

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 71.1 [Amended]

2. The incorporation by reference in 14 CFR 71.1 of the Federal Aviation Administration Order 7400.9F, Airspace Designations and Reporting Points, dated September 10, 1998, and effective September 16, 1998, is amended as follows:

Paragraph 6007 Offshore Airspace Areas

* * * * *

Gulf of Mexico High [Revised]

That airspace extending upward from FL 280 to and including FL 600 bounded on the west, north, and east by a line 12 miles offshore and parallel to the Texas, Louisiana, Mississippi, Alabama, and Florida shorelines; bounded on the south from east to west by the shorelines; bounded on the south from east to west by the southern boundary of the Jacksonville ARTCC, Miami Oceanic CTA/FIR; Merida UTA/UIR, Houston CTA/FIR; Monterrey UTA/UIR, Houston CTA/FIR; to the point of beginning, and that airspace extending upward from 18,000 feet MSL to and including FL 280 bounded on the west, north, and east by a line 12 miles offshore and parallel to the Texas, Louisiana, Mississippi, Alabama, and Florida shorelines bounded on the south from east to west by the southern boundary of the Jacksonville ARTCC, Miami Oceanic CTA/FIR, Houston CTA/FIR and lat. 26°00'00" N.

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Issued in Washington, DC, on March 15, 1999.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 99-6752 Filed 3-18-99; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF TRANSPORTATION

Federal Aviation Administration

14 CFR Part 73

[Airspace Docket No. 98-ASO-19]

RIN 2120-AA66

Amend Controlling and Using Agencies for Restricted Area R-2908, Pensacola, FL

AGENCY: Federal Aviation Administration (FAA), DOT.

ACTION: Final rule.

SUMMARY: This action corrects the title of the controlling agency from "FAA, Pensacola RATCF," to "FAA, Pensacola TRACON," and changes the using agency from "Commander, Training Air Wing Six, Naval Air Station," to "U.S. Navy Flight Demonstration Squadron,

Pensacola NAS, FL," for Restricted Area R-2908, Pensacola, FL.

EFFECTIVE DATE: 0901 UTC, May 20, 1999.

FOR FURTHER INFORMATION CONTACT: Paul Gallant, Airspace and Rules Division, ATA-400, Office of Air Traffic Airspace Management, Federal Aviation Administration, 800 Independence Avenue, SW., Washington, DC 20591; telephone (202) 267-8783.

SUPPLEMENTARY INFORMATION:

The Rule

This action amends 14 CFR part 73 by correcting the title of the controlling agency and changing the using agency for Restricted Area R-2908, Pensacola, FL. This action corrects the title of the controlling agency from "FAA, Pensacola RATCF," to "FAA, Pensacola TRACON." The acronym "RATCF" (Radar Air Traffic Control Facility) applies to radar facilities operated by the U.S. Navy. The facility at Naval Air Station Pensacola is operated by the FAA, therefore, the FAA acronym "TRACON" (Terminal Radar Approach Control) is more appropriate. In addition, this action changes the using agency for R-2908 from "Commander, Training Air Wing Six, Naval Air Station, Pensacola, FL," to "U.S. Navy Flight Demonstration Squadron, Pensacola NAS, FL" to reflect the organization currently responsible for scheduling the airspace.

These administrative changes will not alter the boundaries, altitudes or time of designation of R-2908; therefore, I find that notice and public procedure under 5 U.S.C. 553(b) are unnecessary.

Section 73.29 of part 73 was republished in FAA Order 7400.8F, dated October 27, 1998.

The FAA has determined that this regulation only involves an established body of technical regulations for which frequent and routine amendments are necessary to keep them operationally current. Therefore, this regulation: (1) is not a "significant regulatory action" under Executive Order 12866; (2) is not a "significant rule" under DOT Regulatory Policies and Procedures (44 FR 11034; February 26, 1979); and (3) does not warrant preparation of a regulatory evaluation as the anticipated impact is so minimal. Since this is a routine matter that will only affect air traffic procedures and air navigation, it is certified that this rule will not have a significant economic impact on a substantial number of small entities under the criteria of the Regulatory Flexibility Act.

