separation of the counterweight(s) with resultant spinner damage and propeller vibration. Since this condition is likely to exist or develop on other propellers of the same type design, an AD is being issued which requires removal and replacement of the initial propeller counterweight bolts, which were torqued to 105–100 lb.-ft., and the installation of new bolts torqued to 65–60 lb.-ft.

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

List of Subjects in 14 CFR Part 39

Propellers, Aircraft, Aviation safety, Incorporation by reference.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, § 39.13 of Part 39 of the Federal Aviation Regulations (14 CFR 39.13) is amended by adding the following new AD:

McCauley Accessory Division: Applies to McCauley Model 3AF32C504, 3AF32C505, 3AF32C506, 3AF32C507, 3AF32C508, and 3AF32C509 full feathering propellers with specific serial numbers listed in McCauley Service Bulletin No. 147 installed on, but not limited to, Piper PA–34–220T, Cessna T303, T310P, T310Q, T310R, 320D, 320E, 320F, 335, 340, 340A, 401, 401A, 401B, 402, 402A, 402B, 402C, 414, and 414A type aircraft certificated in all categories.

Compliance required within the next 30 days after the effective date of this AD, unless already accomplished.

A. To prevent possible failures of the counterweight bolts, accomplish the following:

1. Remove propeller spinner (shell).

2. Remove propeller counterweight bolt, P/N A–1635–125, from each blade, and install new P/N A–1635–125 bolt(s), identified with the letter "M" stamped on the head, torqued to 65–60 lb.-ft. in accordance with paragraphs 3 and 4 of McCauley Service Bulletin 147 dated March 4, 1983, or FAA approved equivalent.

3. Reinstall propeller spinner (shell).

B. A special flight permit may be used in accordance with Federal Aviation Regulations 21.197 and 21.199 to operate the aircraft to a base where the AD can be accomplished.

Upon request of the operator, an equivalent means of compliance with the requirements of this AD may be approved by the Manager, Chicago Aircraft Certification Office, FAA, 2300 East Devon Avenue, Des Plaines, Illinois 60018. Portions of the McCauley Service Bulletin No. 147 identified and described in this directive are incorporated herein and made a part hereof pursuant to 5 U.S.C. 552(a)(1). All persons affected by this directive who have not already received this document from the manufacturer may obtain a copy upon request to McCauley Accessory Division, Cessna Aircraft Company, 3535 McCauley Drive, P.O. Box 430, Vandalia, Ohio 45377. This document also may be examined at Rules Docket, Office of Regional Counsel, FAA, Attn: Rules Docket No. 83–ANE–17, 12 New England Executive Park, Burlington, Massachusetts 01803, and may be examined weekdays, except Federal holidays, between 8:00 am and 4:30 pm.

This amendment becomes effective July 5, 1983.

(Secs. 313(a), 601, and 603, Federal Aviation Act of 1958, as amended (49 U.S.C. 1354(a), 1421, and 1423); Sec. 6(c), Department of Transportation Act (49 U.S.C. 1655(c)); 14 CFR 11.89)

Note.—The FAA has determined that this regulation is an emergency regulation that is not considered to be major under Executive Order 12291. It is impracticable for the agency to follow the procedures of Order 12291 with respect to this rule, since the rule must be issued immediately to correct an unsafe condition in aircraft. It has been further determined that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979). If this action is subsequently determined to involve a significant/major regulation, a final regulatory evaluation or analysis, as appropriate, will be prepared and placed in the regulatory docket (otherwise, an evaluation or analysis is not required). A copy of it, when filed, may be obtained by contacting the person identified under the caption **"FOR FURTHER INFORMATION CONTACT."**

Note.—The incorporation by reference provisions of this document were approved by the Director of the Federal Register on July 5, 1983. The referenced bulletin is available at the Federal Register.

Issued in Burlington, Massachusetts, on June 8, 1983.

Robert E. Whittington,

Director, New England Region.

