mR/hr above background) [6] which will be hard to meet without removing tailings when these are the cause. On the other hand, reducing the standard much below 0.02 mR/hr would virtually eliminate flexibility in remedial methods, and provide only a small additional health benefit to those few individuals who might be affected. Assuming the occupants of the building to be in it 75 percent of the time, the proposed cleanup standard would allow gamma radiation doses from the tailings of about 130 mrad per year. This is about twice the average annual outdoor background dose from gamma rays in the western United States.

*Proposed Cleanup Standard for Radiation Hazards Not Associated With Radium-226*

Each gram of natural uranium contains 330,000 pCi of U-238 and 15,000 pCi of U–235. Because it appears in relatively small proportion, uranium-235 and its decay products usually may be ignored in evaluating the hazards of uranium tailings. The dominant hazard from most tailings is the decay products of uranium-238, especially radium-226 and its decay products. This is the reason the proposed cleanup standards specify a limit on the radium-226.

The amount of protection provided by a standard based on radium-226 depends on the extent to which radium has been separated from other radioactive substances, such as thorium, uranium-235, and their decay products, during ore processing. The Department of Energy has determined, for example, that at least one of the processing sites covered under PL 95–604 (Canonsburg, Pa.) has tailings containing higher than usual proportions of uranium-235 decay products. Radium-226 concentrations in the residual material may not be an adequate measure of the radiation hazard in this case.

The environmental pathways and biological effects of some of the thorium and uranium-235 decay products are not as well known as for radium-226. Thus, we are not in a position to set a separate standard for them, nor to say in all cases how effective cleanup standards based on radium-226 will be controlling uranium-235, thorium, and their decay products. However, adequate protection would be provided if, after cleanup, the total risk from all uranium and thorium isotopes and their decay products posed no greater risk than the proposed cleanup standards allow for radium-226 and its decay products. The degree to which any particular site would need to be cleaned up in order to meet this condition will have to be determined following detailed studies of its tailings, and further evaluation of the hazard pathways.

## III. Implementation

Pub. L. 95–604 requires that EPA's standards for uranium mill tailings from inactive processing sites be implemented by the Secretary of Energy. The Secretary or a designee will select and perform remedial actions for designated processing sites in accordance with the standards, with the full participation of any State which shares the cost. Selection and performance of the remedial actions will be with the concurrence of the Nuclear Regulatory Commission and in consultation, as appropriate, with affected Indian tribes and the Secretary of the Interior. The costs of the remedial actions will be borne by the Federal Government and the States as prescribed by law.

The Department of Energy will need to make a radiation survey of open lands and buildings in areas believed to have tailings and determine whether or not tailings are causing the standards to be exceeded. After remedial actions are taken, they must verify compliance with the standards. In order to do this, DOE, working with NRC and the participating State, will need to develop radiological survey, sampling, and measurement procedures to determine necessary and practical cleanup actions, and to certify the results of the cleanup.

These procedures are an important part of making the standards effective. In view of this, we considered providing more details of the implementation as part of our rulemaking. We chose not to do so in order to give more flexibility to the implementers. We believe this is warranted because of widely varying and incompletely known conditions among and within the various processing sites. However, the following clarification of our intentions should help to avoid unproductive use of resources. This could result if the standards were interpreted so strictly that demonstrating compliance would be unreasonably burdensome.

The purpose of our standards is to protect public health and the environment. We designed them to be adequately protective using search and verification procedures whose cost and technical requirements are reasonable. For example, since we intend the cleanup standards for buildings to protect people, measurements in such locations as crawl spaces and furnace rooms are inappropriate. Remedial action decisions should be based on radiation levels in the parts of buildings where people spend substantial amounts of time. The standards for cleanup of land surfaces are designed to limit the exposures of people to gamma radiation, and to limit the level of radon decay products in buildings which might later be built on the land. In most circumstances, no significant harm would be caused by not cleaning up a few square feet of open land contaminated by tailings. Similarly, it would be unreasonable to require proof that all the tailings had been found below the surface of open lands. As in all applications of our proposed cleanup standards, search and verfication procedures which provide a reasonable assurance of compliance with the standards will be adequate. We are confident that DOE and NRC, in consultation with EPA and the States, will adopt implementation procedures consistent with our standards.

[6] Indoor background levels of gamma radiation are much easier to determine and less variable than measurements of background indoor radon decay product concentration.

*Exceptions*

We believe that our proposed standards are the strictest that are justified for general application at all the inactive uranium processing sites covered by Pub. L. 95–604. However, providing greater protection may be reasonable at specific sites. Therefore, we urge the implementers to lower the residual risk as far below the required level as is reasonably achievable.

In the decades since tailings at inactive sites were deposited, weather and people have created a wide range of problems needing remediation. There may be exceptional circumstances for which the standards are unreasonably strict, such as when some clearly undesirable health or environmental side-effects would be caused by meeting them. For example, when tailings are not accessible to the equipment needed for their removal, or where workers might be endangered in trying to remove them, application of the standards should be reconsidered. Similarly, disturbing scarce desert vegetation and soils may not be justified where the standards are only slightly exceeded.

We do not consider cost a reason for noncompliance unless the cost to comply is very high or the benefit is very small. For example, it may not make sense to spend a great deal of money to clean up an infrequently occupied building where the standards are only slightly exceeded.

In order to allow for reasonable implementation of Pub. L. 95–604 in all of the varied circumstances, we are proposing criteria which the implementers may use to determine whether particular circumstances are exceptional. In such exceptional cases, DOE may select and perform remedial actions which come as close to meeting the standards as is reasonable. In the selection of such remedial actions, DOE shall ask any property owners and occupants for their comments, the concurrence of NRC shall be required, and DOE shall inform EPA.

Note.—The costs and benefits of these standards are discussed in the Draft Environmental Impact Statement. However, neither our issuance of interim cleanup standards nor the remainder of our program to set remedial action standards for Pub. L. 95–604 require preparation of an economic analysis under Executive Order 12044. We expect the costs of the remedial action program in any calendar year to be less than the $100 million criterion EPA has established (44 FR 30988–30998, May 29, 1979) for requiring an economic analysis.

Dated: April 14, 1980.

**Douglas M. Costle,**

*Administrator.*

The Administrator of the Environmental Protection Agency hereby proposes to add a Part 192 to Title 40 of the Code of Federal Regulations as follows:

## PART 192—ENVIRONMENTAL PROTECTION STANDARDS FOR URANIUM MILL TAILINGS

**Subpart A—[Reserved]**

**Subpart B—Environmental Standards for Cleanup of Open Lands and Buildings Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites**

Sec.

192.10 Applicability.
192.11 Definitions.
192.12 Standards.
192.13 Effective date.

**Subpart C—Exceptions**

192.20 Criteria for exceptions.
192.21 Remedial actions for exceptional circumstances.
Table A—[Reserved]
Table B

(Authority. Section 275 of the Atomic Energy Act of 1954, (42 U.S.C. 2022), as amended by the Uranium Mill Tailings Radiation Control Act of 1978, Pub. L. 95–604.)

### Subpart A—[Reserved]

### Subpart B—Environmental Standards for Cleanup of Open Lands and Buildings Contaminated with Residual Radioactive Materials from Inactive Uranium Processing Sites

#### § 192.10 Applicability.

This subpart applies to open lands and buildings which are part of any processing site designated by the Secretary of Energy under Pub. L. 95–604, Section 102. Section 101 of Pub. L. 95–604, states that "processing site" means—

(a) Any site, including the mill, containing residual radioactive materials at which all or substantially all of the uranium was produced for sale to any Federal agency prior to January 1, 1971 under a contract with any Federal agency, except in the case of a site at or near Slick Rock, Colorado, unless—

(1) Such site was owned or controlled as of January 1, 1978, or is thereafter owned or controlled, by any Federal agency, or

(2) A license (issued by the (Nuclear Regulatory) Commission or its predecessor agency under the Atomic Energy Act of 1954 or by a State as permitted under section 274 of such Act) for the production at such site of any uranium or thorium product derived from ores is in effect on January 1, 1978, or is issued or renewed after such date; and

(b) Any other real property or improvement thereon which—

(1) Is in the vicinity of such site, and

(2) Is determined by the Secretary, in consultation with the Commission, to be contaminated with residual radioactive materials derived from such site.

Any ownership or control of an area by a Federal agency which is acquired pursuant to a cooperative under this title shall not be treated as ownership or control by such agency for purposes of paragraph (a)(1) of this section. A license for the production of any uranium product from residual radioactive materials shall not be treated as a license for production from ores within the meaning of paragraph (a)(2) of this section if such production is in accordance with section 108(b).

#### § 192.11 Definitions.

(a) Unless otherwise indicated in this subpart, all terms shall have the same meaning as defined in Title I of the Uranium Mill Tailings Radiation Control Act of 1978.

(b) *Remedial action* means action performed under Section 108 of the Uranium Mill Tailings Radiation Control Act of 1978.

(c) *Open land* means any surface or subsurface land which is not a disposal site and is not covered by a building.

(d) *Working Level (WL)* means any combination of short-lived radon decay products in one liter of air that will result in the ultimate emission of alpha particles with a total energy of 130 billion electron volts.

(e) *Dose equivalent* means absorbed dose multiplied by appropriate factors to account for differences in biological effectiveness due to the type and energy of the radiation and other factors. The unit of dose equivalent is the "rem."

(f) *Curie (Ci)* means the amount of radioactive material which produces 37 billion nuclear transformations per second. One picocurie (pCi)=$10^{-12}$ Ci.

#### § 192.12 Standards.

Remedial actions shall be conducted so as to provide reasonable assurance that—

(a) the average concentration of radium-226 attributable to residual radioactive material from any designated processing site in any 5 cm thickness of soils or other materials on open land within 1 foot of the surface, or in any 15 cm thickness below 1 foot, shall not exceed 5 pCi/gm.

(b) The levels of radioactivity in any occupied or occupiable building shall

not exceed either of the values specified in Table B because of residual radioactive materials from any designated processing site.

(c) The cumulative lifetime radiation dose equivalent to any organ of the body of a maximally exposed individual resulting from the presence of residual radioactive materials or byproduct materials shall not exceed the maximum dose equivalent which could occur from radium-226 and its decay products under paragraphs (a) and (b) of this section.

**§ 192.13 Effective date.**

The standards of ths subpart shall be effective 60 days after promulgation of this rule.

## Subpart C—Exceptions

**§ 192.20 Criteria for exceptions.**

Exceptions to the standards may be justifiable under any of the following circumstances:

(a) Public health or safety would be unavoidably endangered in attempting to meet one or more of the requirements of Subpart A or Subpart B of this part.

(b) The goal of environmental protection would be better served by not satisfying cleanup requirements for open land, § 192.12(a) or the corresponding part of § 192.12(c). To justify an exception to these requirements there should be a clearly unfavorable imbalance between the environmental harm and the environmental and health benefits which would result from implementing the standard. The likelihood and extent of current and future human presence at the site may be considered in evaluating these benefits.

(c) The estimated costs of remedial actions to comply with the cleanup requirements for buildings, § 192.12(b) or the corresponding part of § 192.12(c), are unreasonably high relative to the benefits. Factors which may be considered in this judgment include the period of occupancy, the radiation levels in the most frequently occupied areas, and the residual useful lifetime of the building. This criterion can only be used when the values in Table B are only slightly exceeded.

(d) There is no known remedial action to meet one or more of the requirements of Subpart A or Subpart B of this part. Destruction and condemnation of buildings are not considered remedial actions for this purpose.

**§ 192.21 Remedial actions for exceptional circumstances.**

Section 108 of Pub. L. 95–604 requires the Secretary of Energy to select and perform remedial actions with the concurrence of the Nuclear Regulatory Commission and the full participation of any State which pays part of the cost, and in consultation, as appropriate, with affected Indian tribes and the Secretary of the Interior. Under exceptional circumstances satisfying one or more of the conditions 192.20(a), (b), (c), and (d), the Department of Energy may select and perform remedial actions, according to the procedures of Sec. 108, which come as close to meeting the standard to which the exception applies as is reasonable under the exceptional circumstances. In doing so, the Department of Energy shall inform any private owners and occupants of affected properties and request their comments on the selected remedial actions. The Department of Energy shall provide any such comments to the parties involved in implementing Sec. 108 of Pub. L. 95–604. The Department of Energy shall also inform the Environmental Protection Agency of remedial actions for exceptional circumstances under subpart C of this rule.

**Table A—[Reserved]**

**Table B**

| | |
|---|---|
| Average Annual Indoor Radon Decay Product Concentration—including background (WL) | 0.015 |
| Indoor Gamma Radiation—above background (milliroentgen/hour) | 0.02 |

[FR Doc. 80–12306 Filed 4–21–80; 8:45 am]

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Part VI

# Department of Defense

## Corps of Engineers, Department of the Army

## Flood Damage Prevention: Level of Protection for Urban Areas; Policies and Procedures

**DEPARTMENT OF DEFENSE**

**Corps of Engineers, Department of the Army**

**33 CFR Part 396**

**[ER 1105-2-XXX]**

## Flood Damage Prevention: Level of Protection for Urban Areas; Proposed Policies and Procedures

**AGENCY:** Corps of Engineers, DOD.

**ACTION:** Proposed rule.

**SUMMARY:** This regulation provides guidance on the selection of the level of protection for flood damage prevention projects in urban areas, particularly high levees, high floodwalls, and rapid flow channels. Extensive damage and loss of life could occur in urban areas if high levees or high floodwalls were overtopped or overbank flooding occurred from high depth and rapid flow channels. The Standard Project Flood is the goal for minimum level of protection where the damages from floods exceeding the level of protection could be considered a catastrophe.

**DATES:** Comments must be received by June 30, 1980.

**ADDRESS:** Comments to: Department of the Army, Office of the Chief of Engineers, ATTN: (DAEN-CWP-A), WASH, DC 20314.

**FOR FURTHER INFORMATION CONTACT:** Barry Kennedy, Planning Division, Office of the Chief of Engineers (DAEN-CWP-A), WASH, DC 20314. (202-272-0141).

**SUPPLEMENTARY INFORMATION:** The 100-year flood is not established as a criterion for flood damage prevention except in floodplain management considerations. Flood damage prevention projects should be designed for maximum effectiveness, safety, and with consideration of catastrophic flood events. Some situations, such as a short warning, very high velocities, or great depths of inundation, constitute a special class with high potential for a catastrophe and require special care. Accordingly, the Department of the Army proposes to add a new Part 396 to read as set forth below.

Dated: April 15, 1980.

**Forrest T. Gay III,**

*Colonel, Corps of Engineers, Executive Director, Engineer Staff.*

It is proposed to add a new 32 CFR Part 396 to read as follows:

## PART 396—FLOOD PREVENTION: LEVEL OF PROTECTION FOR URBAN AREAS

Sec.

396.1 Purpose.
396.2 Applicability.
396.3 References.
396.4 Definitions.
396.5 Perspective on the Standard Project Flood (SPF) as an appropriate level of protection.
396.6 Policy on level of protection.
396.7 Selection of level of protection.
396.8 Coordination.
396.9 Claims of protection provided within freeboard.

**Authority:** U.S. Water Resources Council, Floodplain Management Guidelines (43 FR 6030), 10 February 1978.

### § 396.1 Purpose.

This regulation provides guidance on the selection of the level of protection to be afforded by Corps of Engineers flood damage prevention projects in urban areas particularly, high levees, high floodwalls and rapid flow channels. It also clarifies the use of freeboard as it relates to level of protection.

### § 396.2 Applicability.

This regulation is applicable to all OCE elements and all field operating activities having Civil Works responsibilities.

### § 396.3 References.

(a) U.S. Water Resources Council, Floodplain Management Guidelines (43 FR 6030), 10 February 1978.

(b) U.S. Water Resources Council Procedures for Evaluation or National Economic Development (NED) Benefits and Costs in Water Resources Planning (Level C); Final Rule (18 CFR Part 713), 14 December 1979.

(c) ER 1105-2-10
(d) ER 1105-2-200
(e) ER 1105-2-250
(f) ER 1105-2-250
(g) ER 1165-2-26
(h) ER 1110-2-1411
(i) ER 1110-2-1601

### § 396.4 Definitions.

For the purposes of this regulation, the following definitions are established:

(a) "Catastrophe" is an event causing sudden and widespread misfortune, destruction or irreplaceable loss; a catastrophe may be said to occur when many human lives are endangered, human lives will likely be or have been lost, or urban property damage occurs extensive enough to cripple activities in the area.

(b) "Freeboard" is the vertical height between the design water surface (profile or flat pool) and the design grade of the flood damage prevention project. Allowances for settlement, aggradation and future increases in flood flows are not included in the freeboard height.

(c) "High levees" are levees of such a height and character that an overtopping as a result of flood waters (with or without failure) may cause depths of inundation and/or velocities that could result in a catastrophe. A similar definition holds for high floodwalls and rapid flow channels.

(d) "Level of protection" is the criterion used to express the flood damage prevention effectiveness of a project and may be based on peak discharge, stage, volume, duration, or any combination of characteristics that significantly affect project functional characteristics. Note that the terms level of protection and project design flood are not always synonymous. Major reaches of a project may have different levels of protection and level of protection may change with time. The general definition of level of protection applicable to any flood damage prevention project is the flood level at which flood damages and/or other adverse effects not eliminated by the project are considered relatively minor. More concise definitions for some specific types of projects are as follows:

(1) *Flood storage (lake).* The flood controlled by lake storage to planned discharge rates at the control (dam), or at a downstream damage location, considering local inflow, which result in relatively minor adverse effects. The flood damage prevention becomes less reliable and level of protection will decrease as the distance downstream of the control (dam) increases.

(2) *Levee and floodwall.* The flood which the levee or floodwall is designed to contain, excluding freeboard. This definition may also apply to paved channels (with a clearly defined top of bank) that carry rapid flow (EM 1110-2-1601, para. 8d). The project design flood and level of protection are the same for levees and floodwalls, exluding residual interior flooding.

(e) "Probable Maximum Flood (PMF)" is the largest flood that might be expected from the most severe combination of critical meteorologic and hydrologic conditions that are reasonably possible in the region.

(f) "Risk" is the probability that one or more flood events will exceed a given magnitude within a specified period of years.

(g) "Standard Project Flood (SPF)" is a hypothetical flood that might be expected from the most severe combination of meteorological and hydrological conditions that are considered reasonably charcteristic of

the geographical region involved, excluding extraordinarily rare combinations. This definition is taken from EM 1110–2–1411, which provides specific instructions for computing the standard project flood.

(h) "Urban areas" are concentrations of habitation and supporting activities and may be parts of cities, towns, or other incorporated or unincorporated political subdivisions of States that occupy an essentially continuous area of developed land, containing such structures as residences, public and commercial buildings, and industrial sites.

**§ 396.5 Perspective on the Standard Project Flood (SPF) as an appropriate level of protection.**

The SPF is not the maximum flood that can occur. The probable maximum flood is commonly on the order of twice the SPF. While the SPF is not determined on the basis of frequency studies, comparisons show the SPFs commonly have exceedence intervals from a few hundred to a few thousand years. If a SPF corresponds to an 0.25 percent chance flood, for instance, there is about a 22 percent risk that it will be exceeded one or more times in a project life of 100 years. This would imply a substantial risk of exceeding such a flood level even though design for SPF may have the appearance of providing a high level of protection.

**§ 396.6 Policy of level of protection.**

(a) Where the damages from floods exceeding the level of protection would be considered a catastrophe, the SPF is the goal for minimum level of protection that district engineers should recommend for urban areas. This policy is particularly applicable to flood damage prevention projects involving high levees, high floodwalls, and rapid flow channels.

(b) In areas not covered by the policy given in § 396.6(a), i.e., there is no indication that floods, up to an SPF, exceeding the level of protection would cause a catastrophe, district engineers may recommend what they determine to be an appropriate degree of protection on the basis of the planning process, as discussed in § 396.7. District engineers shall assure their reports fully document and support their recommendations.

(c) Flooding resulting from interior runoff and seepage—"interior flooding"—must always be evaluated to assess the actual level of protection provided by plans involving levees and floodwalls. Any difference between the level of protection provided by the levee and floodwall structures and the interior flood control system must be explained in the report, accounted for in the project economics and made clear to the public.

**§ 396.7 Selection of level of protection.**

The planning process is described in Part 290 of this chapter, including the formulation and evaluation of alternative measures. In the case of flood damage prevention, the Corps must consider various practicable structural and non-structural measures to achieve the desired level of protection. The one percent chance (100-year) flood is not established as a criteria for flood damage prevention except in floodplain management considerations. Flood damage prevention projects should be designed for maximum effectivenes, safety and with consideration of catastrophic flood events. Other regulations fully describe the types of measures which may be considered. The following procedure should be followed and documented in the feasibility report and in an Advanced Engineering and Design (AE&D) reformulation planning report regardless of the type of flood damage prevention measure:

(a) Formulate plan for the standard project flood.

(b) Formulate other plans for higher (floods up to PMF may be considered) or lower degrees of protection based on the planning objectives established for the study, including such elements as possible loss of life, flood impacts, desires of local interests, environmental and social considerations, and other factors such as design considerations.

(c) Based on level of protection and economic benefits developed in § 396.7 (a) and (b), formulate a plan that provides the greatest level of protection consistent with maximizing net benefits. However, maximization of net benefits will not serve by itself as the decision criteria.

(d) Evaluate the plans formulated in § 396.7 (a), (b), and (c), following the provisions of Part 295 of this chapter and the WRC Manual of Procedures. The estimates of remaining damages must include both average annual damages and the remaining damages from a single occurrence of the standard project flood. The remaining average annual (nonpreventable) damages should include those for all floods greater than the level of protection provided. In addition to damages, assessment of residuals should consider all intangibles, including the physical impacts of flooding. Consider the reliability of the data, the chance and risk of exceeding various floods, and the consequences of exceeding various floods, including the potential for a catastrophe. Some situations, such as a short warning time, very high velocities, or great depths of inundation, constitute a special class with high potential for a catastrophe and require special care. The evaluation data and process should be documented in the report.

(e) Select an appropriate level of protection based on the evaluation in § 396.7(b) and the policy of § 396.6. Plan selection considerations should include local conditions, an analysis of available alternatives and the residual flood conditions, resulting from the alternatives.

(1) The recommended degree of protection and local cooperation requirements must be consistent with the requirements of Executive Order 11988, as implemented by § 396.3 (a) and (g). The provisions of ER 1165–2–26 should be incorporated into the multiobjective planning process of preauthorization studies and in the AE&D planning and design studies.

(2) In urban areas if the district engineer recommends less than SPF protection but greater protection than the one percent chance flood, the report must present at least one alternative with SPF protection and the district engineer's rationale for providing less than SPF protection.

(3) In urban areas, if the district engineer recommends protection less than the one percent flood, the report must present at least one alternative (detailed plan) with protection against the one percent chance flood, in addition to the presentation of at lease one alternative with SPF protection and the district engineer's rationale for selection such level of protection.

(4) In urban areas, if the district engineer recommends SPF protection because of the safety aspects, the report should contain the data on population, structures, flood depths and velocities, possible damages, etc., that led to that decision.

**§ 396.8 Coordination.**

When levels of protection lower than the SPF are being considered for plans involving levees and/or floodwalls in urban areas, division engineers should coordinate with OCE in reviewing the adequacy of proposed flood damage prevention plans. In urban areas, if the district engineer is considering a channel improvement project, which satisfies the requirements of §§ 396.6(b) and 396.7 but which provides protection substantially less than one percent, he should coordinate with the division engineer in determining the adequacy of the level of protection for the location and situation. Coordination should be part of the normal Intensive

Management Program (see ER 1105–2–10).

**§ 396.9 Claims of protection provided within freeboard.**

Statements or implications that a flood damage prevention project, because of freeboard, will protect against any flood larger than the design flood shall not be included in feasibility, post-authorization planning, or other related reports or otherwise communicated to the publc. The potential for flood-fight enhancement of the level of protection may be set forth in the report.

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Part VII

# Department of Housing and Urban Development

## Office of Assistant Secretary for Community Planning and Development

## Community Development Block Grants, Reallocation

**DEPARTMENT OF HOUSING AND URBAN DEVELOPMENT**

**Office of Assistant Secretary for Community Planning & Development**

**24 CFR Part 570**

**[Docket No. R-80-681]**

# Community Development Block Grants—Reallocation

**AGENCY:** Department of Housing and Urban Development (HUD).

**ACTION:** Final rule.

**SUMMARY:** The final rule revises the policies and procedures for the use of reallocated Community Development Block Grant funds. The rule establishes the eligible uses of reallocated funds—primarily meeting financial settlement needs and increasing housing choice either outside areas with lower income or minority concentrations or in a revitalizing neighborhood to enable lower income residents to remain and avoid displacement.

**DATES:** Effective May 22, 1980.

**FOR FURTHER INFORMATION CONTACT:** Richard Kennedy, Small Cities Division, Office of Community Planning and Development, Washington, D.C. 20410; telephone (202) 755-6322. (This is not a toll free number.)

**SUPPLEMENTARY INFORMATION:** On July 30, 1979, the Department published for public comment in the **Federal Register** proposed changes to the procedures for the reallocation of Community Development Block Grant (CDBG) funds. The purpose of the proposed changes was to establish the eligible uses of reallocated funds. Under the final rule, the first priority remains meeting financial settlement needs. The other eligible uses are discussed below.

Interested persons were given until September 28, 1979, to submit written comments. Twenty persons submitted comments. All comments received with respect to the proposed rule were carefully considered.

The amount of Fiscal Year 1979 CDBG funds available for reallocation is estimated to be $17 million. This is a very small portion of all CDBG funds and, therefore, the use of reallocated metropolitan entitlement funds is limited to meeting financial settlement needs and increasing housing choice, including enabling lower income residents to remain in a revitalizing neighborhood. HUD has chosen these purposes because relatively few CDGB funds or other Federal resources are used to meet these important Departmental objectives.

The following paragraphs explain the Department's response to the comments received and other changes made to the proposed regulations.

*570.107(a); (c); and (e).* These paragraphs refer to using metropolitan entitlement funds to be reallocated for increasing housing choice either outside areas with lower income or minority concentrations or in a revitalizing neighborhood to enable lower income residents to remain and avoid displacement. Increasing housing choice is a concept already established by HUD in 24 CFR 891, Subpart E, "Approval of Areawide Housing Opportunity Plans."

HUD has clarified the intent of the phrase "increasing housing opportunities outside areas of undue concentration of lower income or minority households," as found in the proposed regulations. First, the word "undue" is no longer used since it does not contribute to the meaning.

Second, increasing housing opportunities include providing opportunities for persons who live in concentrated areas to choose housing in non-concentrated areas. This was not clear in the proposed rule, and as now stated in paragraph (e), an applicant must specifically show that its program to increase housing opportunities will provide choice. Therefore, the phrase "increasing housing opportunities" is replaced with "increasing housing choice" to indicate that activities to increase the housing supply and to provide choice are both intended uses of these funds.

Two commentors felt that the emphasis on increasing housing opportunities excludes cities which have given attention to this problem in the past, and as a result have less serious problems than many cities which have done little or nothing. Five commentors agreed with the Department, and support increasing housing opportunities. Six commentors felt that communities should not be limited to activities related to increasing housing opportunities for people in areas of concentrations. They advocated giving other community development activities equal priority so that needy communities can apply for funds to alleviate substandard conditions.

The Department considered these comments and decided to expand the concept of increasing housing choice to also include efforts to enable lower income residents to remain in a revitalizing neighborhood. This decision is based on the Department's belief that these are important Departmental missions that warrant use of reallocated funds. As stated earlier, the total amount of funds to be reallocated and used for this purpose is a very small portion of CDBG funds, and represents money which local governments have already had an opportunity to obtain, but for various reasons did not use. Use of these funds specifically for these purposes will ensure that they are effectively used and achieve the objective of the regulations.

*570.107(a).* Several editorial changes are made which clarify the regulatory references used in this paragraph and are not separately discussed here.

The legal and regulatory requirements for the use of funds allocated for use under 24 CFR Subpart H (Categorical Program Settlement Grants) and Section 570.401 (Urgent needs fund) differ from requirements for the use of funds allocated for use as Entitlement or Small Cities discretionary grants. These regulations will not apply, therefore, to funds allocated for use under Subpart H and Section 570.401 and references to these funds are deleted. The first priority for use of the reallocated funds, however, remains meeting financial settlement needs.

Under statutory requirements, these regulations must contain provisions for reassigning to another State funds which are not obligated within a reasonable time. Paragraph (a)(2)(ii) is added to meet this requirement. Because CDBG funds are not likely to meet all of a State's community development needs, HUD does not expect to reassign funds from State to State. The reference to hold harmless funds is deleted in paragraph (a)(3)(i) because no more hold harmless grants will be made. Paragraphs (a)(3) (iii)–(vi), however, apply to recaptured hold harmless funds.

*570.107(b) in the proposed regulations.* For the reasons cited above, this paragraph about recaptured Financial Settlement and urgent needs funds is deleted. All subsequent paragraphs are redesignated (i.e., (c) to (b), (d) to (c), etc.) to reflect this deletion.

*570.107(b).* Seven commentors opposed the restriction contained in the proposed rule which prohibited participating units of an urban county from applying for reallocated funds independently. The rule viewed those individual jurisdictions as part of an urban county, and thus eligible to apply only under its aegis. All the commentors felt this was an unnecessary restriction which served only to eliminate potential sites for expanded housing choice. The Department agrees, and has decided to allow a participating unit of an urban county to apply for reallocated funds.

*570.107(e).* This paragraph now includes clearer explanations of increasing housing choice, which includes efforts to counter displacement. In each, activities related to families are emphasized.

Activities to increase housing choice must insure that a substantial portion of the housing facilitated will be occupied by lower income persons from concentrated areas. Applicants must demonstrate that persons from concentrated areas have the opportunity to select the housing of their choice. Activities may be located within or outside an applicant's jurisdiction, but must be located outside concentrated areas.