Environmental Review

This action is a minor administrative change to amend the names of the controlling and using agencies of an existing restricted area. There are no changes to the dimensions of the restricted area, or to air traffic control procedures or routes as a result of this action. Therefore, this action is not subject to environmental assessments and procedures in accordance with FAA Order 1050.1D, "Policies and Procedures for Considering Environmental Impacts," and the National Environmental Policy Act of 1969.

List of Subjects in 14 CFR Part 73

Airspace, Navigation (air).

Adoption of the Amendment

In consideration of the foregoing, the Federal Aviation Administration amends 14 CFR part 73, as follows:

PART 73—SPECIAL USE AIRSPACE

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

Authority: 49 U.S.C. 106(g), 40103, 40113, 40120; E.O. 10854, 24 FR 9565, 3 CFR, 1959-1963 Comp., p. 389.

§ 73.29 [Amended]

2. § 73.29 is amended as follows:

* * * * *

R-2908 Pensacola, FL [Amended]

By removing "Controlling agency. FAA, Pensacola RATCF," and "Using agency. Commander, Training Air Wing Six, Naval Air Station, Pensacola, FL," and adding "Controlling agency. FAA, Pensacola TRACON," and "Using agency. U.S. Navy Flight Demonstration Squadron, Pensacola NAS, FL."

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Issued in Washington, DC, on March 15, 1999.

Reginald C. Matthews,

Acting Program Director for Air Traffic Airspace Management.

[FR Doc. 99-6751 Filed 3-18-99; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 178

[Docket No. 97F-0213]

Indirect Food Additives: Adjuvants, Production Aids, and Sanitizers

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the food additive regulations to provide for the expanded safe use of phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester as an antioxidant in polypropylene homopolymer and copolymers not to exceed 0.25 percent by weight of polypropylene homopolymer and copolymers. This action is in response to a petition filed by Asahi Denka Kogyo K.K.

DATES: The regulation is effective March 19, 1999; submit written objections and requests for a hearing by April 19, 1999.

ADDRESSES: Submit written objections to the Dockets Management Branch (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Hortense S. Macon, Food and Drug Administration, Center for Food Safety and Applied Nutrition (HFS-206), 200 C St. SW., Washington, DC 20204, 202-418-3086.

SUPPLEMENTARY INFORMATION: In a notice published in the **Federal Register** of June 9, 1997 (62 FR 31433), FDA announced that a petition (FAP 7B4542) had been filed by Asahi Denka Kogyo K.K., Shirahata 5-Chome, Urawa City, Saitama 366, Japan. The petition proposed to amend the food additive regulations in § 178.2010 *Antioxidants and/or stabilizers for polymers* (21 CFR 178.2010) to provide for the expanded safe use of phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl) ester for use: (1) At levels not to exceed 0.25 percent by weight of olefin copolymers complying with § 177.1520 (21 CFR 177.1520) in contact with foods of types I, II, III, IV-B, VI-B, and VIII, as described in Table 1, and under conditions of use B through H, described in Table 2 of § 176.170(c) (21 CFR 176.170(c)), of this chapter, and with foods types IV-A, V, VI-A, VI-C, VII-A, and IX, under conditions of use C through G, as described in § 176.170(c), Tables 1 and 2, respectively; and (2) at levels not to exceed 0.10 percent by weight of either olefin copolymers or polypropylene complying with § 177.1520 which may be used in contact with foods of types IV-A, V, VI-C, VII-A, and IX, under conditions of use H, as described in § 176.170(c) of this chapter, Tables 1 and 2 respectively. When the petition was filed on June 9, 1997, it contained an environmental assessment (EA). In the notice of filing, the agency announced that it was placing the EA on display at the Dockets Management

Branch for public review and comment. No comments were received.

Subsequent to filing of the petition, the petitioner requested that the petition be amended to permit use of the subject additive as an antioxidant in polypropylene homopolymer and copolymers, at a use level not to exceed 0.25 percent by weight, for all food types described in Table 1 under conditions of use B through H as described in Table 2 of § 176.170(c) of this chapter. Therefore, in a notice published in the **Federal Register** of August 28, 1998 (63 FR 46053), FDA announced that the filing notice of June 9, 1997, was amended to include the petitioned additive, phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl) ester for use as an antioxidant in polypropylene homopolymer and copolymers for all food types under conditions of use B through H.

