recent changes in the field organization of the Customs Service. The Fairport Harbor, Ohio, Customs station has been placed under the supervision of the port of Ashtabula/Conneaut, Ohio, and the Lorain, Ohio, Customs station has been placed under the supervision of the port of Sandusky, Ohio. Both stations previously were under the supervision of the port of Cleveland, Ohio. These changes have been made to provide better Customs Service to importers, carriers, and the public.

EFFECTIVE DATE: May 2, 1978.

FOR FURTHER INFORMATION CONTACT:

Robert Schenarts, Inspection and Control Division, U.S. Customs Service, 1301 Constitution Avenue NE., Washington, D.C., 20229, 202-566-8151.

SUPPLEMENTARY INFORMATION:

BACKGROUND

As part of a continuing program to obtain more efficient use of its personnel, facilities, and resources, and to provide better service to importers, carriers, and the public, the Customs Service has placed the Fairport Harbor, Ohio, Customs station under the supervision of the port of Ashtabula/Conneaut, Ohio, and the Lorain, Ohio, Customs station under the supervision of the port of Sandusky, Ohio. Both stations previously were under the supervision of the Customs port of Cleveland, Ohio.

To reflect these changes and to correct the listing for Fairport, Ohio, to its proper name of Fairport Harbor, Ohio, it is necessary to amend § 101.4(c) of the Customs Regulations (19 CFR 101.4(c)), which lists Customs stations and the ports of entry having supervision over these stations.

Because these amendments relate only to matters of agency organization and administration and do not impose any affirmative duty on the public, notice and public procedure thereon are unnecessary, and good cause exists for dispensing with a delayed effective date under 5 U.S.C. 553.

DRAFTING INFORMATION

The principal author of these amendments was Teresa M. Polino, Regulaltions and Legal Publications Division, Office of Regulations and Rulings, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

AMENDMENTS TO THE REGULATIONS

Section 101.4(c) of the Customs Regulations (19 CFR 101.4(c)) is amended by making the following changes:

1. "Fairport, Ohio ——" is corrected to read "Fairport Harbor, Ohio ——" in the column headed "Customs stations" opposite the reference to "Cleveland, Ohio" in the column headed "District". "Ashtabula/Conneaut." is substituted for "Cleveland." in the column headed "Port of entry having supervision" opposite the corrected reference to "Fairport Harbor, Ohio ——" in the column headed "Customs stations".

2. "Sandusky." is substituted for "Cleveland." in the column headed "Port of entry having supervision" opposite the reference to "Lorain, Ohio ——" in the column headed "Customs stations".

(Sec. 1, 37 Stat. 434, section 301, 80 Stat. 379; (5 U.S.C. 301, 19 U.S.C. 1).)

G. R. DICKERSON,
Acting Commissioner of Customs.

Approved: April 19, 1978.

BETTE B. ANDERSON,
Under Secretary of the Treasury.

[FR Doc. 78-11897 Filed 5-1-78; 8:45 am]

[4810-22]

[T.D. 78-124]

PART 159—LIQUIDATION OF DUTIES

Waiver of Countervailing Duties—Handbags From Colombia

AGENCY: Department of the Treasury, Customs Service.

ACTION: Waiver of countervailing duties.

SUMMARY: This notice is to inform the public that a determination has been made to waive countervailing duties that would otherwise be required by section 303 of the Tariff Act of 1930 on imports of leather handbags from Colombia. The waiver is being issued based on actions by the Colombian handbag exporters to phase out the effective export subsidy on these items. The waiver will expire on January 4, 1979 unless revoked earlier.

EFFECTIVE DATE: May 2, 1978.

FOR FURTHER INFORMATION CONTACT:

Richard B. Self, Director, Office of Tariff Affairs, U.S. Treasury Department, 15th and Pennsylvania Avenue NW., Washington, D.C., 202-566-8585.

SUPPLEMENTARY INFORMATION: In T.D. 78-125, published concurrently with this determination, it has been determined that bounties or grants within the meaning of section 303 of the Tariff Act of 1930, as amended (19 U.S.C. 1303), are being paid or bestowed directly or indirectly upon the manufacture, production, or exportation of handbags from Colombia.

Section 303(d) of the Tariff Act of 1930, as amended by the Trade Act of 1974 (Pub. L. 93-618, January 3, 1975), authorizes the Secretary of the Treasury to waive the imposition of countervailing duties during the 4-year period beginning on the date of enactment of the Trade Act of 1974 if he determines that:

(1) Adequate steps have been taken to reduce substantially or eliminate during such period the adverse effect of a bounty or grant which he has determined is being paid or bestowed with respect to any article or merchandise;

(2) There is a reasonable prospect that under section 102 of the Trade Act of 1974, successful trade agreements will be entered into with foreign countries or instrumentalities providing for the reduction or elimination of barriers to or other distortions of international trade; and

(3) The imposition of the additional duty under this section with respect to such article or merchandise would be likely to seriously jeopardize the satisfactory completion of such negotiations.

Based upon analysis of all the relevant factors and after consultations with interested agencies and parties with direct interest in this proceeding, I have concluded that steps have been taken to reduce substantially the adverse effects of the bounty or grant. Specifically the manufacturers/exporters of leather handbags in Colombia are formally committed to the total elimination of the net bounty derived from the tax rebate certificate program (CAT) (or any equivalent or comparable benefit) on exports to the United States of leather handbags between May 1, 1978, and January 1, 1979. Such elimination will be staged according to the following schedule: 50-percent reduction on or before May 1, 1978; 50-percent reduction of the remaining balance on or before August 22, 1978; and total elimination of any remaining net bounty on or before January 1, 1979. The Government of Colombia, which under law can adjust the CAT payment only in December of each year, has promised the Treasury that it will accept the voluntary payment by the handbag exporters to the Government of a portion of the CAT to reflect the phase-out expressed above.

In addition the waiver is conditioned on the absence of aggressive marketing of Colombian handbags in the United States, which the Colombian handbag exporters have promised will not take place.

After consulting with appropriate agencies, including the Department of State, the Department of Labor, the

Department of Commerce, and the Office of the Special Representative for Trade Negotiations, I have further concluded:

(1) That there is a reasonable prospect that, under section 102 of the Trade Act of 1974, successful trade agreements will be entered into with foreign countries or instrumentalities providing for the reduction or elimination of barriers to or other distortions of international trade; and

(2) That the imposition of countervailing duties on leather handbags from Colombia would be likely to seriously jeopardize the satisfactory completion of such negotiations.

