

§ 520.1660d Oxytetracycline hydrochloride soluble powder.

(a) * * *
 (3) Each 1.32 grams of powder contains 1 gram of OTC HCl (packets: 2.39, 4.78, and 9.55 oz.; jars: 2.25 lbs.; and pails: 4.5 lbs.).

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Dated: July 29, 1998.

Margaret Ann Miller,

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

[FR Doc. 98-22266 Filed 8-18-98; 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; Iron Hydrogenated Dextran 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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for intramuscular use of iron hydrogenated dextran injection in baby pigs for prevention or treatment of iron deficiency anemia.

EFFECTIVE DATE: August 19, 1998.

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 200-254 that provides for intramuscular use of iron hydrogenated dextran injection in baby pigs for prevention or treatment of iron deficiency anemia.

Approval of Phoenix Scientific, Inc.'s ANADA 200-254 for iron hydrogenated dextran injection is as a generic copy of Boehringer Ingelheim Vetmedica, Inc.'s NADA 106-772 iron dextran complex injection. The ANADA is approved as of July 14, 1998, and the regulations are amended in § 522.1183(e)(1) (21 CFR 522.1183(e)(1)) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 522.1183(b) provides for the National Academy of Sciences/ National Research Council (NAS/NRC) status of the product. With enactment of

the Generic Animal Drug and Patent Term Restoration Act of 1996, that paragraph is outdated. Therefore, paragraph (b) is removed and reserved.

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 the 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.

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.

§ 522.1183 [Amended]

2. Section 522.1183 *Iron hydrogenated dextran injection* is amended by removing and reserving paragraph (b), and in paragraph (e)(1) by removing "Nos. 000010, 017287, and 050604," and adding in its place "Nos. 000010, 017287, 050604, and 059130".

Dated: July 29, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-22229 Filed 8-18-98; 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 Phoenix Scientific, Inc. The ANADA provides for use of ivermectin topical (pour-on) solution on cattle for the treatment and control of worms, grubs, lice, mites, and flies.

EFFECTIVE DATE: August 19, 1998.

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 200-219 that provides for the topical use of Phoenectin™ Pour-On (5 milligrams of ivermectin per milliliter) for cattle for the treatment and control of gastrointestinal roundworms (including inhibited *Ostertagia ostertagi*), lungworms, grubs, horn flies, sucking and biting lice, and sarcoptic mange mites.

Phoenix Scientific, Inc.'s ANADA 200-219 ivermectin topical (pour-on) solution for cattle is approved as a generic copy of Merial, Ltd.'s NADA 140-841 Ivomec® (ivermectin) Pour-On for Cattle. The ANADA is approved as of July 6, 1998, and 21 CFR 524.1193(b) and (d)(2) are 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 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.

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 by revising paragraphs (b) and (d)(2) to read as follows:

§ 524.1193 Ivermectin pour-on.

* * * * *

(b) *Sponsors.* (1) See No. 050604 in § 510.600(c) of this chapter for use as in paragraph (d) of this section.

(2) See No. 059130 for use as in paragraphs (d)(1), (d)(2)(i), and (d)(3) of this section.

* * * * *

(d) * * *

(2) *Indications for use.* (i) For cattle: It is used 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 eurysternus*, *Damalina bovis*, *Solenoptes capillatus*; horn flies *Haematobia irritans*.

(ii) For cattle: 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.

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Dated: August 3, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98-22226 Filed 8-18-98; 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; Bacitracin Methylene Disalicylate and Chlortetracycline

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 Alpharma Inc. The supplemental NADA provides for using approved single ingredient bacitracin methylene disalicylate (BMD) and chlortetracycline (CTC) Type A medicated articles to make Type B medicated feeds used to make Type C medicated swine feeds.

EFFECTIVE DATE: August 19, 1998.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1652.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 141-059 that provides for combining approved BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) BMD) and CTC® (50, 65, or 70 g/lb CTC) Type A medicated articles to make Type B medicated feed. The Type B medicated feed containing 1 to 3 g/lb BMD and 40 g/lb CTC is used to make Type C medicated swine feed containing 10 to 30 g per ton (g/t) BMD and 400 g/t CTC. The Type C medicated swine feeds are used for treatment of bacterial enteritis caused by *Escherichia coli* and *Salmonella choleraesuis*, and bacterial pneumonia caused by *Pasteurella multocida* susceptible to CTC, and for increased rate of weight gain and improved feed efficiency. The supplemental NADA is approved as of

June 24, 1998, and the regulations are amended in the table in 21 CFR 558.76(d)(1) to reflect the approval. The basis for 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)(3) 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.

List of Subjects in 21 CFR Part 558

Animal drugs, Animal feeds.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under the authority delegated to the Commissioner of Food and Drugs and redelegated to the Center for Veterinary Medicine, 21 CFR part 558 is amended as follows:

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

1. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

2. Section 558.76 is amended in the table in paragraph (d)(1) by revising entry (iv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(1) * * *

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* * *	* * *	* * *	* * *	* * *
(iv) 10 to 30	Swine: for increased rate of weight gain and improved feed efficiency.	For growing and finishing swine.	000004 and 046573