

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.