Accordingly, pursuant to section 303(d) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(d)), I hereby waive the imposition of countervailing duties on handbags from Colombia.

This determination may be revoked, in whole or in part, at any time and shall be revoked whenever the basis supporting such determination no longer exists. Unless sooner revoked or made subject to a resolution of disapproval adopted by either House of the Congress of the United States pursuant to section 303(e) of the Tariff Act of 1930, as amended (19 U.S.C. 1303(e)), this waiver of countervailing duties will, in any event by statute, cease to have force and effect on January 4, 1979.

On or after the date of publication in the FEDERAL REGISTER of a notice revoking this determination, in whole or in part, the day after the date of adoption by either House of Congress of a resolution disapproving this "waiver of countervailing duties," or January 4, 1979, whichever occurs first, countervailing duties will be assessable on handbags imported directly or indirectly from Colombia in accordance with T.D. 78-125, published concurrently with this determination.

The table in § 159.47(f) of the Customs Regulations (19 CFR 159.47(f)) is amended by inserting after the last entry from Colombia under the commodity heading "Handbags," the number of this Treasury decision in the column heading "Treasury Decision," and the words "Imposition of countervailing duties waived" in the column headed "Action."

(R.S. 251, secs. 303, as amended, 624; 46 Stat. 687, 759, 88 Stat. 2051, 2052 (19 U.S.C. 66, 1303), as amended, 1624)

ROBERT H. MUNDHEIM,
General Counsel of the Treasury.

APRIL 24, 1978.

[FR Doc. 78-11811 Filed 5-1-78; 8:45 am]

[4810-22]

[T.D. 78-125]

PART 159—LIQUIDATION OF DUTIES

Leather Handbags From Colombia; Final Countervailing Duty Order

AGENCY: Customs Service, U.S. Treasury.

ACTION: Final countervailing duty order.

SUMMARY: This notice is to advise the public that an investigation has been completed which determined that the Government of Colombia has given benefits considered to be bounties or grants to manufacturers who export leather handbags to the United States. However, countervailing duties are being waived, based upon the criteria established by the Trade Act of 1974, including the actions to be taken by the Colombian handbag exporters to reduce significantly the bounty or grant.

EFFECTIVE DATE: May 2, 1978.

FOR FURTHER INFORMATION CONTACT:

Vincent P. Kane, Duty Assessment Division, U.S. Customs Service, 1301 Constitution Avenue, Washington, D.C. 20229, telephone 202-566-5492.

SUPPLEMENTARY INFORMATION: On November 1, 1977, a "Preliminary Countervailing Duty Determination" was published in the FEDERAL REGISTER (42 FR 57202). The notice stated that it preliminarily had been determined that benefits had been received by Colombian manufacturers and exporters of leather handbags which may constitute bounties or grants within the meaning of section 303 of the Tariff Act of 1930, as amended (19 U.S.C. 1303) (referred to in this notice as "the Act"). The notice stated that the benefits included the granting to manufacturers and exporters tax certificates ("CATS") upon export of the leather handbags and preferential financing for exporters.

The notice further stated that programs preliminarily determined not to be applicable included transportation subsidies, reduced credit insurance costs, freedom from taxes for firms located in designated free trade zones, and import duty exemptions for capital goods used in the production of exports.

Finally, the notice stated that import duty exemptions on raw materials used in the production of handbags for export was not a bounty or grant.

The notice provided interested parties 30 days from the date of publication to submit relevant data, views, or arguments, in writing, with respect to the preliminary determination.

The handbags subject to this determination are classified under item number 706.0820 of the tariff schedules of the United States as leather handbags, other than reptile. The term "handbags" as used in the petition covers "pocketbooks, purses, shoulder bags, clutch bags, and all similar articles by whatever name known, customarily carried by women or girls, but not including luggage of flatgoods."

Subsequent investigation led to the conclusion that alleged preferential export financing through PROEXPO, the Government agency responsible for the program, is not a bounty or grant since it was established that the terms provided through PROEXPO loans are identical to those available commercially.

The effect of the export subsidy (CAT) is offset by certain other factors. These include:

(1) The fact that the CAT is paid on the domestic value added component of the handbag, which effectively reduces the ad valorem benefit for handbags from 12 percent to 9 percent. Generally 75 percent of the value of a handbag in Colombia is produced from domestic materials;

(2) The discount paid by holders of CATS in the stock exchange, thus effectively not providing full value of the CAT when sold;

(3) Devaluation of the peso to the dollar since the certificate is not received on an average of 9 months after application has been made for it;

(4) Customs duties paid by the leather tanners on imported chemicals used in the tanning process. Such fiscal charge has the effect of being an indirect tax that, while not rebated, but would be eligible under the concept of drawback;

(5) Municipal sales taxes imposed on the handbag manufacturers and tanners, which are indirect taxes directly related to the exported handbag. While not rebated on export, they would be eligible under the act;

(6) The present value effect of the CAT resulting from the inflationary impact on its delayed payment. Treasury considered only that 90-day period which the Government of Colombia assured that no CATS could be tendered under any circumstances.

After consideration of all information received, it is hereby determined that leather handbags from Colombia are subject to bounties or grants within the meaning of section 303 of the Act. The bounties or grants are in the form of the export certificates referred to in the preliminary determination, taking into account the offsets described in this notice. The net amount of bounty or grant has been ascertained and determined to be 5.46 percent of the f.o.b. price for export to the United States of leather handbags from Colombia.

Effective on or after May 2, 1978, and until further notice, upon the entry for consumption of such dutiable leather handbags imported directly or indirectly from Columbia, which benefit from these bounties or grants, there shall be collected, in addition to any other duties estimated or determined to be due, countervailing duties in the amount ascertained in accordance with the above declaration. To the extent that it can be established to the satisfaction of the Commissioner of Customs that imports of leather handbags from Colombia are benefitting from a bounty or grant smaller than the amount which otherwise would be applicable under the above declaration, the smaller amount so established shall be assessed and collected.

Any merchandise subject to the terms of this order shall be deemed to have benefited from a bounty or grant if such bounty or grant has been or will be credited or bestowed, directly or indirectly, upon the manufacture, production, or exportation of leather handbags from Colombia.

