Dated: February 8, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 01–5682 Filed 3–7–01; 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; Clindamycin Hydrochloride Liquid

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 abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The supplemental ANADA provides for oral use of clindamycin hydrochloride liquid for treatment of soft tissue and dental infections in cats.

DATES: This rule is effective March 8, 2001.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0212.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed a supplement to approved ANADA 200–193 for Clindamycin Hydrochloride Oral Liquid. The supplemental ANADA provides for use of clindamycin hydrochloride liquid for treatment of soft tissue and dental infections in cats caused by or associated with susceptible strains of certain bacterial species. The supplemental application is approved as of December 27, 2000, and the regulations are amended in 21 CFR 520.447 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.

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 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.

§ 520.447 [Amended]

2. Section 520.447 *Clindamycin hydrochloride liquid* is amended in paragraph (b) in the first sentence by removing ''No. 000009'' and adding in its place ''Nos. 000009 and 059130'' and by removing the second sentence.

Dated: January 30, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 01–5683 Filed 3–7–01; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Milbemycin Oxime Solution

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 Novartis Animal Health US, Inc. The supplemental NADA provides for veterinary prescription use of milbemycin oxime solution to treat ear mite infestations in cats and kittens 4 weeks of age and older and for a repeat treatment, if necessary.

DATES: This rule is effective March 8, 2001.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Novartis Animal Health US, Inc., 3200 Northline Ave., suite 300, Greensboro, NC 27408, filed a supplement to approved NADA 141–163 that provides for the veterinary prescription use of Milbemite ™ Otic Solution (0.1% milbemycin oxime) for the treatment of ear mite infestations in cats and kittens. The supplemental NADA provides for reducing the lower age limit from 8 weeks of age to 4 weeks of age and for repeating treatment one time, if necessary. The NADA is approved as of December 13, 2000, and the regulations are amended in 21 CFR 524.1446 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning December 13, 2000, because the application contains substantial evidence of effectiveness of the drug involved or any studies of animal safety required for approval of the application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(d)(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.

§ 524.1446 [Amended]

2. Section 524.1446 *Milbemycin oxime solution* is amended in paragraph (c)(1) by removing ''as a single treatment'' and in paragraph (c)(2) in the first sentence by removing ''8'' and adding in its place ''4''.

Dated: January 5, 2001.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 01–5684 Filed 3–7–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Bureau of Alcohol, Tobacco and Firearms

27 CFR Part 275

[T.D. ATF–444]

RIN 1512–AC24

Puerto Rican Tobacco Products and Cigarette Papers and Tubes Shipped From Puerto Rico to the United States

AGENCY: Bureau of Alcohol, Tobacco and Firearms (ATF), Treasury.

ACTION: Temporary rule (Treasury decision).

SUMMARY: This temporary rule eliminates ATF on-site supervision of tobacco products and cigarette papers and tubes of Puerto Rican manufacture that are shipped from Puerto Rico to the United States and related ATF forms. Specifically, this temporary rule eliminates the requirements that persons who ship such articles notify ATF prior to the shipment and that an ATF officer inspects, certifies that the amount of tax on such articles has been calculated correctly for, and releases, each shipment. Consequently, four ATF forms are eliminated. However, this rule requires that persons who ship such articles maintain records so that the amount of tax is calculated and recorded for ATF audit and examination. Also, this temporary rule revises certain sections to simplify and clarify and corrects a few typographical errors. In the Proposed Rules section of this **Federal Register**, ATF is also issuing a notice of proposed rulemaking inviting comments on this temporary rule for a 60-day period following the publication of this temporary rule.

EFFECTIVE DATE: This rule is effective March 8, 2001.

FOR FURTHER INFORMATION CONTACT: Robert Ruhf, Regulations Division, Bureau of Alcohol, Tobacco and Firearms, 650 Massachusetts Avenue NW., Washington, DC 20226 (telephone 202–927–8210 or e-mail to alctob@atfhq.atf.treas.gov).

SUPPLEMENTARY INFORMATION:

Background

Elimination of On-Site Supervision and Forms

ATF is eliminating the on-site supervision of, and ATF forms for, shipments of tobacco products and cigarette papers and tubes of Puerto Rican manufacture from Puerto Rico to the United States. ATF believes that the elimination of this supervision and these ATF forms will benefit the companies involved with such shipments and the Government.

ATF has discussed the proposed changes with the three companies in Puerto Rico who currently ship Puerto Rican tobacco products from Puerto Rico to the United States. All of the companies were in favor of eliminating the on-site ATF supervision of shipments of Puerto Rican tobacco products and cigarette papers and tubes from Puerto Rico to the United States. In addition, all of the companies reported that they were ready to use commercial records immediately to replace the ATF forms 2987(5210.8) and 3075(5200.9). The replacement of these ATF forms with commercial records would not be an additional burden since the ATF forms repeat much of the information contained in the companies' commercial records. In fact, it would eliminate the time spent in preparing, distributing and maintaining these ATF forms and arranging for ATF personnel to supervise each shipment.

This temporary rule allows greater flexibility and choice in managing the limited resources of the Bureau. ATF now conducts audits of the commercial records of companies who ship Puerto Rican tobacco products or cigarette papers and tubes from Puerto Rico to the United States. This temporary rule eliminates the requirement that ATF personnel be present at a particular place and time to inspect and certify each shipment. In addition, this temporary rule relieves the Bureau from the costs associated with revising, printing, stocking and distributing the four ATF forms related to shipments of such products from Puerto Rico to the United States.

In addition, this temporary rule eliminates the requirement that an ATF officer prepare a certificate (ATF Forms 2989 and 3074) for each shipment of Puerto Rican tobacco products or cigarette papers or tubes. These certificates are affixed to the outside of the package of each container and state that the United States tax has been paid. We believe that these certificates are not necessary to protect the revenue and do not improve compliance with the Federal excise tax on tobacco products and cigarette papers and tubes. For commercial shipments, the records maintained by the manufacturer or shipper may be examined by an appropriate ATF officer to determine that the tax has been paid. In the case of noncommercial mail shipments, an appropriate ATF officer may request ATF Form 5000.25, Excise Tax Return—Alcohol and Tobacco (Puerto Rico), from the taxpayer as evidence that the tax has been paid.

Delegations

In the sections of the regulations that are affected by this document, we have removed references to specific ATF officers with whom an ATF Form is filed. The instructions on the ATF form specify the ATF officer with whom the ATF form is filed. Also, we changed ''ATF officer'' in § 275.106(b) to read ''appropriate ATF officer''. The ''appropriate ATF officer'' is specified in a delegation order, ATF O 1130.16A. Conforming changes for referencing this ATF order have also been made in this document. The titles of ATF officials in the sections of this part which are not revised by this temporary rule will be updated by a future technical amendment.

Other Changes

Whenever possible, we tried to simplify and clarify the format and language of the particular sections involved. For example, we revised § 275.121 by revising its language and used a chart to explain some of its requirements. Also, we have made a conforming and clarifying addition to the definition of ''records'' in § 275.11. This addition will ensure that persons in Puerto Rico who ship Puerto Rican tobacco products or cigarette papers or