Activities to enable lower income residents to remain in their neighborhood must take place in a neighborhood experiencing revitalization and substantial displacement of lower income residents as a result of private reinvestment.

In the proposed regulations, activities for which funds may be used to increase housing choice were listed by reference at the end of § 570.107(e). To emphasize that only activities eligible under Subpart C, "Eligible Activities," are approvable, the reference to these activities is now found in the introductory part of § 570.107(e). As in the proposed rule, activities to increase housing choice must also be listed as eligible in § 570.404(c).

Several commentors criticized the use of Areawide Housing Opportunity Plan (AHOP) agencies as funding vehicles for reallocated funds. One felt it is too difficult in many instances for a city to work with communities outside city control or authority. Another commentor felt that AHOPs were designed exclusively for large cities and surrounding suburbs. One commentor claimed that minority areas cannot get an AHOP approved, and are therefore at a great disadvantage when applying for reallocated funds. HUD believes that with effective Areawide Planning Organizations (APO) and local support, the AHOP can be a successful means of expanding housing choice. The Department has modified, however, the considerations used in reallocating these funds among the State's SMSAs. The Area Manager will reallocate these funds to jurisdictions participating in an approved AHOP to the extent the AHOP has the needs and capacity to use the funds considering the relative needs of the State's SMSAs with no approved AHOP especially the SMSA(s) in which the funds originated. Lack of an AHOP does not preclude receipt of these funds.

*570.107(e)(2).* Two commentors stated that the regulations should include a statement of the Area Manager's responsibility to notify all potential applicants of the availability of reallocated funds and the selection criteria that will be used. The Department appreciates this concern, but feels that the Area Manager should have the option of soliciting applications from communities which can best use reallocated funds for the purposes described in paragraph (e). To use these limited funds efficiently and effectively, the Department believes it is important to avoid developing a required formal system. However, the Department has decided that when a substantial amount of funds is available for reallocation the Area Manager will publicly solicit informal proposals from all interested, eligible applicants.

*570.107(e)(3).* Two commentors felt the proposed rule gave the Secretary too much discretion when no fundable applications are received. The Department, however, feels that this discretion is important for the most effective and timely use of the funds. The Secretary is bound by the Housing and Community Development Act of 1974, as amended, to use the funds for eligible CDBG activities, and therefore could not use the funds for activities totally unrelated to community needs. HUD, therefore, has opted to leave this discretionary authority in the final rule.

*570.107(f).* One commentor mentioned the need for funds in the Metro Small Cities Fund, and suggested raising the threshold to $1,000,000 to achieve this end. Another commentor recommended lowering the threshold to $150,000 to provide more funds for entitlement cities. The Department is lowering the threshold amount from $350.000 to $100,000. This will allow HUD to use more of the reallocated funds to increase housing choice to counter displacement especially in those Area Offices with limited amounts of funds to be reallocated.

*570.107(g)(1).* To clarify that applicants for reallocated funds to be used to meet financial settlement needs will have already met some of their application requirements, a reference to § 570.107(c)(1) is added. Section 570.107(c)(1) states that "a financial settlement need occurs when there are one or more approvable financial settlement applications pending which were not approved in the last financial settlement competition because of a lack of funds."

Applicants for reallocated funds to be used to meet financial settlement needs must comply with the statutory application requirements found in Section 104 of the Housing and Community Development Act of 1974, as amended. These requirements are now included in § 570.107(g)(1) by reference to § 570.404(d). Applicants that have already met some of these requirements (for the community development program, housing assistance plan, or cost analysis) through their applications for entitlement or Small Cities discretionary funds may incorporate such by reference.

*570.107(g)(2).* To correct an oversight in the proposed regulations, this paragraph now requires that applicants provide every certification required in 24 CFR 570.307, "Certifications."

To conform with current AHOP procedures and actual program operation, the phrase "low-income" is changed to "lower-income" wherever it appears in Section 570.107 of the regulations. The term "lower-income persons" is defined as a member of a family whose income does not exceed 80 percent of the median family income of the metropolitan area, or in the case of families residing in nonmetropolitan areas, of all nonmetropolitan areas of the State.

A Finding of Inapplicability with respect to Environmental Impact has been prepared in accordance with HUD's Procedures for Protection and Enhancement of Environmental Quality. A copy of this Finding is available for inspection and copying in the Office of the Rules Docket Clerk.

This rule is not listed in the Department's semiannual agenda of significant rules, published pursuant to Executive Order 12044.

Accordingly, 24 CFR Part 570, Subpart B, is amended to read as follows:

I. To reflect the changes in the content of regulations in Part 570, Subpart B, *Allocation and Distribution of Funds,* the table of contents is amended to read as follows:

**Subpart B—Allocation and Distribution of Funds**

Sec.
570.100 General.
570.101 Allocation between metropolitan and nonmetropolitan areas.
570.102 Basic grant amounts.
570.103 Hold-harmless grants.
570.104 Funds for discretionary grants.
570.105 Qualifications as urban county.
570.106 Qualification and submission dates.
570.107 Reallocation.

II. § 570.107 is revised to read as follows:

**§ 570.107 Reallocation.**

(a) *General.* This section governs reallocated funds originally allocated for use under 24 CFR 570, Subparts D, (Entitlement Grants, referred to in this section as "entitlement funds") and F (Small Cities Program, referred to in this

section as "Small Cities discretionary funds").

(1) *Purpose of reallocated funds.* Entitlement funds to be reallocated shall be used to meet financial settlement needs pursuant to Subpart H. After financial settlement needs are met, metropolitan entitlement funds of $100,000 or more to be reallocated shall be used for increasing housing choice, either outside of areas with lower income or minority concentrations or in a revitalizing neighborhood to enable lower income residents to remain and avoid displacement. Activities which fulfill these purposes are described in § 570.107(e).

Nonmetropolitan entitlement funds, metropolitan entitlement funds of less than $100,000, and Small Cities discretionary funds to be reallocated shall be assigned to the Small Cities discretionary balances and used according to § 570.107(f).

(2) Funds to be reallocated shall remain in the State in which they originate except as provided in paragraph (a)(2)(ii).

(i) If the funds originate in a State served by two Area Offices, then use of the funds shall be limited to the jurisdiction of the Area Office from which the funds originate.

(ii) Metropolitan and nonmetropolitan funds to be reallocated from amounts described in paragraphs (a)(3) (i) and (ii) which are not obligated under any of the applicable provisions of this Section within a reasonable time, as determined by the Secretary, shall be reassigned by the Secretary pursuant to § 570.107(c) to metropolitan and nonmetropolitan areas, respectively, of States other than the State in which the funds originate, based on a determination of unmet needs for reallocated funds.

(3) Subject to limitations on the availability of funds in appropriations acts, funds to be reallocated are—

(i) Amounts allocated to metropolitan cities and urban counties for entitlement grants which are not applied for or for which applications are disapproved by the Secretary;

(ii) Amounts allocated to metropolitan areas or nonmetropolitan areas for Small Cities discretionary grants which the Secretary determines, on the basis of applications and other evidence available, are not likely to be fully obligated by the Secretary within a reasonable time after the end of the fiscal year for which the allocation has been made;

(iii) Amounts recovered as a result of a grant reduction under 24 CFR 570.910, "Corrective and remedial actions";

(iv) Amounts available as a result of a reduction or withdrawal of a grant under 24 CFR 570.911, "Reduction or withdrawal of grant";

(v) Amounts recovered under the provisions of 24 CFR 570.913, "Other remedies for noncompliance";

(vi) Amounts returned to HUD as a result of a termination of, withdrawal from, or failure to complete an approved Community Development Program; or

(vii) Amounts remaining after closeout of a grant under the provisions of § 570.512, "Grant closeouts".

(b) *Eligible applicants.* (1) States and units of general local government as defined in 24 CFR 570.3(v), including those participating in an urban county, are eligible to apply for reallocated funds. Only those applicants eligible to apply under 24 CFR 570 Subpart F, "Small Cities Program", however, are eligible to apply for reallocated funds assigned to Small Cities discretionary balances.

(2) Funds to be reallocated which were originally allocated to a metropolitan area shall be used only by metropolitan applicants. Funds which were originally allocated to a nonmetropolitan area shall be used only by nonmetropolitan applicants.

(c) *Assignment of funds to be reallocated.* (1) Metropolitan and nonmetropolitan entitlement funds to be reallocated shall be used first for financial settlement needs in the metropolitan and nonmetropolitan areas, respectively, in the State in which the funds originate. These funds shall be reallocated as soon as practicable. For the purpose of this section, a financial settlement need occurs when there are one or more otherwise approvable financial settlement applications pending which were not approved in the last financial settlement competition because of a lack of funds.

(2) During each Federal fiscal year quarter, funds to be reallocated that are not used to meet financial settlement needs shall accumulate in funding pools separated according to: the State in which the funds originate; whether the funds are from metropolitan or nonmetropolitan allocations; and whether the funds are entitlement or Small Cities discretionary balances funds. At the end of each quarter, the Area Manager shall reallocate the funds in each funding pool, according to the following:

(i) Metropolitan entitlement funds to be reallocated which are $100,000 or more shall be used as described in § 570.107(e).

(ii) At the discretion of the Area Manager, metropolitan entitlement funds to be reallocated in amounts less than $100,000 shall be: assigned to the Area Office's metropolitan Small Cities discretionary balance for the State in which the funds originate, and used according to § 570.107(f); or held over to the next quarter to be added to additional metropolitan funds that may become available for reallocation. At the end of the last quarter in the fiscal year, however, these funds shall only be used according to § 570.107(f).

(iii) Nonmetropolitan Entitlement (hold-harmless) funds to be reallocated shall be assigned to the Area Office's nonmetropolitan Small Cities discretionary balance for the State in which the funds originate. These funds shall be used according to § 570.107(f).

(iv) Small cities discretionary funds to be reallocated shall remain in the Small Cities metropolitan or nonmetropolitan discretionary balance to which they were originally assigned. These funds shall be used according to the provisions of § 570.107(f).

(d) *Timing.* Funds to be reallocated shall be used as soon as practicable after they have been assigned according to § 570.107(c).

(e) *Reallocation of metropolitan entitlement funds in excess of $100,000.* Funds reallocated acording to § 570.107(c)(2)(i) shall be used to increase housing choice, especially for families, either outside of areas with concentrations of lower income or minority persons or in a revitalizing neighborhood to enable lower income residents to remain and avoid displacement.

Activities to increase housing choice outside areas with concentrations of lower income or minority persons may be located within or outside the applicant's jurisdiction. Each applicant must set forth a specific mechanism or program which ensures that a reasonable proportion of the housing facilitated with these funds can be expected to be occuped by persons from concentrated areas. Each applicant must specifically demonstrate that its proposed activities will provide opportunities for lower income persons living in concentrated areas to choose housing in non-concentrated areas. Each proposed activity to conduct outreach programs for persons living in concentrated areas must include a mechanism for providing fair housing information to these persons.

Activities which enable lower income residents to remain in their neighborhood must be located in a neighborhood which is experiencing revitalization and substantial displacement of lower income residents as a result of private reinvestment.

All activities undertaken with these funds must be eligible for funding in accordance with 24 CFR 570 Subpart C,

"Eligible Activities." Activities which increase housing choice outside concentrated areas must also be listed as eligible in 24 CFR 570.404(c), "Areawide programs, Eligible activities."

The Area Manager shall reallocate the funds to jurisdictions participating in an approved Areawide Housing Opportunity Plan (AHOP) to the extent the State's AHOP(s) has the needs and capacity to use the funds within a reasonable period of time and can achieve the purposes of this paragraph, considering the relative needs of other SMSAs within the State, especially the needs of the SMSA in which the funds originated.

(1) In reallocating the funds to jurisdictions participating in an approved AHOP, the following apply:

(i) An approved AHOP is one which has been approved by the Secretary in accordance with Suppart E,"Approval of Areawide Housing Opportunity Plan of 24 CFR 891, and is in effect at the time funds are reallocated to its participating jurisdictions.

(ii) In selecting jurisdictions to receive these funds, HUD and the Areawide Planning Organization which developed the approved AHOP shall use the procedures established in accordance with 24 CFR 570.404(e), "Areawide programs, Selection process".

(2) In inviting applicant not participating in an approved AHOP, the Area Manager shall consider which jurisdictions have the greatest concentrations of lower income and minority households, where there is the greatest opportunity for success, the applicant's past history, and an applicant's willingness to use the funds according to § 570.107(e). Although a formal competition need not be held, the Area Manager shall invite applications from more applicants than the amount of funds available can accommodate. In addition, when a substantial amount of funds is to be reallocated under these provisions, the Area Manager shall publicly solicit informal proposals from interested eligible applicants in a selected metropolitan area or areas.

(3) If no fundable applications are received, the Secretary reserves the right to reallocate the funds for other purposes, subject to limitations in § 570.107(a)(2)(ii).

(f) *Reallocation of Small Cities Discretionary Funds.* The Area Manager shall use Small Cities discretionary funds to be reallocated (including entitlement funds which have been assigned to the Small Cities discretionary balances under § 570.107(c)(2))—

(1) to fund any application not selected for funding in the most recent Small Cities discretionary competition due to a procedural error made by HUD; or

(2) to fund the most highly ranked unfunded application or applications from the most recent Small Cities discretionary competition; or

(3) to add the funds to the next Small Cities discretionary competition.

(g) *Application requirements for reallocated funds.* Applicants for funds reallocated pursuant to this section shall comply with the following application requirements:

(1) *Financial settlement.* When reallocated funds are to be used to meet financial settlement needs as defined in § 570.107(c)(1), the applicant shall meet the application requirements set forth in 24 CFR 570 Subpart H, "Categorical Program Settlement Grants" and § 570.404(d), "Areawide programs, Application requirements", except that all certifications described in 24 CFR 570.307 are required. An applicant that has already met the application requirements for a community development program, a Housing Assistance Plan, or a cost analysis pursuant to Subpart F or Subpart D may incorporate such by reference.

(2) *Other entitlement funds.* Applications for metropolitan entitlement funds to be reallocated accordingly to § 570.107(e) shall meet the requirements set forth in 24 CFR 570.404(d), "Areawide programs, Application requirements", except that all certifications described in 24 CFR 570.307 are required. Requirements for applications for entitlement funds which are added to a Small Cities discretionary balance are described in § 570.107(g)(3).

(3) *Small Cities Discretionary funds.* Applications and preapplications for funds to be reallocated which are added to a Small Cities discretionary balance shall meet the requirements set forth in 24 CFR Subpart F, "Small Cities Program". In many instances, an applicant described in § 570.107(f) (1) or (2) will have met all or some of the application requirements.

III. For conformity with § 570.107, § 570.409 is cancelled and reserved for future use.

**§ 570.409 Reserved.**

IV. To reflect the cancellation and reservation of § 570.409, the Table of Contents for Subpart E, Applications and Criteria for Discretionary Grants, is amended to read as follows:

(Title I, Housing and Community Development Act of 1974 (42 U.S.C. 5301 et seq.): Title I, Housing and Community Development Act of 1977 (Pub. L. 95–128); and 7(d). Department of Housing and Urban Development Act (42 U.S.C. 3538(d)).)

(Section 7(o) of the Department of HUD Act, 42 U.S.C. 3535(o), Section 324 of the Housing and Community Development Amendments of 1979.)

## Subpart E—Applications and Criteria for Discretionary Grants

Sec.

570.400 General.
570.401 Urgent needs fund.
570.402 Reserved.
570.403 New Communities.
570.404 Areawide programs.
570.405 Guam, the Virgin Islands, American Samoa, and the Trust Territory of the Pacific Islands.
570.406 Innovative projects.
570.407 Federally recognized disasters.
570.408 Inequities funds.
570.409 Reserved.

Issued at Washington, D.C., April 16, 1980.

**Robert C. Embry, Jr.,**

*Assistant Secretary for Community Planning and Development.*

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Part VIII

# Department of Health, Education, and Welfare

Office of Education

Biomedical Sciences Program

**DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

**Office of Education**

**45 CFR Part 161l**

## Biomedical Sciences Program

**AGENCY:** Office of Education, HEW.

**ACTION:** Final regulations.

**SUMMARY:** The Commissioner issues final regulations for the Biomedical Sciences Program enacted by the Education Amendments of 1978. The regulations govern the awarding of direct discretionary grants to institutions of higher education for the purpose of preparing talented, economically disadvantaged secondary school students for entrance into colleges and universities to participate in program of study leading to careers in the biomedical sciences.

**DATES:** These regulations are expected to take effect 45 days after they are transmitted to Congress. Regulations are usually transmitted to Congress several days before they are published in the **Federal Register.** The effective date is changed by statute if Congress disapproves the regulations or takes certain adjournments. If you want to know the effective date of these regulations, call or write the Office of Education contact person.

**FOR FURTHER INFORMATION CONTACT:** Ms. Joan DeSantis, Acting Director of the Biomedical Sciences Program, Bureau of School Improvement, (Room 1630, Donohoe Bldg.), 400 Maryland Avenue, S.W., Washington, D.C. 20202. Telephone (202) 472–2649.

**SUPPLEMENTARY INFORMATION:**

### General Information

The Commissioner published a notice of proposed rulemaking in the **Federal Register** on June 25, 1979 (44 FR 37170). During the comment period, 28 persons submitted a total of 78 comments in writing. In addition, 23 persons made 66 comments at public hearings held in ten regional office cities of the Department of Health, Education, and Welfare on August 1, 1979. All persons who commented expressed overall support for the regulations.

### Background

The Biomedical Sciences Program originated as a separate bill (H.R. 10736) in the 95th Congress. Hearings were held on March 2, 1978 before the House Subcommittee on Elementary, Secondary, and Vocational Education of the Committee on Education and Labor. Almost all provisions of the original bill were later included as Part L of Title III of the Elementary and Secondary Education Act of 1965, as amended by the Education Amendments of 1978 (Pub. L. 95–561).

Testimony at the hearings brought out a number of characteristics about medical resources in areas which have high concentrations of disadvantaged families:

(a) Blacks represent about 12 percent of the population, but only about 2 percent of physicians are black.

(b) Many blacks and other minority groups, such as Hispanics and Native Americans, grow up under the severe handicap of being educationally and economically disadvantaged. Because of the areas in which they grow up, either the scope or quality of courses which should prepare them for entrance into college are not offered in the secondary schools they attend, or they are discouraged from taking such courses.

(c) Students from these areas often receive little motivation for academic achievement from home or school.

(d) Availability of health care in areas with high concentrations of disadvantaged families is at a much lower level than that in other community areas.

(e) There is some evidence that students from disadvantaged backgrounds often return to their former—or to a similar—neighborhood to provide health care after they enter a profession in one of the biomedical sciences.

As a result of these characteristics, the program emphasizes a number of provisions:

(a) Students will participate in a multi-year program beginning in the ninth grade.

(b) Formal instruction will be provided in science, mathematics, and English.

(c) Students will engage in a variety of activities which will help them develop the qualifications needed to prepare for careers in the biomedical science professions.

(d) Students will be exposed to a variety of biomedical expertise and resources in the community.

(e) Parents will be encouraged to become involved in the program.

(f) Students will receive comprehensive academic and career counseling.

### Overview of the Regulations

The Biomedical Sciences Program regulations contain the following information and requirements:

Definitions
Eligible applicants and students
Selection of students
Nature, duration, limit on number, and State review of applications
Conditions and information required to continue projects
Criteria for the approval of applications
Allowable and nonallowable costs
Coordination among projects.

The regulations do not include certain types of information and requirements which are found in the Education Division General Administrative Regulations (EDGAR).

In addition, the statute contains additional information not in the regulations, including the basis for determining the amount of a grant, and the amount of an appropriation to be set aside for program evaluation.

### Summary of comments and responses

The following is a summary of comments received and the responses. The comments appear in the order of the sections of the final regulations. Several commenters recommended changes in statutory requirements. These changes would require amendments passed by Congress and cannot be made by regulation.

§ *161l.3 Definitions.*

(1) *Comment.* A few commenters stated that the definition of "biomedical science" in the statute was too narrow and unclear. They suggested that the definition be broadened to include careers in other occupations in the allied health fields.

*Response.* No change has been made in the regulations. The term "biomedical science" is defined in section 382(2) of the statute and cannot be changed by regulation. Although the statute mentions certain professions, other fields relevant to the study of human biology are not excluded. Thus, allied health fields are included in the definition and can be considered biomedical sciences for purposes of this program.

(2) *Comment.* A few commenters objected to the definition of "Biomedical sciences project," stating that it is confusing and is inconsistent with other provisions of the regulations.

*Response.* A change has been made. The definition is unnecessary and has been deleted.

(3) *Comment.* One commenter recommended that "student from an economically disadvantaged background" not be defined.

*Response.* No change has been made. The definition is in section 382(7) of the statute.

(4) *Comment.* Two commenters objected to the definition of "Rural

area." One commenter stated that the definition is too restrictive. An applicant would not be able to recruit 100 students in such a low-density population area. The same person also commented that the definition conflicts with the designation of a "health manpower shortage area," which uses a ratio of one health professional for each 3,000 residents. The second commenter stated that the definition for "Rural area" conflicts with the definition for "Secondary school system which has a relatively high proportion of students from an economically disadvantaged background."

*Response.* No change has been made. The definition of "Rural area" is the same as that used in other Office of Education programs. The definition is compatible with a "health manpower shortage area." Section 383(b) of the statute and § 1611.40 of the regulations require the Office of Education to give special consideration to projects in either a "health manpower shortage area" or a "rural area." Although the Office of Education recognizes the large area needed to meet the requirements of the program, the definition does not conflict with the definition for "Secondary school system which has a relatively high proportion of students from an economically disadvantaged background." The area served is defined by the applicant. This ensures that the area can be large enough so that the required number of qualified ninth grade students can participate.

(5) *Comment.* A request has been made for clarification of the definition of "Secondary school system which has a relatively high proportion of students from an economically disadvantaged background."

*Response.* A change has been made. The revised definition is based on the requirements in Title I of the Elementary and Secondary Education Act of 1965, as stated in Part 116 of Title 45 of the Code of Federal Regulations, for determining eligible school attendance areas for Title I services. The reason for using the Title I requirements in the Biomedical Sciences Program is to achieve consistency among programs serving economically disadvantaged students and to simplify the task of determining the area served by a Biomedical Sciences project. By contacting the secondary schools or the school district, an applicant can learn which secondary schools qualify for Title I services and, therefore, which secondary schools qualify for the Biomedical Sciences Program as having "a relatively high proportion of students from an economically disadvantaged background."

*§ 1611.4 Eligible applicants.*

*Comment.* One commenter recommended that nonprofit private organizations should be eligible to apply. Another recommended that community organizations that know the target students well should be eligible. Another stated that an applicant should demonstrate that it possesses a record of expertise in providing continuing support for target students. Another suggested clarification of an institution of higher education as an applicant to include two-year community colleges.

*Response.* No change has been made. Section 383(a) of the statute requires the Commissioner to make grants to institutions of higher education. A two-year community college would qualify as an institution of higher education as defined in § 1611.3(c). This type of an institution, however, must enter into an agreement with a "school of biomedical science" as defined in section 382(6) of the statute.

*§ 1611.5 Eligible participants.*

(1) *Comment.* Two commenters recommended that the income level for participation be raised to include middle income families.

*Response.* No change has been made. The statute mandates the level of income as 50 percent or less of the national median income for families of comparable size.

(2) *Comment.* Three commenters recommended that students be given greater flexibility in selecting the year in which they enroll in a project. And two others commented that ninth grade students are too young. All contend that many students do not develop an interest in the biomedical sciences until the last year or two of high school.

*Response.* No change has been made. Section 384(a)(4) of the statute requires that a project initially enroll at least 100 ninth grade students. Section 382(9) of the statute also allows for including certain other students. Tenth graders can participate if they qualify, and eleventh and twelfth graders who had 100 clock hours of project activities in a similar project or comparable program during a previous year can participate. These requirements for participation are supported by legislative history, which emphasizes the importance of instruction in a multi-year program.

(3) *Comment.* One commenter recommended that eleventh and twelfth grade students who have transferred into a project from a school having a similar project must have successfully completed 100 clock hours of project activities in a former project. Another commenter stated that a grantee should be allowed to use project funds for students who were not a part of the original group but who enrolled after the first year of the project.

*Response.* A change has been made. The words "participated satisfactorily for a full academic year" in § 1611.5(d)(1) in the proposed regulations have been changed to "participated satisfactorily for at least 100 clock hours of project activities during the academic year" in § 1611.5(f)(1) of these regulations. A grantee may use project funds for eligible tenth, eleventh, or twelfth grade students who were not part of the original group, but these students must qualify as economically disadvantaged.

(4) *Comment.* Ten commenters supported participation by students who are not from economically disadvantaged backgrounds. Two other commenters objected to their participation.

*Response.* Language in §§ 1611.5(e) and 1611.51(b) has been modified to clarify the allowable participation in project activities by students who are not eligible because they do not come from economically disadvantaged backgrounds. Participation by these students is subject to two conditions: (1) project funds may not be used to provide services for them (for example, they may not receive stipends, instructors and counselors may not receive additional compensation to serve them, and payment may not be made for the cost of the students' transportation, materials, or equipment); and (2) the number of these students may not exceed 15 percent of the total number of project participants from economically disadvantaged backgrounds to ensure that their participation does not dilute the effectiveness of instruction and other experience for participating students from economically disadvantaged backgrounds.

(5) *Comment.* One commenter requested clarification of student eligibility if family income changes.

*Response.* A change has been made. Section 1611.5(c) has been added to clarify that once a student qualifies as being from an economically disadvantaged background, he or she may continue to participate for the duration of the project regardless of any changes in family income. It is also possible that a non-low-income student who participated during one or more years under the conditions provided in § 1611.5(e) becomes eligible for financial assistance during a succeeding year because that student meets the low-income requirement. If that student has

participated satisfactorily for 100 clock hours of project activities while participating under provisions of § 1611.5(e) and subsequently becomes eligible for financial assistance, he or she will continue to be eligible for financial assistance for the duration of the project.

(6) *Comment.* One commenter requested clarification of "similar objectives" of Upward Bound and Talent Search which would entitle students in these projects to transfer to Biomedical Science projects.

*Response.* No change has been made. In general, if Upward Bound and Talent Search students are receiving instruction and experience similar to that outlined in section 381 of the Act, they would qualify as having participated in a program comparable to a project.

(7) *Comment.* Two commenters recommended that students attending nonprofit private schools which have a record of racial or other discrimination should not be eligible to participate.

*Response.* No change has been made. These regulations do not cover questions of past performance concerning civil rights laws. The civil rights laws and regulations that a grantee must comply with are listed in § 100a.500 of EDGAR.

(8) *Comment.* One commenter suggested clarification of the request for information about family income from parents.

*Response.* No change has been made. As a result of other programs for the economically disadvantaged, this information may be on file in many LEAs. If not, parents may be asked for information about their income in order to determine whether their children are eligible to participate in the program.

*§ 1611.6 Selection of Students*

(1) *Comment.* Three commenters recommended that language which emphasizes tests as a means of selecting students be modified.

*Response.* A change has been made. The words "Comprehensive test data and" have been deleted from § 1611.6(c)(2). In addition, § 1611.6(d)(4) has been added to emphasize the statutory requirement that due notice shall be taken of difficulties inherent in traditional testing methods. The intent of this provision is to ensure that the content of any test used in the selection process or the conditions under which it is administered do not put any student at a disadvantage compared to other students because of racial, national, ethnic, or cultural backgrounds. All students should have a clear understanding of the language of the test questions and of the instructions for taking the test.

(2) *Comment.* One commenter suggested that science teachers, rather than counselors, are the persons most qualified to determine a student's potential success in a biomedical profession. Another recommended that community groups, such as minority based community councils, serve the function of student selection.

*Response.* No change has been made. Section 384(a)(5) of the statute already gives science teachers a prominent role in selecting students. In addition, § 1611.6(c)(1) provides for nominations from three out of five sources. Teachers, counselors, and community representatives are three of five groups named, the others being principals and parents or students.

(3) *Comment.* One commenter recommended the addition of selection criteria as follows: "evaluation adapted to the child's cultural norm" and "other innovative strategies for identification of potential for success in the Biomedical Sciences Program."

*Response.* No change has been made. Language in § 1611.6(c)(2) is designed to produce the desired results. In response to other comments, the language is expressed broadly to allow flexibility to account for cultural differences.

(4) *Comment.* One commenter recommended that an effective screening mechanism be established for identifying talented students. The expertise of an institution of higher education is needed to assist local educational agencies to identify talented students. Another suggested that in areas where Talent Search projects are operating, staff members of these projects be used to help identify target students for the Biomedical Sciences Program.

*Response.* No change has been made. Provisions for selecting students described in § 1611.6 are comprehensive enough to achieve the results recommended. Staff members of Talent Search projects would be an appropriate source of help.

*§ 1611.20 Nature of projects.*

(1) *Comment.* Four commenters recommended that instruction and other activities not be confined to hours when school is not in regular session.

*Response.* A change has been made. The language "when secondary schools are not in normal operation" in § 1611.20(e) has been deleted. New language allows students to participate in the program at times which do not conflict with their regular instruction, such as science, mathematics, and English, and, to the extent feasible, which do not conflict with their participation in extra-curricular activities. These provisions have been moved to a new paragraph § 1611.20(f), and the paragraphs that follow have been redesignated.

(2) *Comment.* Six persons commented on the amount of involvement of a variety of individuals and groups in the project. Two commenters specifically supported involvement of LEAs, parents, and ethnically oriented community groups. Another recommended that they become involved during the developmental stage. Two recommended deletion of requirements such as cooperative arrangements and agreements among the applicant, LEA(s), and schools of biomedical sciences. Another recommended that the regulations be more general to allow greater flexibility in conducting the project.