Notwithstanding the above, a "Notice of Waiver of Countervailing Duties" is being published concurrently with this order which covers leather handbags from Colombia subject to this investigation in accordance with section 303(d) of the Act. At such time as the waiver ceases to be effective, in whole or in part, a notice will be published setting forth the deposit of estimated countervailing duties which will be required at the time of entry, or withdrawal from warehouse, for consumption of each product then subject to the payment of countervailing duties.

The table in § 159.47(f) of the Customs Regulations (19 CFR 159.47(f)) is amended by inserting under the column headed "Country," the name "Colombia," and inserting the words "leather handbags," in the column headed "Commodity," the number of this Treasury Decision in the column headed "Treasury Decision," and the words "Bounty Declared-Rate" in the column headed "Action."

(R.S. 251, as amended, secs. 303, 624, 46 Stat. 687, as amended, 759 (19 U.S.C. 66, 1303, 1624).)

Pursuant to Reorganization Plan No. 26 of 1950 and Treasury Department Order 190 (Revision 15), March 16, 1978, and the provisions of the Treasury Department Order No. 165, Revised, November 2, 1954, and § 159.47 of the Customs Regulations (19 CFR 159.47); insofar as they pertain to the issuance of a final countervailing duty determination by the Commissioner of Customs, are hereby waived.

ROBERT H. MUNDHEIM.
General Counsel of the Treasury.

APRIL 24, 1978.

[FR Doc. 78-11812 Filed 5-1-78; 8:45 am]

[4110-03]

Title 21—Food and Drugs

CHAPTER I—FOOD AND DRUG ADMINISTRATION, DEPARTMENT OF HEALTH, EDUCATION, AND WELFARE

SUBCHAPTER A—GENERAL

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

Advisory Committees; Establishment and Terminations

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and the public advisory committee procedures (21 CFR Part 14), this document announces the establishment of one advisory committee and the termination of three others. This document adds to and deletes from the agency's list of standing advisory committees.

EFFECTIVE DATES: May 2, 1978, authority for the committee being established will end on April 10, 1980, unless the Secretary formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT:

Richard L. Schmidt, Committee Management Office (HFS-20), Food and Drug Administration, Department of Health, Education, and Welfare, 5600 Fishers Lane, Rockville, Md. 20857, 301-443-2765.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) and § 14.40(b) (21 CFR 14.40(b)), the Food and Drug Administration announces the establishment of the Anti-Infective and Topical Drugs Advisory Committee by the Secretary of the Department of Health, Education, and Welfare.

The committee will review and evaluate data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases, dermatological disorders, and ocular disease, and it will make appropriate recommendations to the Commissioner of Food and Drugs. The committee will consist of 15 members.

Concurrently with the establishment, the Secretary approved the termination of the Anti-Infective Agents Advisory Committee, the Dermatology Advisory Committee, and the Ophthalmic Drugs Advisory Committee. Under § 14.55(b) (21 CFR 14.55(b)), FDA announces the termination of these committees.

Therefore, under the Federal Food, Drug, and Cosmetic Act (section 701(a), 52 Stat. 1055 (21 U.S.C. 371(a))) and under authority delegated to the Commissioner (21 CFR 5.1), Part 14 is amended in § 14.100 by revising paragraph (c)(2) and deleting paragraphs (c)(8) and (15) and marking them "reserved," as follows:

§ 14.100 List of standing advisory committees.

* * * * * *

(c) * * *

(2) Anti-Infective and Topical Drugs Advisory Committee.

(i) Date established: April 10, 1978.

(ii) Function: Reviews and evaluates data concerning the safety and effectiveness of marketed and investigational prescription drugs for use in infectious diseases, dermatological disorders, and ocular diseases, and makes appropriate recommendations to the Commissioner.

* * * * * *

Effective date: Since this is a technical conforming amendment to Part 14, the Commissioner finds that there is good cause for the rule to be effective immediately upon publication in the FEDERAL REGISTER, May 2, 1978.

(Sec. 701(a), 52 Stat. 1055 (21 U.S.C. 371(a)).)

Dated: April 24, 1978.

WILLIAM F. RANDOLPH,
Acting Associate Commissioner for Compliance.

[FR Doc. 78-11718 Filed 5-1-78; 8:45 am]

[4110-03]

SUBCHAPTER H—MEDICAL DEVICES

[Docket No. 77N-0110]

EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL DEVICE REQUIREMENTS

Procedures for Consideration of Applications

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: This rule prescribes the procedures for applying to the Food and Drug Administration (FDA) for an exemption from the Federal preemption provisions of section 521 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360k). Section 521(a) preempts certain State or local device laws by providing that no State or local government may establish or

continue in effect any requirement with respect to the safety and effectiveness of a medical device that is different from or in addition to a requirement applicable to the device under the act. Section 521(b) provides that, under certain conditions and in accordance with specified procedures, FDA may exempt a State or local requirement from the preemption provisions of section 521(a).

EFFECTIVE DATE: July 3, 1978.

FOR FURTHER INFORMATION CONTACT:

Joseph M. Sheehan, Bureau of Medical Devices (HFK-70), Food and Drug Administration, Department of Health, Education, and Welfare, 8757 Georgia Avenue, Silver Spring, Md. 20910, 301-427-7114.

SUPPLEMENTARY INFORMATION: The proposal on which this final regulation is based was published in the FEDERAL REGISTER of June 14, 1977 (42 FR 30383). Interested persons were given until August 15, 1977 to comment on the proposal. Twenty comments were received. Most of the comments questioned the agency's interpretation of section 521 of the Federal Food, Drug, and Cosmetic Act.

Section 521(a) of the act provides for preemption of State and local requirements applicable to a medical device intended for human use that are different from or in addition to requirements applicable under the act. Section 521(b) provides that FDA may, by regulation issued after notice and an opportunity for an oral hearing, exempt a state or local medical device requirement from preemption under such conditions as the Commissioner may prescribe if the requirement is: (1) More stringent than Federal requirements applicable to the device under the act, or (2) required by compelling local conditions and compliance with it would not cause the device to be in violation of any applicable requirement under the act.

In the FEDERAL REGISTER of February 15, 1977 (42 FR 9186), FDA issued a proposal relating to an application for exemption from Federal preemption of medical device requirements filed by the State of California. Interested persons were given 60 days to submit written comments on the proposal. An oral hearing on the proposal was held on July 19, 1977. Many views presented in the written comments and at the oral hearing on the California application relate to the general procedures for applying for exemption from preemption and to FDA's interpretation of the scope of section 521 of the act. Accordingly, these views were also considered in the preparation of this final regulation.

