

manufacture fibers satisfying the definition also may use the subclass name in making required fiber content disclosures on labels.

The Commission has decided to simplify slightly the definition of "lastol" that Dow proposed and the Commission published for comment. The definition the Commission is adopting, however, is consistent with the definition, as proposed, as well as with the definition of "olefin" in rule 7(m). The new definition of "lastol" defines the fiber generically in terms of its chemical composition, and identifies its physical elasticity and heat resistance characteristics. In addition, the Commission is reducing the minimum percentage by weight of ethylene and other olefin unit constituting the polymer in the final definition of "lastol" from 99 percent, as proposed, to 95 percent to account for a small percentage of inorganic molecules in the fiber that, according to Dow, are not included in the polymer.

Accordingly, for the reasons discussed above, the Commission amends rule 7(m) of the Textile Rules by adding the following sentence at the end:

Where the fiber-forming substance is a cross-linked synthetic polymer, with low but significant crystallinity, composed of at least 95 percent by weight of ethylene and at least one other olefin unit, and the fiber is substantially elastic and heat resistant, the term *lastol* may be used as a generic description of the fiber.

III. Effective Date

The Commission is making the amendments effective today, January 27, 2003, as permitted by 5 U.S.C. 553(d), because the amendments do not create new obligations under the rule; rather, they merely create a fiber name and definition that the public may use to comply with the rule.

IV. Regulatory Flexibility Act

In the NPR, the Commission tentatively concluded that the provisions of the Regulatory Flexibility Act relating to an initial regulatory analysis, 5 U.S.C. 603–604, did not apply to the proposal because the amendments, if promulgated, would not have a significant economic impact on a substantial number of small entities. The Commission believed that the proposed amendments would impose no additional obligations, penalties, or costs. The amendments simply would allow covered companies to use a new generic name as an alternative to an existing generic name for that defined subclass of fiber, and would impose no additional labeling requirements. To

ensure, however, that no substantial economic impact was overlooked, the Commission solicited public comment in the NPR on the effects of the proposed amendments on costs, profits, competitiveness of, and employment in small entities. 67 FR 36551, at 36554 (May 24, 2002).

No comments were received on this issue. Accordingly, the Commission hereby certifies, pursuant to the Regulatory Flexibility Act, 5 U.S.C. 605(b), that the amendments promulgated today will not have a significant economic impact on a substantial number of small entities.

V. Paperwork Reduction Act

These amendments do not constitute "collection[s] of information" under the Paperwork Reduction Act of 1995, Pub. L. 104–13, 109 Stat. 163, 44 U.S.C. chapter 35 (as amended), and its implementing regulations, 5 CFR part 1320 *et seq.* Those procedures for establishing generic names that do constitute collections of information, 16 CFR 303.8, have been submitted to OMB, which has approved them and assigned them control number 3084–0101.

List of Subjects in 16 CFR Part 303

Labeling, Textile, Trade practices.

VI. Text of Amendments

For reasons set forth in the preamble, 16 CFR part 303 is amended as follows:

PART 303—RULES AND REGULATIONS UNDER THE TEXTILE FIBER PRODUCTS IDENTIFICATION ACT

1. The authority citation for part 303 continues to read as follows:

Authority: Sec. 7(c) of the Textile Fiber Products Identification Act (15 U.S.C. 70e(c)).

2. In § 303.7, paragraph (m) is amended by adding a sentence at the end, to read as follows:

§ 303.7 Generic names and definitions for manufactured fibers.

* * * * *

(m) * * * Where the fiber-forming substance is a cross-linked synthetic polymer, with low but significant crystallinity, composed of at least 95 percent by weight of ethylene and at least one other olefin unit, and the fiber is substantially elastic and heat resistant, the term *lastol* may be used as a generic description of the fiber.

* * * * *

By direction of the Commission.

Donald S. Clark,

Secretary.