*Response.* No change has been made. Section 384 of the statute specifically requires that the project be carried out in cooperation with the public and nonprofit private schools in the area in which the applicant is located, and to use community resources related to the biomedical sciences. These resources should be used by the applicant as appropriate, both for developing and conducting the project.

(3) *Comment.* Two persons commented on provisions for counseling. One recommended that the project provide specific career counseling in fields such as podiatry. Another recommended that students receive counseling for entrance into college for training leading to careers in the biomedical sciences.

*Response.* No change has been made. Section 384(a)(8) of the statute requires each project to provide academic and career counseling. Criteria in § 1611.41 also emphasize counseling.

(4) *Comment.* One commenter recommended that the regulations specify the academic subjects to be included in the participant's instructional program.

*Response.* A change has been made. A new § 1611.20(e) specifies the areas of study that are required by Section 381 of the statute.

(5) *Comment.* One commenter suggested that language in § 1611.20(k)(1) be changed from "in enrolling" to "who have enrolled." As now expressed, the language gives the impression that during the fifth year the project will only assist participants to enroll in college, and not those who have enrolled in college.

*Response.* A change has been made by adding language at the end of § 1611.20(m)(1) as follows: "and

assistance to participating students who have enrolled in postsecondary institutions."

(6) *Comment.* One commenter suggested that applicants have an option of providing a project either during the academic year or during the summer, the latter to avoid conflict with student participation in extra-curricular activities and to take advantage of a larger selection of facilities and staff.

*Response.* No change has been made. Section 384(a)(9) of the statute specifies that the project provide courses in each academic year of the project. Section 384(a)(10) further specifies that the project be offered "in the summer following each academic year of the project."

*§ 161l.21 Duration of projects.*

(1) *Comment.* Three commenters recommended that the Office of Education make multi-year grants for the five-year projects. One requested clarification of this section.

*Response.* No change has been made. Office of Education policy is to award a single-year grant, even if the project period is for more than one year. Continuation awards for the second and subsequent years of the project period are judged according to the standards in 45 CFR 100a.253 of EDGAR and §§ 161l.22 and 161l.23 of this part.

(2) *Comment.* One commenter requested clarification of the nature of the project each year beginning with the ninth grade.

*Response.* No change has been made. The applicant should plan a program of instruction and experiences commensurate with achievement standards for each year of secondary school (grades 9 through 12) in which a student is enrolled. Section 161l.20(m) of the regulations explains the nature of the project during the fifth year.

*§ 161l.22 Conditions required to continue projects.*

(1) *Comment.* Five commenters recommended that the number of ninth grade, talented, economically disadvantaged students required for the original project be substantially reduced, particularly for rural areas. One commenter supported the 100-student requirement.

*Response.* No change has been made. Section 384(a)(4) of the statute specifically requires at least 100 ninth grade students who are talented and economically disadvantaged to initially participate in the project.

(2) *Comment.* Two commenters recommended that the basis for computing the retention rate of students for second and subsequent years of the project be changed to allow students to enroll after the first year and be counted together with the original students.

*Response.* No change has been made. Section 384(b) of the statute specifies the retention rate to continue a project, and does not include students enrolled after the first year.

(3) *Comment.* One commenter recommended that a continuing project should compete against other continuing projects, not against new applications.

*Response.* No change has been made. A project is approved for a period of five years. It does not compete against other projects after the first year. Although it does not compete, it must meet certain conditions and provide certain information to continue, as specified in 45 CFR 100a.253 of EDGAR and § 161l.22 and § 161l.23 of this part.

(4) *Comment.* One commenter recommended academic assistance to enable students to attain grade level competency in the required subjects to encourage them to pursue their ideal toward a career in the biomedical sciences.

*Response.* No change has been made. The nature of the project as described in § 161l.20 is to provide students with instruction, counseling, and other experiences which will motivate and prepare them to pursue careers in the biomedical sciences.

(5) *Comment.* Two commenters recommended that standards be developed to assure that participants demonstrate performance as well as potential. One of them also recommended that the standards be aimed at the highest level of the biomedical science profession, such as doctor of medicine.

*Response.* No change has been made. Section 161l.22(a) of the regulations require applicants to design an evaluation which will demonstrate satisfactory student competency. Standards cannot be applied to a level of any specified profession, because the program allows students to prepare for study leading to careers in any biomedical science field.

*§ 161l.23 Information required to continue projects.*

*Comment.* One commenter recommended that in order to continue a project, a grantee provide specific information about participation by nonprofit private school students.

*Response.* A change has been made. Language in § 161l.23 (a) and (b) has been changed from "The number of target students" to "The number of target students in public schools and the number of target students in nonprofit private schools."

*§ 161l.31 Limitation on the number of applications.*

(1) *Comment.* One commenter recommended that an institution of higher education not be limited to a total of four projects.

*Response.* No change has been made. If an applicant has received grants for four five-year projects, it has established a record of success which should attract alternate sources of funding. In addition, by limiting the number of grants an institution of higher education can receive, the Office of Education will be in a better position to carry out the intent of Congress to approve applications which "assure that projects are offered in a diversity of geographic settings" (Section 383(b) of the Act).

(2) *Comment.* One commenter stated that a contradiction exists between the provision allowing an applicant to receive up to four grants and the provision giving "priority to programs not previously offered" (§ 161l.40).

*Response.* No change has been made. Giving priority to programs not previously offered does not exclude funded applicants from applying for new projects. Section 161l.40 provides that priority be given to programs not previously offered when they and those previously offered "are judged to be relatively equal (within 10 points of one another)." A program previously offered which scores more than ten points higher than one not previously offered will be funded over the program not previously offered.

(3) *Comment.* Two persons commented on the number of applications allowed in a single year. One commenter urged that an institution of higher education be allowed to submit more than one application a year or to include more than one LEA in an application. Another asked whether more than one institution within a statewide system would be eligible to apply within a single year.

*Response.* No change has been made. Institutions of higher education have many options. An applicant may enter into a cooperative agreement with one or more LEAs in recruiting target students. In areas of high density population, an applicant may recruit more students than in the basic group of 100 ninth grade students. It also may reduce the size of the geographic area from which students are drawn, thus allowing other institutions of higher education to recruit students in adjoining areas for another project. Institutions may apply as a consortium, working with one or more LEAs, as authorized by § 161l.4. In response to the second commenter, one or more

institutions administered separately within statewide system may be separate applicants.

*§ 1611.32 State review of applications.*

*Comment.* One commenter recommended deletion of the requirement to submit an application to a State educational agency or to the State agency responsible for higher education because of the delay that may be encountered in submitting the application to the Office of Education.

*Response.* No change has been made. Because State agencies have had experience in many Federal and State programs for disadvantaged students, their comments could substantially improve the projects. There is no basis for fear of delaying submission of a project; under 45 CFR 100a.156 of EDGAR, an applicant may send a copy of the application to the State for review at the same time that it submits the application to the Office of Education. EDGAR (45 CFR 100a.158) provides that the Office of Education can establish a deadline for receipt of comments from the State.

*§ 1611.40 How the Commissioner evaluates an application.*

*Comment.* Nineteen commenters recommended either more emphasis on special considerations identified in § 1611.44, of the proposed regulations, less emphasis on them, or the addition of other considerations.

*Response.* No change has been made. Section 383(b) of the statute identifies the priorities and special considerations which projects are to receive. The Commissioner has no authority to delete them or to add others. To combine related provisions of the regulations under a single heading, the special considerations have been renumbered as § 1611.40(d), and § 1611.44 has been deleted.

*§ 1611.41 Selection criteria the Commissioner uses.*

(1) *Comment.* Three persons commented on evaluation criteria. One urged that an effective evaluation system be developed. Another urged that a standard evaluation format be established to provide comparable information from all grantees. A third commenter requested clarification of the nature and scope of the evaluation.

*Response.* The evaluation criteria have been simplified in § 1611.41(d). These criteria and the evaluation required in § 1611.22(a) as a condition to continue projects provide for effective evaluations within a generally standard format, while allowing enough flexibility to take into account unique circumstances of individual grantees. In addition to the evaluation which each grantee must conduct, section 387(b) of the statute requires that an amount not to exceed five percent of an appropriation must be used to conduct evaluations of the projects. The Commissioner has the responsibility of determining the nature and scope of evaluations through the use of these funds.

(2) *Comment.* One commenter recommended a redistribution of points for the criteria on "Plan of operation" and "Quality of key personnel" in § 1611.42 (a) and (b) of the proposed regulations, specifically to reduce the number of points assigned to the EDGAR criteria for these areas.

*Response.* A change has been made. The Commissioner believes that special emphasis should be given to criteria on "Plan of operation" and "Quality of key personnel" to successfully implement the Biomedical Sciences Program. Therefore the criteria have been reevaluated, resulting in a reorganization of several categories. The points assigned to § 1611.41 (a) and (b) have been increased to reflect the special program emphasis. In addition, § 1611.41(a) and other sections on the selection criteria have been simplified and reorganized.

*§ 1611.50 Allowable costs.*

(1) *Comment.* Two commenters recommended raising the student stipend substantially above $30.

*Response.* No change has been made. Section 386(b) of the statute specifies that students "may be paid a stipend in an amount not in excess of $30 per month, except in exceptional cases as determined by the Commissioner."

(2) *Comment.* One commenter recommended that the cost of transportation for students be allowed, especially in suburban and rural areas where public transportation is not available.

*Response.* No change has been made. Section 1611.50(b)(3) allows transportation from the primary school site to other training facilities, but not for transportation from the students' homes to school sites. The cost of transportation in some areas could consume a substantial portion of the grant, thus depriving students of much of the instruction and other experience they were transported to obtain.

**Comments Not Covered by the Regulations**

*Comment.* Three commenters urged that the level of funding which a grantee receives for each student be raised substantially above $2,400.

*Response.* The regulations do not address the amount of a grant for each student. Section 383(c) of the statute states that the amount of money a grantee may receive for a project "may not exceed an amount equal to $2,400 for each talented student from an economically disadvantaged background who was a full participant in the project in the academic year ending in that fiscal year." However, the same section of the statute specifies that the grantee may receive funds for "special expenses approved by the Commissioner for its summer program . . . ."

**Other Changes**

In response to suggestions by the public and other interested parties, these final regulations contain provisions that were not in the notice of proposed rulemaking. These include (1) certain provisions of the statute governing this program; and (2) the general selection criteria found in the Education Division General Administrative Regulations (EDGAR 45 CFR 100a.202 through 100a.206). The purpose of incorporating these provisions into the final regulations is to enable applicants and grantees to understand better the requirements of this program without having to refer to these additional documents.

The reader will find a citation of statutory or other legal authority in parentheses on the line following each substantive section of the regulations.

(Catalog of Federal Domestic Assistance No. 13.691, Biomedical Sciences Program)

Dated: April 15, 1980.

**William L. Smith,**

*U.S. Commissioner of Education.*

The Commissioner amends Title 45 of the Code of Federal Regulations by adding a new Part 1611 to read as follows:

## PART 1611—BIOMEDICAL SCIENCES PROGRAM

### Subpart A—General

Sec.

1611.1 The Biomedical Sciences Program.
1611.2 Regulations that apply to the Biomedical Sciences Program.
1611.3 Definitions.
1611.4 Eligible applicants.
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1611.6 Selection of students.

### Subpart B—Projects the Office of Education Assists Under This Program

1611.20 Nature of projects.
1611.21 Duration of projects.
1611.22 Conditions required to continue projects.

1611.23 Information required to continue projects.

**Subpart C—How To Apply for a Grant**

1611.30 Procedures for applying.
1611.31 Limitation on the number of applications.
1611.32 State review of applications.

**Subpart D—How a Grant Is Made**

1611.40 How the Commissioner evaluates an application.
1611.41 Selection criteria the Commissioner uses.

**Subpart E—Conditions That Must Be Met by a Grantee**

1611.50 Allowable costs.
1611.51 Non-allowable costs.
1611.52 Coordination among the projects.

**Authority:** Title III, Part L, Elementary and Secondary Education Act of 1965, as amended by the Education Amendments of 1978, (Pub. L. 95-561), 20 U.S.C. 3051-3057; 92 Stat. 2223-2227.

## Subpart A—General

### § 1611.1 The Biomedical Sciences Program.

The Commissioner awards grants to institutions of higher education to—

(a) Motivate and educate secondary school students from an economically disadvantaged background to prepare for and enter into careers in the biomedical sciences;

(b) Assist these students to develop the skills and competencies essential to success in these careers and to overcome disadvantages resulting from foreign language barriers;

(c) Instill in these students awareness and concern for the health of their families and communities; and

(d) Introduce these students to the opportunities and challenges of serving in communities that have a need for persons trained in the biomedical sciences.

(20 U.S.C. 3051)

### § 1611.2 Regulations that apply to the Biomedical Sciences Program.

The following regulations apply to the Biomedical Sciences Program:

(a) The Education Division General Administrative Regulations (EDGAR) in—

(1) 45 CFR Part 100a (Direct Grant Programs); and

(2) 45 CFR Part 100c (Definitions).

(b) The regulations in this Part 1611.

(20 U.S.C. 1221e-3(a)(1))

### § 1611.3 Definitions.

(a) *Definitions in EDGAR.* The following terms used in this part are defined in 45 CFR Part 100c:

Application
Award
Budget
Budget period
Commissioner
EDGAR
Equipment
Fiscal year
Grant period
Local educational agency (LEA)
Nonprofit
Private
Project period
Public
Secondary school
State educational agency (SEA)

(b) *Definitions in the Act.* Terms defined in the Act (section 382) include:

Applicant
Biomedical science
Full participant
Project
Public secondary school system
School of biomedical science
Talented student from an economically disadvantaged background
Target student

(c) *Program definitions.* As used in this part:

"Act" means Title III, Part A and Part L, of the Elementary and Secondary Education Act of 1965, as amended by the Education Amendments of 1978 (Pub. L. 95-561).

"Institution of higher education" means an educational institution in any State which meets the requirements in Section 1201(a) of the Higher Education Act of 1965 as amended. Two-year community colleges may qualify as "institutions of higher education."

"Nonprofit private secondary school system" means a non-public secondary school or group of secondary schools which is recognized or certified by the SEA as meeting State criteria for secondary schools.

"Rural area" means an area that is not included within a Standard Metropolitan Area (as defined by the U.S. Bureau of Census). A rural area cannot contain any city, town, borough, village, or other subcounty political unit with a population over 2,500.

"Secondary school system which has a relatively high proportion of students from an economically disadvantaged background" means a secondary school or schools which qualify as eligible school attendance areas under Titile I of the Elementary and Secondary Education Act of 1965, as amended, as having high concentrations of children from low-income families.

"Students from an economically disadvantaged background" means an individual from a family which had, during the preceding year, an income equal to 50 percent or less of the national median income for families of comparable size and (1) who is enrolled in good standing in the ninth, tenth, eleventh, or twelfth grade of a secondary school; and (2) whose access to higher educational opportunity in the biomedical sciences is significantly limited due to the income of the individual's family.

(20 U.S.C. 3052, 3053(a) and (b) 3054(a)(2)(A))

### § 1611.4 Eligible applicants.

(a) The Commissioner awards grants to institutions of higher education on a competitive basis under selection procedures and criteria of this part and of EDGAR.

(b) Two or more institutions of higher education may join in applying if a joint project may serve better the purpose of the program, as in rural areas.

(20 U.S.C. 3053)

### § 1611.5 Eligible participants.

(a) An institution of higher education may enroll in an approved project only students who—

(1) Are talented as determined by criteria stated in § 1611.6;

(2) Are from an economically disadvantaged background, as defined in §1611.3(c); and

(3)(i) Reside in the area served by the secondary school system which has been designated under § 1611.20(c); or

(ii) Attend a public or nonprofit private school in the area served by the secondary school system.

(b) In determining whether a student comes from an economically disadvantaged background, and is eligible to participate, an applicant or an LEA may request the parents to provide a statement regarding their annual income.

(c) A student who qualifies as being from an economically disadvantaged background remains eligible for purposes of paragraph (a)(2) of this section through the duration of the project regardless of any change in family income.

(d) An institution of higher education may enroll in a project—

(1) Eligible students who are in the ninth or tenth grade; and

(2) Eligible students who are in the eleventh or twelfth grade who have participated satisfactorily for at least 100 clock hours of project activities in the project or in a program comparable to the project during the student's enrollment in the ninth or tenth grade.

(e) Talented students who do not qualify as coming from economically disadvataged backgrounds may participate in project activities, provided that—

(1) No Federal funds provided under this part are used to provide services for those students; and

(2) Their number does not exceed 15 percent of the number of talented economically disadvantaged students enrolled in the project.

(f) The project may include among its students who are considered to come from a comparable program only those students who—

(1) Transferred to the project school from another school having a similar project in which the student participated satisfactorily for at least 100 clock hours of project activities during the academic year; or

(2) Participated satisfactorily during an academic year for at least 100 clock hours of project activities—but who are no longer enrolled—in a program having similar objectives and providing similar experiences as the Biomedical Sciences Program. Certain Upward Bound and Talent Search projects may qualify if they provide similar activities and meet similar objectives.

(g) The project may enroll in its summer session only students who were full participants during the previous academic year. Students are not required to participate in the summer session.

(20 U.S.C. 3052 (7), (8), and (9), 3054(a) (4) and (10))

**§ 161l.6 Selection of students.**

(a) An applicant shall establish criteria for the selection of students and plan for recruitment activities. The applicant shall consult on these matters with appropriate officials of the public and nonprofit private secondary schools serving the target area.

(b) The responsibility for selection of students to participate in a project rests with officials of the LEA(s) and appropriate nonprofit private schools with the concurrence of the participating institution(s) of higher education.

(c) Selection criteria shall include—

(1) Nominations of students having potential to successfully complete a course of study leading to a career in one of the biomedical sciences by at least one person from each of three of the following categories who knows a student being considered:

(i) Teachers.

(ii) Principals.

(iii) Counselors.

(iv) Parents or students.

(v) Community representatives or other appropriate persons.

(2) Information available on each student's achievement and aptitude which enables the applicant institution of higher education and the secondary schools to determine the student's potential to successfully complete a course of study leading to a career in one of the biomedical sciences; and

(3) Other criteria established by the applicant, the LEA(s) and nonprofit private school(s) involved.

(d) The grantee shall—

(1) Publicize widely to target students and their parents the opportunity to participate in the project and, before the selection process begins, inform target students and other interested persons about the criteria for selection;

(2) Ensure that individuals from non-English speaking backgrounds are not denied an opportunity for selection because of lack of proficiency in the English language;

(3) Not deny any eligible student participation in the program on the basis of a single test or selection criterion;

(4) Take due notice of difficulties inherent in traditional testing methods; and

(5) Ensure that students enrolled in nonprofit private secondary schools are provided an equitable opportunity to participate in the project.

(20 U.S.C. 3052 (7) and (8), 3054(a) (2) and (5))

## Subpart B—Projects the Office of Education Assists under This Program

**§ 161l.20 Nature of projects.**

The Commissioner funds only those projects in the Biomedical Sciences Program that meet all of the following conditions:

(a) The project is developed by the applicant in consultation with the following persons:

(1) Administrators no lower than principal or dean of public and nonprofit private secondary schools of the area.

(2) Teachers of public and nonprofit private secondary schools of the area.

(3) Interested parents.

(4) Interested target students.

(5) Interested professionals in biomedical science fields.

(b) The project is prepared in terms of a formal agreement among appropriate officials of the applicant institution, schools of biomedical sciences, and the LEA(s) involving the public and nonprofit private secondary schools of the project.

(c) The project is carried out in cooperation with a public or nonprofit private secondary school system or with a combination of these systems which has a relatively high proportion of students from an economically disadvantaged background as defined in § 161l.3(c) of these regulations.

(d) The plan for the proposed project carefully outlines the respective responsibilities of all personnel directly involved in the project—as well as the commitments of resources—by the applicant institution, the school(s) of biomedical sciences involved, and the related public and nonprofit private secondary schools.

(e) A grantee provides—

(1) An intensive academic program in mathematics, the sciences, and English;

(2) Study skill development;

(3) Experiences in laboratory and health care delivery settings; and

(4) Frequent exposure to individuals trained, or receiving training, in the biomedical sciences.

(f) A grantee offers instruction and other project activities for at least 100 clock hours in each academic year at times which do not conflict with—

(1) The regular program of instruction, such as science, mathematics, and English at the school in which a student is enrolled; and

(2) To the extent feasible, the student's participation in extra-curricular activities at the school.

(g) The project includes arrangements to use—

(1) The research and other facilities and personnel of schools of biomedical science located in the area in which the project is offered;

(2) The special knowledge of individuals from economically disadvantaged backgrounds who live in the project area;

(3) The expertise of teachers in secondary schools and institutions of higher education located in the project area; and

(4) The talents and expertise of other groups, such as parent-teacher associations, foundations, civic groups, and professional organizations.

(h) The project provides counseling to students who are participants and to those who were participants in previous academic years on the range of opportunities available in the biomedical sciences upon completion of high school, college, and professional training, and on the financial and other requirements to pursue these opportunities.

(i) The project includes provisions for a summer session that will accommodate all of the target students who wish to enroll.

(j) For a summer program the grantee provides—for at least 15 hours a week during a period of at least six weeks—academic instruction, laboratory training, field work, and other experiences in biological sciences.

(k) The project provides for coordination of its activities and services with those of other public and private agencies and organizations and with other projects that are funded under this program.

(l) The project provides for the equitable participation of students

enrolled in nonprofit private secondary schools in the area to be served.

(m) The fifth year of the five-year project must focus on the following:

(1) Assistance to participating target students in enrolling in post-secondary institutions and assistance to participating students who have enrolled in postsecondary institutions.

(2) Evaluation of—

(i) Students' progress; and

(ii) The effect of the project experiences on students' interests and actions in undertaking postsecondary school studies in preparation for a career in one of the biomedical sciences.

(3) Program activities for participating target students who are still enrolled in a secondary school involved in the project.

(20 U.S.C. 3051, 3054(a))

**§ 161l.21 Duration of projects.**

(a) The Commissioner approves projects for a five-year project period.

(b) Each grant for an approved five-year project period shall be for a budget period of one year.

(20 U.S.C. 3054(a)(1))

**§ 161l.22 Conditions required to continue projects.**

(a) The applicant shall design an evaluation that will determine the eligibility of students to continue in the project in the second and subsequent years. In order to be eligible to continue in the project in any academic year, the student must have—

(1) Participated satisfactorily in at least 100 clock hours of project activities during the previous academic year;

(2) Demonstrated success for his or her grade level in science, mathematics, English, and other curriculum offerings as measured by an evaluation activity similar to one used to measure the achievement of students in regular school programs; and

(3) Demonstrated potential for success in biological sciences as measured by satisfactory performance in laboratory and other work-related experience.

(b)(1) In its first academic year, the project must enroll at least 100 talented students who are from an economically disadvantaged background and who are in the ninth grade.

(2) In order to receive funds to continue the project during the third year, not less than 50 percent of the original ninth grade students who were full participants during the first academic year must remain full participants during the second academic year.

(3) In order to receive funds to continue the project during the fourth year, not less than 25 percent of the original ninth grade students who were full participants during the first academic year must remain full participants during the third academic year.

(4) In order to receive funds to continue the project during the fifth year, not less than 12½ percent of the original ninth grade students who were full participants during the first academic year must remain full participants during the fourth academic year.

(5) Students participating in project activities under § 161l.5(e) who are not from economically disadvantaged backgrounds shall not be counted for purposes of the requirements in this subsection.

(20 U.S.C. 3052(3), 3054(b))

**§ 161l.23 Information required to continue projects.**

For each year of the grant, the grantee shall report to the Commissioner the following information:

(a) The number of target students in public schools and the number of target students in nonprofit private schools who have participated satisfactorily in the project for at least 100 clock hours in the academic year.

(b) The number of target students in public schools and the number of target students in nonprofit private schools who will participate during the following year.

(c) Changes in the nature, scope, and schedule of activities to be conducted in the academic year program and summer program during the following year.

(d) An itemized budget for the academic year program and summer program for the following year.

(20 U.S.C. 3054(a)(1))

## Subpart C—How To Apply for a Grant

**§ 161l.30 Procedures for applying.**

In applying for a grant, an institution of higher education shall follow the procedures and meet the requirements stated in EDGAR.

(20 U.S.C. 1221e-3(a)(1), 3055)

**§ 161l.31 Limitation on the number of applications.**

(a) An institution of higher education may submit only one application for a new project in a fiscal year for assistance under this part.

(b) During the second and subsequent years of a project, a grantee may apply for another project in competition with other applicants for new projects.

(c) An institution of higher education may receive grants for a maximum of four projects.

(20 U.S.C. 3053(b), 3055)

**§ 161l.32 State review of applications.**

(a) The Commissioner does not approve an application from an institution of higher education unless its SEA—and the State authority for higher education, if it is different from the SEA—has had an opportunity to review and comment on the application. Neither the SEA nor the State authority for higher education may disapprove an application.

(b) The applicant shall follow the requirements in 45 CFR 100a.155 and 100a.156 of EDGAR concerning State comment procedures.

(20 U.S.C. 3055)

## Subpart D—How a Grant Is Made

**§ 161l.40 How the Commissioner evaluates an application.**

(a) The Commissioner evaluates an application on the basis of criteria in § 161l.41.

(b) The Commissioner awards up to 100 points for these criteria.

(c) The maximum possible score for each complete criterion is indicated in parentheses next to the heading of that criterion.

(d) Among proposed projects that are judged to be relatively equal (within 10 points of one another), the Commissioner—

(1) Gives priority to programs not previously offered;

(2) Gives special consideration to projects located in health manpower shortage areas (designated under section 332 of the Public Health Service Act) or in a rural area; and

(3) Takes into account the location of the projects to assure a diversity of geographic settings.

(20 U.S.C. 3053(b), 3055)

**§ 161l.41 Selection criteria the Commissioner uses.**

(a) *Plan of operation.* (17 points)

(1) The Commissioner reviews each application for information that shows the quality of the plan of operation for the project.

(2) The Commissioner looks for information that shows—

(i) High quality in the design of the project;

(ii) An effective plan of management that insures proper and efficient administration of the project;

(iii) A clear description of how the objectives of the project relate to the purpose of the program;

(iv) The way the applicant plans to use its resources and personnel to achieve each objective;

(v) A clear description of how the applicant will provide equal access and treatment for eligible project

participants who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women;

(C) Handicapped persons; and

(vi) For grants made after October 1, 1980, a clear description of how the applicant will satisfy the applicable requirements for consultation with private school officials and opportunity for participation by private school students.

(b) *Quality of key personnel.* (13 points)

(1) The Commissioner reviews each application for information that shows the qualifications of the key personnel the applicant plans to use on the project.

(2) The Commissioner looks for information that shows—

(i) The qualifications of the project director (if one is to be used);

(ii) The qualifications of each of the other key personnel to be used in the project;

(iii) The time that each person referred to in paragraphs (b)(2)(i) and (ii) of this section will commit to the project; and

(iv) The extent to which the applicant, as part of its nondiscriminatory employment practices, encourages applications for employment from persons who are members of groups that have been traditionally underrepresented, such as—

(A) Members of racial or ethnic minority groups;

(B) Women; and

(C) Handicapped persons; and

(D) The elderly.

(3) To determine personnel qualifications, the Commissioner considers experience and training, in fields related to the objectives of the project, as well as other information that the applicant provides.

(c) *Budget and cost effectiveness.* (10 points)

(1) The Commissioner reviews each application for information that shows that the project has an adequate budget and is cost effective.

(2) The Commissioner looks for information that shows—

(i) The budget for the project is adequate to support the project activities; and

(ii) Costs are reasonable in relation to the objectives of the project.

(d) *Evaluation plan.* (8 points)

(1) The Commissioner reviews each application for information that shows the quality of the evaluation plan for the project. (Cross-reference—See 45 CFR 100a.590 Evaluation by the grantee.)

(2) The Commissioner looks for information that shows methods of evaluation that are appropriate for the project and, to the extent possible, are objective and produce data that are quantifiable.

(e) *Adequacy of resources.* (10 points)

(1) The Commissioner reviews each application for information that shows that the applicant plans to devote adequate resources to the project.

(2) The Commissioner looks for information that shows—

(i) The facilities that the applicant plans to use are adequate; and

(ii) The equipment and supplies that the applicant plans to use are adequate.

(f) *Nature and scope of the project.* (15 points)

(1) The Commissioner reviews each application for information that adequately shows the nature and scope of the project.

(2) The Commissioner looks for information that shows—

(i) How the project is tailored to the geographic conditions and the characteristics of the population of each area to be served;

(ii) A plan consisting of activities, procedures to carry out the activities, and anticipated results of the activities for each year and each summer session of the five-year project;

(iii) The degree to which LEA officials, teachers, representatives of nonprofit private schools, interested students and parents, community representatives, and others have participated in the design of the project;

(iv) The manner in which the applicant will select target students and an explanation of selection procedures the applicant will use to ensure objectivity;

(v) The method by which the applicant will allow talented students who are not economically disadvantaged participate in the project activities without reducing the nature and quality of services for participating target students;

(vi) The ways in which the applicant will identify the individual needs of participating target students, design appropriate programs, and provide counseling to students;

(vii) Criteria for retention of students in the project, procedures for measuring student progress, and methods to be used in identifying and analyzing any student problems and drop-out conditions; and

(viii) The applicant's plans to involve parents of participating target students in—

(A) Appropriate project activities;

(B) Evaluation of student progress; and

(C) Career counseling.

(g) *Scope and variety of personnel involved in or related to projects in the biomedical sciences.* (7 points)

(1) The Commissioner reviews each application for information that clearly shows that a wide variety of professional personnel are involved in or related to the project.