In a related action, FDA's new regulations governing professional and patient labeling and conditions for sale of hearing aids became effective on August 25, 1977. Because these new requirements preempted some existing State and local requirements relating to hearing aids, and because five States had filed applications for exemption from preemption, FDA issued a notice in the FEDERAL REGISTER of October 18, 1977 (42 FR 55648) inviting the remaining State and local governments to file within 30 days, applications for exemption from preemption for requirements governing labeling and conditions for sale of hearing aids. This notice was intended to expedite FDA's consideration of applications for exemption from preemption for hearing aid requirements by encouraging simultaneous submissions by affected State and local governments. FDA stated its intention to evaluate each such application on its own merits, but to publish in a single FEDERAL REGISTER notice a proposed regulation to grant or to deny each such application for exemption, and to hold a single hearing on the proposed regulation. Appropriate FEDERAL REGISTER notices will be published in the near future. When appropriate, the Commissioner intends to adopt this consolidated approach in considering future applications for exemption from preemption.

RESPONSE TO COMMENTS

1. Many comments stated that there is no basis in the act or in the legislative history to justify the interpretation of section 521 of the act set forth in the first sentence of proposed § 808.1(d). That sentence stated that State and local requirements are preempted only when FDA has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific FDA requirements.

The comments generally argued that all State and local medical device requirements were preempted as of May 28, 1976, the date of enactment of the Medical Device Amendments of 1976 (Pub. L. 94-295) (the Amendments). Some comments also noted that if there is no FDA requirement then any State requirement is "in addition to" the FDA requirement and is, therefore, preempted by the plain language of section 521 of the act. Other comments disputed the statement in the preamble to the proposal that a regulatory hiatus could result if State and local requirements were considered preempted before FDA could implement Federal requirements. These comments noted that the Amendments provide broad protection to the public from unsafe and ineffective medical devices. Comments also pointed out that the Congressional intent in enacting section 521 was to assure that interstate commerce would not be unduly burdened by the imposition of a substantial number of differing requirements applicable to a medical device by State and local governments and that this indicated that immediate preemption was intended. Comments also compared section 521 of the act to section 903 of S. 510 (the Senate version of the Amendments) which, had it been enacted, would have limited preemption only to devices subject to FDA standards or premarket approval, and to the preemption provisions included in other Federal acts. The thrust of these comments was that the language in section 521 is broader than the language in the other preemption provisions and therefore Congress intended a broader scope of preemption.

The Commissioner believes that both the language of section 521 of the act and the legislative history of the Amendments support the interpretation expressed in the proposal. Section 521(a) clearly states that:

> no State * * * may establish or continue in effect with respect *to a device* intended for human use *any requirement*—
>
> (1) which is different from, or in addition to, any requirement applicable under this Act to *the device*, and
>
> (2) which relates to the safety or effectiveness of *the device* or to any other matter included in a requirement applicable to *the device* under this Act. [Emphasis added.]

Thus, from a plain reading of section 521 of the act it is clear that the scope of preemption is limited to instances where there are specific FDA requirements applicable to a particular device or class of devices. As noted in the preamble to the proposal, a prime example is the preemption of divergent State or local requirements relating to hearing aid labeling and conditions for sale, which occurred when the new FDA hearing aid regulations took effect on August 25, 1977. Here, only requirements relating to labeling and conditions for sale were preempted, not all State or local requirements regulating other facets of hearing-aid distribution.

The language of section 521 of the act also does not support the argument that any State or local requirement is "in addition to" an FDA requirement if there is no FDA requirement. The phrase "or in addition to, any requirement applicable under this Act to the device" means that an FDA requirement must exist before preemption can occur. Moreover, the references in the comments to other Federal preemption statutes and bills do not support a different conclusion.

Finally, the interpretation of section 521 expressed in the regulation is more consistent with the Congressional intent of the Amendments than the

interpretation urged by the comments. The entire thrust of the Amendments is to provide FDA with new and additional authority to assure that only safe and effective medical devices are permitted on the market. See, for example, House of Representatives Rept. No. 94-853, 94th Cong., 2d Sess. 3, 5-13, 17, 23, and 59 (1976); House of Representatives Conference Rept. No. 94-853, 94th Cong., 2d Sess. 51 et seq. (1976). There is nothing in the legislative history to indicate Congress intended that the Amendments should result in less protection for the public, which would be the natural consequence of State Controls being eliminated during the considerable period of time it will take for FDA to implement fully the new authorities provided in the Amendments.

Yet, interpretations urged by the comments would provide less public protection from unsafe and ineffective medical devices because State and local regulation of medical devices would be reduced or eliminated before compensating FDA regulations could become effective. For example, many States have laws governing labeling and conditions for sale of hearing aids. Under the theory espoused in the comments, these laws were preempted on May 28, 1976, although the FDA regulations on hearing aids did not become effective until August 25, 1977. In the interim, presumably, hearing aids were regulated neither by the States nor FDA. In the absence of a specific Congressional directive to this effect, however, the Commissioner will not adopt such a position.

The Commissioner also believes that the interpretation expressed in the regulation will not cause an undue burden on interstate commerce because it merely allows State and local requirements to continue in effect until FDA establishes a national policy on the regulation of specific devices. Thus, since there is no duplication between FDA and State programs, there is no greater burden on interstate commerce than if the Amendments had not been enacted.

2. Several comments stated that there is no basis in the act or in the legislative history for the statement in proposed § 808.1(d)(2) that section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act. Some comments argued that if a State or local requirement is not exactly identical to the FDA requirement it is "different from" the FDA requirement. Other comments argued that even if a State or local requirement is exactly identical to the FDA requirement it is "in addition to" the FDA requirement and therefore preempted. Comments also pointed out that a State or local requirement that is exactly identical in language to the FDA requirement may be interpreted or applied in such a way as to make it "different from" an FDA requirement. Some comments also noted that it is not clear in the proposed regulation when FDA would consider requirements to be substantially identical.