[FR Doc. 83-17900 Filed 7-1-83; 8:45 am]

BILLING CODE 4910-13-M

DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 101

[T.D. 83-146]

Change in the Customs Service Field Organization

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: This document amends the Customs Regulations to change the Customs Service field organization by extending and redefining the geographical limits of the port of Seattle, Washington, within the consolidated Customs port of entry of Puget Sound, Washington. The change is being made because commercial operations requiring the services of Customs personnel have been established in areas beyond the territory within the current limits of the Seattle port.

EFFECTIVE DATE: August 4, 1983.

FOR FURTHER INFORMATION CONTACT: Richard C. Coleman, Office of Inspection, U.S. Customs Service, 1301 Constitution Avenue, NW., Washington, D.C. 20229 (202–566–8157).

SUPPLEMENTARY INFORMATION:

Background

The limits of the consolidated Customs port of entry of Puget Sound, Washington, were extended by T.D. 79–169, published in the **Federal Register** on June 15, 1979 (44 FR 34478). Since that time commercial operations requiring the services of Customs personnel have been established in areas beyond the territory within the current limits of the Seattle, Washington, port, which is within the consolidated port of entry of Puget Sound. The volume of cargo moving through the port of Seattle, Washington, has grown substantially and many new facilities for clearing, storing, and forwarding imported merchandise have moved or are contemplating moving from their waterfront locations to facilities outside of the present port limits. As part of Customs continuing program to obtain more efficient use of its personnel, facilities, and resources, and in order to provide better service to carriers, importers, and the public, on November 30, 1981, Customs published a notice in the **Federal Register** (46 FR 58093), proposing to extend and redefine the geographical limits of the Puget Sound port of entry. The document proposed to eliminate specific reference to the ports of "Kenmore Air Harbor" and "Renton Municipal Airport and Seaplane Base," as set forth in T.D. 79–169, with the territories encompassed by both of those ports included within the limits of the port of Seattle, as extended. Neither Kenmore Air Harbor nor Renton Municipal Airport and Seaplane Base is manned continually by Customs personnel. Both are serviced by Customs personnel from Seattle on an "as-needed" basis. In addition to the port of Seattle, as extended, the consolidated port of Puget Sound includes all of the area within the present port limits of Anacortes, Bellingham, Everett, Friday Harbor, Neah Bay, Olympia, Port Angeles, Port Townsend, and Tacoma, Washington. Other than extending the port limits of Seattle, there will be no change in Customs service to the other ports in the Puget Sound port of entry.

No comments were received in response to the notice proposing this change. Accordingly, after further review of the matter, it has been determined to adopt the change with one minor alteration. The description of the geographical limits of the port of Seattle within the consolidated port of Puget Sound, Washington, as stated in the notice proposing the change, is modified and simplified in this document. Instead of using geographical sections to describe the territorial boundaries of the Seattle port, popular names of streets are substituted. The area described is the same, but the description is now simpler and more comprehensible. This document amends § 101.3, Customs Regulations (19 CFR 101.3), to change the Customs field organization by extending and redefining the geographical limits of the consolidated port of entry of Puget Sound.

Changes in the Customs Service Field Organization

Under the authority vested in the President by section 1 of the Act of August 1, 1914, 38 Stat. 623, as amended (19 U.S.C. 2), and delegated to the Secretary of the Treasury by Executive Order No. 10289, September 17, 1951 (3 CFR 1949–1953 Comp., Ch. II) and pursuant to authority provided by Treasury Department Order No. 101–5 (47 FR 2449), the limits of the consolidated port of Puget Sound, Washington, are extended and redefined to be as follows:

The ports of Seattle (section 35, Township 27 North, Range 3 East, West Meridian, County of Snohomish, and the geographical area within the boundaries beginning at the intersection of N.W. 205th Street and the waters of Puget Sound, proceeding in an easterly direction along the King County line to its intersection with 100th Avenue N.E., thence southerly along 100th Avenue N.E. and its continuation to the intersection of 100th Avenue S.E. and 240th Street S.E., thence westerly along 240th Street S.E. to its intersection with N.W. 205th Street, the point of beginning, County of King, all within the State of Washington), Anacortes, Bellingham, Everett, Friday Harbor, Neah Bay, Olympia, Port Angeles, Port Townsend, and the territory in Tacoma beginning at the intersection of the westernmost city limits of Tacoma and The Narrows and proceeding in an easterly, then southerly, then easterly direction along the city limits of Tacoma to its intersection with Pacific Highway (U.S. Route 99), then proceeding in a southerly direction along Pacific Highway to its intersection with Union Avenue Extended and continuing in a southerly direction along Union Avenue Extended to its intersection with the northwest corner of McChord Air Force Base, then proceeding along the northern, then western, then southern boundary of McChord Air Force Base to its intersection, just west of Lake Mondress, with the northern boundary of the Fort Lewis Military Reservation, then proceeding in an easterly direction along the northern boundary of the Fort Lewis Military Reservation to its intersection with Pacific Avenue, then proceeding in a southerly direction along Pacific Avenue to its intersection with National Park Highway, then proceeding in a southeasterly direction along National Park Highway to its intersection with 224th Street, East, then proceeding in an easterly direction along 244th Street, East, to its intersection with Meridian Street, South then proceeding in a northerly direction along Meridian Street to the northern boundary of Pierce County, then proceeding in a westerly direction along the northern boundary of Pierce County to its intersection with Puget Sound, then proceeding in a generally southwesterly direction along the banks of the East Passage of Puget Sound, Commencement Bay, and The Narrows to the point of intersection with the westernmost city limits of Tacoma, including all points and places on the southern boundary of the Juan de Fuca Strait from the eastern port limits of Neah Bay to the western port limits of Port Townsend, all points and places on the western boundary of Puget Sound, including Hood Canal, from the port limits of Port Townsend to the northern port limits of Olympia, all points and places on the southern boundary of Puget Sound from the port limits of Olympia to the western port limits of Tacoma, and all points and places on the eastern boundary of Puget Sound and contiguous waters from the port limits of Tacoma north to the southern port limits of Bellingham, all in the State of Washington.

List of Subjects in 19 CFR Part 101

Customs duties and inspection, Imports, Organization.

Amendment to the Regulations

PART 101—GENERAL PROVISIONS

§ 101.3 [Amended]

To reflect this change, the column headed "Ports of entry" in the list of Customs regions, districts, and ports of entry in § 101.3, Customs Regulations (19 CFR 101.3), is amended by removing "Kenmore Air Harbor" and inserting "T.D. 83-146" in place of "T.D. 79–169", in the description for the consolidated port of entry of Puget Sound, Washington, in the Seattle, Washington, Customs district.

Executive Order 12291

Because this amendment relates to the organization of the Customs Service, pursuant to section 1(a)(3) of E.O. 12291, it is not subject to that E.O.

Regulatory Flexibility Act

The provisions of the Regulatory Flexibility Act relating to an initial and final regulatory flexibility analysis (5 U.S.C. 603, 604) are not applicable to this amendment. Customs routinely establishes, expands, and consolidates Customs ports of entry throughout the United States to accommodate the volume of Customs-related activity in various parts of the country. Although this change may have a limited effect upon some small entities in the Puget Sound area, it is not expected to be significant because the extension of the limits of Customs ports of entry in other locations has not had a significant economic impact upon a substantial number of small entities to the extent contemplated by the Regulatory Flexibility Act. Accordingly, it is certified under the provisions of section 3 of the Regulatory Flexibility Act (5 U.S.C. 605(b)) that the amendment will not have a significant economic impact on a substantial number of small entities.

Drafting Information

The principal author of this document was James S. Demb, Regulations Control Branch, U.S. Customs Service. However, personnel from other Customs offices participated in its development.