(2) The Commissioner looks for information that shows—

(i) The variety of professional persons—such as representatives from professional medical and dental societies, local hospitals and clinics, scientific laboratories, business firms, labor organizations, and voluntary and civic groups—who will assist, counsel, or motivate project participants; and

(ii) The services that principals, teachers, counselors, and other secondary school personnel involved will provide to facilitate the full participation of target students and to supplement the services and resources provided by the applicant.

(h) *Training of personnel involved in or related to projects in the biomedical sciences.* (5 points)

(1) The Commissioner reviews each application for information that shows that personnel involved in the project receive quality training.

(2) The Commissioner looks for information that shows—

(i) Activities to assist university faculty members and consultants to understand the characteristics and needs of participating target students and to adjust their instructional and counseling methods accordingly; and

(ii) Activities to train secondary school teachers to modify or strenghten their instruction and train counselors to provide special services so that the special activities of the project and the regular school program will be mutually supplementary to the benefit of each participating target student.

(i) *Cooperation among institutions, agencies, and organizations.* (10 points)

(1) The Commissioner reviews each application for information that shows how institutions, agencies, and organizations cooperate to achieve program objectives.

(2) The Commissioner looks for information that shows—

(i) Procedures to be used for coordinating services and resources—public, professional, voluntary, private, and civic agencies, organizations, and institutions—concerned with motivating and helping economically disadvantaged youth to seek careers in the biomedical sciences;

(ii) Procedures to coordinate project activities with the participating target

students' regular program of studies in the secondary schools; and

(iii) Plans for coordinating the project with other Federal and State programs for the economically disadvantaged that will help meet current student needs and enrich their experiences, and for assisting the students to seek and participate in programs that provide opportunity for postsecondary school study in the biomedical sciences.

(j) *Quality of dissemination.* (5 points)

(1) The Commissioner reviews each application for information that shows the quality of project dissemination.

(2) The Commissioner looks for information that shows—

(i) Plans for identifying successful practices, materials, and other results from the project;

(ii) Plans for assisting the participating LEAs and nonprofit private schools to incorporate practices, materials, and other results into their regular educational programs in order to apply the benefits of the project to other students as early as possible; and

(iii) Plans to make information about the project available to interested agencies and institutions and the general public.

(20 U.S.C. 1221e-3(a)(1), 3055)

## Subpart E—Conditions That Must Be Met by a Grantee

### § 161l.50 Allowable costs.

(a) Grants to institutions of higher education are governed by the provisions of EDGAR and the Act (section 386).

(b) A grantee may use funds awarded under this part to meet the cost of project activities (section 384(a)) and of other direct and indirect costs of project activities. These costs may include, but are not limited to the following:

(1) Stipends and necessary travel expenses of university faculty members and consultants directly incurred as a result of the project.

(2) Stipends for participating target students that meet the following conditions:

(i) During the academic year, a stipend—based on a minimum of 100 hours of participation per academic year—is not to exceed $30 per month.

(ii) The grantee shall prorate the amount of the stipend according to the number of hours during which the target student participated each month.

(iii) The participating target student shall receive no additional pay from project funds for work performed as a part of project activities.

(3) Transportation for participating target students for field trips or other activities away from project sites in the most economically feasible manner.

(4) Meals and housing for participating target students provided by the institution in special cases—e.g., weekend residential workshops, special events, or field trips—only if these costs cannot be met in any other feasible way.

(5) Stipends for personnel to work with participating target students, provided this work is not a part of their normal assignment or working day.

(6) Transportation and meals for educational personnel who are working with target students to participate in project activities that are specifically explained in the application, if these costs cannot be met in any other feasible way.

(7) Transportation and meals for parents of target students to participate in special events related to the project which are specifically explained in the application, if these costs cannot be met in any other feasible way.

(c)(1) The grantee may use funds for summer sessions for expenditures similar to those stated in § 161l.50(b), except that a stipend for each participating target student shall be no more than the prevailing minimum wage based on full-time participation not to exceed 20 hours per week.

(2) In order to receive a stipend, a participating target student must provide evidence of satisfactory participation in summer project activities, including—

(i) Regular attendance; and

(ii) Performance in accordance with standards established by the grantee and described in the application.

(20 U.S.C. 3054(a), 3056)

### § 161l.51 Non-allowable costs.

(a) The grantee may not use project funds for any cost that any institution or agency involved in the project would incur if a project were not in operation.

(b) The grantee may not use project funds for any additional costs related to providing instruction, training, or other services under § 161l.5(e) for talented secondary school students who do not qualify as economically disadvantaged.

(c) The grantee may not use project funds for any costs related to construction, renovation, or remodeling of any facilities.

(20 U.S.C. 3054, 3056)

### § 161l.52 Coordination among the projects.

During the project period, each of the grantees shall cooperate and coordinate efforts with all other grantees through activities, including the following:

(a) An exchange of materials and information describing project participants, activities, facilities, and resources.

(b) An exchange of evaluation designs and reports.

(c) Consultation among project directors.

(20 U.S.C. 3055(b))

[FR Doc. 80-12330 Filed 4-21-80; 8:45 am]

BILLING CODE 4110-02-M

## DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

### Office of Education

### Biomedical Sciences Program

**AGENCY:** Office of Education, HEW.

**ACTION:** Notice of Closing Date for Transmittal of Applications for New Projects for Fiscal Year 1980.

Applications are invited for new projects under the Biomedical Sciences Program.

Authority for this program is contained in Title III, Part L, of the Elementary and Secondary Education Act, as amended by Pub. L. 95–561. (20 U.S.C. 3053)

This program issues awards to individual institutions of higher education or to combinations of these institutions.

The purpose of the awards is to assist these institutions in motivating and educating talented secondary school students from an economically disadvantaged background to prepare for and enter into careers in the biomedical sciences.

*Closing date for transmittal of applications:*

An application for a grant must be mailed or hand delivered by June 25, 1980.

*Applications delivered by mail:*

An application sent by mail must be addressed to the U.S. Office of Education, Application Control Center, Attention: 13.691, Washington, D.C. 20202.

An applicant must show proof of mailing consisting of one of the following:

(1) A legibly dated U.S. Postal Service postmark.

(2) A legible mail receipt with the date of mailing stamped by the U.S. Postal Service.

(3) A dated shipping label, invoice, or receipt from a commercial carrier.

(4) Any other proof of mailing acceptable to the U.S. Commissioner of Education.

If an application is sent through the U.S. Postal Service, the Commisioner does not accept a private metered postmark or a private mail receipt as proof of mailing. An applicant should note that the U.S. Postal Service does not uniformaly provide a dated postmark. Before relying on this method, an applicant should check with its local post office.

An applicant is encouraged to use registered or at least first class mail. Each late applicant will be notified that its applicatoin will not be considered.

*Applications delivered by hand:*

An application that is hand delivered must be taken to the U.S. Office of Education, Application Control Center, Room 5673, Regional Office Building 3, 7th and D Streets, S.W., Washington, D.C.

The Application Control Center will accept a hand-delivered application between 8:00 a.m. and 4:30 p.m. (Washington, D.C., time) daily, except Saturdays, Sundays, and Federal holidays.

An application that is hand delivered will not be accepted after 4:30 p.m. on the closing date.

*Available funds:*

It is expected that approximately $3.0 million will be available for the Biomedical Sciences Program.

It is estimated that these funds could support 8 to 10 new projects.

The anticipated award for each new project will be between $260,000 and $300,000.

However, these estimates do not bind the U.S. Office of Education to a specific number of grants or to the amount of any grant unless that amount is otherwise specified by statute or regulations.

*Application forms:*

Application forms and program information packages are expected to be ready for mailing by May 12, 1980. They may be obtained by writing to the Bureau of School Improvement, U.S. Office of Education (Room 3700, Donohoe Building), 400 Maryland Avenue, S.W., Washington, D.C. 20202.

Applications must be prepared and submitted in accordance with the regulations, instructions, and forms included in the program information package. The Commissioner strongly urges that the narrative portion of the application not exceed 25 pages in length. The Commissioner further suggests that applicants not submit information that is not required.

*Applicable regulations:*

Regulations applicable to this program include the following:

(a) Regulations governing the Biomedical Sciences Program (45 CFR Part 161l).

These regulations are in final in this issue of the **Federal Register** in the rules and regulations section.

(b) The Education Division General Administrative Regulations (EDGAR) (45 CFR Parts 100a and 100c) which were published in final recently in the **Federal Register.**

*Further Information:*

For further information contact Ms. Joan DeSantis, Acting Director, Biomedical Sciences Program, Bureau of School Improvement, U.S. Office of Education (Room 3700, Donohoe), 400 Maryland Avenue, S.W., Washington, D.C. 20202, Telephone: (202) 472–2649.

(20 U.S.C. 3053)

Dated: April 15, 1980.

(Catalog of Federal Domestic Assistance No. 13.691, Biomedical Sciences Program)

**William L. Smith,**

*Commissioner of Education.*

[FR Doc. 80–12265 Filed 4–21–80; 8:45 am]

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federal register

Tuesday
April 22, 1980

Part IX

# Department of Labor

## Office of the Secretary

## Rules of Practice for Administrative Proceedings Enforcing Labor Standards in Federal and Federally Assisted Construction Contracts and Federal Service Contracts

**DEPARTMENT OF LABOR**

**Office of The Secretary**

**29 CFR Part 6**

## Rules of Practice for Administrative Proceedings Enforcing Labor Standards in Federal and Federally Assisted Construction Contracts and Federal Service Contracts

**AGENCY:** Department of Labor.

**ACTION:** Proposed rule.

**SUMMARY:** The proposed revisions to this part are intended to provide administrative hearings in enforcement cases and substantial interest proceedings involving the Davis-Bacon and related acts, the Service Contract Act, and the Contract Work Hours and Safety Standards Act, and substantial variance and arm's length proceedings under the Service Contract Act. These revisions are designed to make such proceedings as uniform as possible.

**DATES:** Comments must be received on or before May 27, 1980.

**ADDRESS:** Send comments to Ronald G. Whiting, Associate Solicitor, General Legal Services, Office of the Solicitor, Department of Labor, Room N2464, New Department of Labor Building, 200 Constitution Ave., N.W., Washington, D.C. 20210

**FOR FURTHER INFORMATION CONTACT:** Gail V. Coleman, Counsel for Contract Labor Standards, General Legal Services, Office of the Solicitor, Department of Labor, Room N2464, New Department of Labor Building, 200 Constitution Ave., N.W., Washington, D.C. 20210. Phone 202–523–8268.

**SUPPLEMENTARY INFORMATION:** To make more uniform proceedings under the Davis-Bacon and related acts, the Service Contract Act and the Contract Work Hours and Safety Standards Act, it is proposed to publish in Part 6 of Title 29 rules for all such administrative proceedings before Administrative Law Judges.

Under this proposal when a decision is issued by an Administrative Law Judge appeals may be taken to the Wage Appeals Board (see 29 CFR Part 7) when the Davis-Bacon and related acts are involved, and to the Board of Service Contract Appeals (see 29 CFR Part 8) when the Service Contract Act is involved. Contract Work Hours and Safety Standards Act appeals would be treated as Davis-Bacon Act appeals if the Davis-Bacon and related acts are involved, and as Service Contract Act appeals when the Service Contract Act is involved, both in proceedings under Part 6 of Title 29 and in taking appeals pursuant to Parts 7 and 8 of Title 29. It is also proposed to eliminate appeals to the Administrator.

Because effective administration dictates the need to fashion the proceedings to the specific problems usually involved (thus precluding complete uniformity), there are set out in Subparts B, C, D and E of Part 6 of this title specific variations from the general provisions in subpart A of Part 6 of this Title, which applies to all.

Subpart B of Part 6 of this title, containing rules for enforcement proceedings under the Service Contract Act, is primarily a restatement of the existing procedures, with proposed revisions to permit consideration of violations of the Contract Work Hour and Safety Standards Act where the contract at issue was subject to the Service Contract Act, in order to expedite processing of such violations and to provide an opportunity for a hearing regarding such violations.

Subpart C of Part 6 of this title contains similar procedures for the Davis-Bacon and related acts, expanding upon the procedures currently set forth in 29 CFR 5.11(b), and proposing procedures for hearings before Administrative Law Judges in debarment cases rather than the informal hearings currently conducted pursuant to 29 CFR 5.6.

Subpart D of Part 6 of this title contains proposed procedures for hearings to determine if a debarred person or firm has such an interest in another firm that the latter firm is debarred for purposes of debarment pursuant to the Service Contract Act, the Davis-Bacon Act and proposed § 5.12(a)(1) (currently § 5.6(b)(1)) of Part 5 of this title. Specific regulations regarding such proceedings do not currently exist.

Subpart E of Part 6 of this title contains proposed procedures for substantial variance and arm's length proceedings pursuant to Section 4(c) of the Service Contract Act. It is proposed to revise the current procedures for substantial variance hearings under § 4.10 of Part 4 of this title to provide for more expedited decisionmaking. The same procedures are proposed to apply for arm's length hearings, which are not specifically provided for in the existing regulations.

The proposed revisions to Part 6 of this title should be considered in conjunction with proposed §§ 4.10, 4.11 and 4.12 of Part 4 of this title, and proposed §§ 5.11 and 5.12 of Part 5 of this title, published in the **Federal Register** on December 28, 1979 (44 FR 77036, and 77080). Time for comment on those sections has been extended to coincide with comments on Part 6 of this title.

Part 6 of this title is procedural in character, and is designed to assure the substantive rights granted under Parts 4 and 5 of this title and under the laws with which those parts deal. Accordingly, as the Part 6 is not a significant regulation within the meaning of Executive Order 12044 and this Department's guidelines, no regulatory analysis is necessary.

It is proposed to amend Part 6 of Title 29 as set forth below.

Signed at Washington, D.C., on this 17th day of April 1980.

**Ray Marshall,**

*Secretary of Labor, U.S. Department of Labor.*

## PART 6—RULES OF PRACTICE FOR ADMINISTRATIVE PROCEEDINGS ENFORCING LABOR STANDARDS IN FEDERAL AND FEDERALLY ASSISTED CONSTRUCTION CONTRACTS AND FEDERAL SERVICE CONTRACTS

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**Authority:** Secs. 4 and 5, 79 Stat. 1034, 1035 as amended by 86 Stat. 789, 790, 41 U.S.C. 353 and 354; 5 U.S.C. 301; Reorg. Plan No. 14 of 1950, 64 Stat. 1267, 5 U.S.C. Appendix; 46 Stat. 1494, as amended by 49 Stat. 1011, 78 Stat. 238, 40 U.S.C. 276a; 76 Stat. 357–359, 40 U.S.C. 327–332; 48 Stat. 948, as amended by 63 Stat. 108, 72 Stat. 967, 40 U.S.C. 276c.

## Subpart A—General

### § 6.1 Applicability of rules.

This part provides the rules of practice for administrative proceedings under the Service Contract Act, the Davis-Bacon Act and related statutes listed in § 5.1 of Part 5 of this title which require payment of wages determined in accordance with the Davis-Bacon Act, the Contract Work Hours and Safety Standards Act, and the copeland Act. See Parts 4 and 5 of this title.

### § 6.2 Definitions.

(a) "Administrator" means the Administrator of the Wage and Hour Division, Employment Standards Administration, U.S. Department of Labor, or authorized representative.

(b) "Associate Solicitor" means the Associate Solicitor for General Legal Services, Office of the Solicitor, U.S. Department of Labor, Washington, D.C. 20210.

(c) "Chief Administrative Law Judge" means the Chief Administrative Law Judge, U.S. Department of Labor, 1111 20th Street, N.W., Suite 700, Washington, D.C. 20036.

(d) "Respondent" means the contractor, subcontractor, person alleged to be responsible under the contract or subcontract, or any firm, corporation, partnership, or association in which such person or firm is alleged to have a substantial interest against whom the proceedings are brought.

### § 6.3 Service; copies of documents and pleadings.

(a) *Manner of service.* Service upon any party shall be made by the party filing the pleading or document by delivering a copy or mailing a copy to the last known address. When a party is represented by an attorney, the service should be upon the attorney.

(b) *Proof of service.* A certificate of the person serving the pleading or other document by personal delivery or by mailing, setting forth the manner of said service shall be proof of the service. Where service is made by mail, service shall be complete upon mailing.

(c) *Service upon Department, number of copies of pleading or other documents.* An original and three copies of all pleadings and other documents shall be filed with the Department of Labor, the original and one copy with the Administrative Law Judge before whom the case is pending, one copy with the attorney representing the Department during the hearing, and one copy with the Associate Solicitor.

### § 6.4 Computation of time.

Saturdays, Sundays, and holidays shall be included in computing the time allowed for filing any document or paper under this part, but when such time expires on such a day, such period shall be extended to include the next following day which is not a Saturday, Sunday or holiday.

### § 6.5 Motions and requests.

Motions or requests shall be filed with the Chief Administrative Law Judge, except that those made during the course of the hearing shall be filed with the Administrative Law Judge or shall be stated orally and made part of the transcript. Each motion or request shall state the particular order, ruling, or action desired, and the grounds therefor. The Administrative Law Judge is authorized to rule upon all motions or requests filed or made prior to the filing of the decision.

### § 6.6 Depositions.

(a) *When, how, and by whom taken.* For good cause shown, the testimony of any witness may be taken by deposition in any proceeding, after a complaint has been filed. Depositions may be taken upon written interrogatories or orally before any person having power to administer oaths.

(b) *Application.* Any party desiring to take the deposition of a witness shall make application in writing to the Administrative Law Judge, setting forth the reasons why such deposition should be taken; the time when, the place where, and the name and address of the person before whom the deposition is to be taken; the name and address of each witness; and the subject matter concerning which each witness is expected to testify.

(c) *Notice.* Such notice as the Administrative Law Judge shall order shall be given for the taking of a deposition, but this shall not be less than 5 days' written notice when the deposition is to be taken within the United States and not less than 20 days' written notice when the deposition is to be taken elsewhere.

(d) *Taking and receiving in evidence.* Each witness testifying upon deposition shall be sworn, and the adverse party shall have the right to cross-examine. The questions pro-pounded and the answers thereto, together with all objections made, shall be reduced to writing, read to and subscribed by the witness, and certified by the officer authorized to administer oaths. Thereafter, the officer shall seal the deposition, with two copies thereof, in an envelope and mail the same by registered mail to the Administrative Law Judge. Subject to such objections to the questions and answers as were noted at the time of taking the deposition and would be valid were the witness personally present and testifying, such deposition may be read and offered in evidence by the party taking it as against any party who was present or represented at the taking of the deposition or who had due notice thereof. No part of a deposition shall be admitted in evidence except for the limited purpose of impeachment, unless there is a showing that the witness is unavailable to testify (including a witness outside of the State in which the hearing is held).

### § 6.7 Subpoenas.

All applications under the Service Contact Act for subpoenas ad testificandum and subpoenas duces tecum shall be made in writing to the Administrative Law Judge. Application for subpoenas duces tecum shall specify as exactly as possible the documents to be produced, showing their general relevancy and reasonable scope.

### § 6.8 Production of documents and witnesses.

The parties, who shall be deemed to be the Department of Labor and the respondent(s), may serve on any other party a request to produce documents or witnesses in the control of the party served, setting forth with particularity the documents or witnesses requested. The party served shall have 15 days to

respond or object thereto unless a shorter or longer time is ordered by the Administrative Law Judge. The parties shall produce documents and witnesses to which no privilege attaches which are in the control of the party, if so ordered by the Administrative Law Judge upon motion therefor by a party. If a privilege is claimed, it must be specifically claimed in writing prior to the hearing or orally at the hearing, including the reasons therefor.

**§ 6.9 Witnesses and fees.**

Witnesses subpoenaed by any party shall be paid the same fees and mileage as are paid for like services in the District Court of the United States. The witness fees and mileage shall be paid by the party at whose instance the witnesses appear.

**§ 6.10 Administrative Law Judge.**

(a) *Who presides.* All hearings shall be presided over by an Administrative Law Judge appointed under section 11 of the Administrative Procedure Act.

(b) *How assigned.* The presiding Administrative Law Judge shall be designated by the Chief Administrative Law Judge.

(c) *Powers.* Administrative Law Judges shall have all powers necessary to the conduct of fair and impartial hearings, including the following:

(1) To administer oaths and affirmations;

(2) To issue subpoenas in proceedings under the Service Contract Act upon proper applications as provided in § 6.7 of this title;

(3) To rule upon offers of proof and receive relevant evidence;

(4) To take or cause to be taken depositions and to determine their scope;

(5) To regulate the course of the hearing and the conduct of the parties and their counsel therein;

(6) To hold conferences for the settlement or simplification of the issues by consent of the parties;

(7) To consider and rule upon procedural requests;

(8) To make and file decisions in conformity with this part;

(9) To take any action authorized by the rules in this part or in conformance with the Administrative Procedure Act.

(d) *Consultation.* The Administrative Law Judge shall not consult any person or party on any fact in issue unless upon notice and opportunity for all parties to participate.

(e) *Disqualification of Administrative Law Judge.* (1) When an Administrative Law Judge deems himself/herself disqualified to preside in a particular proceeding, he/she shall withdraw therefrom by notice on the record directed to the Chief Administrative Law Judges.

(2) Whenever any party believes the Administrative Law Judge for any reason to be disqualified to preside, or to continue to preside, in a particular proceeding, that party shall file with the Chief Administrative Law Judge a motion to disqualify and remove such Administrative Law Judge, such motion to be supported by affidavits setting forth the alleged grounds for disqualification. The Chief Administrative Law Judge shall rule upon the motion.

(f) *Contemptuous conduct: failure or refusal of a witness to appear or answer.* Contemptuous conduct at any hearing before an Administrative Law Judge shall be ground for exclusion from the hearing. The failure or refusal of a witness to appear at any hearing or to answer any question which has been ruled to be proper shall be ground for the action provided in section 5 of the Act of June 30, 1936 (41 U.S.C. 39) and, in the discretion of the Administrative Law Judge, for striking out all or part of the testimony which may have been given by such witness.

**§ 6.11 Prehearing conferences.**

(a) Upon his/her own motion or the motion of the parties, the Administrative Law Judge may direct the parties or their counsel to meet with the Administrative Law Judge for a conference to consider:

(1) Simplification of the issues;

(2) Necessity or desirability of amendments to pleadings for purposes of clarification, simplification, or limitation;

(3) Stipulations, admissions of fact and contents and authenticity of documents;

(4) Limitation of the number of expert witnesses; and

(5) Such other matters as may tend to expedite the disposition of the proceeding.

(b) The record shall show the matters disposed of by order and by agreement in such pretrial conferences. The subsequent course of the proceedings shall be controlled by such action.

**§ 6.12 Appearances.**

(a) *Representation.* The parties may appear in person, by counsel, or otherwise.

(b) *Failure to appear.* In the event that a party appears at the hearing and no party appears for the opposing side, the party who is present shall have an election to present evidence in whole or such portion thereof sufficient to make a prima facie case before the Administrative Law Judge. Failure to appear at a hearing shall not be deemed to be a waiver of the right to be served with a copy of the Administrative Law Judge's decision and to file a petition for review thereof with the Board of Service Contract Appeals or the Wage Appeals Board, as appropriate.

**§ 6.13 Hearing.**

(a) *Order of proceeding.* Except as may be determined otherwise by the Administrative Law Judge, counsel for the Department of Labor shall proceed first at the hearing.

(b) *Evidence*—(1) *In general.* The testimony of witnesses shall be upon oath or affirmation administered by the Administrative Law Judge and shall be subject to such cross-examination as may be required for a full and true disclosure of the facts. The Administrative Law Judge may exclude evidence which is immaterial, irrelevant, or unduly repetitious.

(2) *Objections.* If a party objects to the admission or rejection of any evidence or to the limitation of the scope of any examination or cross-examination or the failure to to limit such scope, the party shall state briefly the grounds for such objection. Ruling on all objections shall appear in the record. Only objections made before the Administrative Law Judge may be relied upon subsequently in the proceeding. Formal exception to an adverse ruling is not required.

(c) *Official notice.* Official notice may be taken of any material fact not appearing in evidence in the record, which is among the traditional matters of judicial notice and also concerning which the Department of Labor by reason of its functions is presumed to be expert: *Provided,* That the parties shall be given adequate notice, at the hearing or by reference in the Administrative Law Judge's decision of the matters so noticed, and shall be given adequate opportunity to show the contrary.

(d) *Transcript.* A transcript shall be made of the proceeding.

**§ 6.14 Transmission of record.**

If a petition for review of the Administrative Law Judge's decision is filed with the Board of Service Contract Appeals or the Wage Appeals Board, the Chief Administrative Law Judge shall promptly transmit the record of the proceeding to the appropriate Board. The record shall include: The pleadings, motions, and requests filed in written form, rulings thereon, the transcript of the testimony and proceeding taken at the hearing, together with the exhibits admitted in evidence, and documents or papers filed in connection with prehearing conferences, such proposed findings of fact, conclusions of law,

orders, and supporting reasons, as may have been filed, the Administrative Law Judge's decision, and such other documents as may have been filed in the proceeding. If a petition for review is not filed within the time prescribed in this part, the Chief Administrative Law Judge shall so advise the Administrator.

## Subpart B—Enforcement Proceedings Under the Service Contract Act (and Under the Contract Work Hours and Safety Standards Act for Contracts Subject to the Service Contract Act)

### § 6.20 Complaints.

(a) Enforcement proceedings under the Service Contract Act and under the Contract Work Hours and Safety Standards Act for contracts subject to the Service Contract Act, may be instituted by the Deputy Solicitor or Regional Solicitors by issuing a complaint and causing the complaint to be served upon the respondent.

(b) The complaint shall contain a clear and concise factual statement of the grounds for relief and the relief requested.

(c) The Administrative Law Judge shall notify the parties of the time and place for a hearing.

### § 6.21 Answer.

(a) Within 20 days after the service of the complaint, the respondent shall file an answer with the Chief Administrative Law Judge. The answer shall be signed by the respondent or his/her attorney.

(b) The answer shall (1) contain a statement of the facts which constitute the grounds of defense, and shall specifically admit, explain, or deny, each of the allegations of the complaint unless the respondent is without knowledge, in which case the answer shall so state; or (2) state that the respondent admits all of the allegations of the complaint. The answer may contain a waiver of hearing. Failure to file an answer to or plead specifically to any allegation of the complaint shall constitute an admission of such allegation.

(c) Failure to file an answer shall constitute grounds for waiver of hearing and entry of a default judgment unless respondent shows good cause for such failure to file. In preparing his decision of default judgment the Administrative Law Judge shall adopt as findings of fact the materal facts alleged in the complaint and shall order the appropriate relief and/or sanctions.

### § 6.22 Amendments to pleadings.

At any time prior to the close of the hearing record, the complaint or answer may be amended with the permission of the Administrative Law Judge and on such terms as he/she may approve. Such amendments shall be allowed when justice and the presentation of the merits are served thereby, provided there is no prejudice to the objecting party's presentation on the merits. A continuance in the hearing may be granted or the record left open to enable the new allegations to be addressed.

### § 6.23 Consent findings and order.

(a) At any time prior to the receipt of evidence or, at the discretion of the Administrative Law Judge, prior to the issuance of the decision of the Administrative Law Judge, the parties may enter into consent findings and an order disposing of the proceedings in whole or in part.

(b) Any agreement containing consent findings and an order disposing of a proceeding in whole or in part shall also provide:

(1) That the order shall have the same force and effect as an order made after full hearing;

(2) That the entire record on which any order may be based shall consist solely of the complaint and the agreement;

(3) A waiver of any further procedural steps before the Administrative Law Judge and Board of Service Contract Appeals regarding those matters which are the subject of the agreement; and

(4) A waiver of any right to challenge or contest the validity of the findings and order entered into in accordance with the agreement.

(c) Within 30 days after receipt of an agreement containing consent findings and an order disposing of the disputed matter in whole, the Administrative Law Judge shall accept such agreement by issuing a decision based upon the agreed findings and order. If such agreement disposes of only a part of the disputed matter, a hearing shall be conducted on the matters remaining in dispute.

### § 6.24 Decision of the Administrative Law Judge.

(a) *Proposed findings of fact, conclusions, and order.* Within 30 days of filing of the transcript of the testimony or such additional time as the Administrative Law Judge may allow, each party may file with the Administrative Law Judge proposed findings of fact, conclusions of law, and order, together with a supporting brief expressing the reasons for such proposals. Such proposals and brief shall be served on all parties, and shall refer to all portions of the record and to all authorities relied upon in support of each proposal.

(b) *Decision of the Administrative Law Judge.* (1) Within a reasonable time after the time allowed for the filing of proposed findings of fact, conclusions of law, and order, or after submission of an agreement containing consent findings and order, the Administrative Law Judge shall make his/her decision, which shall become the final decision in the administrative process unless a petition for review is filed, as provided in § 6.25 of this title. The decision of the Administrative Law Judge shall include a statement of findings and conclusions, with reasons and bases therefor, upon each material issue of fact, law, or discretion presented on the record. The decision of the Administrative Law Judge shall be based upon a consideration of the whole record, including any admissions made under §§ 6.21, 6.22, and 6.23 of this title. It shall be supported by reliable, probative, and substantial evidence. Such decision shall be in accordance with the regulations and rulings continued in Parts 4 and 5 and other pertinent parts of this title.

(2) If the respondent is found to have violated the Service Contract Act, the Administrative Law Judge shall include in his/her decision an order as to whether the respondent is to be relieved from the ineligible list as provided in Section 5(a) of the Act, and, if relief is ordered, findings of the unusual circumstances, within the meaning of Section 5(a) of the Act, which are the basis therefor. If respondent is found to have violated the provisions of the Contract Work Hours and Safety Standards Act, the Administrative Law Judge shall issue an order as to whether the respondent is to be subject to the ineligible list as provided in § 5.12(a)(1) of Part 5 of this title including any findings of aggravated or willful violations. If wages and/or fringe benefits are found due under the Service Contract Act and/or the Contract Work Safety Standards Act and are unpaid, no relief from the ineligible list shall be ordered except on condition that such wages and/or fringe benefits are paid.

