

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Ter., St. Joseph, MO 64503, filed a supplement to ANADA 200–265 that provides for use of PRAZI-C (praziquantel) Tablets for the removal of certain tapeworm parasites in dogs. Phoenix Scientific, Inc.'s PRAZI-C Tablets are approved as a generic copy of Bayer HealthCare LLC's Tape Worm Tabs approved under NADA 111–798. The supplemental ANADA is approved as of September 15, 2004, and the regulations are amended in 21 CFR 520.1870 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 Division of Dockets Management (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.

■ 2. Section 520.1870 is amended by revising paragraph (b)(2) to read as follows:

§ 520.1870 Praziquantel tablets.

* * * * *

(b) * * *

(2) No. 059130 for use of the product described in paragraph (a)(1) of this

section, as in paragraph (c)(1) of this section.

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Dated: October 14, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 04–23761 Filed 10–22–04; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 524

Ophthalmic and Topical Dosage Form New Animal Drugs; Ivermectin Topical 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 an abbreviated new animal drug application (ANADA) filed by Norbrook Laboratories, Ltd. The ANADA provides for topical use of ivermectin on cattle for treatment and control of various species of external and internal parasites.

DATES: This rule is effective October 25, 2004.

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: lonnie.luther@fda.gov.

SUPPLEMENTARY INFORMATION: Norbrook Laboratories, Ltd., Station Works, Newry BT35 6JP, Northern Ireland, filed ANADA 200–272 for NOROMECTIN (ivermectin) Pour On for Cattle. 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. Norbrook Laboratories, Ltd.'s NOROMECTIN Pour-On for Cattle is approved as a generic copy of Merial Ltd.'s IVOMEC Pour-On for Cattle, approved under NADA 140–841. The application is approved as of September 13, 2004, and the regulations are amended in 21 CFR 524.1193 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 Division of Dockets Management (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 is amended in paragraph (b)(2) by adding in numerical order “055529”.

Dated: October 8, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 04–23760 Filed 10–22–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF THE TREASURY

Internal Revenue Service

26 CFR Parts 1 and 602

[TD 9160]

RIN 1545–AY35

Information Reporting Under Section 6050P for Discharges of Indebtedness

AGENCY: Internal Revenue Service (IRS), Treasury.

ACTION: Final regulations.