Alfred R. De Angelus,

Acting Commissioner of Customs.

Approved: June 23, 1983.

John M. Walker, Jr.,

Assistant Secretary of the Treasury.

[FR Doc. 83-17993 Filed 7-1-83; 8:45 am]

BILLING CODE 4820-02-M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 82F-0284]

Indirect Food Additives; Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of decanoic acid, octanoic acid, sodium 1-octanesulfonate, and isopropyl alcohol as components of a sanitizing solution to be used on food-contact surfaces. This action responds to a petition filed by Economics Laboratory, Inc.

DATES: Effective July 5, 1983; objections by August 4, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Blondell Anderson, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, DC 20204, 202–472–5740

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 1, 1982 (47 FR 43428), FDA announced that a petition (FAP 2B3647) had been filed by Economics Laboratory, Inc., Osborn Bldg., St. Paul, MN 55102, proposing that the food additive regulations be amended to provide for the safe use of decanoic acid, octanoic acid, sodium 1-octanesulfonate, and isopropyl alcohol as components of sanitizing solutions to be used on food-contact surfaces.

FDA has evaluated the data in the petition and other relevant material and concludes that the proposed food additive use is safe and that the regulations should be amended as set forth below.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in § 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The agency's finding of no significant impact and the evidence supporting that finding may be seen in the Dockets Management Branch (address above), between 9 a.m. and 4 p.m. Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging, Sanitizing solutions.

Therefore, under the Federal Food, Drug, and Cosmetic Act (secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Foods (21 CFR 5.61 as revised February 4, 1983; 48 FR 5251), Part 178 is amended in § 178.1010 by adding new paragraphs (b)(27) and (c)(22), to read as follows:

PART 178—INDIRECT FOOD ADDITIVES: ADJUVANTS, PRODUCTION AIDS, AND SANITIZERS

§ 178.1010 Sanitizing solutions.

* * * * *

(b) * * *

(27) An aqueous solution containing decanoic acid (CAS Reg. No. 334–48–5), octanoic acid (CAS Reg. No. 124–07–2), and sodium 1-octanesulfonate (CAS Reg. No. 5324–84–5). Additionally, the aqueous solution may contain isopropyl alcohol (CAS Reg. No. 67–63–0) as an optional ingredient. This solution is limited to use on dairy processing equipment.

(c)* * *

(22) Solutions identified in paragraph (b)(27) of this section shall provide, when ready to use, at least 109 parts per million and not more than 218 parts per million of total active fatty acids and at least 156 parts per million and not more than 312 parts per million of the sodium 1-octanesulfonate.

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before August 4, 1983 submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective July 5, 1983.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: June 24, 1983.

Sanford A. Miller,

Director, Bureau of Foods.

(FR Doc. 83-17905 Filed 7-1-83; 8:45 am)

BILLING CODE 4160-01-M

---

21 CFR Part 179

[Docket No. 80F-0368]

Irradiation in the Production, Processing and Handling of Food

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the safe use of a source of gamma radiation to reduce or control microbial contamination in specific spices and vegetable seasonings. This action is in response to a food additive petition filed by Radiation Technology, Inc.

DATES: Effective July 5, 1983; objections by August 4, 1983.

ADDRESS: Written objections to the Dockets Management Branch (HFA–305), Food and Drug Administration, Rm. 4–62, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Clyde A. Takeguchi, Bureau of Foods (HFF–334), Food and Drug Administration, 200 C St. SW., Washington, D.C. 20204, 202–472–5690.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of October 17, 1980 (45 FR 69044), FDA announced that a food additive petition (FAP OM3516) has been filed by Radiation Technology, Inc., Lake Denmark Rd., Rockaway, NJ 07866, proposing that § 179.22 (21 CFR 179.22) be amended to provide for the safe use of a cobalt 60 or a cesium 137 source of gamma radiation to reduce or control microbial contamination in spices, natural flavorings, and dehydrated vegetable seasonings by irradiating those foods at doses up to 1 megarad

(Mrad) (which is equivalent to 10 kiloGray (10 kGy)).[1]

In a March 18, 1983 letter, Radiation Technology, Inc., amended its petition to list the specific spices and vegetable seasonings covered by the petition.