(3) The Administrative Law Judge shall make no findings regarding liquidated damages under the Contract Work Hours and Safety Standards Act unless the complaint states that a recommendation for waiver or reduction in damages has been received from the Federal agency.

### § 6.25 Petition for review.

Within 40 days after the date of the decision of the Administrative Law Judge (or such additional time as is

granted by the Board of Service Contract Appeals), any party aggrieved thereby may file a petition for review thereof with supporting reasons. Such party shall transmit the petition in writing to the Board of Service Contract Appeals pursuant to Part 8 of this title, with a copy thereof to the Chief Administrative Law Judge. The petition shall refer to the specific findings of fact, conclusions of law, or order at issue. A petition concerning the decision on the ineligibility list shall also state the unusual circumstances or lack thereof under the Service Contract Act, and/or the aggravated or willful violations of the Contract Work Hours and Safety Standards Act or lack thereof, as appropriate.

**§ 6.26 Ineligible list.**

(a) Upon the final decision of the Administrative Law Judge or the Board of Service Contract Appeals, as appropriate, the Administrator shall promptly forward to the Comptroller General the name of any respondent found in violation of the Service Contract Act, including the name of any firm, corporation, partnership, or association in which the respondent has a substantial interest, unless such decision orders relief from the ineligible list because of unusual circumstances.

(b) Upon the final decision of the Administrative Law Judge or the Board of Service Contract Appeals, as appropriate, the Administrator promptly shall forward to the Comptroller General the name of any respondent found to be in aggravated or willful violation of the Contract Work Hours and Safety Standards Act, and the name of any firm, corporation, partnership, or association in which the respondent has a substantial interest.

## Subpart C—Enforcement Proceedings Under the Davis-Bacon Act and Related Prevailing Wage Statutes, the Copeland Act, and the Contract Work Hours and Safety Standards Act (Except Under Contracts Subject to the Service Contract Act)

**§ 6.30 Referral to Administrative Law Judge.**

(a) Upon timely receipt of a request for a hearing under §§ 5.11 or 5.12 of Part 5 of this title, the Administrator shall refer the case to the Chief Administrative Law Judge by Order of Reference, to which shall be attached an authenticated copy of the notification letter to the respondent from the Administrator and response thereto, for designation of an Administrative Law Judge to conduct such hearings as may be necessary to decide the disputed matters. A copy of the Order of Reference and attachments thereto shall be served upon the person or firm requesting the hearing.

(b) The notification letter from the Administrator and response thereto shall be given the effect of a complaint and answer, respectively, for purposes of the administrative proceedings. The notification letter and response shall be in accordance with the provisions of § 512(b) of Part 5 of this title.

**§ 6.31 Amendments to pleadings.**

At any time prior to the closing of the hearing record, the complaint (notification letter) or answer (response) may be amended with the permission of the Administrative Law Judge and upon such terms as he/she may approve. For proceedings pursuant to § 5.11 of Part 5 of this title, such an amendment may include a statement that debarment action is warranted under § 5.12(a)(1) of Part 5 of this title or under Section 3(a) of the Davis-Bacon Act. Such amendments shall be allowed when justice and the presentation of the merits are served thereby, provided there is no prejudice to the objecting party's presentation on the merits. A continuance in the hearing may be granted or the record left open to enable the new allegations to be addressed.

**§ 6.32 Consent findings and order.**

(a) At any time prior to the receipt of evidence or, at the discretion of the Administrative Law Judge, prior to the issuance of the decision of the Administrative Law Judge, the parties may enter into consent findings and an order disposing of the proceeding in whole or in part.

(b) Any agreement containing consent findings and an order disposing of a proceeding in whole or in part shall also provide:

(1) That the order shall have the same force and effect as an order made after full hearing;

(2) That the entire record on which any order may be based shall consist solely of the complaint and the agreement;

(3) That any order concerning debarment under the Davis-Bacon Act (but not under any of the other statutes listed in § 5.1 of Part 5 of this title) shall constitute a recommendation to the Comptroller General;

(4) A waiver of any further procedural steps before the Administrative Law Judge and the Wage Appeals Board regarding those matters which are the subject of the agreement; and

(5) A waiver of any right to challenge or contest the validity of the findings and order entered into in accordance with the agreement.

(c) Within 30 days after receipt of an agreement containing consent findings and an order disposing of the disputed matter in whole, the Administrative Law Judge shall accept such agreement by issuing a decision based upon the agreed findings and order. If such agreement disposes of only a part of the disputed matter, a hearing shall be conducted on the matters remaining in dispute.

**§ 6.33 Decision of the Administrative Law Judge.**

(a) *Proposed findings of fact, conclusions, and order.* Within 30 days of filing of the transcript of the testimony or such additional time as the Administrative Law Judge may allow, each party may file with the Administrative Law Judge proposed findings of fact, conclusions of law, and order, together with a supporting brief expressing the reasons for such proposals. Such proposals and brief shall be served on all parties, and shall refer to all portions of the record and to all authorities relied upon in support of each proposal.

(b) *Decision of the Administrative Law Judge.*

(1) Within a reasonable time after the time allowed for filing of proposed findings of fact, conclusions of law, and order, or after submission of an agreement containing consent findings and order, the Administrative Law Judge shall make his/her decision, which shall become the final decision in the administrative process unless a petition for review is filed, as provided in § 6.34 of this title. The decision of the Administrative Law Judge shall include a statement of findings and conclusions, with reasons and bases therefor, upon each material issue of fact, law, or discretion presented on the record. Such decision shall be in accordance with the regulations and rulings contained in Part 5 and other pertinent parts of this title. The decision of the Administrative Law Judge shall be based upon a consideration of the whole record, including any admissions made in the respondent's answer (response) and § 6.32 of this title. It shall be supported by reliable, probative, and substantial evidence.

(2) If the respondent is found to have violated the labor standards provisions of any of the statutes listed in § 5.1 of Part 5 of this title other than the Davis-Bacon Act, and if debarment action was requested pursuant to the complaint (notification letter) or any amendment thereto, the Administrative Law Judge shall issue an order as to whether the

respondent is to be subject to the ineligible list as provided in § 5.12(a)(1) of this title, including any findings of aggravated or willful violations. If the respondent is found to have violated the Davis-Bacon Act, and if debarment action was requested, the Administrative Law Judge shall issue as a part of his/her order a recommendation as to whether respondent should be subject to the ineligible list pursuant to Section 3(a) of the Act, including any findings regarding respondent's disregard of obligations to employees and subcontractors. If wages are found due and are unpaid, no relief from the ineligible list shall be ordered or recommended except on condition that such wages are paid.

(3) The Administrative Law Judge shall make no findings regarding liquidated damages under the Contract Work Hours and Safety Standards Act unless the complaint states that a recommendation for waiver or reduction in damages has been received from the Federal agency.

**§ 6.34 Petition for review.**

Within 40 days after the date of the decision of the Administrative Law Judge (or such additional time as is granted by the Wage Appeals Board), any party aggrieved thereby may file a petition for review thereof with supporting reasons. Such party shall transmit the petition in writing to the Wage Appeals Board, pursuant to Part 7 of this title, with a copy thereof to the Chief Administrative Law Judge. The petition shall refer to the specific findings of fact, conclusions of law, or order at issue. A petition concerning the decision on debarment shall also state the aggravated or willful violations and/or disregard of obligations to employees and subcontractors, or lack thereof, as appropriate.

**§ 6.35 Ineligible list.**

Upon the final decision of the Administrative Law Judge or Wage Appeals Board, as appropriate, regarding violations of any statute listed in § 5.1 of Part 5 of this title other than the Davis-Bacon Act, the Administrator promptly shall forward to the Comptroller General the name of any respondent found to have committed aggravated or willful violations of the labor standards provisions of such statute, and the name of any firm, corporation, partnership, or association in which the respondent has a substantial interest. Upon the final decision of the Administrative Law Judge or Wage Appeals Board, as appropriate, regarding violations of the Davis-Bacon Act, the Administrator promptly shall forward to the Comptroller General any recommendation regarding debarment action against a respondent, and the name of any firm, corporation, partnership, or association in which such respondent has a substantial interest.

## Subpart D—Substantial Interest Proceedings

**§ 6.40 Scope.**

This subpart supplements the procedures contained in § 4.12 of Part 4 and § 5.12 of Part 5 of this title, and states the rules of practice applicable to hearings to determine whether persons or firms whose names appear on the ineligible list pursuant to Section 5(a) of the Service Contract Act or § 5.12(a) of Part 5 of this title have a substantial interest in a firm, corporation, partnership, or association other than those listed on the ineligible list; and/or to determine whether persons or firms whose names appear on the ineligible list pursuant to Section 3(a) of the Davis-Bacon Act have an interest in a firm, corporation, partnership, or association other than those listed on the ineligible list.

**§ 6.41 Referral to Chief Administrative Law Judge.**

(a) Upon timely receipt of a request for a hearing under § 4.12 of Part 4 or § 5.12 of Part 5 of this title, or on his/her own motion, the Administrator shall refer the case to the Chief Administrative Law Judge by Order of Reference, to which shall be attached an authenticated copy of the findings of the Administrator and response thereto, for designation of an Administrative Law Judge to conduct such hearings as may be necessary to decide the disputed matters. A copy of the Order of Reference and attachments thereto shall be served upon the person or firm requesting the hearing.

(b) The findings of the Administrator and response thereto shall be given the effect of a complaint and answer, respectively, for purposes of the administrative proceedings.

**§ 6.42 Amendments to pleadings.**

At any time prior to the closing of the hearing record, the complaint (Administrator's findings) or answer (response) may be amended with the permission of the Administrative Law Judge and upon such terms as he/she may approve. Such amendments shall be allowed when justice and the presentation of the merits are served thereby, provided there is no prejudice to the objecting party's presentation on the merits. A continuance in the hearing may be granted or the record left open to enable the new allegations to be addressed.

**§ 6.43 Consent findings and order.**

(a) At any time prior to the receipt of evidence or, at the discretion of the Administrative Law Judge, prior to the issuance of the decision of the Administrative Law Judge, the parties may enter into consent findings and an order disposing of the proceeding in whole or in part.

(b) Any agreement containing consent findings and an order disposing of a proceeding in whole or in part shall provide:

(1) That the order shall have the same force and effect as an order made after full hearing;

(2) That the entire record on which any order may be based shall consist solely of the complaint and the agreement;

(3) A waiver of any further procedural steps before the Administrative Law Judge and the Board of Service Contract Appeals or Wage Appeals Board, as appropriate, regarding those matters which are the subject of the agreement; and

(4) A waiver of any right to challenge or contest the validity of the findings and order entered into in accordance with the agreement.

(c) Within 30 days after receipt of an agreement containing consent findings and an order disposing of the disputed matter in whole, the Administrative Law Judge shall accept such agreement by issuing a decision based upon the agreed findings and order. If such agreement disposes of only a part of the disputed matter, a hearing shall be conducted on the matters remaining in dispute.

**§ 6.44 Decision of the Administrative Law Judge.**

(a) *Proposed findings of fact, conclusions, and order.* Within 30 days of filing of the transcript of the testimony, each party may file with the Administrative Law Judge proposed findings of fact, conclusions of law, and order, together with a supporting brief expressing the reasons for such proposals. Such proposals and brief shall be served on all parties, and shall refer to all portions of the record and to all authorities relied upon in support of each proposal.

(b) *Decision of the Administrative Law Judge.* Within 60 days after the time allowed for filing of proposed findings of fact, conclusions of law, and order, or within 30 days after submission of an agreement containing consent findings

and order, the Administrative Law Judge shall make his/her decision which shall become the final decision in the administrative process 30 days after service thereof unless a petition for review is filed, as provided in § 6.45 of this title. The decision of the Administrative Law Judge shall include a statement of findings and conclusions, with reasons and bases therefor, upon each material issue of fact, law, or discretion presented on the record. Such decision shall be in accordance with the regulations and rulings contained in Parts 4 and 5 and other pertinent parts of this title. The decision of the Administrative Law Judge shall be based upon a consideration of the whole record, including any admissions made in the repondent's answer (response) and § 6.43 of this title.

**§ 6.45 Petition for review.**

Within 30 days after the date of the decision of the Administrative Law Judge, any party aggrieved thereby may file a petition for review thereof with supporting reasons. Such party shall transmit the petition in writing to the Board of Service Contract Appeals if the proceeding was under the Service Contract Act, or to the Wage Appeals Board if the proceeding was under § 5.12(a)(1) of Part 5 of this title or under Section 3(a) of the Davis-Bacon Act, with a copy thereof to the Chief Administrative Law Judge. The petition for review shall refer to the specific findings of fact, conclusions of law, or order at issue.

**§ 6.46 Ineligible list.**

Upon the final decision of the Administrative Law Judge, Board of Service Contract Appeals, or Wage Appeals Board, as appropriate, the Administrator promptly shall forward to the Comptroller General the names of any firm, corporation, partnership, or association in which a person or firm debarred pursuant to Section 5(a) of the Service Contract Act or § 5.12(a) of Part 5 of this title has a substantial interest; and/or the name of any firm, corporation, partnership, or association in which a person or firm debarred pursuant to Section 3(a) of the Davis-Bacon Act has an interest.

## Subpart E—Substantial Variance And Arm's-Length Proceedings

**§ 6.50 Scope.**

This subpart supplements the procedures contained in §§ 4.10 and 4.11 of Part 4 of this title and states the rules of practice applicable to hearings under Section 4(c) of the Act to determine whether the collectively bargained wages and fringe benefits otherwise required to be paid under that section and Sections 2(a) (1) and (2) of the Act are substantially at variance with those which prevail for services of a character similar in the locality, and/or to determine whether the wages and fringe benefits provided in the collective bargaining agreement were reached as a result of arm's-length negotiations.

**§ 6.51 Referral to Chief Administrative Law Judge.**

(a) Referral pursuant to § 4.10 or § 4.11 of Part 4 of this title will be by an Order of Reference from the Administrator to the Chief Administrative Law Judge, to which will be attached the material submitted by the applicant or any other material the Administrator considers relevant and, for proceedings pursuant to § 4.11 of this title, a copy of the findings of the Administrator. A copy of the Order of Reference and all attachments will be sent by mail to the persons who may be affected by the determination of the issue, including the agency whose contract is involved, the parties to the collective bargaining agreement, any contactor or subcontractor performing on the contract or known to be desirous of bidding thereon or performing services thereunder, any unions or other authorized representatives of service employees employed or who may be expected to be employed by such contractor or subcontractor on the contract work. The Order of Reference will have attached a certificate of service naming all interested persons who have been served.

(b) Accompanying the Order of Reference and attachments will be a notice advising that any interested person, including the applicant, who intends to participate in the proceeding shall submit a written response to the Chief Administrative Law Judge within 20 days of the date on which the certificate of service indicates the Order of reference was mailed. The notice will state that such a response shall include:

(1) A statement of the interested person's case;

(2) A list of witnesses the interested person will present, a summary of the testimony each is expected to give, and copies of all exhibits proposed to be proffered;

(3) A list of persons who have knowledge of the facts for whom the interested person requests that subpoenas be issued and a brief statement of the purpose of their testimony; and

(4) A certificate of service in accordance with § 6.3 of this title on all interested persons, including the Administrator.

**§ 6.52 Appointment of Administrative Law Judge and notification of prehearing conference and hearing date.**

Upon receipt from the Administrator of an Order of Reference, notice to the parties, attachments and certificate of service, the Chief Administrative Law Judge shall appoint an Administrative Law Judge to hear the case. The Administrative Law Judge shall promptly notify all interested persons of the time and place of a prehearing conference and of the hearing which shall be held immediately upon the completion of prehearing conference. The date of the prehearing conference and hearing shall be not less than 30 nor more than 40 days from the date on which the certificate of service indicates the Order of Reference was mailed.

**§ 6.53 Prehearing Conference.**

(a) At the prehearing conference the Administrative Law Judge shall attempt to determine the exact areas of agreement and disagreement raised by the Administrator's Order of Reference and replies thereto, so that the evidence and arguments presented at the hearing will be relevant, complete, and as brief and concise as possible.

(b) Any interested person desiring to file proposed findings of fact and conclusions of law shall submit them to the Administrative Law Judge at the prehearing conference.

(c) If the parties agree that no hearing is necessary to supplement the written evidence and the views and arguments that have been presented, the Administrative Law Judge shall forthwith render his/her final decision. The Administrative Law Judge in his/her discretion may permit submission of additional written evidence or argument, such as data accompanied by affidavits attesting to its validity or depositions, within ten days of commencement of the prehearing conference.

**§ 6.54 Hearing.**

(a) Except as provided in § 6.53(c) of this title, the hearing shall commence immediately upon the close of the prehearing conference. All matters remaining in controversy, including the presentation of additional evidence, shall be considered at the hearing. There shall be a minimum of formality in the proceeding consistent with orderly procedure.

(b) To expedite the proceeding the Administrative Law Judge shall, after consultation with the parties, set reasonable guidelines and limitations for the presentations to be made at the

hearing. The Administrative Law Judge may limit cross-examination and may question witnesses.

(c) Evidence which is not subject to cross-examination such as affidavits or depositions may be admitted at the discretion of the Administrative Law Judge. The Administrative Law Judge may also require that unduly repetitious testimony be submitted as affidavits. Such affidavits shall be submitted within three days of the conclusions of the hearing.

(d) Counsel for the Administrator shall participate in the proceeding to the degree he/she deems appropriate.

(e) An expedited transcript shall be made of the hearing and of the prehearing conference.

**§ 6.55 Closing of record.**

The Administrative Law Judge shall close the record promptly and not later than 10 days after the date of commencement of the prehearing conference. Post-hearing briefs may be permitted, but the filing of briefs shall not delay issuance of the decision of the Administrative Law Judge pursuant to § 6.56 of this title.

**§ 6.56 Decision of the Administrative Law Judge.**

Within 15 days of receipt of the transcript, the Administrative Law Judge shall render his/her decision containing findings of fact and conclusions of law. The decision of the Administrative Law Judge shall be based upon consideration of the whole record, and shall be in accordance with the regulations and rulings contained in Part 4 and other pertinent parts of this title. Unless a petition for review is filed with the Board of Service Contract Appeals pursuant to Part 8 of this title within 10 days of issuance of the Administrative Law Judge's decision, the Administrator shall promptly issue any wage determination which may be required as a result of the decision.

**§ 6.57 Petition for review.**

Within 10 days after the date of the decision of the Administrative Law Judge, any interested person who participated in the proceedings before the Administrative Law Judge may file a petition for review by the Board of Service Contract Appeals. The petition shall refer to the specific findings of fact, conclusions of law, or order excepted to and the specific pages of transcript relevant to the petition for review.

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Tuesday
April 22, 1980

Part X

# Department of Labor

## Office of the Secretary

## Practice Before the Board of Service Contract Appeals

**DEPARTMENT OF LABOR**

**Office of the Secretary**

**29 CFR Part 8**

## Practice Before the Board of Service Contract Appeals

**AGENCY:** Department of Labor.

**ACTION:** Proposed rule.

**SUMMARY:** It is proposed to establish a Board of Service Contract Appeals to hear appeals from decisions of the Department of Labor and appeals from hearings by Administrative Law Judges held pursuant to 29 CFR Part 6 involving Service Contract Act matters and related Contract Work Hours and Safety Standards Act matters.

**DATE:** Comments must be received on or before May 27, 1980.

**ADDRESS:** Send comments to Ronald G. Whiting, Associate Solicitor, General Legal Services, Office of the Solicitor, Department of Labor, Room N2464, New Department of Labor Building, 200 Constitution Ave., N.W., Washington, D.C. 20210.

**FOR FURTHER INFORMATION CONTACT:**

Gail V. Coleman, Counsel for Contract Labor Standards, General Legal Services, Office of the Solicitor, Department of Labor, Room N2464, New Department of Labor Building, 200 Constitution Ave., N.W., Washington, D.C. 20210. Phone 202–523–8268.

**SUPPLEMENTARY INFORMATION:** It is proposed to establish a Board of Service Contract Appeals to hear appeals from final decision of the Department of Labor concerning Service Contract Act wage determinations and other matters and to hear appeals from Administrative Law Judge's decisions under Subparts B, D and E of 29 CFR Part 6.

The Board, as proposed, will be constituted similarly to the Wage Appeals Board, which hears petitions for review of decisions under the Davis-Bacon and Related Acts, and will have jurisdiction comparable to that of the Wage Appeals Board.

In appeals of wage determinations, the Board is not authorized to request postponement of contract action, and will not ordinarily review a wage determination after award, exercise of option, or extension of a contract.

Accordingly, it is proposed to issue a new Part 8 to Title 29 which will read as set forth below.

Signed Washington, D.C., on this 17th day of April, 1980.

Ray Marshall,

*Secretary of Labor, U.S. Department of Labor.*

## PART 8—PRACTICE BEFORE THE BOARD OF SERVICE CONTRACT APPEALS

### Subpart A—Purpose and Scope

Sec.

8.1 Purpose and Scope

### Subpart B—Review of Wage Determinations

8.2 Who may file petitions for review.
8.3 When to file.
8.4 Contents of petitions.
8.5 Filing of wage determination record.
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### Subpart C—Review of Other Proceedings and Related Matters

8.7 Review of decisions in other proceedings.
8.8 Filing of administrative record.
8.9 Disposition by the Board of Service Contract Appeals.

### Subpart D—General Procedural Matters

8.10 Filing and service.
8.11 Presentations of other interested persons.
8.12 Intervention; other participation.
8.13 Right to counsel.
8.14 Consolidations.
8.15 Motions; extensions of time.
8.16 Oral proceedings.
8.17 Decision of the Board.
8.18 Public information.

**Authority:** Secs. 4 and 5, 79 Stat. 1034, 1035, as amended by 86 Stat. 789, 790, 41 U.S.C. 353, 354; 5 U.S.C. 301; Reorg. Plan No. 14 of 1950, 64 Stat. 1267, 5 U.S.C. Appendix; 76 Stat. 357–359, 40 U.S.C. 327–332.

### Subpart A—Purpose and Scope

#### § 8.1 Purpose and scope.

(a) This part contains the rules of practice of the Board of Service Contract Appeals (hereinafter referred to as the Board).

(b) The Board has jurisdicition to hear and decide in its discretion appeals concerning questions of law and fact from final decisions of the Department of Labor, and from decisions of Administrative Law Judges under Subparts B, D, and E of Part 6 of this title, arising under the Service contract Act and the Contract Work Hours and Safety Standards Act where the contract is also subject to the Service Contract Act. The Board shall not have jurisidiction to pass on the validity of any portion of the Code of Federal Regulations which has been duly promulgated through notice and comment by the Department of Labor and shall observe the requirements thereof, where pertinent, in its decisions. The jurisdiction of the Board is limited to:

(1) Wage determinations issued under the Service Contract Act;

(2) Substantial variance proceedings or arm's-length negotiations proceedings pursuant to Section 4(c) of the Service Contract Act;

(3) Debarment or other enforcement proceedings;

(4) Proceedings to determine substantial interest of debarred persons or firms;

(5) Decisions of the Wage-Hour Administrator regarding recommendations of a Federal agency for adjustment or waiver of liquidated damages assessed under the Contract Work Hours and Safety Standards Act;

(6) Other final actions of the Department of Labor; or

(7) Other matters specifically referred to the Board by the Secretary of Labor.

(c) In exercising its discretion as to whether to accept review, the Board shall consider, among other things, timeliness, the nature of the relief sought, matters of undue hardship or injustice, and the public interest.

(d) In considering the matters within the scope of its jurisdiction the Board shall act as the authorized representative of the Secretary of Labor.

(e) The Board is an appellate body. It may remand with appropriate instructions any case for the taking of additional evidence and the making of new or modified findings by reason of the additional evidence.

### Subpart B—Review of Wage Determinations

#### § 8.2 Who may file petitions for review.

(a) Any interested person who is seeking a modification or other change in a wage determination under the Service Contract Act and who has requested the Wage-Hour Administrator or authorized representative to make such modification or other change under § 4.55 of Part 4 of this title, and the request has been denied, shall have a right to petition for review of the action taken by that officer.

(b) For purposes of this subpart, the term "interested person" shall mean:

(1) Any employee or any labor organization which represents an employee who is likely to be employed or to seek employment under a contract containing a particular wage determination, or any contractor or an association representing a contractor who is likely to seek a contract or to work under a contract containing a particular wage determination; and

(2) The Federal agency(s) which will administer a proposed contract

containing a particular wage determination issued pursuant to the Service Contract Act.

**§ 8.3 When to file.**

(a) Requests for review of wage determinations must be filed within 15 days of the Wage-Hour Administrator's decision denying a request to make a change in the wage determination.

(b) The Board shall under no circumstances request any administering agency to postpone any contract action because of the filing of a petition.

**§ 8.4 Contents of petition.**

(a) A petition for review of a wage determination shall:

(1) Be in writing and signed by the petitioner or his/her counsel (or other authorized representative);

(2) Be addressed to the Board of Service Contract Appeals;

(3) Identify clearly the wage determination, location where the contract will be performed, if known, and the agency concerned;

(4) State that the petitioner has requested reconsideration of the wage determination in question and describe briefly the action taken in response to the request;

(5) Contain a short and plain statement of the grounds for review;

(6) Be accompanied by supporting data, views, or arguments; and

(7) Contain a statement that all data or other evidence submitted have previously been submitted to the Administrator.

(b) A petition shall indicate whether or not the petitioner consents to the disposition of the questions involved by a single member of the Board.

**§ 8.5 Filing of wage determination record.**

The Associate Solicitor for General Legal Services shall, promptly after service of the petition, file with the Board the record upon which the Administrator's findings and conclusions were based.

**§ 8.6 Disposition by the Board of Service Contract Appeals.**

(a) The Board may decline review of any case whenever in its judgment review would be inappropriate because of lack of timeliness, the nature of the relief sought, or other reasons. A case will be reviewed upon the affirmative vote of one member.

(b) Except as provided in paragraphs (c) and (d) of this section, the Board shall not review a wage determination after award, exercise of option, or extension of a contract, unless such procurement action was taken without a wage determination required pursuant to §§ 4.4 and 4.5 of Part 4 of this title.

(c) A wage determination may be reviewed after award, exercise of option, or extension of a contract if it is issued after a finding by an Administrative Law Judge that a substantial variance exists between collectively bargained wage rates and/or fringe benefits otherwise required to be paid pursuant to Section 4(c) of the Act and those prevailing for services of a character similar in the locality, or after a finding that such collective bargaining agreement was not reached as a result of arm's length negotiations.

(d) Where a petition for review of a wage determination is filed prior to award, exercise of option, or extension of a contract, the Board may review the wage determination after such award, exercise of option, or extension of a contract if the issue is one of general applicability. The Board's decision shall not affect the contract after such award, exercise of option, or extension.

(e) The Board shall decide the case upon the basis of all relevant matters contained in the entire record before it and shall not consider any data not submitted to the Wage-Hour Administrator with the request for reconsideration. The Board in its decision affirming modifying, or setting aside the wage determination, shall include a statement of reasons or bases for the actions taken. In any remand of a case as provided in § 8.1(e) of this title, the Board shall include appropriate instructions.

## Subpart C—Review of Other Proceedings and Related Matters

**§ 8.7 Review of decisions in other proceedings.**

(a) Any aggrieved person shall have a right to file a petition for review with the Board from any final written decision by the Department of Labor, and any party shall have a right to file a petition for review from any decision or recommendation of an administrative law judge under Subpart B, D, or E of Part 6 of this title arising under the Service Contract Act, or under the Contract Work Hours and Safety Standards Act where the contract is also subject to the Service Contract Act.

(b) A petition for review of a decision under Part 6 of this title shall be filed within the time limits set forth therein. A petition for review of any other decision (except a petition filed under subpart B) shall be filed within 60 days of the decision of which review is sought, except that if a case has been referred to the Board by the Administrator pursuant to §§ 4.11 or 4.12 of this title, a brief in support of the aggrieved person's position shall be filed within 30 days of the filing of the administrative record by the Administrator.

(c) The petition shall state concisely the points relied upon, and shall be accompanied by a statement setting forth supporting reasons. The petition shall also indicate whether or not the petitioner consents to the disposition of the questions involved by a single member.

**§ 8.8 Filing of administrative record.**

(a) If a petition for review has been filed concerning a decision pursuant to Part 6 of this title, the Chief Administrative Law Judge shall promptly forward the record of the proceeding before the Administrative Law Judge to the Board.

(b) If a petition for review has been filed concerning a final decision of the Department of Labor (other than a wage determination), the Associate Solicitor for General Legal Services shall promptly file with the Board a record upon which the decision was based.

**§ 8.9 Disposition by the Board of Service Contract Appeals.**

(a) The Board may decline review of any case whenever in its judgment review would be inappropriate because of lack of timeliness, the nature of the relief sought, or other reasons. A case will be reviewed upon the affirmative vote of one member.

(b) The Board shall pass upon the points raised in the petition upon the basis of the entire record before it. The Board may affirm, modify or set aside, in whole or in part, the decision under review and shall issue a decision including a statement of reasons or bases for the actions taken. The Board shall modify or set aside findings of fact only when it determines that those findings are clearly erroneous. In any remand of a case as provided in § 8.1(e) of this title, the Board shall include any appropriate instructions.

## Subpart D—General Procedural Matters

**§ 8.10 Filing and service.**

(a) *Filing.* All papers submitted to the Board under this part shall be filed with the Executive Secretary of the Board of Service Contract Appeals, U.S. Department of Labor, Washington, D.C. 20210.

(b) *Number of copies.* An original and four copies of all papers shall be submitted.