In the amended filing notice of August 28, 1998, the agency incorrectly stated that it was placing the EA for the petition on display at the Dockets Management Branch for public review and comment. Instead, the original EA was maintained at the Dockets Management Branch. On October 15, 1998, the petitioner submitted a claim of categorical exclusion under new § 25.32(i) (21 CFR 25.32(i)), in accordance with the procedures in 21 CFR 25.15(a) and (d). Because the agency had not completed the review of an EA for the use of the subject additive that was described in the amended filing notice, the agency reviewed the claim of categorical exclusion under § 25.32(i) for this final rule.

FDA has evaluated data in the petition and other relevant material. Based on this information, the agency concludes that: (1) The proposed use of the additive is safe, (2) the additive will achieve its intended technical effect, and therefore, (3) that the regulations in § 178.2010 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 Center for Food Safety and Applied Nutrition by appointment with the information contact person listed above. As provided in § 171.1(h), 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 determined under § 25.32(i) that this action is of a type that does not individually or

cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

This final rule contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

Any person who will be adversely affected by this regulation may at any time on or before April 19, 1999, file with the Dockets Management Branch (address above) written objections thereto. Each objection shall be separately numbered, and each numbered objection shall specify with particularity the provisions of the regulation to which objection is made and the grounds for the objection. 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 document. Any objections received in response to the regulation may be seen in the Dockets Management Branch between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects in 21 CFR Part 178

Food additives, Food packaging. Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Director, Center for Food Safety and Applied Nutrition, 21 CFR part 178 is amended to read as follows:

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

1. The authority citation for 21 CFR part 178 continues to read as follows:

Authority: 21 U.S.C. 321, 342, 348, 379e.

2. Section 178.2010 is amended in the table in paragraph (b) by revising the entry for "phosphorous acid, cyclic neopentetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl) ester" in item "1." under the heading "Limitations" to read as follows:

§ 178.2010 Antioxidants and/or stabilizers for polymers. (b) * * *

* * * * *

| Substances | Limitations |
|---|--|
| <p>* * * Phosphorous acid, cyclic neopentantetrayl bis(2,6-di-<i>tert</i>-butyl-4-methylphenyl)ester (CAS Reg. No. 80693-00-1). * * *</p> | <p>* * * For use only: 1. At levels not to exceed 0.25 percent by weight of polypropylene homopolymer and copolymers complying with § 177.1520 of this chapter, for use with all food types described in table 1 of § 176.170(c) of this chapter only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter. * * *</p> |

Dated: March 1, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99-6667 Filed 3-18-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Lincomycin Hydrochloride Soluble Powder

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for use of 40- and 80-gram packets and 32-ounce containers of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and broiler chickens for the control of necrotic enteritis.

EFFECTIVE DATE: March 19, 1999.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, has filed ANADA 200-241 that provides for use of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of

dysentery (bloody scours) and for broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin. The ANADA provides for use of 40- and 80-gram packets and 32-ounce containers of product.

The ANADA is approved as a generic copy of Pharmacia & Upjohn's NADA 111-636, Lincomix® Soluble Powder. ANADA 200-241 is approved as of February 4, 1999, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis for approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 5630 Fishers Lane, rm.1061, Rockville, MD 20852, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

List of Subjects in 21 CFR Part 520

Animal drugs.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

Authority: 21 U.S.C. 360b.

2. Section 520.1263c is amended by adding a sentence to the end of paragraph (a) and by revising paragraph (b) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications.* * * * The 40-gram measuring device contains lincomycin hydrochloride equivalent to 16 grams of lincomycin (the measuring device is packaged with a 32-ounce jar).

(b) *Sponsors.* Approval for use of 40- and 80-gram packet to Nos. 000009 and 017144 in § 510.600(c) of this chapter. Approval for use of 40- and 80-gram packet and 32-ounce jar to No. 051259 in § 510.600(c) of this chapter.

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Dated: February 26, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99-6671 Filed 3-18-99; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Doramectin

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of a supplemental new animal drug application (NADA) filed by Pfizer,