In a March 27, 1981 advance notice of proposed rulemaking (46 FR 18992), the agency stated that, based upon a report from the Bureau of Foods Irradiated Food Committee (BFIFC), it was considering, inter alia, adoption of a policy, that a food class comprising only a minor portion of the daily diet and irradiated at a dose of 5 Mrad or less may be considered safe for human consumption based upon minimal biological testing, but restricted this recommendation solely to spices. The BFIFC concluded that the types of radiolytic products from individual spices and their concentrations in the diet would be so low as to be of no safety concern.

In the review process for this petition, the agency has utilized information submitted by the petitioner, as well as information already in the agency files. FDA has evaluated the available data, and concludes that the proposed use of gamma radiation is safe and that the regulations should be amended as set forth below.

Even though the agency expects to propose comprehensive regulations for food irradiation in the near future, the agency is promulgating this regulation because the outstanding questions regarding the petitioned change in regulations have been resolved and because the agency believes that there is no need to delay this regulation to accommodate the agency's independent rulemaking process.

This amendment also deletes the phrase "low dose" from the title of § 179.22 to read: "Gamma radiation for the treatment of food." This is an editorial change only; it does not change the substances or uses previously authorized.

In accordance with § 171.1(h) (21 CFR 171.1(h)), the petition and the documents that FDA considered and relied upon in reaching its decision to approve the petition are available for inspection at the Bureau of Foods (address above) by appointment with the information contact person listed above. As provided in 21 CFR 171.1(h)(2), the agency will delete from the documents any materials that are not available for public disclosure before making the documents available for inspection.

The agency has previously considered the potential enviromental effects of this regulation as announced in the notice of filing published in the **Federal Register**. No new information or comments have been received that would alter the agency's previous determination that there is no significant impact on the human environment and that an environmental impact statement is not required.

List of Subjects in 21 CFR Part 179

Food additives, Food packaging, Irradiation of foods.

Therefore, under the Federal Food, Drug, and Cosmetic Act (§§ 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348)) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10), Part 179 is amended in § 179.22 by revising the section heading and by alphabetically inserting the following item in the list of substances in paragraph (b):

PART 179—IRRADIATION IN THE PRODUCTION, PROCESSING, AND HANDLING OF FOOD

§ 179.22 Gamma radiation for the treatment of food.

* * * * *

(b) * * *

Food for irradiation	Limitations	Use
Garlic powder; Onion powder; Spices, dried: allspice; anise; basil; bay leaves; caraway seed; cardamon; celery seed; chervil; cinnamon; cloves; coriander; cumin seed; dill seed; fennel seed; fenugreek; ginger; horseradish; mace; marjoram; mustard seed; mustard flour; nutmeg; oregano; paprika; parsley; pepper, black; pepper, white; pepper, red; rosemary; saffron; sage; savory; star aniseed; tarragon; thyme; turmeric.	Absorbed dose: Not to exceed 10 kiloGray (kGy) (1 megarad (Mrad)).	Control of micro-organisms.
* * * * *		

* * * * *

Any person who will be adversely affected by the foregoing regulation may at any time on or before August 4, 1983, submit to the Dockets Management Branch (address above) written objections thereto and may make a written request for a public hearing on the stated objections. Each objection shall be separately numbered and each numbered objection shall specify with particularity the provision of the regulation to which objection is made. Each numbered objection on which a hearing is requested shall specifically so state; failure to request a hearing for any particular objection shall constitute a waiver of the right to a hearing on that objection. Each numbered objection for which a hearing is requested shall include a detailed description and analysis of the specific factual information intended to be presented in support of the objection in the event that a hearing is held; failure to include such a description and analysis for any particular objection shall constitute a waiver of the right to a hearing on the objection. Three copies of all documents shall be submitted and shall be identified with the docket number found in brackets in the heading of this regulation. Received objections may be seen in the office above between 9 a.m. and 4 p.m., Monday through Friday.

