

30d-1" to read "Section 30(e) of the 1940 Act and Rule 30e-1".

By the Commission.

Dated: February 27, 2001.

Margaret H. McFarland,

Deputy Secretary.

[FR Doc. 01-5244 Filed 3-2-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Oxytetracycline Injection

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 Pennfield Oil Co. The ANADA provides for the subcutaneous administration of oxytetracycline injectable solution in cattle.

DATES: This rule is effective March 5, 2001.

FOR FURTHER INFORMATION CONTACT:

Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

SUPPLEMENTARY INFORMATION: Pennfield Oil Co., 14040 Industrial Rd., Omaha, NE 68137, filed a supplement to ANADA 200-154 that provides for the use of PENNOX™ (oxytetracycline) 200 Injection as treatment for various bacterial diseases in cattle and swine. The supplemental ANADA provides for the subcutaneous administration of oxytetracycline injectable solution in beef cattle, nonlactating dairy cattle, and calves, including preruminating (veal) calves. The supplemental ANADA is approved as of January 12, 2001, and the regulations are amended in 21 CFR 522.1660 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 Subject in 21 CFR Part 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

§ 522.1660 [Amended]

2. Section 522.1660 *Oxytetracycline injection* is amended in the second sentence in paragraph (d)(1)(iii) by removing "Sponsor 000010," and by adding in its place "Sponsors 000010 and 053389".

Dated: February 8, 2001.

Claire M. Lathers,

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

[FR Doc. 01-5223 Filed 3-2-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Ivermectin

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 use of ivermectin injection for the treatment and control of various species of external and internal parasites in cattle, swine, reindeer, and American bison.

DATES: This rule is effective March 5, 2001.

FOR FURTHER INFORMATION CONTACT:

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

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506-0457, filed ANADA 200-228 that provides for use of Phoenectin™ (ivermectin) Injection for cattle and swine. The ANADA provides for use of a 1 percent solution of ivermectin, by subcutaneous injection, in cattle for the treatment and control of various species of gastrointestinal nematodes, lungworms, grubs, lice, and mites; in swine for the treatment and control of various species of gastrointestinal nematodes, lungworms, lice, and mites; in reindeer for the treatment and control of warbles; and in American bison for the treatment and control of grubs. The ANADA is approved as a generic copy of Merial Ltd.'s NADA 128-409 for Ivomec® (ivermectin) Injection.

ANADA 200-228 is approved as of December 27, 2000, and the regulations are amended in 21 CFR 522.1192 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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:

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

2. Section 522.1192 is amended by revising paragraph (b) to read as follows:

§ 522.1192 Ivermectin injection.

* * * * *

(b) *Sponsors.* See No. 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section. See No. 059130 in § 510.600(c) of this chapter for use as in paragraphs (d)(2), (d)(3), (d)(4), and (d)(6) of this section.

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Dated: February 12, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-5222 Filed 3-2-01; 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 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 Med-Pharmex, Inc. 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 March 5, 2001.

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

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767-1861, filed

ANADA 200-299 for 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. Med-Pharmex's Ivermectin Pour-On for Cattle is approved as a generic copy of Merial Limited's IVOMEC® (ivermectin) Pour-On for Cattle, approved under NADA 140-841. ANADA 200-299 is approved as of December 28, 2000, and the regulations in § 524.1193 (21 CFR 524.1193) are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary. Section 524.1193 is further revised to reflect current format and to reflect the expiration of 3 years of marketing exclusivity granted to Merial Ltd., in 1997 (62 FR 38907, July 21, 1997), for which revisions were made to § 524.1193 (63 FR 44384, August 19, 1998).

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 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.

2. Section 524.1193 is amended in paragraph (a) by adding "(mL)" after "milliliter"; by revising paragraph (b); by redesignating paragraph (d) as paragraph (e) and by adding new paragraph (d); and by revising redesignated paragraph (e) to read as follows:

§ 524.1193 Ivermectin pour-on.

* * * * *

(b) *Sponsors.* See Nos. 050604, 051259, and 059130 in § 510.600(c) of this chapter for use as in paragraph (e) of this section.

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) *Conditions of use.* (1) *Amount.* One mL per 22 pounds of body weight.

(2) *Indications for use in cattle.* It is used topically for the treatment and control of: Gastrointestinal roundworms (adults and fourth-stage larvae) *Ostertagia ostertagi* (including inhibited stage), *Haemonchus placei*, *Trichostrongylus axei*, *T. colubriformis*, *Cooperia* spp., *Oesophagostomum radiatum*; (adults) *O. venulosum*, *Strongyloides papillosus*, *Trichuris* spp.; lungworms (adults and fourth-stage larvae) *Dictyocaulus viviparus*; cattle grubs (parasitic stages) *Hypoderma bovis*, *H. lineatum*; mites *Chorioptes bovis*, *Sarcoptes scabiei* var. *bovis*; lice *Linognathus vituli*, *Haematopinus euryesternus*, *Damalina bovis*, *Solenoptes capillatus*; horn flies *Haematobia irritans*. It is also used to control infections of gastrointestinal roundworms *O. ostertagi*, *O. radiatum*, *H. placei*, *T. axei*, *Cooperia punctata*, and *C. oncophora* for 14 days after treatment.

(3) *Limitations.* Do not treat cattle within 48 days of slaughter. Because a withdrawal time in milk has not been established, do not use in female dairy cattle of breeding age.

Dated: February 12, 2001.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 01-5221 Filed 3-2-01; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Monensin, Bacitracin Methylenedisalicylate, and Roxarsone

AGENCY: Food and Drug Administration, HHS.