The Commissioner believes that a common sense reading of section 521 of the act supports the "substantially identical" concept in § 808.1(d)(2). Thus, while a State or local requirement may differ in some nonessential manner from an FDA requirement, if it is substantially identical to an FDA requirement it is not "different from" the FDA requirement within the meaning of section 521, and therefore not preempted. It is not necessary that a State or local requirement be exactly identical in wording to an FDA requirement in order to be "substantially identical" so long as there is substantial identity between the FDA and the State or local requirement. In determining whether a State requirement meets this criterion, the Commissioner must consider whether the State requirement is so different as to interfere with the FDA requirement or as to injure public health by imposing an undue burden on interstate commerce. Thus, although the wording of a State or local requirement may not be identical to the FDA requirement, it may be substantially identical if the thrust or effect of the State or local requirement is the same as that of the FDA requirement.

The Commissioner also cannot accept the argument that an identical State or local requirement is preempted because it is "in addition to" the FDA requirement. Such an interpretation of section 521 renders meaningless the "different from" language of section 521 because under this theory any State and local requirement would be preempted whether or not it was actually "different from" an FDA requirement.

When determining whether a State or local requirement is preempted, however, the Commissioner will consider how the requirement is interpreted and applied, not merely the literal language of the applicable statute. This approach is consistent with the recent Supreme Court decision in *Jones* v. *Rath Packing Co.*, 97 S. Ct. 1305, 1309 (1977), a case involving the preemptive effects of food labeling requirements under the Fair Packaging and Labeling Act, the Federal Food, Drug, and Cosmetic Act, and the Wholesome Meat Act. The court there noted that in determining whether or not a Federal statute preempts a State statute, it is necessary "to consider the relationship between state and federal laws as they are interpreted and applied, not merely as they are written."

Finally, to clarify when FDA will consider State or local requirements to be "substantially identical," a new definition of "substantially identical" has been added to § 808.3.

3. Several comments objected to proposed § 808.1(d)(6), which stated that section 521(a) of the act does not preempt State or local requirements respecting general enforcement, such as requirements for inspection of factory records, registration and licensing of manufacturers, and prohibition of adulteration and misbranding of devices. The comments argued that there is no basis in the act or in the legislative history to support the contention that these types of requirements are not requirements with respect to a device within the meaning of section 521 of the act.

The Commissioner believes that State laws relating to inspection, registration, and licensing usually are not requirements "with respect to a device" within the meaning of section 521 of the act because they generally pertain either to persons who manufacture or distribute devices or to places where devices are manufactured, and not directly to devices. In order for a State provision to be a requirement with respect to a device within the meaning of section 521 of the act—and thereby a candidate for preemption—it must relate to the device itself.

Similarly, a State statute prohibiting the sale of an adulterated or misbranded device is not a "requirement with respect to a device" because it applies to the person who would sell the device—and thereby cause the violation—and not to the device itself. Thus, as a general proposition, State prohibitions against the sale of adulterated or misbranded devices are not preempted. Where, however, the State establishes a particular substantive provision defining what constitutes adulteration or misbranding, e.g., a specific type of labeling, this would be a "requirement" within the meaning of section 521 of the act because it relates directly to a device. If such a provision were "different from" or "in addition to" an FDA requirement, it would be preempted. Section 808.1(d)(6) is changed to clarify this position. In determining whether the provision is "different from" or "in addition to" an FDA requirement (that is, in determining whether it is "substantially identical"), the key factor is how the statute is actually applied by the State or local government. Thus, if such a State or local provision, as it is drafted, is "substantially identical" to the adulteration or misbranding provisions of sections 501 and 502 of the act (21 U.S.C. 351 and 352), but it is interpreted or applied to a specific device in such a way as to make it "different from" or "in addition to" the FDA requirements, that interpretation or application would be preempted.

4. Several comments stated that it is unclear in the proposed regulation whether or when State and local premarket approval requirements are preempted.

Like all other medical device requirements, different or additional State and local premarket approval requirements are preempted when FDA establishes specific counterpart regulations or there are other specific requirements applicable to the device under the act. For a device classified in class III under sections 513(f) and 520(l) of the act (21 U.S.C. 360c(f) and 360j(l)), the counterpart FDA requirement—the requirement that the product have premarket approval—was established by operation of the act immediately upon enactment of the Amendments on May 28, 1976. For a device in commercial distribution before the date of enactment of the Amendments (or a substantially equivalent device) that is classified in class I under section 513(d) of the act (21 U.S.C. 360c(d)), the FDA requirement—in this instance actually a determination that the product is not subject to premarket approval or a performance standard—is established on the date of final classification of the device. For a device classified into class II, one part of the FDA requirement—that the product is not subject to premarket approval—is established on the date of final classification; the other part of the FDA requirement will be established when an FDA standard for the product is promulgated. For a device classified in class III under section 513(d) of the act, the counterpart FDA requirement is established on the date the device can not lawfully be marketed without approval of an application for premarket approval under section 501(f)(1)(A) of the act (21 U.S.C. 351(f)(1)(A)). Once these FDA requirements are established, different or additional State requirements are preempted. The Commissioner believes that no change in the final regulation is necessary to reflect this position.

5. Several comments objected to proposed § 808.5, which provided for the granting of advisory opinions on issues related to preemption of State and local requirements. Some comments suggested that FDA should not issue advisory opinions with respect to whether a State or local requirement or proposed requirement would be exempted from preemption unless FDA has all the information required for an application for exemption from preemption and provides an opportunity for a public hearing. These comments argued that if FDA issues an opinion that a requirement may be exempted from preemption and the State or local government later files an application for exemption, the Commissioner would be prejudiced by his previous opinion. Other comments stated that FDA should not issue advisory opinions with respect to proposed legislation pending before a State or local legislative body because the advisory opinion may be based on incomplete information and may have an undue influence on the legislative process.

The Commissioner believes that enough procedural safeguards are built into the process of issuing FDA advisory opinions to overcome the objections raised by the comments. Section 10.85 (21 CFR 10.85), which is incorporated by reference in proposed § 808.5, provides that the Commissioner may refuse a request for an advisory opinion if the request contains incomplete information on which to base an informed advisory opinion. Section 10.85 also provides that an advisory opinion may be amended or revoked at any time. The Commissioner will carefully review an application for exemption from preemption for a State or local requirement where he has previously issued an advisory opinion indicating whether an exemption might be granted, and the application will be judged on its own merits notwithstanding the earlier advisory opinion. In cases in which the Commissioner issues an advisory opinion on pending legislation, application of the advisory opinion will be limited to the facts presented when the opinion is issued, and the opinion will not apply if the legislation is changed significantly upon enactment.