Effective date. This regulation shall become effective July 5, 1983.

(Secs. 201(s), 409, 72 Stat. 1784–1788 as amended (21 U.S.C. 321(s), 348))

Dated: June 29, 1983.

Mark Novitch,

Deputy Commissioner of Food and Drugs.

[FR Doc. 83-18087 Filed 7-1-83; 8:45 am]

BILLING CODE 4160-01-M

[1] The System International (SI) unit for expressing the amount of absorbed radiation dose is the Gray (joules/kilogram, abbreviated Gy). The older term is rad. The quivalent value in rads (100 rads = 1 Gy) will be enclosed in parentheses. The prefixes kilo (k) and mega (M) represent a thousandfold and a millionfold, respectively. For example, 1 kilorad means a thousand rads and 1 megarad means a million rads.

---

21 CFR Parts 510, 522, 546, 555, and 558

Animal Drugs, Feeds, and Related Products; Change in Sponsor

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the change of sponsor of several new animal drug applications (NADA's) from Rachelle Laboratories, Inc., to Pfizer, Inc.

EFFECTIVE DATE: July 5, 1983.

FOR FURTHER INFORMATION CONTACT: David L. Gordon, Bureau of Veterinary Medicine (HFV–238), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–6243.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017, filed several supplemental NADA's providing for a change of sponsor from Rachelle Laboratories, Inc., 700 Henry Ford Ave., Long Beach, CA 90801. NADA's affected by this change of sponsor are as follows:

NADA No.	Drug name
49-287	Chlortetracycline calcium complex premix.
49-948	Oxytetracycline HC1 with 2% lidocaine injection.
60-852	Chlortetracycline HC1.
65-061	Tetracycline HC1 syrup.
65-066	Tetracycline HC1 film coated tablets.
65-069	Tetracycline HC1 capsules.
65-140	Tetracycline HC1 soluble powder.
65-241	Chloramphenicol capsules.
65-463	Chloramphenicol injection.
65-464	Chloramphenicol oral solution.
91-127	Oxytetracycline HC1 injection.
91-668	Chlortetracycline calcium complex-sulfamethazine-procaine penicillin G premix.
99-402	Oxytetracycline HC1 injection
100-901	Chlortetracycline HC1.
100-903	Chlortetracycline calcium complex premix.
130-660	Dexamethasone sterile solution (injection).

The regulations are amended in § 510.600(c) to delete Rachelle Laboratories, Inc., as the sponsor of an approved NADA, and in several sections in 21 CFR Parts 522, 546, 555, and 558 to provide for the new sponsor. This action concerns a change of sponsor and does not involve any changes in manufacturing facilities, equipment, procedures, controls, or production personnel. Under the Bureau of Veterinary Medicine's supplemental approval policy (42 FR 64367; December 23, 1977), this is a type of approval which does not require reevaluation of the safety and effectiveness data in the parent applications.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting requirements.

21 CFR Part 522

Animal drugs, Injectable.

21 CFR Part 546

Animal drugs, Antibiotics, Tetracyclines.

21 CFR Part 555

Animal drugs, Antibiotics, Chloramphenicol.

21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act (sec. 512 (i) and (n), 82 Stat. 347, 350–351 (21 U.S.C. 360b (i) and (n))) and under authority delegated to the Commissioner of Food and Drugs (21 CFR 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Parts 510, 522, 546, 555, and 558 are amended as follows:

PART 510—NEW ANIMAL DRUGS

§ 510.600 [Amended]

1. Part 510 is amended in § 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* in paragraph (c)(1) by removing the entry "Rachelle Laboratories, Inc." and in paragraph (c)(2) by removing the entry "000196."