(c) *Manner of service.* Service under this part shall be personal or by mail. Service by mail is complete on mailing.

(d) *Proof of service.* Papers filed with the Board shall contain an acknowledgement of service by the person served or proof of service in the form of a statement of the date and the manner of service and the names of the person or persons served, certified by the person who made service.

(e) *Service upon the Department of Labor and other interested parties.* A copy of all documents filed with the Board shall be served upon the Associate Solicitor, Division of General Legal Services, U.S. Department of Labor, Washington, D.C. 20210; the Federal agency involved; and all other interested parties.

**§ 8.11 Presentations of other interested persons.**

(a) Where a petition has been filed for review of a wage determination or final decision of the Wage and Hour Division, the Associate Solicitor for General Legal Services shall file a statement in support of the decision.

(b) Interested persons other than the petitioner (including the Associate Solicitor for General Legal Services for petitions for review of proceedings under Part 6 of this title) shall have a reasonable opportunity as specified by the Board in particular cases to submit to the Board written data, views, or arguments relating to the petition.

**§ 8.12 Intervention; other participation.**

For good cause shown, the Board may permit any interested person or party to intervene or otherwise participate in any proceeding held by the Board. Except when requested orally before the Board, a petition to intervene or otherwise participate shall be in writing (original and four copies) and shall state with precision and particularity:

(a) The petitioner's relationship to the matters involved in the proceedings, and

(b) The nature of the presentation which the petitioner would make.

**§ 8.13 Right to counsel.**

Each interested person or party shall have the right to appear in person or by counsel or other representative in any proceeding before the Board.

**§ 8.14 Consolidations.**

Upon its own initiative or upon motion of any interested person or party, the Board may consolidate any proceeding or concurrently consider two or more appeals which involve substantially the same persons or parties, or issues which are the same or closely related, if it finds that such consolidation or concurrent review will contribute to a proper dispatch of its business and to the ends of justice, and it will not unduly delay consideration of any such appeals.

**§ 8.15 Motions; extensions of time.**

(a) Except as otherwise provided in this part, any application for an order or other relief shall be made by motion. Except when made orally before the Board, motions shall be in writing and shall be accompanied by proof of service on all other parties or interested persons. If a motion is supported by briefs, affidavits, or other papers, they shall be served and filed with the motion. Any party or interested person, as the case may be, may respond to the motion within such time as may be provided by the Board.

(b) Requests for extension of time as to the filing of papers or oral presentation shall be in the form of a motion under paragraph (a) of this section.

**§ 8.16 Oral proceedings.**

(a) With respect to any proceedings before it, the Board may upon its own initiative or upon request of any interested person or party direct the interested persons or parties to appear before the Board or its designee at a specified time and place in order to simplify the issues presented or to take up any other matters which may tend to expedite or facilitate the disposition of the proceeding.

(b) In its discretion, the Board or a single presiding member may permit oral argument in any proceeding. The Board or the presiding member shall prescribe the time and place for argument and the time allocated for argument. A petitioner wishing to make oral argument should make the request therefore in the petition.

**§ 8.17 Decision of the Board.**

Unless the petitioner consents to disposition by a single member, decisions of the Board shall be by majority vote.

**§ 8.18 Public information.**

Subject to the provisions of Part 70 of this title, all papers and documents made a part of the official record in the proceedings of the Board and decisions of the Board shall be made available for public inspection during usual business hours at the Office of the Board of Service Contract Appeals, U.S. Department of Labor, Washington, D.C. 20210.

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federal register

Tuesday
April 22, 1980

Part XI

# Department of Labor

## Office of the Secretary

## Work Incentive Programs for AFDC Recipients Under Title IV of the Social Security Act; New Procedures To Determine the WIN Sanction Period

**DEPARTMENT OF LABOR**

**Office of the Secretary**

**29 CFR Part 56**

## Work Incentive Programs for AFDC Recipients Under Title IV of the Social Security Act; New Procedures To Determine the WIN Sanction Period

**AGENCY:** Employment and Training Administration (ETA), Labor and Office of Human Development Services (OHDS), HEW.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Work Incentive (WIN) Program regulations for Aid to Families with Dependent Children (AFDC) applicants and recipients who must register for employment and training, and related services. (See also 45 CFR Part 224 published elsewhere in this separate Part XI). These amendments remove provisions which impose periods of AFDC grant ineligibility (sanction periods) on persons who are deregistered from the WIN program for failure or refusal to participate without good cause. Instead of the fixed sanction period, these regulations establish an individually determined sanction period that is based on the length of time that the person refused to participate. The length of time "the person refused to participate" will be the period between the date of determination that the person refused to participate, and the date on which a "Notice of Intended Deregistration" is sent to the person by the WIN office.

Procedures to determine when the period of failure or refusal to participate without good cause begins are set forth in these amendments.

**EFFECTIVE DATE:** April 22, 1980.

**FOR FURTHER INFORMATION CONTACT:** Merwin S. Hans, Executive Director, National Coordination Committee, Work Incentive Program, Room 5102, Patrick Henry Building, 601 D Street, NW., Washington, D.C. 20213, (202) 376–6694.

**SUPPLEMENTARY INFORMATION:**

### Background

On November 17, 1978, a Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** (43 FR 53771) to propose amendments to the regulations governing the Work Incentive (WIN) Program for AFDC applicants and recipients who are required to register for the WIN program. Persons who voluntarily register with WIN are not subject to any sanctions which affect their AFDC grant.

These regulatory amendments are necessary to comply with a U.S. District Court decision and judgment entered on September 14, 1977. The case of *McLean* v. *Califano*, 458 F. Supp. 285 (S.D.N.Y. 1977), invalidated the regulations at 29 CFR 56.77 and 45 CFR 224.77 which imposed fixed periods of AFDC grant ineligibility (sanction periods) on individuals who are deregistered from the WIN program for failure or refusal to participate without good cause. After that, similar judgments were entered in other jurisdictions, and in *Crosby* v. *Califano*, Civil Action No. 78–3067 (S.D. Ill.), the court entered, on May 22, 1979, an order applying to all jurisdictions not previously covered.

The courts found that fixed sanction periods do not comport with Section 402(a)(19)(F) of the Social Security Act (Act). This section requires generally that States not take into account an individual's need in determining the amount of assistance for the period he or she refuses to participate in the WIN program without good cause. The courts ordered flexible sanction periods based upon the actual periods during which a person failed or refused to participate in the WIN program without good cause. The Departments of Labor and of Health, Education, and Welfare (Departments) are complying with these orders. The final regulations provide that the length of the WIN sanction period after a mandatory registrant is deregistered for failure or refusal to participate without good cause will correspond in each case to the length of time that the individual failed or refused to participate. During the sanction period, the individual will not be permitted to register in the WIN program and, therefore, will not be eligible for the AFDC grant.

### Public Comment

One hundred fifteen (115) comments were received in response to the proposed regulations from: Federal and State agencies; legal services, welfare rights, and community action organizations; attorneys involved in the litigation actions; interstate conferences of State agencies; and private individuals. The comments contained many constructive suggestions which have been adopted. There were several principal areas of concern:

*1. Specificity*

*Comment:* Many of the commenters requested that the regulations be specific as to how to identify the beginning date from which to compute the length of time during which a sanction will apply. They felt that the proposed regulations permitted too much latitude for subjective or judgmental decisions by WIN staff that could be detrimental to registrants. They also felt that the proposed regulation would be difficult to implement with any measure of uniformity.

*Response:* In order to maximize uniform, objective decisions by WIN staff on the length of the sanction period, the beginning and ending dates are as specified in § 56.51(c) and (d). If a refusal to participate is overt, § 56.51(d)(1) specifies that the beginning date for computing the length of the sanction period is the first date on which the registrant expressly refuses to participate. In the case of de facto refusals, § 56.51(d)(2) specifies that a refusal to participate in the program consists of a current act or pattern of behavior which the WIN staff finds to imply a failure or refusal to participate.

A written notice will be sent to the individual, advising him or her that the WIN staff finds a pattern of behavior which indicates failure to participate without good cause in the WIN program. This same written notice will advise the individual of the adverse implications of such continued behavior. The notice also will provide an appointment date for an interview with the WIN staff to discuss the matter.

This appointment date will be the first date of the sanction period if a person fails to keep the appointment, or appears and refuses to participate in the program [§ 56.51(d)(2)(i) and (ii)]. Similarly, if an individual appears for an appointment but manifests behavior from which refusal to participate is clearly evident, the appointment date is again the beginning date for computing the length of the sanction period [§ 56.51(d)(2)(iii)].

*2. Registrants Who Rescind Their Agreements To Participate*

State and local agencies commented that registrants would be able to avoid participating in the WIN program yet still manage to skirt any sanction by alternately agreeing and refusing to participate in the WIN program. Although the Departments cannot prevent registrants from making bad faith agreements to participate, they have added § 56.51(d)(2)(iv) to help minimize this problem.

Under § 56.51(d)(2)(iv), if an individual agrees to participate when called to the WIN office to discuss a de facto failure or refusal to participate, but later fails or refuses without good cause to respond to an appointment notice or to participate in employment and training activities, the sanction period

will begin immediately upon this subsequent refusal. Within 10 days the WIN office will send the individual a "Notice of Appointment" informing him or her to appear for conciliation.

*3. Length of Sanction Period*

*Comment:* A number of comments favored longer, as well as shorter, sanction periods. Some favored even longer sanction periods for persons who are deregistered for the second time because of failure or refusal to participate without good cause in the WIN program.

*Response:* The length of the sanction period in all instances conforms to the courts' conclusions in *McLean* and *Crosby* that section 402(a)(19)(F) of the Act allows deregistration for the period of time for which the individual refuses without good cause to participate. These decisions thus limit the Departments' discretion to set different sanction periods for individuals being deregistered for the second time.

*4. Protecting Rights of Registrants*

*Comment:* Many commenters questioned whether the proposed regulations clearly and completely explained the effect of WIN sanctions on AFDC grants. Specifically commenters expressed two concerns. First, they thought that registrants would not understand that longer conciliation efforts could mean longer periods of AFDC ineligibility. Some suggested that, due to the potentially adverse consequences of protracted conciliation efforts, registrants should have the right to participate in deciding when to terminate the conciliation effort. Second, they feared that registrants would not have an opportunity to dispute the WIN staff's determination of the length of the sanction period.

*Response:* The final regulations have taken these comments into consideration. In response to the first concern, § 56.63(a) requires that WIN staff advise the registrant of his or her right to terminate the conciliation period and alert him or her that the WIN staff will include the time spent in conciliation as part of the time the person refused or failed to participate in the WIN program in the event conciliation efforts fail and the WIN staff have to determine the length of the sanction period.

In response to the second concern, § 56.63(b) (2) and (3) assure that a registrant be fully informed of the sanction issues that may be subject to a hearing by requiring that the "Notice of Intended Deregistration" inform the registrant: (1) of the initial date and length of the sanction period, and (2) that this determination is an appealable issue in the WIN program. If the registrant questions the length of the sanction period before or during the hearing, it becomes an issue which the hearing officer must decide [see § 56.65 and § 56.68(a)(5)].

*5. Administration and Implementation*

*Comment:* Officials from States that issue computerized AFDC grants on a monthly basis and others commented that administering and implementing individually determined sanction periods which require making AFDC payments for part of a month will be problematic.

State officials pointed out that many sanctions for less than a month would be disregarded for expediency. They further asserted that before a sanction of short duration would be processed, the sanction period would have elapsed and the person would again be eligible for registration and the AFDC grant. Finally, they indicated that implementing flexible sanctions would be time consuming and costly, and would require extensive record maintenance.

*Response:* The Departments believe computerized payments systems can accommodate grant payments for part of a month. More importantly, however, permitting States to "round off" the length of the sanction period for adminstrative convenience would be directly counter to the courts' interpretations of the statutory requirement that the sanction period be for "if and for so long as" the registrant fails to participate in WIN without good cause. To the extent that rounding off would result in a sanction period longer in duration than the period of a registrant's failure to participate, these decisions forbid the practice. States do, however, have the discretion to begin applying a sanction period of the determined duration at the beginning of the next convenient month following the mailing of the "Notice of Intended Deregistration" to the registrant.

**Summary of Changes From the Notice of Proposed Rulemaking**

1. *Section 56.51(a)(1).* The NPRM left intact the current § 56.51(a), which lists the AFDC sanction applied to a mandatory registrant who is a caretaker relative, the only dependent child in a family or one of several dependent children in a family. The final regulation adds to § 56.51(a)(1) a cross-reference to 45 CFR 233.100(a)(5)(i) which explains the sanction for unemployed parents whose families receive AFDC on the basis of their unemployment.

When reconsidering the NPRM, the Departments found § 56.51(a) inadequate to the extent that it failed to identify the sanction applied to an unemployed father who is not registered with WIN. Under section 407(b)(2)(C)(i) of the Social Security Act, if the family of this father received AFDC on the basis of his unemployment, the entire family becomes ineligible for benefits unless the father is exempt from the WIN registration requirement. Therefore, the Departments have supplemented the final version of § 56.51(a) with a cross-reference to 45 CFR 233.100(a)(5)(i), which implements section 407(b)(2)(C)(i). The Departments plan to amend the regulations in the near future to provide a fuller treatment of this statutory sanction, and will publish a Notice of Proposed Rulemaking at that time.

Also, in *Califano* v. *Westcott*, 99 S. Ct. 2655 (1979), the Supreme Court ruled that, in States operating Unemployed Father programs, families made needy by the unemployment of the mother could become eligible for AFDC benefits in the same amounts and under the same standards as families made needy by the unemployment of the father. Accordingly, the cross-reference in § 56.51(a) directs readers to 45 CFR 233.100(a)(5)(i) for the sanction applicable when an unemployed mother or father whose family receives AFDC on the basis of her or his unemployment fails or refuses to participate in WIN.

2. *Section 56.51(b).* The Departments have added a new § 56.51(b) to explain the penalty for a voluntary registrant who fails or refuses to participate in the WIN program. The purpose of this addition is to clarify WIN sanctions for individuals who participate in the WIN program even though participation is not a condition for their receipt of AFDC. The WIN staff may sanction these individuals by deregistering them, but deregistration will not affect their AFDC benefits. This new paragraph (b) replaces the current paragraph (c) of § 56.51.

3. *Section 56.51(d).* The final regulation explains how the Departments determine when a de facto failure or refusal to participate in the WIN program begins. These rules are explained above in the discussion of the Departments' response to comments.

4. *Section 56.63(a).* The most significant change in this section is that the final rule permits the registrant to terminate the conciliation effort. The WIN staff must advise the registrant that he or she has this right and that the sanction period corresponds to the conciliation period. When necessary, the WIN staff must help registrants prepare

the written statement requesting termination of conciliation.

The final regulation also adds two time limits. First, conciliation efforts must now begin no later than 10 days following the failure or refusal to participate. Second, the WIN staff must now mail the "Notice of Intended Deregistration" within two days after the WIN staff or the registrant terminates the conciliation period without resolving the failure or refusal to participate.

5. *Section 56.68(a)(6).* This paragraph did not appear in the NPRM. It assures deregistered individuals a hearing on whether the WIN staff properly refused to reregister them.

While refusal to participate begins when the individual is a registrant, it can continue after deregistration and following the conclusion of the sanction period. After the sanction period has elapsed and before reregistration may be permitted, the individual may be expected to establish for the WIN staff his or her willingness to participate in the WIN program. Evidence of willingness to participate could be evidence showing that the circumstances and barriers to full participation in WIN that caused the most recent deregistration have been removed, and that no new circumstances or barriers have arisen since the deregistration that would interfere with renewal of complete participation.

The Departments decided to specify that a WIN hearing is available on the issue of a deregistered individual's willingness to participate in order to eliminate any confusion arising from the general restriction that WIN hearings are available only to registrants. Because a refusal to reregister could result in a denial of AFDC, the Departments wanted to specify that a hearing is available on this issue.

This regulation has been reviewed under the criteria in Executive Order 12044. It does not require a Regulatory Analysis, since it does not meet the threshold of criteria on economic impact.

The appropriate Sections of Title 29 Part 56 are revised as follows:

## PART 56—WORK INCENTIVE PROGRAM FOR AFDC RECIPIENTS UNDER TITLE IV OF THE SOCIAL SECURITY ACT

### Subpart F—Deregistration and Sanctions

1. Section 56.51 is amended by revising paragraph (a); redesignating existing paragraphs (b) and (d) as new paragraphs (e) and (f), deleting existing paragraph (c), and by adding new paragraphs (b), (c), and (d); as follows:

**§ 56.51 Sanctions.**

A State plan under Title IV–A of the Act shall provide that:

(a) When an AFDC recipient, who is a mandatory registrant in the WIN program, has been found to have failed or refused without good cause to participate in the program, sanctions shall apply for a period equal to the length of time that the registrant failed or refused to participate in the program. In such cases:

(1) If the individual is a caretaker relative receiving AFDC benefits, the State will not take into account his or her needs in determining the family's need for assistance, but the State will provide assistance in the form of protective or vendor payments or foster care for the remaining members of the assistance unit. When the State makes protective or vendor payments, the non-participating caretaker relative may not be the protective payee. (If the individual is an unemployed father or mother on the basis of whose unemployment the family is receiving AFDC Unemployed Parent benefits, see 45 CFR 233.100(a)(5)(i)).

(2) If the individual is the only dependent child in the family, the State will deny assistance for the family.

(3) If the individual is one of several dependent children in the family, the State will deny assistance for the child and will not take into account the child's needs in determining the family's need for assistance.

(b) When the State finds that an AFDC recipient who is a voluntary registrant has failed or refused to participate in the WIN program without good cause, the State will deregister the individual for a period equal to the length of time the registrant failed or refused to participate, but the individual's AFDC grant shall not be affected.

(c) The WIN program staff shall measure the sanction period resulting from a failure or refusal to participate without good cause by the length of time that elapsed from the beginning date of failure or refusal to participate as determined under paragraph (d) of this section, until the date the "Notice of Intended Deregistration" was mailed to the registrant.

(d) A WIN registrant may manifest failure or refusal to participate in the WIN program either by an overt (express) refusal or by a de facto failure to participate.

(1) An overt (express) refusal is a written or oral statement by an individual that he or she will not participate in the WIN program. The beginning date for counting the length of the sanction period following an overt refusal will be the date of that refusal.

(2) A de facto refusal is any current act or pattern of behavior consisting of a series of current events from which failure or refusal to participate can be implied. Where the failure or refusal to participate is implied, the WIN sponsor shall send a notice setting an appointment for the individual to come to the WIN office and discuss the act or pattern of behavior in question. The notice shall explain the reasons for the appointment and the consequence of failure to keep the appointment.

(i) If the individual fails without good cause to keep the appointment, the appointment date will be the beginning date of failure or refusal to participate for the purpose of counting the length of the sanction period.

(ii) If the individual keeps the appointment and refuses to participate at that time, the appointment date will be the beginning date of failure or refusal to participate.

(iii) If the individual keeps the appointment, but his or her behavior clearly manifests a refusal to participate, the appointment date will be the beginning date for counting the length of the sanction period.

(iv) If the individual keeps the appointment and agrees to participate, but subsequently fails or refuses without good cause to respond to an appointment notice or to participate in employment and training activities required under section 402(a)(19)(F) of the Act, the beginning date for counting the length of the sanction period shall be the date of this subsequent failure or refusal.

2. Section 56.63 is amended by revising paragraph (a); revising the introductory text in paragraph (b); redesignating existing paragraph (b)(2) through (b)(7) as new paragraph (b)(3) through (b)(8), by adding a new paragraph (b)(2) and by revising redesignated paragraph (b)(3); as follows:

**§ 56.63 Requirement of conciliation and notice.**

(a) The WIN staff must exhaust efforts toward conciliatory resolution of disputes between the WIN staff and the registrant before the WIN staff issues a "Notice of Intended Deregistration." This conciliation effort shall begin as soon as possible, but no later than 10 days following the date of failure or refusal to participate as determined under § 56.51(d) of this Part, and may continue for a period not to exceed 30

days. However, either the WIN staff, or the registrant upon written request, *may* terminate this period sooner when either believes that the dispute cannot be resolved by conciliation. The WIN staff shall advise the registrant of the right to terminate the conciliation effort and, where necessary, assist in preparing the written statement. The WIN staff must also advise the registrant that the time spent in conciliation is counted in calculating the length of the sanction period.

(b) Within two working days after the WIN staff or the registrant terminates the conciliation period without resolution of the matter, the WIN staff shall mail to the registrant by registered mail a "Notice of Intended Deregistration." This notice must include:

* * * * *

(2) The date that the WIN staff determined to be the beginning date of the failure or refusal to participate in the WIN program without good cause, and the consequent length of the sanction period.

(3) Notification of the registrant's right to a hearing if the registrant believes that the proposed action is incorrect, or the length of the sanction period is incorrect, provided a request for a hearing is filed as prescribed in § 56.64 of this Part.

* * * * *

3. Paragraph (a) of § 56.65 is revised to read as follows:

**§ 56.65 Issues subject to a hearing.**

(a) Under the WIN adjudication system a hearing officer will hear and decide WIN program issues arising subsequent to registration by uncertified and certified registrants. The issues for which a hearing may be requested include, but are not limited to, a registrant's failure or refusal to appear for appraisal or for assignment to a WIN component; unresolved WIN grievances; a registrant's failure or refusal without good cause to accept employment or otherwise participate in the WIN program; and the WIN staff determination of the length of the sanction period.

* * * * *

4. Section 56.68 is amended by: revising paragraphs (a)(5) and (a)(6); adding a new paragraph (b); and redesignating the existing paragraphs (b) and (c) as (c) and (d); as follows:

**§ 56.68 Decisions of the hearing officer.**

(a) * * *

(5) That the length of the period during which the registrant failed or refused to participate was not correctly determined by the WIN staff.

(6) Whether following conclusion of the sanction period, the WIN staff correctly refused to reregister the individual for cause.

(b) The hearing officer may render such other decisions as are appropriate to the issue or issues before him or her for resolution. However, a hearing officer must not consider the validity or constitutionality or either the Act or the regulations in this Part.

* * * * *

5. Paragraph (a) of § 56.77 is revised to read as follows:

**§ 56.77 Subsequent WIN registration of deregistered individuals.**

(a) An individual who has been deregistered on the basis of a determination that he or she failed or refused to participate without good cause in the WIN program may again register for WIN by making an application. This can be done provided the sanction period specified in § 56.51(c) of this Part has elapsed and the individual has given evidence to the WIN staff of willingness to participate in the program.

* * * * *

(Secs. 402(a)(7), 402(a)(19), 430–444, and 1102 of the Social Security Act, as amended, 49 Stat. 647 (42 U.S.C. 602(a)(7), 602(a)(19), 630–644, and 1302))

Signed at Washington, D.C. this 8th day of April, 1980.

**Ray Marshall,**

*Secretary of Labor.*

Signed at Washington, D.C. this 15th day of April, 1980.

**Patricia Roberts Harris,**

*Secretary of Health, Education, and Welfare.*

[FR Doc. 12385 Filed 4–21–80; 8:45 am]

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April 22, 1980

Part XII

# Department of Health, Education, and Welfare

## Office of Human Development Services

## Work Incentive Programs for AFDC Recipient Under Title IV of the Social Security Act; New Procedures to Determine the WIN Sanction Period

**DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE**

**Office of Human Development Services**

**45 CFR Part 224**

## Work Incentive Programs for AFDC Recipient Under Title IV of the Social Security Act; New Procedures To Determine the WIN Sanction Period

**AGENCIES:** Office of Human Development Services (OHDS), HEW; and Employment and Training Administration (ETA), Labor.

**ACTION:** Final rule.

**SUMMARY:** This rule amends the Work Incentive (WIN) Program regulations for Aid to Families with Dependent Children (AFDC) applicants and recipients who must register for employment and training, and related services. (See also 29 CFR Part 56 published elsewhere in Separate Part XI). These amendments remove provisions which impose fixed periods of AFDC grant ineligibility (sanction periods) on persons who are deregistered from the WIN program for failure or refusal to participate without good cause. Instead of the fixed sanction period, these regulations establish an individually determined sanction period that is based on the length of time that the person refused to participate. The length of time "the person refused to participate" will be the period between the date of determination that the person refused to participate, and the date on which a "Notice of Intended Deregistration" is sent to the person by the WIN office.

Procedures to determine when the period of failure or refusal to participate without good cause begins are set forth in these amendments.

**EFFECTIVE DATE:** April 22, 1980.

**FOR FURTHER INFORMATION CONTACT:** Merwin S. Hans, Executive Director, National Coordination Committee, Work Incentive Program, Room 5102—Patrick Henry Building, 601 D Street, N.W., Washington, D.C. 20213. (202) 376–6694.

**SUPPLEMENTARY INFORMATION:**

### Background

On November 17, 1978, a Notice of Proposed Rulemaking (NPRM) was published in the **Federal Register** (43 Fed. Reg. 53771) to propose amendments to the regulations governing the Work Incentive (WIN) Program for AFDC applicants and recipients who are required to register for the WIN program. Persons who voluntarily register with WIN are not subject to any sanctions which affect their AFDC grant.

These regulatory amendments are necessary to comply with a U.S. District Court decision and judgment entered on September 14, 1977. The case of *McLean* v. *Callifano,* 458 F. Supp. 285 (S.D.N.Y. 1977), invalidated the regulations at 29 CFR 56.77 and 45 CFR 224.77 which imposed fixed periods of AFDC grant ineligibility (sanction periods) on individuals who are deregistered from the WIN program for failure or refusal to participate without good cause. After that, similar judgments were entered in other jurisdictions, and in *Crosby* v. *Califano,* Civil Action No. 78–3067 (S.D. Ill.), the court entered, on May 22, 1979, an order applying to all jurisdictions not previously covered.

The courts found that fixed sanction periods do not comport with Section 402(a)(19)(F) of the Social Security Act (Act). This section requires generally that States not take into account an individual's need in determining the amount of assistance for the period he or she refuses to participate in the WIN program without good cause. The courts ordered flexible sanction periods based upon the actual periods during which a person failed or refused to participate in the WIN program without good cause. The Departments of Labor and of Health, Education, and Welfare (Departments) are complying with these orders. The final regulations provide that the length of the WIN sanction period after a mandatory registrant is deregistered for failure or refusal to participate without good cause will correspond in each case to the length of time that the individual failed or refused to participate. During the sanction period, the individual will not be permitted to register in the WIN program and, therefore, will not be eligible for the AFDC grant.

### Public Comment

One hundred fifteen (115) comments were received in response to the proposed regulations from: Federal and State agencies; legal services, welfare rights, and community action organizations; attorneys involved in the litigation actions; interstate conferences of State agencies; and private individuals. The comments contained many constructive suggestions which have been adopted. There were several principal areas of concern:

*1. Specificity*

*Comment:* Many of the commenters requested that the regulations be specific as to how to identify the beginning date from which to compute the length of time during which a sanction will apply. They felt that the proposed regulations permitted too much latitude for subjective or judgmental decisions by WIN staff that could be detrimental to registrants. They also felt that the proposed regulation would be difficult to implement with any measure of uniformity.

*Response:* In order to maximize uniform, objective decisions by WIN staff on the length of the sanction period, the beginning and ending dates are as specified in § 224.51(c) and (d). If a refusal to participate is overt, § 224.51(d)(1) specifies that the beginning date for computing the length of the sanction period is the first date on which the registrant expressly refuses to participate. In the case of de facto refusals, § 224.51(d)(2) specifies that a refusal to participate in the program consists of a current act or pattern of behavior which the WIN staff finds to imply a failure or refusal to participate.

A written notice will be sent to the individual, advising him or her that the WIN staff finds a pattern of behavior which indicates failure to participate without good cause in the WIN program. This same written notice will advise the individual of the adverse implications of such continued behavior. The notice also will provide an appointment date for an interview with the WIN staff to discuss the matter.

This appointment date will be the first date of the sanction period if a person fails to keep the appointment, or appears and refuses to participate in the program [section 224.51(d)(2)(i) and (ii)]. Similarly, if an individual appears for an appointment but manifests behavior from which refusal to participate is clearly evident, the appointment date is again the beginning date for computing the length of the sanction period [section 224.51(d)(2)(iii)].

*2. Registrants Who Rescind Their Agreements To Participate*

State and local agencies commented that registrants would be able to avoid participating in the WIN program yet still manage to skirt any sanction by alternately agreeing and refusing to participate in the WIN program. Although the Departments cannot prevent registrants from making bad faith agreements to participate, they have added § 224.51(d)(2)(iv) to help minimize this problem.

Under § 224.51(d)(2)(iv), if an individual agrees to participate when called to the WIN office to discuss a de facto failure or refusal to participate, but later fails or refuses without good cause to respond to an appointment notice or to participate in employment and

training activities, the sanction period will begin immediately upon this subsequent refusal. Within 10 days the WIN office will send the individual a "Notice of Appointment" informing him or her to appear for conciliation.

*3. Length of Sanction Period*

*Comment:* A number of comments favored longer, as well as shorter, sanction periods. Some favored even longer sanction periods for persons who are deregistered for the second time because of failure or refusal to participate without good cause in the WIN program.

*Response:* The length of the sanction period in all instances conforms to the courts' conclusions in *McLean* and *Crosby* that section 402(a)(19)(F) of the Act allows deregistration for the period of time for which the individual refuses without good cause to participate. These decisions thus limit the Departments' discretion to set different sanction periods for individuals being deregistered for the second time.

*4. Protecting Rights of Registrants*

*Comment:* Many commenters questioned whether the proposed regulations clearly and completely explained the effect of WIN sanctions on AFDC grants. Specifically, commenters expressed two concerns. First, they thought that registrants would not understand that longer conciliation efforts could mean longer periods of AFDC ineligibility. Some suggested that, due to the potentially adverse consequences of protracted conciliation efforts, registrants should have the right to participate in deciding when to terminate the conciliation effort. Second, they feared that registrants would not have an opportunity to dispute the WIN staff's determination of the length of the sanction period.