The Commissioner believes that advisory opinions can be very useful in cases in which preemption is uncertain, and he encourages State and local governments, affected industries, and interested individuals to request advisory opinions in such cases. This practice will enable the Commissioner to clarify the uncertain status of State and local regulation of medical devices. As stated in the preamble to the proposed regulation, future FEDERAL REGISTER announcements of FDA actions that involve medical devices will discuss the preemption impact of the proposed actions of different or additional State or local requirements.

6. Several comments argued that FDA should not grant an exemption from preemption merely on a finding that the State or local requirement is more stringent than the FDA requirement or is required by compelling local conditions and would not cause the device to be in violation of any requirement under the act. The comments suggested that FDA should require the State or local government to show that granting an exemption will not cause an undue burden on interstate commerce and will result in a benefit in proportion to the cost of compliance.

It should be noted that section 521(b) of the act makes the granting of an exemption from preemption discretionary with the Commissioner. The two criteria mentioned in the comments are merely initial determinations that must be made before the Commissioner may exercise this discretion. The Commissioner intends to weigh carefully all of the consequences before granting an application for exemption from preemption.

Proposed § 808.25(g)(3) provided that the Commissioner may not grant an exemption if he determines that the granting of an exemption would not be in the best interest of the public health, taking into account the potential effect on the public health of granting or denying an exemption, e.g., additional cost to consumer, availability of needed products, etc. All other factors such as burdens on interstate commerce, compelling local conditions, and stringency will be weighted against these public health considerations. To enable FDA to make more informed judgments on these matters, § 808.20(c) is changed in the final regulation to require applicants to provide information on how the public health may be benefitted and how interstate commerce may be affected if an exemption is granted.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 521, 701, 52 Stat. 1055-1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371)) and under authority delegated to the Commissioner (21 CFR 5.1), Chapter I of Title 21 of the Code of Federal Regulations is amended as follows:

PART 15—PUBLIC HEARING BEFORE THE COMMISSIONER

1. By revising § 15.1(b) to read as follows:

§ 15.1 Scope.

* * * * *

(b) Pursuant to specific provisions in other sections of this chapter, a matter pending before the food and Drug Administration is subject to a public hearing before the Commissioner. Such specific provisions are in § 330.10(a)(8) of this chapter relating to review of the safety, effectiveness, and labeling of over-the-counter drugs, and in Part 808 of this chapter relating to exemptions from preemption of requirements for devices.

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PART 25—ENVIRONMENTAL IMPACT CONSIDERATIONS

2. By adding new § 25.1(d)(6) to read as follows:

§ 25.1 Applicability.

* * * * *

(d) * * *

(6) Promulgation of a regulation exempting from preemption a requirement of a State or political subdivision concerning a device, or publication of a notice denying an application for such exemption.

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3. By adding new Part 808 to read as follows:

PART 808—EXEMPTIONS FROM FEDERAL PREEMPTION OF STATE AND LOCAL MEDICAL DEVICE REQUIREMENTS

Subpart A—General Provisions

Sec.
808.1 Scope.
808.3 Definitions.
808.5 Advisory opinions.

Subpart B—Exemption Procedures

808.20 Application.
808.25 Procedures for processing an application.
808.35 Revocation of an exemption.

Subpart C—Listing of Specific State and Local Exemptions [Reserved]

AUTHORITY: Secs. 521, 701, 52 Stat. 1055–1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371).

Subpart A—General Provisions

§ 808.1 Scope

(a) This part prescribes procedures for the submission, review, and approval of applications for exemption from Federal preemption of State and local requirements applicable to medical devices under section 521 of the act.

(b) Section 521(a) of the act contains special provisions governing the regulation of devices by States and localities. That section prescribes a general rule that after May 28, 1976, no State or political subdivision of a State may establish or continue in effect any requirement with respect to a medical device intended for human use having the force and effect of law (whether established by statute, ordinance, regulation, or court decision), which is different from, or in addition to, any requirement applicable to such device under any provision of the act and which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under the act.

(c) Section 521(b) of the act contains a provision whereby the Commissioner of Food and Drugs may, upon application by a State or political subdivision, allow imposition of a requirement which is different from, or in addition to, any requirement applicable under the act to the device (and which is thereby preempted) by promulgating a regulation in accordance with this part exempting the State or local requirement from preemption. The granting of an exemption does not affect the applicability to the device of any requirements under the act. The Commissioner may promulgate an exemption regulation for the preempted requirement if he makes either of the following findings:

(1) That the requirement is more stringent than a requirement under the act applicable to the device; or

(2) That the requirement is required by compelling local conditions and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act.

(d) State or local requirements are preempted only when the Food and Drug Administration has established specific counterpart regulations or there are other specific requirements applicable to a particular device under the act, thereby making any existing divergent State or local requirements applicable to the device different from, or in addition to, the specific Food and Drug Administration requirements. There are other State or local requirements that affect devices that are not preempted by section 521(a) of the act because they are not "requirements applicable to a device" within the meaning of section 521(a) of the act. The following are examples of State or local requirements that are not regarded as preempted by section 521 of the act:

(1) Section 521(a) does not preempt State or local requirements of general applicability where the purpose of the requirement relates either to other products in addition to devices (e.g., requirements such as general electrical codes, and the Uniform Commercial Code (warranty of fitness)), or to unfair trade practices in which the requirements are not limited to devices.

(2) Section 521(a) does not preempt State or local requirements that are equal to, or substantially identical to, requirements imposed by or under the act.

(3) Section 521(a) does not preempt State or local permits, licensing, registration, certification, or other requirements relating to the approval or sanction of the practice of medicine, dentistry, optometry, pharmacy, nursing, podiatry, or any other of the healing arts or allied medical sciences or related professions or occupations that administer, dispense, or sell devices. However, regulations issued under section 520(e) or (g) of the act may impose restrictions on the sale, distribution, or use of a device beyond those prescribed in State or local requirements. If there is a conflict between such restrictions and State or local requirements, the Federal regulations shall prevail.

(4) Section 521(a) does not preempt specifications in contracts entered into by States or localities for procurement of devices.

(5) Section 521(a) does not preempt criteria for payment of State or local obligations under Medicaid and similar Federal, State or local health-care programs.