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS NOT SUBJECT TO CERTIFICATION

2. Part 522 is amended as follows:

§ 522.540 [Amended]

a. In § 522.540 *Dexamethasome injection* in paragraph (d)(2)(iii) by removing "000196" and inserting in its place "000069."

§ 522.1662a [Amended]

b. In § 522.1662a *Oxytetracycline hydrochloride injection* in paragraph (c)(2) by removing "000196" and inserting in its place "000069."

§ 522.1662b [Amended]

c. In § 522.1662b *Oxytetracycline hydrochloride with lidocaine injection* in paragraph (b) by removing "and 000196."

PART 546—TETRACYCLINE ANTIBIOTIC DRUGS FOR ANIMAL USE

3. Part 546 is amended as follows:

§ 546.180a [Amended]

a. In § 546.180a *Tetracycline hydrochloride capsules* in paragraph (c)(5)(ii)(*c*) by removing "000196" and inserting in its place "000069."

§ 546.180b [Amended]

b. In § 546.180b *Tetracycline tablets* in paragraph (c)(3)(i)(*a*) by removing "000196" and inserting in its place "000069."

§ 546.180e [Amended]

c. In § 546.180e *Tetracycline oral liquid* in paragraph (c)(5)(i)(*d*) by removing "000196" and inserting in its place "000069."

PART 555—CHLORAMPHENICOL DRUGS FOR ANIMAL USE

4. Part 555 is amended as follows:

§ 555.110b [Amended]

a. In § 555.110b *Chloramphenicol capsules* in paragraph (c)(2)(i) by removing "000196" and inserting in its place "000069."

§ 555.110c [Amended]

b. In § 555.110c *Chloramphenicol oral solution* in paragraph (c)(2)(i) by removing "000196" and inserting in its place "000069."

§ 555.210 [Amended]

c. In § 555.210 *Chloramphenicol injection* in paragraph (c)(2) by removing "000196" and inserting in its place "000069."

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. Part 558 is amended as follows:

§ 558.15 [Amended]

a. In § 558.15 *Antibiotic, nitrofuran, and sulfonamide drugs in the feed of animals,* in paragraph (g)(1) is amended in the table in the first column under "Drug sponsor" by removing "Rachelle Laboratories, Inc.," where it appears twice and inserting in its place "Pfizer, Inc."

§ 558.145 [Amended]

b. In § 558.145 *Chlortetracycline, procaine penicillin, and sulfamethazine* in paragraph (b)(1) by removing

"000196" and inserting in its place "000069."

Effective date: July 5, 1983.

(Sec. 512(i) and (n), 82 Stat. 347, 350-351 (21 U.S.C. 360b(i) and (n)))

Dated: June 28, 1983.

Max L. Crandall,

Associate Director for Surveillance and Compliance.

[FR Doc. 83-17903 Filed 7-1-83; 8:45 am]

BILLING CODE 4160-01-M

21 CFR Part 558

New Animal Drugs for Use In Animal Feeds; Salinomycin

AGENCY: Food and Drug Administration.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a new animal drug application (NADA) filed by A. H. Robins Co. providing for use of a premix containing salinomycin to make a finished broiler feed used for preventing coccidiosis caused by certain *Eimeria* spp.

EFFECTIVE DATE: July 5, 1983.

FOR FURTHER INFORMATION CONTACT: Adriano R. Gabuten, Bureau of Veterinary Medicine (HFV-135), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-443-4913.

SUPPLEMENTARY INFORMATION:

A. H. Robins Co., 1211 Sherwood Ave., P.O. Box 26609, Richmond, VA 23261, filed NADA 128-686 to provide for use of 30 grams salinomycin (salinomycin sodium biomass) per pound of premix to make finished broiler feeds containing 40 to 60 grams salinomycin per ton of broiler feed for the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima.* The medicated feed is to be fed continuously as the sole ration to broiler chickens only and is not to be fed to laying chickens. The NADA is approved and the regulations are amended accordingly. The basis of approval is discussed in the freedom of information (FOI) summary.