*Response:* The final regulations have taken these comments into consideration. In response to the first concern, § 224.63(a) requires that WIN staff advise the registrant of his or her right to terminate the conciliation period and alert him or her that the WIN staff will include the time spent in conciliation as part of the time the person refused or failed to participate in the WIN program in the event conciliation efforts fail and the WIN staff have to determine the length of the sanction period.

In response to the second concern, §§ 224.63(b)(2) and (3) assure that a registrant be fully informed of the sanction issues that may be subject to a hearing by requiring that the "Notice of Intended Deregistration" inform the registrant: (1) of the initial date and length of the sanction period, and (2) that this determination is an appealable issue in the WIN program. If the registrant questions the length of the sanction period before or during the hearing, it becomes an issue which the hearing officer must decide [see § 224.65 and § 224.68(a)(5)].

*5. Administration and Implementation*

*Comment:* Officials from States that issue computerized AFDC grants on a monthly basis and others commented that administering and implementing individually determined sanction periods which require making AFDC payments for part of a month will be problematic.

State officials pointed out that many sanctions for less than a month would be disregarded for expediency. They further asserted that before a sanction of short duration would be processed, the sanction period would have elapsed and the person would again be eligible for registration and the AFDC grant. Finally, they indicated that implementing flexible sanctions would be time consuming and costly, and would require extensive record maintenance.

*Response:* The Departments believe computerized payments systems can accommodate grant payments for part of a month. More importantly, however, permitting States to "round off" the length of the sanction period for administrative convenience would be directly counter to the courts' interpretations of the statutory requirement that the sanction period be for "if and for so long as" the registrant fails to participate in WIN without good cause. To the extent that rounding off would result in a sanction period longer in duration than the period of a registrant's failure to participate, these decisions forbid the practice. States do, however, have the discretion to begin applying a sanction period of the determined duration at the beginning of the next convenient month following the mailing of the "Notice of Intended Deregistration" to the registrant.

**Summary of Changes From the Notice of Proposed Rulemaking**

1. *Section 224.51(a)(1).* The NPRM left intact the current § 224.51(a), which lists the AFDC sanction applied to a mandatory registrant who is a caretaker relative, the only dependent child in a family or one of several dependent children in a family. The final regulation adds to § 224.51(a)(1) a cross-reference to 45 CFR 233.100(a)(5)(i) which explains the sanction for unemployed parents whose families receive AFDC on the basis of their unemployment.

When reconsidering the NPRM, the Departments found § 224.51(a) inadequate to the extent that it failed to identify the sanction applied to an unemployed father who is not registered with WIN. Under section 407(b)(2)(C)(i) of the Social Security Act, if the family of this father received AFDC on the basis of his unemployment, the entire family becomes ineligible for benefits unless the father is exempt from the WIN registration requirement. Therefore, the Departments have supplemented the final version of § 224.51(a) with a cross-reference to 45 CFR 233.100(a)(5)(i), which implements § 407(b)(2)(C)(i). The Departments plan to amend the regulations in the near future to provide a fuller treatment of this statutory sanction, and will publish a Notice of Proposed Rulemaking at that time.

Also, in *Califano* v. *Westcott,* 99 S. Ct. 2655 (1979), the Supreme Court ruled that, in States operating Unemployed Father programs, families made needy by the unemployment of the mother could become eligible for AFDC benefits in the same amounts and under the same standards as families made needy by the unemployment of the father. Accordingly, the cross-reference in § 224.51(a) directs readers to 45 CFR 233.100(a)(5)(i) for the sanction applicable when an unemployed mother or father whose family receives AFDC on the basis of her or his unemployment fails or refuses to participate in WIN.

2. *Section 224.51(b).* The Departments have added a new section 224.51(b) to explain the penalty for a voluntary registrant who fails or refuses to participate in the WIN program. The purpose of this addition is to clarify WIN sanctions for individuals who participate in the WIN program even though participation is not a condition for their receipt of AFDC. The WIN staff may sanction these individuals by deregistering them, but deregistration will not affect their AFDC benefits. This new paragraph (b) replaces the current paragraph (c) of section 224.51.

3. *Section 224.51(d).* The final regulation explains how the Departments determine when a de facto failure or refusal to participate in the WIN program begins. These rules are explained above in the discussion of the Departments' response to comments.

4. *Section 224.63(a).* The most significant change in this section is that the final rule permits the registrant to terminate the conciliation effort. The WIN staff must advise the registrant that he or she has this right and that the sanction period corresponds to the conciliation period. When necessary, the WIN staff must help registrants prepare

the written statement requesting termination of conciliation.

The final regulation also adds two time limits. First, conciliation efforts must now begin no later than 10 days following the failure or refusal to participate. Second, the WIN staff must now mail the "Notice of Intended Deregistration" within two days after the WIN staff or the registrant terminates the conciliation period without resolving the failure or refusal to participate.

5. *Section 224.68(a)(6).* This paragraph did not appear in the NPRM. It assures deregistered individuals a hearing on whether the WIN staff properly refused to reregister them.

While refusal to participate begins when the individual is a registrant, it can continue after deregistration and following the conclusion of the sanction period. After the sanction period has elapsed and before reregistration may be permitted, the individual may be expected to establish for the WIN staff his or her willingness to participate in the WIN program. Evidence of willingness to participate could be evidence showing that the circumstances and barriers to full participation in WIN that caused the most recent deregistration have been removed, and that no new circumstances or barriers have arisen since the deregistration that would interfere with renewal of complete participation.

The Departments decided to specify that a WIN hearing is available on the issue of a deregistered individual's willingness to participate in order to eliminate any confusion arising from the general restriction that WIN hearings are available only to registrants. Because a refusal to reregister could result in a denial of AFDC, the Departments wanted to specify that a hearing is available on this issue.

This regulation has been reviewed under the criteria in Executive Order 12044. It does not require a Regulatory Analysis, since it does not meet the threshold of criteria on economic impact.

The appropriate sections of Title 45, Part 224 are revised as follows:

## PART 224—WORK INCENTIVE PROGRAM FOR AFDC RECIPIENTS UNDER TITLE IV OF THE SOCIAL SECURITY ACT

### Subpart F—Deregistration and Sanctions

1. Section 224.51 is amended by revising paragraph (a); redesignating existing paragragh (b) and (d) as new paragraph (e) and (f), deleting existing paragraph (c), and by adding new paragraphs (b), (c), and (d); as follows:

**§ 224.51 Sanctions.**

A State plan under Title IV–A of the Act shall provide that:

(a) When an AFDC recipient, who is a mandatory registrant in the WIN program, has been found to have failed or refused without good cause to participate in the program, sanctions shall apply for a period equal to the length of time that the registrant failed or refused to participate in the program. In such cases:

(1) If the individual is a caretaker relative receiving AFDC benefits, the State will not take into account his or her needs in determining the family's need for assistance, but the State will provide assistance in the form of protective or vendor payments or foster care for the remaining members of the assistance unit. When the State makes protective or vendor payments, the non-participating caretaker relative may not be the protective payee. (If the individual is an unemployed father or mother on the basis of whose unemployment the family is receiving AFDC Unemployed Parent benefits, see 45 CFR § 233.100(a)(5)(i)).

(2) If the individual is the only dependent child in the family, the State will deny assistance for the family.

(3) If the individual is one of several dependent children in the family, the State will deny assistance for the child and will not take into account the child's needs in determining the family's need for assistance.

(b) When the State finds that an AFDC recipient who is a voluntary registrant has failed or refused to participate in the WIN program without good cause, the State will deregister the individual for a period equal to the length of time the registrant failed or refused to participate, but the individual's AFDC grant shall not be affected.

(c) The WIN program staff shall measure the sanction period resulting from a failure or refusal to participate without good cause by the length of time that elapsed from the beginning date of failure or refusal to participate as determined under paragraph (d) of this section, until the date the "Notice of Intended Deregistration" was mailed to the registrant.

(d) A WIN registrant may manifest failure or refusal to participate in the WIN program either by an overt (express) refusal or by a de facto failure to participate.

(1) An overt (express) refusal is a written or oral statement by an individual that he or she will not participate in the WIN program. The beginning date for counting the length of the sanction period following an overt refusal will be the date of that refusal.

(2) A de facto refusal is any current act or pattern of behavior consisting of a series of current events from which failure or refusal to participate can be implied. Where the failure or refusal to participate is implied, the WIN sponsor shall send a notice setting an appointment for the individual to come to the WIN office and discuss the act or pattern of behavior in question. The notice shall explain the reasons for the appointment and the consequence of failure to keep the appointment.

(i) If the individual fails without good cause to keep the appointment, the appointment date will be the beginning date of failure or refusal to participate for the purpose of counting the length of the sanction period.

(ii) If the individual keeps the appointment and refuses to participate at that time, the appointment date will be the beginning date of failure or refusal to participate.

(iii) If the individual keeps the appointment, but his or her behavior clearly manifests a refusal to participate, the appointment date will be the beginning date for counting the length of the sanction period.

(iv) If the individual keeps the appointment and agrees to participate, but subsequently fails or refuses without good cause to respond to an appointment notice or to participate in employment and training activities required under section 402(a)(19)(F) of the Act, the beginning date for counting the length of the sanction period shall be the date of this subsequent failure or refusal.

### Subpart G—The WIN Adjudication System

2. Section 224.63 is amended by revising paragraph (a); revising the introductory text in paragraph (b); redesignating existing paragraph (b)(2) through (b)(7) as new paragraph (b)(3) through (b)(8), by adding a new paragraph (b)(2) and by revising redesignated paragraph (b)(3); as follows:

**§ 224.63 Requirement of conciliation and notice.**

(a) The WIN staff must exhaust efforts toward conciliatory resolution of disputes between the WIN staff and the registrant before the WIN staff issues a "Notice of Intended Deregistration." This conciliation effort shall begin as soon as possible, but no later than 10

days following the date of failure or refusal to participate as determined under § 224.51(d) of this Part, and may continue for a period not to exceed 30 days. However, either the WIN staff, or the registrant upon written request, *may* terminate this period sooner when either believes that the dispute cannot be resolved by conciliation. The WIN staff shall advise the registrant of the right to terminate the conciliation effort and, where necessary, assist in preparing the written statement. The WIN staff must also advise the registrant that the time spent in conciliation is counted in calculating the length of the sanction period.

(b) Within two working days after the WIN staff or the registrant terminates the conciliation period without resolution of the matter, the WIN staff shall mail to the registrant by registered mail a "Notice of Intended Deregistration." This notice must include:

* * * * *

(2) The date that the WIN staff determined to be the beginning date of the failure or refusal to participate in the WIN program without good cause, and the consequent length of the sanction period.

(3) Notification of the registrant's right to a hearing if the registrant believes that the proposed action is incorrect, or the length of the sanction period is incorrect, provided a request for a hearing is filed as prescribed in § 224.64 of this Part.

* * * * *

3. Paragraph (a) of § 224.65 is revised to read as follows:

**§ 224.65 Issues subject to a hearing.**

(a) Under the WIN adjudication system a hearing officer will hear and decide WIN program issues arising subsequent to registration by uncertified and certified registrants. The issues for which a hearing may be requested include, but are not limited to, a registrant's failure or refusal to appear for appraisal or for assignment to a WIN component; unresolved WIN grievances; a registrant's failure or refusal without good cause to accept employment or otherwise participate in the WIN program; and the WIN staff determination of the length of the sanction period.

* * * * *

4. Section 224.68 is amended by: revising paragraphs (a)(5) and (a)(6); adding a new paragraph (b); and redesignating the existing paragraphs (b) and (c) as (c) and (d); as follows:

**§ 224.68 Decisions of the hearing officer.**

(a) * * *

(5) That the length of the period during which the registrant failed or refused to participate was not correctly determined by the WIN staff.

(6) Whether following conclusion of the sanction period, the WIN staff correctly refused to reregister the individual for cause.

(b) The hearing officer may render such other decisions as are appropriate to the issue or issues before him or her for resolution. However, a hearing officer must not consider the validity or constitutionality of either the Act or the regulations in this Part.

* * * * *

5. Paragraph (a) of § 224.77 is revised to read as follows:

**§ 224.77 Subsequent WIN registration of deregistered individuals.**

(a) An individual who has been deregistered on the basis of a determination that he or she failed or refused to participate without good cause in the WIN program may again register for WIN by making an application. This can be done provided the sanction period specified in § 224.51(c) of this Part has elapsed and the individual has given evidence to the WIN staff of willingness to participate in the program.

* * * * *

(Secs. 402(a)(7), 402(a)(19), 430–444, and 1102 of the Social Security Act, as amended, 49 Stat. 647 (42 U.S.C. 602(a)(7)), 602(a)(19), 630–644, and 1302))

Signed at Washington, D.C. this 15th day of April, 1980.

**Patricia Roberts Harris,**

*Secretary of Health, Education, and Welfare.*

Signed at Washington, D.C. this 8th day of April, 1980.

**Ray Marshall,**

*Secretary of Labor.*

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Part XIII

# Department of Agriculture

## Food and Nutrition Service

## Food Stamp Act of 1977; SSI/Food Stamp Joint Application Processing

**DEPARTMENT OF AGRICULTURE**

**Food and Nutrition Service**

**7 CFR Parts 272, 273**

**[Amtd. 158]**

## Food Stamp Act of 1977; SSI/Food Stamp Joint Aplication Processing

**AGENCY:** Food and Nutrition Service, USDA.

**ACTION:** Final rule.

**SUMMARY:** This final rule implements section 11(i)(2) in full, and section 11(j), in part, of the Food Stamp Act of 1977, which provide for the food stamp certification of households containing applicants for and recipients of Supplemental Security Income (SSI) and social security benefits. Proposed regulations on this provision were published at 44 FR 70684, December 7, 1979. Many SSI recipients are also eligible for food stamps, but have found participation difficult. To simplify participation in both programs, these regulations allow certain SSI applicants and recipients to apply for food stamps at offices of the Social Security Administration (SSA).

**EFFECTIVE DATE:** August 1, 1980.

**FOR FURTHER INFORMATION CONTACT:** Larry R. Carnes, Chief, Policy and Regulations Section, Program Standards Branch, Program Development Division, Family Nutrition Programs, Food and Nutrition Service, United States Department of Agriculture, Washington, D.C. 20250; 202–447–9075. The Final Impact Statement describing the options considered in developing this final rule and the impact of implementing the rule is available from Claire Lipsman, Director, Program Development Division, FNS, USDA, Washington, D.C. 20250.

**SUPPLEMENTARY INFORMATION:** This final action has been reviewed under USDA procedures established in Secretary's Memorandum 1955 to implement Executive Order 12044 and has been classified not significant.

### Introduction

To make it easier for SSI recipients to obtain food stamps, the Congress included a provision in the Food Stamp Act of 1977 requiring the Secretaries of Agriculture and Health, Education and Welfare to develop a procedure by which households in which all members are SSI recipients could apply for food stamps at Social Security Administration (SSA) offices, Section 11(i)(2), Title XIII, Pub. L. 95–113, 91 Stat. 973, September 29, 1977.

The Department published proposed rulemaking on December 7, 1979, encouraging interested parties to comment by February 8, 1980. On December 21, 1979 (44 FR 75648) the Department reduced the comment period to forty-six days ending on January 22, 1980, and also reduced the implementation period originally proposed. The Department took this action in accordance with settlement negotiations in the lawsuit of *The Action Alliance of Senior Citizens, et. al. v. Bergland, et. al. (E. D. Pennsylvania),* which sought the implementation of section 11(i)(2) of the Food Stamp Act of 1977.

During the comment period the Department received 128 letters. Thirty two State Welfare agencies, 40 local welfare agencies, and 43 interest groups commented. In addition to the request for written comments, the Department held a public meeting on January 24, 1980 to receive and discuss comments on the proposed rulemaking. Two representatives of interest groups made formal presentations and a total of six representatives of interest groups took part in a discussion of the proposed rulemaking.

In light of the comments the Department has made significant changes in the regulations. The preamble addresses only those changes actually made from the proposed regulations and those issues of the greatest concern where changes were not made. Because the explanation of many of this rule's provisions is set forth in the proposed rule of December 7, 1979, it may be necessary to refer to that publication for an understanding of the procedures for jointly processing SSI and food stamp applications.

### Processing Options

In its proposed rulemaking of December 7, 1979 (7 CFR Part 273) the Department set forth two options by which SSA and FNS could implement the pertinent sections of the Food Stamp Act of 1977. The first option would apply to households consisting entirely of SSI applicants or recipients (pure SSI households). These households would complete a food stamp application and be interviewed by an SSA employee. The second option would be open to any household containing at least one SSI recipient and, in some cases, applicants for and recipients of benefits under Title II of the Social Security Act (Retirement, Survivors and Disability Insurance [RSDI]). This second option would implement section 11(j), in part. It would allow these households to apply for food stamps by providing for the assignment of an employee of the State agency to the SSA office to receive and process these applications. The Department proposed giving each State agency the authority to choose between the two options for any SSA office, subject to a negotiated agreement with SSA.

Twenty-one commenters generally favored the procedures in the proposed regulations; 16 commenters generally opposed them. Three interest groups recommended the automatic processing of all SSI applicants and recipients while three State agencies and three local agencies opposed the concept of joint application processing.[1] Because the Food Stamp Act requires certification according to prescribed standards and requires some form of joint processing for households in which all members are recipients of SSI, it is not within the authority of the Department to refrain from instituting joint application processing for these households.

As stated above, the Department is offering State agencies two options for processing food stamp applications through SSA offices. The first option gives SSA the authority to accept applications and conduct interviews. The second allows a State agency to retain that authority on the condition that the State agency and SSA agree to the outstationing of a food stamp caseworker at the SSA office. The Department offered State agencies these options in recognition of States' widely varying circumstances regarding staffing, funding and administrative procedures as well as the disparate caseloads from SSA office to office.

There was a clear division of the commenters into three groups. One group favored the use of optional procedures for the reasons stated above. A second group of commenters opposed the involvement of SSA in the certification process, favoring instead mandatory outstationing in all SSA offices. This opposition was based upon the fewer number of people served (pure SSI households only), the inexperience of SSA's employees with the Food Stamp Program and the longer time allowed to provide expedited service.

Contrasting with these positions was that of the third group which favored total processing by SSA. These commenters, chiefly State agencies, did not believe that outstationing was cost effective because of the small caseloads

[1] Whenever "joint processing" appears in these regulations, it refers to both the limited application service which SSA provides to pure SSI households and to the broader certification processing by State agencies' outstationed workers. The joint processing of householdes under this rule is distinct from the joint processing of PA/GA households under paragraph 273.2(j) of the Food Stamp Regulations.

that would be served in many SSA offices. These commenters further objected to option one, which they viewed as divided, rather than joint processing. Their suggestion was to give SSA total responsibility for administering the Food Stamp Program for SSI applicants and recipients, from intake to issuance.

The Department continues to offer the proposed options to the State agencies with some modifications in the belief that only in this way can these added services be implemented without causing a deterioration in service to the food stamp caseload as a whole. Both options provide those services required by the Food Stamp Act of 1977 and, in fact, offer additional services to applicants and recipients. Mandatory outstationing would either significantly increase the Program's administrative costs through a greatly expanded work force or would require a transfer of caseworkers from existing food stamp offices. This would reduce the level of service in those offices. The other suggested alternative, exclusive administration by SSA of the Program for SSI households, does not appear to be contemplated by the language of the statute, nor does it appear to fulfill the intent of Congress, as indicated in the House Report (H.R. Rep. No. 95–464, 95th Cong., 1st Sess., p. 98).

In addition, we are defining SSI as only Federal SSI payments made under title XVI of the Social Security Act, federally administered optional supplementary payments made under section 1616 of that Act, or federally administered mandatory supplementary payments made under section 212(a) of Pub. L. 93–66.

The Department had intended, in the proposed regulations, that the choice between the two processing options be left solely to the State agencies. However, SSA has noted that in a number of its offices there is no space available for the State agencies' use. Therefore, the final regulations make the second option (outstationing) conditional upon the concurrence of SSA. State agencies may choose option one (SSA processing) without SSA's concurrence.

*Applications.* The proposed regulations would have required State agencies choosing option one to use the national food stamp application or an equally concise version of their own forms. State agencies implementing option two (outstationing, referred to as colocation in the proposed rule of December 7, 1979) could use their own FNS approved application forms. The commenters made two principal objections to the proposal. Some commenters criticized the Department for not requiring the use of a simplified affidavit and verification contained in the SSI case file. However, the proposal does not place a cumbersome paperwork burden on the household. Under option one, SSA employees will complete the application for the household using much of the information already obtained during the interview for SSI. This procedure also makes the processing of the food stamp applications independent of SSI's application process which in many cases (such as those involving disability) is a complicated and lengthy one.

Other commenters objected to the limitation placed on State agencies' applications under option one that they not exceed the national food stamp application in length and complexity. Many States use multiprogram or generic applications to determine eligibility for a wide range of benefits and services. These States were reluctant to devise another form which might be confusing to clients and caseworkers alike, and might even be incompatible with their computer systems. Because of these comments the Social Security Administration has agreed to consider the use of any State food stamp application form after the State food stamp agency has obtained approval of the form by FNS. FNS approval assures State designed forms conform to the model food stamp application, with allowable deviations, as approved by the Office of Management and Budget (OMB). A variant State form will be approved by SSA if in the judgement of SSA the form is no more complex than the national form. In the same way, a multipurpose form may be considered by SSA if the form has all relevant food stamp questions clearly delineated from other questions. These food stamp questions must be no more complex than those in the national food stamp application. SSA will complete only those portions of a multipurpose application which are relevant to the food stamp program since joint application processing does not extend to other programs that may be covered by the State form. Since SSA employees and not clients will complete the form, there will be no burden on clients.

The Department and SSA have clarified the use of State agency applications under option one by requiring SSA to approve, deny or comment upon their use within thirty days of their submission to SSA. In accordance with proposed § 272.3(b)(2) of the regulations regarding guidelines (published at 44 FR 65318, November 9, 1979), FNS will approve, deny, or comment upon State agency applications within thirty days of their submittal.

*SSA Jurisdictions Crossing State Lines*

In those SSA offices whose jurisdictions cross State lines, each State agency will be responsible for those applicants and recipients who reside within its boundaries. Therefore, each State agency will have to choose which option it will implement in that particular SSA office subject to the concurrence of SSA. However, State agencies and SSA may agree to cooperative arrangements, such as the sharing of one outstationed caseworker by two State agencies.

**Option One: SSA Processing**

*Entitlement.* The Department limited entitlement under this option to pure SSI households, that is, households in which all members are applicants for, or recipients of SSI, and who are neither certified for food stamps nor have applied for food stamps during the previous thirty days. Joint processing would be available when the households contact SSA for any business. Five commenters favored the limitation to pure SSI households while two favored a broadening of the entitlement to include all households. The Department has retained the proposed entitlement standards for this option in the interests of maintaining a high level of service. Expanding the coverage of these regulations to include mixed and non-SSI households would require the SSA staff to deal with information not covered in SSI determinations.

This expansion could weaken the delivery of services to food stamp and SSI clients alike. The Department has adopted a State agency's suggestion to clarify the standards of entitlement by excluding households who have food stamp applications pending, even beyond the thirtieth day after filing.

*Completing Applications.* The proposed regulations required that SSA forward completed applications to State agencies within one working day. Two State agencies stressed their need for completed applications. One State agency suggested that it be allowed to pend all jointly processed cases until SSA obtained and forwarded all verification. State and local agencies expressed concern that applications would not be complete and that documentation would not explain what work SSA had accomplished on the case. To facilitate the forwarding and completing of food stamp applications,

the final rulemaking requires the use of a transmittal form by SSA. This form will contain references to all verification obtained by the SSA employee. The procedures for the forwarding of the applications are being left to the State agencies and SSA, although they are encouraged to develop a more rapid procedure than the mails, such as a courier service.

The Department and SSA did, however, consider a number of alternatives to the proposed regulations. One alternative was to require SSA to inform applicants of what verification was needed and to obtain it as part of the verification procedure for SSI. A second alternative was to postpone verification for the first month, as is done with expedited service. However, the final regulations give the State agencies sufficient time to obtain all necessary verification, making these alternatives unnecessary. The Department will consider the possibility of conducting a demonstation project in the future to study these alternate procedures for obtaining verification in joint processing.

*Information for Applicants.* A number of commenters stated that many applicants will be unfamiliar with their rights and responsibilities under the food stamp regulations. Others may not know how to obtain and use food coupons. The Department is requiring State agencies to develop and supply for SSA distribution informational materials which will inform applicants of the address and telephone number of their food stamp offices, their right to fair hearings, their responsibility to report changes, which commodities may be purchased with food stamps, and other basic information. Providing this information at the time of application and referring applicants with problems to their food stamp offices will avoid confusion. This requirement will also enhance the delivery of accurate and timely benefits.

*Time limits.* The normal processing time limit of thirty days starts with the filing of the application at SSA. Seventeen State and local agencies opposed this provision, stating that it did not give them enough time to process the applications. Three interest groups and one local government supported the provision.

The Department has retained this proposal in the final rule because of the clients' rights to the timely delivery of benefits under section 11(e)(3) of the Food Stamp Act of 1977. SSA is required to forward the application to the State agency within one working day, leaving about 25 days for the State agency to complete the certification process. This procedure gives food stamp offices as much processing time as they usually would have when they schedule office interviews for other applicants after the filing date, or when they process applications received in the mail.

By contrast the proposed regulations provided that the time limit for expedited service would begin with the receipt of the application by the State agency, rather than at the time of filing at the Social Security Office. Fourteen interest groups and one State agency opposed the provision on the grounds that it delayed the issuance of coupons to households which are destitute or without income. Two State agencies and one local agency supported the provision. The Department is retaining the proposal. Unlike the 30 day processing provision which is required by the Food Stamp Act of 1977 the specific time period for expedited service is set by regulation and not statute. For a State agency to meet an expedited service standard beginning with filing at the SSA office, the State agency may be forced to give coupons on an expedited basis without any documentation of the case whatsoever. For purposes of program accountability it is essential that a State agency at least be in possession of the application form. Furthermore, the final regulations retain the requirement that SSA inform food stamp applicants of the availability of faster service at their food stamp offices. An eligible household's entitlement to coupons begins on the date the applicant submits the application to the SSA office. For expedited service, it is only the expedited processing time limit that begins when the State agency receives the form.

The proposed rulemaking required SSA to prescreen all applicants for possible entitlement to expedited service. Four State agencies opposed this provision as a waste of time, since the propsed regulations also require the State agencies to perform an identical screening. The Department is retaining this provision so as to provide the most rapid service possible to those households entitled to expedited service, and to inform those households of their right to apply immediately at their food stamp offices. A household which chooses to apply for expedited processing in the food stamp office may simply take its application, as it had been completed at SSA, to the food stamp office. There the State agency will process the application, including screening for expedited processing.

*Telephone Applications.* SSA allows SSI applicants to provide information over the telephone. The proposed regulations required SSA to take food stamp applications from pure SSI households over the telephone and send the forms to the applicants for signature. Applicants would then return the forms to SSA, which would forward them to the State agency. Three commenters opposed the use of telephone interviews and one suggested that such households be referred to their local food stamp offices. However, the Department is concerned that simply referring these households to food stamp offices would not comply with the intent of the Congress, which was to allow SSI households to apply for food stamps through SSA offices. Therefore, clients living in pure SSI households who apply for SSI by telephone will be entitled to apply for food stamps by telephone as well. However, the applicant will be given the option of sending the food stamp application directly to the local food stamp office or to SSA. If the applicant chooses the latter, SSA will forward it to the State agency.

*Work Registration.* The Department proposed that work registration would be conducted by state agencies. Seven commenters wanted work registration to be done in the SSA office, where the interviewing official could most efficiently determine the applicant's fitness for work. Four commenters suggested that disability be presumed for those applicants not exempt because of age. One commenter suggested that the SSI and food stamp definitions of disability be made identical. The Department has changed the proposed provision in order to temporarily waive the requirement for work registration. One half of all applicants for SSI benefits based on disability are eventually found by SSA to be disabled. Of the remainder, many are not disabled according to the SSI program's criteria of long-term, severely debilitating illness or injury, but may be unable to work at the time of application. In the event of a denial of SSI eligibility, such households would have their work registration status reexamined when applying for continued food stamp benefits.

*Bilingual requirements.* Three state agencies and thirteen interest groups opposed the provision in the proposed regulations which exempted SSA from the Food Stamp Program's bilingual requirement. At this time, SSA is preparing to conduct a survey of its clients' bilingual needs. The bilingual standards which SSA will ultimately devise will be based upon the needs indicated as a result of this survey for both the SSI and RSDI programs, and not simply the particular segment to

which this rulemaking applies. For this reason, the Department and SSA have not adopted the Food Stamp Program's bilingual standards for use in joint application processing.

**Option Two: State Agency Processing**

*Entitlement.* There are two distinct services to which food stamp clients are entitled under this option.

In the proposed rulemaking the Department extended entitlement to joint application processing to mixed SSI households (those containing at least one SSI applicant/recipient and others) and to pure and mixed Title II households (those containing at least one applicant/recipient of Retirement, Survivors and Disability Insurance) under limited circumstances. Under this final rulemaking SSA may approve the joint processing of pure and mixed Title II households when it will enhance the efficiency of both food stamp and SSA program operations. These Title II and Title XVI households entitled to joint application processing shall be allowed to apply and be interviewed for food stamps at SSA offices using this option. The filing dates of such a household's application will be the date it is submitted to an outstationed food stamp worker.