(6)(i) Section 521(a) does not preempt State or local requirements respecting general enforcement, e.g., requirements that State inspection be permitted of factory records concerning all devices, registration, and licensing requirements for manufacturers and others, and prohibition of manufacture of devices in unlicensed establishments. However, Federal regulations issued under sections 519 and 520(f) of the act may impose requirements for records and reports and good manufacturing practices beyond those prescribed in State or local requirements. If there is a conflict between such regulations and State or local requirements, the Federal regulations shall prevail.

(ii) Generally, section 521(a) does not preempt a State or local requirement prohibiting the manufacture of adulterated or misbranded devices. Where, however, such a prohibition has the effect of establishing a substantive requirement for a specific device, e.g., a specific labeling requirement, then the prohibition will be preempted if the requirement is different from, or in addition to, a Federal requirement established under the act. In determining whether such a requirement is preempted, the determinative factor is how the requirement is interpreted and enforced by the State or local government and not the literal language of the statute, which may be identical to a provision in the act.

(7) Section 521(a) does not preempt State or local provisions respecting delegations of authority and related administrative matters relating to devices.

(8) Section 521(a) does not preempt a State or local requirement whose sole purpose is raising revenue or charging fees for services, registration, or regulatory programs.

(9) Section 521(a) does not preempt State or local requirements of the types that have been developed under the Atomic Energy act of 1954 (42 U.S.C. 2011 note), as amended, the Radiation Control for Health and Safety Act of 1968 (Pub. L. 90-602 (42 U.S.C. 263b et seq.)) and other Federal statutes, until such time as the Food and Drug Administration issues specific requirements under the Federal Food, Drug, and Cosmetic Act applicable to these types of devices.

(e) It is the responsibility of the Food and Drug Administration, sub-

ject to review by Federal courts, to determine whether a State or local requirement is equal to, or substantially identical to, requirements imposed by or under the act, or is different from, or in addition to, such requirements, in accordance with the procedures provided by this part. However, it is the responsibility of States and political subdivisions to determine initially whether to seek exemptions from preemption. Any State or political subdivision whose requirements relating to devices are preempted by section 521(a) may petition the Commissioner of Food and Drugs for exemption from preemption, in accordance with the procedures provided by this part.

§ 808.3 Definitions.

(a) "Act" means the Federal Food, Drug, and Cosmetic Act.

(b) "Compelling local conditions" includes any factors, considerations, or circumstances prevailing in, or characteristic of, the geographic area or population of the State or political subdivision that justify exemption from preemption.

(c) "More stringent" refers to a requirement of greater restrictiveness or one that is expected to afford to those who may be exposed to a risk of injury from a device a higher degree of protection than is afforded by a requirement applicable to the device under the act.

(d) "Political subdivision" or "locality" means any lawfully established local governmental unit within a State which unit has the authority to establish or continue in effect any requirement having the force and effect of law with respect to a device intended for human use.

(e) "State" means a State, American Samoa, the Canal Zone, the Commonwealth of Puerto Rico, the District of Columbia, Guam, Johnston Island, Kingman Reef, Midway Island, the Trust Territory of the Pacific Islands, the Virgin Islands, and Wake Island.

(f) "Substantially identical to" refers to the fact that a State or local requirement does not significantly differ in effect from a Federal requirement.

§ 808.5 Advisory opinions.

(a) Any State, political subdivision, or other interested person may request an advisory opinion from the Commissioner with respect to any general matter concerning preemption of State or local device requirements or with respect to whether the Food and Drug Administration regards particular State or local requirements, or proposed requirements, as preempted.

(1) Such an advisory opinion may be requested and may be granted in accordance with § 10.85 of this chapter.

(2) The Food and Drug Administration, in its discretion and after consultation with the State or political subdivision, may treat a request by a State or political subdivision for an advisory opinion as an application for exemption from preemption under § 808.20.

(b) The Commissioner may issue an advisory opinion relating to a State or local requirement on his own initiative when he makes one of the following determinations:

(1) A requirement with respect to a device for which an application for exemption from preemption has been submitted under § 808.20 is not preempted by section 521(a) of the act because it is: (i) Equal to or substantially identical to a requirement under the act applicable to the device, or (ii) is not a requirement within the meaning of section 521 of the act and therefore is not preempted;

(2) A proposed State or local requirement with respect to a device is not eligible for exemption from preemption because the State or local requirement has not been issued in final form. In such a case, the advisory opinion may indicate whether the proposed requirement would be preempted and, if it would be preempted, whether the Food and Drug Administration would propose to grant an exemption from preemption;

(3) Issuance of such an advisory opinion is in the public interest.

Subpart B—Exemption Procedures

§ 808.20 Application.

(a) Any State or political subdivision may apply to the Food and Drug Administration for an exemption from preemption for any requirement that is preempted. An exemption may only be granted to a State or political subdivision for a requirement that it has enacted and that has been enacted, promulgated, or issued in final form by the authorized body or official of the State or political subdivision so as to have the force and effect of law. However, an application for exemption may be submitted before the effective date of the requirement.

(b) An application for exemption shall be in the form of a letter to the Commissioner of Food and Drugs and shall be signed by an individual who is authorized to request the exemption on behalf of the State or political subdivision. Four copies of the letter and any accompanying material, as well as any subsequent reports or correspondence concerning an application, shall be submitted to the Hearing Clerk (HFC-20), Food and Drug Administration, Room 4-65, 5600 Fishers Lane, Rockville, Md. 20857. The outside wrapper of any application, report, or correspondence should indicate that it concerns an application for exemption from preemption of device requirements.

(c) For each requirement for which an exemption is sought, the application shall include the following information to the fullest extent possible, or an explanation of why such information has not been included:

(1) Identification and a current copy of any statute, rule, regulation, or ordinance of the State or political subdivision considered by the State or political subdivision to be a requirement which is preempted, with a reference to the date of enactment, promulgation, or issuance in final form. The application shall also include, where available, copies of any legislative history or background materials pertinent to enactment, promulgation, or issuance of the requirement, including hearing reports or studies concerning development or consideration of the requirement. If the requirement has been subject to any judicial or administrative interpretations, the State or political subdivision shall furnish copies of such judicial or administrative interpretations.

(2) A comparison of the requirement of the State or political subdivision and any applicable Federal requirements to show similarities and differences.

(3) Information on the nature of the problem addressed by the requirement of the State or political subdivision.