In accordance with the freedom of information provisions of Part 20 (21 CFR Part 20) and § 514.11(e)(2)(ii) (21 CFR 514.11(e)(2)(ii)), a summary of safety and effectiveness data and information submitted to support approval of this application may be seen in the Dockets Management Branch (HFA-305), Food and Drug Administration, Rm. 4-62, 5600 Fishers Lane, Rockville, MD 20857, from 9 a.m. to 4 p.m., Monday through Friday.

The Bureau of Veterinary Medicine has carefully considered the potential environmental effects of this action and has concluded that the action will not have a significant impact on the human environment and that an environmental impact statement therefore will not be prepared. The Bureau of Veterinary Medicine's finding of no significant impact and the evidence supporting this finding, contained in an environmental impact analysis report (pursuant to 21 CFR 25.1(j)), may be seen in the Dockets Management Branch (address above).

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

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 5.10) and redelegated to the Bureau of Veterinary Medicine (21 CFR 5.83), Part 558 is amended by adding new § 558.550 to read as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

§ 558.550 Salinomycin.

(a) *Approvals.* Premix level of salinomycin sodium biomass equivalent to 30 grams of salinomycin sodium activity per pound to No. 000031 in § 510.600(c) of this chapter.

(b) *Assay limit.* Premix: 100 to 120 percent of labeled amount. Finished feed: 80 to 120 percent of labeled amount of drug.

(c) *Conditions of use.* It is used in complete broiler feeds as follows:

(1) *Amount per ton.* 40 to 60 grams.

(2) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. maxima, E. brunetti,* and *E. mivati.*

(3) *Limitations.* Feed continuously as sole ration. Do not feed to layers. Not approved for use with pellet binders. May be fatal if accidentally fed to adult turkeys or horses.

Effective date. July 5, 1983.

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

Dated: June 27, 1983.

Lester M. Crawford,

Director, Bureau of Veterinary Medicine.

[FR Doc. 83-17904 Filed 7-1-83; 8:45 am]

BILLING CODE 4160-01-M

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Parts 1, 92, and 161

[CGD 78-079b]

St. Marys River Vessel Traffic Service

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: This final rule, in conjuction with the final rule for CGD 78-079a which was published on April 14, 1983 at 48 FR 16059, transfers and revises the anchorage and navigation regulations for the St. Marys River, Michigan. The existing anchorage and navigation regulations are outdated and do not entirely reflect current practices on the waterway. The new regulations, the majority of which correspond with the existing regulations, will benefit the user by modernizing the existing rules, removing outdated requirements, and arranging the regulations in a format that is common to other vessel traffic management measures.

EFFECTIVE DATE: August 4, 1983.

FOR FURTHER INFORMATION CONTACT: Mr. Edward J. LaRue, Jr., (202) 426-4958.

SUPPLEMENTARY INFORMATION: On January 5, 1981, the Coast Guard published a Notice of Proposed Rulemaking (NPRM) regarding these regulations (46 FR 946). Interested persons were requested to submit comments and five letters were received from individuals, professional organizations, and other Federal agencies. The comments, suggestions, and actions taken are summarized under "Discussion of Comments".

On March 1, 1983, the Inland Navigation Rules came into effect on the Great Lakes. Because several sections of the existing St. Marys River regulations (33 CFR Part 92) were in conflict with the statutory Inland Navigation Rules, the Coast Guard published a final rule on April 14, 1983 (CGD 78-079a; 48 FR 16059) solely to eliminate those conflicts. That rulemaking deleted six sections of the existing St. Marys River regulations. The deletion of these sections was discussed in the NPRM. Although several comments were received, none addressed any of the deleted sections. The purpose of the expedited action was to eliminate the conflicts in the rules before the Great Lakes navigation season was in full swing.

This action deals with the remainder of the regulations discussed in the NPRM.