A separate issue is the matter of inquiring about the Food Stamp Program. Section 11(e)(2) of the Food Stamp Act of 1977 guarantees to all households the right to apply for the program upon demand (H.R. Rep. No. 95–464, 95th Cong., 1st sess., page 269). This includes the right to obtain a food stamp application.

Therefore, this final rule requires all State agency outstationed workers to distribute food stamp applications to all persons requesting them. Further, outstationed workers must accept food stamp applications from any applicants. If a household which is not entitled to joint application processing submits a food stamp application to an outstationed worker, that worker will forward the application to the client's correct food stamp office on the same day. For those non-jointly processed households, the time limits for processing their applications will begin when they are received at the correct food stamp offices.

*Time limits.* The time limits for both normal and expedited service processing begin when an applicant submits an application to an outstationed worker. This provision appears in the Preamble to the proposed regulations but not in the text itself. The Department has changed the text to clarify this policy.

*Part-time outstationing.* Where outstationing is in effect the proposed regulations required an outstationed worker during an SSA office's entire operating hours. Some commenters supported part-time outstationing because it would be cost effective for them. The Department will not allow a mixture of outstationing and SSA processing. Because outstationing provides joint application processing to more people than does SSA processing, a mixture of the two could seriously confuse and inconvenience applicants, caseworkers and claims representatives.

However, subject to the agreement of SSA and the State agency, a State agency may outstation caseworkers only when applicants will actually be referred to them. For example, some offices may refer clients to the food stamp worker from mid-morning to the end of the day only. The outstationed worker need only be in the SSA office during these hours. This provision may make outstationing cost effective without causing a deterioration in services.

So that applicants will not be delayed in applying for food stamps, the Department is requiring State agencies to adopt procedures to minimize the time between the SSI and food stamp interviews. While the food stamp interview need not follow immediately, it is intended that the joint application process be a continuous one.

*Eligibility determinations.* Eight interest groups and one member of the public recommended that the Department require outstationed caseworkers to make eligibility determinations during the interview. The Department had decided not to incorporate this requirement for the following reasons. An immediate determination is not practical if further verification is necessary to arrive at a final determination. An example would be a household claiming utilities exceeding the utility standard; immediate certification using the standard could be detrimental to the household. Neither the Food Stamp Act of 1977 nor current regulations require an immediate determination for any households. It is also not reasonable to require such a determination if it would delay interviews for others wishing to apply. Since most eligibility determinations are based upon certain pre-interview, interview, and post-interview casework functions, to have taken the approach suggested would disrupt many reliable methods of guaranteeing quality casework as well as client service.

**Verification**

The proposed regulations discussed the use of the State Data Exchange (SDX) in verifying a household's circumstances, but omitted the use of the Beneficiary Data Exchange (BENDEX). On January 7, 1980, routine user status for BENDEX was given to the Food Stamp Program by the Social Security Administration. The Department discussed this change in its final rulemaking dated January 31, 1980, 45 FR 7208 (also republished on February 1, 1980, 45 FR 7229), regarding the provision of Social Security Numbers. This final rulemaking includes verification of social security numbers through BENDEX. BENDEX also contains information on the wages earned by SSA's claimants. These claimants are protected by the Tax Reform Act, which restricts the use of wage information. Because the Food Stamp Program now lacks the authority to use this part of the system, wages may not be verified through BENDEX.

The proposed rules provided for the verification of an applicant's initial SSI payment by a bimonthly check through SDX data. Nineteen commenters opposed the provision and four approved it. Those opposed found it to be burdensome, often unreliable and less efficient than having SSA notify the State agency. As a result this requirement is deleted from the regulations. As part of the SSA-State agency joint food stamp processing agreement, States may negotiate, on behalf of project areas, to have SSA provide initial eligibility and payment data where the local area is unable to access accurate and timely data through the State's SDX. However, SSA may challenge a State's determination that it does not have the computer capability to use SDX data. If SSA, FNS, and the State are unable to resolve this matter, and SSA determines that a State does have the capability to provide accurate and timely SDX data to the food stamp project area, SSA is not required to provide alternate means of transmitting initial SSI eligibility and payment data. In any event, State agencies are encouraged to periodically check SDX and BENDEX for SSI determinations. SSA will work with State agencies to improve the use of SDX and BENDEX.

The proposed regulations permitted State agencies to contact applicants by telephone to clarify information contained on their application. Some commenters stated that such a contact could be viewed as a second interview. In permitting State agencies to contact applicants who have already been interviewed by SSA, the Department is

not permitting a second interview. The proposed and final regulations restrict further contact to cover only improperly completed applications, missing mandatory verfication and specific questionable information.

**Recertifications**

The proposed regulations required State agencies to recertify jointly processed households like all other households through the local food stamp office. The only special provision originally proposed was that the recertification could be accomplished by mail, without an office interview. At the January 24, 1980 public meeting there was strong opposition to requiring recertifications through the local food stamp offices. The commenters feared that the jointly processed households would be lost to the Program if they were transferred to the welfare agencies.

Recertification through the joint application process is difficult to implement because SSI and food stamps have different procedures for determining continuing eligibility. Food stamp eligibility automatically terminates with the expiration of the food stamp certification period which, by law, may not exceed one year (Section 3(c) of the Food Stamp Act of 1977). SSI eligibility does not expire within a fixed time period; the redetermination is not performed according to the schedule for food stamp recertifications. SSA also relies increasingly upon redeterminations by mail, without interviews. It is not practical at this time to restructure the SSI procedure to effect only a portion of its recipients. Because the State agency will keep the household's case record, SSA would not be able to use it as a reference during a food stamp recertification interview.

Under option one or option two the final rule allows a jointly processed household to file for recertification through an SSA office where it is otherwise entitled to joint processing, under the following conditions: The household has received a notice of expiration for food stamps; A household member goes to an SSA office for an SSI redetermination interview; and The interview occurs within the period for making a timely application for continued food stamp benefits.

Under option one SSA will accept a recipient's application, complete a transmittal form and forward them to the State agency. The State agency would then process the application. Under option two the outstationed worker will accept the application, interview the recipient and process the application. Under both option one and option two, recipients will receive uninterrupted benefits.

Under these final regulations, recipients still retain their right to apply for continued benefits through their food stamp offices. If they do so, they may be entitled to out-of-office interviews according to § 273.2(e)(2). The regulations do not prohibit State agencies from certifying SSI households by other means, such as the procedures for recertifying by mail currently used by the New York Department of Social Services.

**Reporting Changes**

The proposed regulations did not provide for the reporting of changes through the joint application process. Five commenters requested that reporting changes through Social Security offices be allowed. Because of budgetary restrictions and the absence of statutory requirements that this service be provided, the Department has not adopted this suggestion. Households who apply under the provisions of this rule are subject to the reporting requirements of § 273.12.

**Other Provisions**

*Certification Periods.* The comments indicated widespread misunderstanding of the proposed rulemaking's provision on certification periods. Under joint processing eligible households were to be certified for a period of up to 12 months. A State agency could assign a certification period to coincide with adjustments to the SSI benefit amount. By using the phrase "up to 12 months" the Department allowed households to receive certification periods appropriate to their circumstances, from one month to twelve. Thirteen commenters favored 12 month periods for all jointly processed households, six supported different periods for different households, and eleven supported certification periods coinciding with SSI.

The Department continues to require certification periods of different lengths because of the wide variety of households entitled to joint application processing. These include pure and mixed SSI households, and, in some cases, pure and mixed Title II households. These households have varying degrees of stability in terms of their composition and income. One single certification period would not necessarily provide all households with appropriate service, nor would it necessarily enhance the integrity of the Program. However, State agencies will assign to jointly processed households the longest suitable certification period, in order to give clients greater convenience and reduce administrative costs.

This approach is reinforced by a change in the rules requiring the use of a notice of expiration in those cases denied SSI benefits, where the State agency believes that the factors resulting in the SSI denial may also affect food stamp eligibility or benefit levels. The change would require the termination of eligibility the month following the month the notice is sent. The household would, however, receive sufficient prior notification so as not to suffer an interruption in benefits if otherwise eligible. This change is very similar to the approach used for Public Assistance households.

*Implementation.* The proposed rulemaking allowed 120 days for implementation. As noted above, the implementation period was reduced to the first day of the month following the ninetieth day after publication of the rule. Three commenters favored the reduced period, while six supported the longer period. However, in light of consent order agreed to in *Action Alliance,* the Department is requiring State agencies to implement this final rulemaking on the first day of the month following the ninetieth day after publication of the rule, or August 1, 1980. Implementation will occur in all project areas on the same day to ensure national uniformity.

At the time of publication, there are three "cash-out States," that is, States in which SSI recipients are not eligible for food stamps because their SSI benefits are increased to include food stamp benefits. The final rulemaking adds a provision for such states if their cash-out status terminates. Former cash-out states must implement this rulemaking no later than the first day of the month after the ninetieth day after the Secretary of Health, Education, and Welfare determines that the State no longer qualifies for cash-out. This will give the State agency, SSA and FNS sufficient time to effectively implement joint application processing, including negotiating an agreement between the State agency and SSA, training personnel, distributing forms and notifying the public.

Designated food stamp project areas will shortly begin to participate in the SSI/Elderly Cash-out Demonstration Project, and as such will be exempt from joint processing requirements pursuant to Section 17(b)(1) of the Food Stamp Act of 1977. Of these, some will participate as demonstration sites, providing cash to SSI/Elderly households instead of food coupons to test the effect of cash benefits on participation by target households.

Other project areas will serve as comparison sites, continuing to providing coupons to SSI/Elderly households without offering joint processing. Comparison sites have been temporarily exempted from the joint processing procedures during the demonstration. Use of comparison sites will also permit FNS and SSA to compensate for external variables, such as inflation, which, like joint processing, may influence the level of participation by target households.

Both demonstration and comparison sites are being exempted from implementation of the joint processing regulations until the first day of the month following the ninetieth day after the demonstration project ends. It has been determined, pursuant to Section 17(B)(1) of the Act, that waiver of the joint processing requirement in these limited circumstances is necessary for the Cash-out Demonstration Project to be conducted.

The exclusion of joint processing in selected demonstration and comparison sites is also reflective of the needs of the Social Security office service areas involved in the demonstration. The exclusion of joint processing at these sites will relieve them of the potential confusion that would result if both the joint processing and demonstration project regulations were in effect at the same time in the same office. On this point, it is important to note that some Social Security office service areas encompass more than designated demonstration and comparison sites because of their geographic boundaries. The Secretary has determined that those portions of food stamp project areas which are not demonstration or comparison sites but which are located within SSA office service areas which contain demonstration or comparison sites, will also be exempt from the joint processing regulations. The application of joint processing in these project areas would require the SSA office to distinguish between excluded and joint processing households and, again, to apply both sets of regulations simultaneously. This could lead to delays and potential errors in service which would jeopardize the study and result in poor service to the food stamp population.

*Training.* The training of State agency personnel in the procedures of SSI-food stamp joint processing is the responsibility of the State agency. The Social Security Administration will train its own employees. It is expected that State agencies and SSA will cooperate informally, to work out methods to exchange information and expertise. This informal cooperation may take the form of orientation visits to SSA and State agency offices and participation in joint training sessions.

*Outreach.* The basic outreach function for this rulemaking is carried out by SSA when it offers joint application processing to households applying for SSI in person or by telephone. In addition, SSA will include in its mail-redetermination package a stuffer referring those clients to their food stamp office or, in the case of pure SSI households, advising them that they may apply for food stamps at either their SSA office or food stamp office. The stuffer will also inform clients of their right to an out-of-office certification interview.

To prepare for the implementation of these regulations, State agencies are required to publicize this new service through press releases, informational posters and brochures. FNS will issue model language for outreach materials.

*Quality Control.* As stated in the Preamble to the December 7, 1979 proposed rulemaking, any incorrect information obtained through SSA's processing of applications will not be included in the determination of a State agency's coupon allotment error rate. The Department will publish a regulatory amendment to this effect to be implemented on August 1, 1980.

*Administrative Costs.* All of the administrative costs to the SSA for performing these food stamp functions will be reimbursed by USDA.

*Restoration of Lost Benefits.* It is possible that through joint processing some households will lose benefits to which they are entitled. As an example this could be due to the loss of applications between SSA and the State agencies. The Department has included in the final rule a provision which extends entitlement to lost benefits to these households.

Therefore, Parts 272 and 273 are amended as follows:

## PART 272—REQUIREMENTS FOR PARTICIPATING STATE AGENCIES

1. New subparagraph (17) is added to paragraph 272.1(g) to read as follows:

**§ 272.1 General terms and conditions.**

* * * * *

(g) *Implementation.* * * *

(17) *Amendment 158.* (i) The procedures contained in Part 273 regarding SSI food stamp joint application processing shall become effective on August 1, 1980 for all State agencies except that:

(A) In those areas designated as SSI/Elderly Cash-out Demonstration Project Sites or Demonstration Project Comparison Sites, implementation of these provisions will be delayed. In addition, Social Security office service areas which contain either demonstration projects sites or demonstration comparison sites will be temporarily exempted, in their entirety, from implementation of these provisions whether or not their boundaries are co-terminous with demonstration project sites and/or demonstration comparison site boundaries. This temporary exemption removes the administrative problem of the same SSA office simultaneously operating under both joint processing and cash-out regulations. The procedures contained in this rulemaking shall become effective for these project areas on the first day of the month following the ninetieth day after the termination of the demonstration project.

(B) State agencies in SSI cash-out States as defined in § 273.20 shall not implement the provisions of this rulemaking. In the event an SSI cash-out State loses that status, the State agency shall implement the provisions of this rulemaking on the first day of the month following the ninetieth day after the Secretary of Health, Education, and Welfare determines that the State no longer qualifies for cash-out status.

(ii) State agencies shall distribute fliers advising of the changes contained in this amendment to public and general assistance offices, local Social Security offices, any interested organizations, particularly those dealing with the elderly or disabled, and those places where the elderly or disabled congregate, such as housing units senior citizens centers, and elderly feeding programs. Also, posters explaining the changes shall be displayed in food stamp certification offices and shall be made available to public and general assistance offices, local Social Security offices and any other interested groups. State agencies shall notify all organizations on their outreach contact lists of the changes and of the availability of posters and fliers. State agencies shall issue press releases to the news media advising of the impending program changes. FNS will supply State agencies with model language describing the changes which State agencies may use in their publications.

* * * * *

## PART 273—CERTIFICATION OF ELIGIBLE HOUSEHOLDS

2. In § 273.2, a sentence is added to § 273.2(f) (5)(ii), a new subparagraph (8) is added to § 273.2(f) and a new subparagraph (k), previously reserved, is

added to § 273.2. These changes read as follows:

**§ 273.2 Application processing.**

* * * * *

(f) *Verification.* * * *

(5) *Responsibility for obtaining verification.* * * *

(ii) * * * The State agency shall not require the household to personally present verification at a food stamp office.

* * * * *

(8) *State Data Exchange (SDX) and Beneficiary Data Exchange (BENDEX).* The State agency shall have the option of verifying SSI benefit payments through the State Data Exchange (SDX) and the Beneficiary Data Exchange (BENDEX), but only to the extent permitted by data exchange agreements, or through verification provided by the household. The State agency shall not verify wages through BENDEX. The State agency may use SDX and BENDEX data to verify other food stamp eligibility criteria provided the household is given an opportunity to verify the information from another source if the SDX or BENDEX information is contradictory to the household's information or is unavailable. However, determination of a household's eligibility and benefit level shall not be delayed past the application processing time standards of § 273.2(g) if the SDX or BENDEX data are unavailable. The State agency may access SDX and BENDEX data without a release statement from the household provided the State agency makes the appropriate data request to SSA or executes any SDX or BENDEX data exchange agreements required by the SSA. The State agency may access SDX and BENDEX on a need-to-know basis.

* * * * *

(k) *SSI households.* For purposes of this paragraph, SSI is defined as Federal SSI payments made under Title XVI of the Social Security Act, federally administered optional supplementary payments under section 1616 of that Act, or federally administered mandatory supplementary payments made under § 212(a) of Pub. L. 93–66. Except in cash-out States (§ 273.20), households not participating in the Food Stamp Program, which have not applied for food stamps in the thirty preceeding days, and which do not have applications pending, shall apply and be certified for food stamp benefits in accordance with the procedures described in § 273.2(k)(1)(i) or § 273.2(k)(1)(ii) and with the notice, procedural and timeliness requirements of the Food Stamp Act of 1977 and its implementing regulations. These households' food stamp eligibility and benefit levels shall be based solely on food stamp eligibility criteria. The State agency shall make an eligibility determination based on information provided by SSA or by the household.

(1) *Initial application and eligibility determination.* At each SSA office, the State agency shall either arrange for SSA to complete and forward food stamp applications, or the State agency shall outstation State food stamp eligibility workers at the SSA Offices with SSA's concurrence, based upon an agreement negotiated between the State agency and the SSA.

(i) If the State agency arranges with the SSA to complete and forward food stamp applications the following actions shall be taken:

(A) Whenever a member of a household consisting only of SSI applicants or recipients transacts business at an SSA office, the SSA shall inform the household of:

(*1*) Its right to apply for food stamps at the SSA office without going to the food stamp office; and

(*2*) Its right to apply at a food stamp office if it chooses to do so.

(B) The SSA will accept and complete food stamp applications received at the SSA Office from SSI households and forward them, within one working day after receipt of a signed application, to a designated office of the State agency. SSA shall also forward to the State agency a transmittal form which will be approved by SSA and FNS. The SSA will use the national food stamp application form for joint processing. State agencies may substitute a State food stamp application, provided that prior approval is received from both FNS and SSA. SSA shall approve, deny, or comment upon FNS approved State food stamp applications within thirty days of their submission to SSA.

(C) SSA will accept and complete food stamp applications from SSI households received by SSA staff in contact stations. SSA will forward all food stamp applications from SSI households to the designated food stamp office.

(D) The State agency shall designate an address for the SSA to forward food stamp applications and accompanying information to the State agency for eligibility determination. Applications and accompanying information must be forwarded to the agreed upon address in accordance with the time standards contained in § 273.2(k)(1)(i)(B).

(E) The State agency shall make an eligibility determination and issue food stamp benefits to eligible SSI households within 30 days following the date the application was received by the SSA. Applications shall be considered filed for normal processing purposes when the signed application is received by SSA. The expedited processing time standards shall begin on the date the State agency receives a food stamp application. Food stamp applications and supporting documentation sent to an incorrect food stamp office shall be sent to the correct office, by the State agency, within one working day of their receipt in accordance with § 273.2(c)(2)(ii).

(F) Households in which all members are applying for or participating in SSI will not be required to see a State eligibility worker, or otherwise be subjected to an additional State interview. The food stamp application will be processed by the State agency. The State agency shall not contact the household further in order to obtain information for certification for food stamp benefits unless: the application is improperly completed; mandatory verification required by § 273.2(f)(1) is missing; or, the State agency determines that certain information on the application is questionable. In no event would the applicant be required to appear at the food stamp office to finalize the eligibility determination. Further contact made in accordance with this subparagraph shall not constitute a second food stamp certification interview.

(G) The SSA shall refer non-SSI households and those in which not all members have applied for or receive SSI to the correct food stamp office. The State agencies shall process those applications in accordance with the procedures noted in § 273.2. Applications from such households shall be considered filed on the date the signed application is taken at the correct State agency office, and the normal and expedited processing time standards shall begin on that date.

(H) The SSA shall prescreen all applications for entitlement to expedited services on the day the application is received at the SSA office and shall mark "Expedited Processing" on the first page of all households' applications that appear to be entitled to such processing. The SSA will inform households which appear to meet the criteria for expedited service that benfits may be isued a few days sooner if the household applies directly at the food stamp office. The household may take the application from SSA to the food stamp office for screening, an interview, and processing of the application.

(I) The State agency shall prescreen all applications received from the SSA for entitlement to expedited service on

the day the application is received at the correct food stamp office. All SSI households entitled to expedited service shall be certified in accordance with § 273.2(i) except that the expedited processing time standard shall begin on the date the application is recieved at the correct State agency office.

(J) The State agency shall develop and implement a method to determine if members of SSI households whose applications are forwarded by the SSA are already participating in the Food Stamp Program directly through the State agency.

(K) If SSA takes an SSI application or redetermination on the telephone from a member of a pure SSI household, a food stamp application shall also be completed during the telephone interview. In these cases, the food stamp application shall be mailed to the claimant for signature for return to the SSA office or to the State agency. SSA shall then forward any food stamp applications it receives to the State agency. The State agency may not require the household to be interviewed again in the food stamp office. The State agency shall not contact the household further in order to obtain information for certification for food stamp benefits except in accordance with § 273.2(k)(1)(i)(F).

(L) To SSI recipients redetermined for SSI by mail, the SSA shall send a stuffer informing them of their right to file a food stamp application at the SSA office (if they are members of a pure SSI household) or at their local food stamp office, and their right to an out-of-office food stamp interview to be performed by the State agency if the household is unable to appoint an authorized representative.

(M) Section 272.4 bilingual requirements shall not apply to the Social Security Administration.

(N) State agencies shall provide and SSA shall distribute an information sheet or brochure to all households processed under this subparagraph. This material shall inform the household of the following: the address and telephone number of the household's correct food stamp office, the remaining actions to be taken in the application process, and a statement that a household should be notified of the food stamp determinations within thirty days and can contact the food stamp office if it receives no notification within thirty days, or has other questions or problems. It shall also include the client's rights and responsibilities (including fair hearings, authorized representatives, out-of-office interviews, reporting changes and timely reapplication), information on how and where to obtain coupons, and how to use coupons (including the commodities clients may purchase with coupons).

(O) As part of the SSA-State agency joint food stamp processing agreement, States may negotiate, on behalf of project areas, to have SSA provide initial eligibility and payment data where the local area is unable to access accurate and timely data through the State's SDX. However, in negotiating such agreements, SSA may challenge a State's determination that it does not have the computer capability to use SDX data. If SSA, FNS, and the State are unable to resolve this matter, and SSA determines that a State does have the capability to provide accurate and timely SDX data to the food stamp project area, SSA is not required to provide alternate means of transmitting initial SSI eligibility and payment data.

(ii) If the State agency chooses to outstation eligibility workers at SSA offices, with SSA's concurrence, the following actions shall be completed.

(A) SSA will provide adequate space for State food stamp eligibility workers in SSA offices.

(B) The State agency shall have at least one outstationed worker on duty at all time periods during which households will be referred for food stamp application processing. In most cases this would require the availability of an outstationed worker throughout normal SSA business hours.

(C) The following households shall be entitled to file food stamp applications with, and be interviewed by an outstationed eligibility worker:

(*1*) Households containing an applicant for or recipient of SSI;

(*2*) Households which do not have an applicant for or recipient of SSI, but which contain an applicant for or recipient of benefits under Title II of the Social Security Act, if the State agency and SSA have an agreement to allow the processing of such households at SSA offices.

(D) Households shall be interviewed for food stamps on the day of application unless there is insufficient time to conduct an interview. The State agency shall arrange for the outstationed worker to interview applicants as soon as possible.

(E) The State agency shall not refuse to provide service to persons served by the SSA office because they do not reside in the county or project area in which the SSA office is located, provided, however, that they reside within the jurisdictions served by the SSA office and the State agency. The State agency is not required to process the applications of persons who are not residing within the SSA office jurisdiction but who do reside within the State agency's jurisdiction, other than to forward the forms to the correct food stamp offices.

(F) The State agency may permit the eligibility worker outstationed at the SSA to determine the eligibility of households, or may require that completed applications be forwarded elsewhere for the eligibility determination.

(G) Applications from households entitled to joint processing through an outstationed eligibility worker shall be considered filed on the date they are submitted to that worker. Both the normal and expedited service time standards shall begin on that date.

(H) Households not entitled to joint processing shall be entitled to obtain and submit applications at the SSA office. The outstationed eligibility worker need not process these applications except to forward them to the correct food stamp office where they shall be considered filed upon receipt (any activities beyond acceptance and referral of the application would require SSA concurrence). Both the normal and expedited service time standards shall begin on that date.

(iii) Regardless of whether the State agency or SSA conducts the food stamp interview, the following actions shall be taken:

(A) *Verification.* (*1*) The State agency shall ensure that information required by § 273.2(f) is verified prior to certification for households initially applying. Households entitled to expedited certification services shall be processed in accordance with § 273.2(i).

(*2*) The State agency has the option of verifying SSI benefit payments through the State Data Exchange (SDX), the Beneficiary Data Exchange (BENDEX) and/or through verification provided by the household.

(*3*) The State agency may verify other information through SDX and BENDEX but only to the extent permitted by data exchange agreements with SSA. The State agency may not verify wage information through BENDEX.

Information verified through SDX or BENDEX shall not be reverified unless it is questionable. Households shall be given the opportunity to provide verification from another source if all necessary information is not available on the SDX or the BENDEX, or if the SDX/BENDEX information is contradictory to other household information.

(B) *Certification period.* (*1*) State agencies shall certify households under these procedures for up to twelve months, according to the standards in § 273.10(f), except for State agencies

which must assign the initial certification period to coincide with adjustments to the SSI benefit amount as designated in § 273.10(f)(3)(iv).

(*2*) In cases jointly processed in which the SSI determination results in denial, and the State agency believes that food stamp eligibility or benefit levels may be affected, the State agency shall send the household a notice of expiration advising that the certification period will expire the end of the month following the month in which the notice is sent and that it must reapply if it wishes to continue to participate. The notice shall also explain that its certification period is expiring because of changes in circumstances which may affect food stamp eligibility or benefit levels and that the household may be entitled to an out-of-office interview, in accordance with § 273.2(e)(2).

(C) *Changes in Circumstances.* (*1*) Households shall report changes in accordance with the requirements in § 273.12. The State agency shall process changes in accordance with § 273.12.

(*2*) Within ten days of learning of the determination of the application for SSI through SDX, the household, advisement from SSA where SSA agrees to do so for households processed under § 273.2(k)(1)(i), or from any other source, the State agency shall take required action in accordance with § 273.12. State agencies are encouraged to monitor the results of the SSI determination through SDX and BENDEX to the extent practical.

(*3*) The State agency shall process adjustments to SSI cases resulting from mass changes, in accordance with provisions of § 273.12(e).

(D) *SSI households applying at the food stamp office.* The State agency shall allow SSI households to submit food stamp applications to local food stamp offices rather than through the SSA if the household chooses. In such cases all verification, including that pertaining to SSI program benefits, shall be provided by the household, by SDX or BENDEX, or obtained by the State agency rather than being provided by the SSA.

(E) *Restoration of Lost Benefits.* The State agency shall restore to the household benefits which were lost whenever the loss was caused by an error by the State agency or by the Social Security Administration through joint processing. Such an error shall include, but not be limited to, the loss of an applicant's food stamp application after it has been filed with SSA or with a State agency's outstationed worker. Lost benefits shall be restored in accordance with § 273.17.

(2) *Recertification.* (i) The State agency shall complete the application process and approve or deny timely applications for recertification in accordance with § 273.14 of the food stamp regulations. A face-to-face interview shall be waived if requested by a household consisting entirely of SSI participants unable to appoint an authorized representative. The State agency shall provide SSI households with a notice of expiration in accordance with § 273.14(b), except that such notification shall inform households consisting entirely of SSI recipients that they are entitled to a waiver of a face-to-face interview if the household is unable to appoint an authorized representative.

(ii) Jointly processed households which have received a food stamp notice of expiration and go to an SSA office for an SSI redetermination shall be entitled to make a timely application for food stamp recertification at the SSA office.

(A) In SSA offices where § 273.2(k)(1)(i) is in effect, SSA shall accept the application of a pure SSI household and forward the completed application, transmittal form and any available verification to the designated food stamp office. Where SSA accepts and refers the application in such situations, the household shall not be required to appear at a second office interview, although the State agency may conduct an out-of-office interview, if necessary.

(B) In SSA offices where § 273.2(k)(1)(ii) is in effect, the outstationed worker shall accept the application and interview the recipient and the State agency shall process the application according to § 273.14.

* * * * *

3. New paragraph (l) is added to § 273.7 to read as follows:

**§ 273.7 Work registration requirements.**

* * * * *

(l) Household members who are applying for SSI and for food stamps under § 273.2(k)(1)(i) shall have the requirement for work registration waived until:

(1) They are determined eligible for SSI and thereby become exempt from work registration, or

(2) They are determined ineligible for SSI and where applicable, a determination of their work registration status is then made through recertification procedures in accordance with § 273.2(k)(1)(iii)(B)(*2*), or through other means.

* * * * *

**Note.**—No new reporting and/or record keeping requirements are anticipated in this amendment which require the forwarding of forms to the Office of Management and Budget for approval in accordance with the Federal Reports Act of 1942.

**Authority:** 91 Stat. 958 (7 U.S.C. 2011–2027).

(Catalog of Federal Domestic Assistance Programs No. 10551, Food Stamp)

Dated: April 18, 1980.

**Carol Tucker Foreman,**

*Assistant Secretary for Food and Consumer Services.*

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This is a voluntary program. (See OFR NOTICE FR 32914, August 6, 1976.)

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Documents normally scheduled for publication on a day that will be a Federal holiday will be published the next work day following the holiday.

Comments on this program are still invited. Comments should be submitted to the Day-of-the-Week Program Coordinator, Office of the Federal Register, National Archives and Records Service, General Services Administration, Washington, D.C. 20408

## REMINDERS

The items in this list were editorially compiled as an aid to **Federal Register** users. Inclusion or exclusion from this list has no legal significance. Since this list is intended as a reminder, it does not include effective dates that occur within 14 days of publication.

### Rules Going Into Effect Today

Note: There were no items eligible for inclusion in the list of **Rules Going Into Effect Today.**

### List of Public Laws

Note: No public bills which have become law were received by the Office of the Federal Register for inclusion in today's **List of Public Laws.**

**Last Listing April 16, 1980**

*Advance Orders are now Being Accepted for Delivery in About 6 Weeks*

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