(4) Identification of which (or both) of the following bases is relied upon for seeking an exemption from preemption:

(i) The requirement is more stringent than a requirement applicable to a device under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing how and why the requirement of the State or political subdivision is more stringent than requirements under the act.

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any applicable requirement under the act. If the State or political subdivision relies upon this basis for exemption from preemption, the application shall include information, data, or material showing why compliance with the requirement of the State or political subdivision would not cause a device to be in violation of any applicable requirement under the act and why the requirement is required by compelling local conditions. The application shall also explain in detail the compelling local conditions that justify the requirement.

(5) The title of the chief administrative or legal officers of that State or local agency that has primary responsibility for administration of the requirement.

(6) When requested by the Food and Drug Administration, any records concerning administration of any require-

ment which is the subject of an exemption or an application for an exemption from preemption.

(7) Information on how the public health may be benefitted and how interstate commerce may be affected, if an exemption is granted.

(8) Any other pertinent information respecting the requirement voluntarily submitted by the applicant.

(d) If litigation regarding applicability of the requirement is pending, the State or political subdivision may so indicate in its application and request expedited action on such application.

§ 808.25 Procedures for processing an application.

(a) Upon receipt of an application for an exemption from preemption submitted in accordance with § 808.20, the Commissioner shall notify the State or political subdivision of the date of such receipt.

(b) If the Commissioner finds that an application does not meet the requirements of § 808.20, he shall notify the State or political subdivision of the deficiencies in the application and of the opportunity to correct such deficiencies. A deficient application may be corrected at any time.

(c) After receipt of an application meeting the requirements of § 808.20, the Commissioner shall review such application and determine whether to grant or deny an exemption from preemption for each requirement which is the subject of the application. The Commissioner shall then issue in the FEDERAL REGISTER a proposed regulation either to grant or to deny an exemption from preemption. The Commissioner shall also issue in the FEDERAL REGISTER a notice of opportunity to request an oral hearing before the Commissioner or the Commissioner's designee.

(d) A request for an oral hearing may be made by the State or political subdivision or any other interested person. Such request shall be submitted to the Hearing Clerk within the period of time prescribed in the notice and shall include an explanation of why an oral hearing, rather than submission of written comments only, is essential to the presentation of views on the application for exemption from preemption and the proposed regulation.

(e) If a timely request for an oral hearing is made, the Commissioner shall review such a request and may grant a legislative-type informal oral hearing pursuant to Part 15 of this chapter by publishing in the FEDERAL REGISTER a notice of the hearing in accordance with § 15.20 of this chapter. The scope of the oral hearing shall be limited to matters relevant to the application for exemption from preemption and the proposed regulation. Oral or written presentations at the oral hearing which are not relevant to the application shall be excluded from the administrative record of the hearing.

(f) If a request for hearing is not timely made or a notice of appearance is not filed pursuant to § 15.21 of this chapter, the Commissioner shall consider all written comments submitted and publish a final rule in accordance with paragraph (g) of this section.

(g) (1) The Commissioner shall review all written comments submitted on the proposed rule and the administrative record of the oral hearing, if an oral hearing has been granted, and shall publish in the FEDERAL REGISTER a final rule in subpart C of this part identifying any requirement in the application for which exemption from preemption is granted, or conditionally granted, and any requirement in the application for which exemption from preemption is not granted.

(2) The Commissioner may issue a regulation granting or conditionally granting an application for an exemption from preemption for any requirement if the Commissioner makes either of the following findings:

(i) The requirement is more stringent than a requirement applicable to the device under the act;

(ii) The requirement is required by compelling local conditions, and compliance with the requirement would not cause the device to be in violation of any requirement applicable to the device under the act.

(3) The Commissioner may not grant an application for an exemption from preemption for any requirement with respect to a device if the Commissioner determines that the granting of an exemption would not be in the best interest of public health, taking into account the potential burden on interstate commerce.

(h) An advisory opinion pursuant to § 808.5 or a regulation pursuant to paragraph (g) of this section constitutes final agency action.

§ 808.35 Revocation of an exemption.

(a) An exemption from preemption pursuant to a regulation under this part shall remain effective until the Commissioner revokes such exemption.

(b) The Commissioner may by regulation, in accordance with § 808.25, revoke an exemption from preemption for any of the following reasons:

(1) An exemption may be revoked upon the effective date of a newly established requirement under the act which, in the Commissioner's view, addresses the objectives of an exempt requirement and which is described, when issued, as preempting a previously exempt State or local requirement.

(2) An exemption may be revoked upon a finding that there has occurred a change in the bases listed in § 808.20(c)(4) upon which the exemption was granted.

(3) An exemption may be revoked if it is determined that a condition placed on the exemption by the regulation under which the exemption was granted has not been met or is no longer being met.

(4) An exemption may be revoked if a State or local jurisdiction fails to submit records as provided in § 808.20(c)(6).

(5) An exemption may be revoked if a State or local jurisdiction to whom the exemption was originally granted requests revocation.

(6) An exemption may be revoked if it is determined that it is no longer in the best interests of the public health to continue the exemption.

(c) An exemption that has been revoked may be reinstated, upon request from the State or political subdivision, if the Commissioner, in accordance with the procedures in § 808.25, determines that the grounds for revocation are no longer applicable except that the Commissioner may permit abbreviated submissions of the documents and materials normally required for an application for exemption under § 808.20.

Subpart C—Listing of Specific State and Local Exemptions [Reserved]

Effective date: This regulation shall become effective July 3, 1978.

(Secs. 521, 701, 52 Stat. 1055–1056 as amended, 90 Stat. 574 (21 U.S.C. 360k, 371).)

Dated: April 24, 1978.

SHERWIN GARDNER,
Acting Commissioner of Food and Drugs.

[FR Doc. 11719 Filed 5-1-78; 8:45 am]

[4110-03]

SUBCHAPTER B—FOOD FOR HUMAN CONSUMPTION

[Docket No. 77F-0374]

PART 172—FOOD ADDITIVES PERMITTED FOR DIRECT ADDITION TO FOOD FOR HUMAN CONSUMPTION

Sodium Lauryl Sulfate

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The food additive regulations are being amended to provide for safe use of sodium lauryl sulfate as a wetting agent in the partition of high and low melting fractions of crude vegetable oils and animal fats. A petition had been filed by DeLaval Separator Co. proposing this safe use.

DATES: Effective May 2, 1978, objections by June 1, 1978.