[FR Doc. 03–1739 Filed 1–24–03; 8:45 am]

BILLING CODE 6750–01–P

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 Phoenix Scientific, Inc. The ANADA provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis.

DATES: This rule is effective January 27, 2003.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, St. Joseph, MO 64506–0457, filed ANADA 200–303 for Lincomycin Hydrochloride Soluble Powder. The application provides for oral use of lincomycin soluble powder to make medicated drinking water for administration to swine for the treatment of swine dysentery or to broiler chickens for the control of necrotic enteritis. Phoenix Scientific's Lincomycin Hydrochloride Soluble Powder is approved as a generic copy of Pharmacia & Upjohn's LINCOMIX Soluble Powder, approved under NADA 111–636. ANADA 200–303 is approved as of October 1, 2002, and the regulations are amended in 21 CFR 520.1263c to reflect the approval. The basis of 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.

FDA 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to congressional review requirements in 5 U.S.C. 801-808.

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.

§ 520.1263c [Amended]

2. Section 520.1263c *Lincomycin hydrochloride soluble powder* is amended in paragraph (b) by removing "and 051259" and by adding in its place "051259, and 059130".

Dated: January 7, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-1685 Filed 1-24-03; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Pour- On

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 First Priority, Inc. The ANADA provides for topical use of ivermectin on cattle for treatment and control of various species of external and internal parasites.

DATES: January 27, 2003.

FOR FURTHER INFORMATION CONTACT:

Lonnie W. Luther, Center for Veterinary Medicine (HFV-104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301-827-8549, e-mail: lluther@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: First Priority, Inc., 1585 Todd Farm Dr., Elgin, IL 60123, filed ANADA 200-340 for PRIVERMECTIN (ivermectin). The application provides for topical use of 0.5 percent ivermectin solution on cattle for the treatment and control of various species of gastrointestinal nematodes, lungworms, grubs, horn flies, lice, and mites. First Priority's PRIVERMECTIN is approved as a generic copy of Merial Ltd.'s IVOMEC Pour-On for Cattle, approved under NADA 140-841. The ANADA is approved as of December 4, 2002, and 21 CFR 524.1193 is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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, 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.

This rule does not meet the definition of "rule" in 5 U.S.C. 804(3)(A) because it is a rule of "particular applicability." Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801-808.

List of Subjects in 21 CFR Part 524

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

§ 524.1193 [Amended]

2. Section 524.1193 *Ivermectin pour-on* is amended in paragraph (b) by adding "058829," after "051311,".

Dated: January 6, 2003.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 03-1686 Filed 1-24-03; 8:45 am]

BILLING CODE 4160-01-S

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[FL-82-200309a; FRL-7443-3]

Approval and Promulgation of Implementation Plans; Florida: Approval of Revisions to the Florida State Implementation Plan

AGENCY: Environmental Protection Agency (EPA).

ACTION: Direct final rule.

SUMMARY: EPA is approving revisions to the Florida State Implementation Plan (SIP) submitted on September 7, 1999, by the State of Florida through the Florida Department of Environmental Protection (FDEP). The purpose of the revisions to rule 62-212.400 is to correct discrepancies between State and Federal rule language on exemptions from Prevention of Significant Deterioration and to include additional provisions.

DATES: This direct final rule is effective March 28, 2003 without further notice, unless EPA receives adverse comment by February 26, 2003. If adverse comment is received, EPA will publish a timely withdrawal of the direct final rule in the **Federal Register** and inform the public that the rule will not take effect.

ADDRESSES: All comments should be addressed to Heidi LeSane at the EPA, Region 4 Air Planning Branch, 61 Forsyth Street, SW., Atlanta, Georgia 30303-8960.

Copies of the state submittal are available at the following addresses for inspection during normal business hours:

Environmental Protection Agency,
Atlanta Federal Center, Region 4 Air
Planning Branch, 61 Forsyth Street
SW., Atlanta, Georgia 30303-8960.