§ 178.2010 Antioxidants and/or stabilizers for polymers.

(b) * * *

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Substances	Limitations
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Phosphorous acid, cyclic neopentanetetrayl bis(2,6-di-*tert*-butyl-4-methylphenyl)ester (CAS Reg. No. 80693–00–1).	For use only: 1. At levels not to exceed 0.25 percent by weight of polypropylene homopolymer and copolymers complying with § 177.1520 of this chapter, for use with all food types described in table 1 of § 176.170(c) of this chapter only under conditions of use B through H described in table 2 of § 176.170(c) of this chapter.
* * *	* * * *

Dated: March 1, 1999.

L. Robert Lake,

Director, Office of Policy, Planning and Strategic Initiatives, Center for Food Safety and Applied Nutrition.

[FR Doc. 99–6667 Filed 3–18–99; 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; Lincomycin Hydrochloride Soluble Powder

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 use of 40- and 80-gram packets and 32-ounce containers of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and broiler chickens for the control of necrotic enteritis.

EFFECTIVE DATE: March 19, 1999.

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, has filed ANADA 200–241 that provides for use of lincomycin hydrochloride soluble powder to make medicated drinking water for swine for the treatment of dysentery (bloody scours) and for broiler chickens for the control of necrotic enteritis caused by *Clostridium perfringens* susceptible to lincomycin. The ANADA provides for use of 40- and 80-gram packets and 32-ounce containers of product.

The ANADA is approved as a generic copy of Pharmacia & Upjohn's NADA 111–636, Lincomix® Soluble Powder. ANADA 200–241 is approved as of February 4, 1999, and the regulations are amended in 21 CFR 520.1263c 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)(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 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 520.1263c is amended by adding a sentence to the end of paragraph (a) and by revising paragraph (b) to read as follows:

§ 520.1263c Lincomycin hydrochloride soluble powder.

(a) *Specifications.* * * * The 40-gram measuring device contains lincomycin hydrochloride equivalent to 16 grams of lincomycin (the measuring device is packaged with a 32-ounce jar).

(b) *Sponsors.* Approval for use of 40- and 80-gram packet to Nos. 000009 and 017144 in § 510.600(c) of this chapter. Approval for use of 40- and 80-gram packet and 32-ounce jar to No. 051259 in § 510.600(c) of this chapter.

* * * * *

Dated: February 26, 1999.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 99–6671 Filed 3–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Doramectin

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 Pfizer,

Inc. The supplemental NADA provides for extended use of doramectin in cattle for persistent control of nematodes including *Haemonchus placei* for 14 days after treatment.

EFFECTIVE DATE: March 19, 1999.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7575.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, filed supplemental NADA 141–061 that provides for subcutaneous and intramuscular use of Dectomax® (doramectin) 1 percent injectable solution in cattle to control infections and to protect from reinfection with *H. placei* for 14 days after treatment. The persistent use is in addition to the approved use in cattle for treatment and control of various gastrointestinal roundworms, lungworms, eyeworms, grubs, sucking lice, and mange mites, and to control infections and to protect from reinfection with *Cooperia oncophora* for 14 days, *Ostertagia ostertagi* for 21 days, and *Cooperia punctata, Oesophagostomum radiatum*, and *Dictyocaulus viviparus* for 28 days after treatment.

Supplemental NADA 141–061 is approved as of February 1, 1999, and the regulations are amended in 21 CFR 522.770(d)(1)(ii) 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 data and information submitted to support approval of the supplemental 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 supplemental approval for food-producing animals qualifies for 3 years of marketing exclusivity beginning February 1, 1999, because the supplement contains substantial evidence of the effectiveness of the drug involved, any studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplemental application and conducted or sponsored by the applicant. Exclusivity applies only to the added indication for use of doramectin injection to control infections and to protect cattle from reinfection with *H. placei* for 14 days after treatment.

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.

§ 522.770 [Amended]

2. Section 522.770 *Doramectin* is amended in paragraph (d)(1)(ii) by adding after ''*Cooperia oncophora*'' the phrase ''and *Haemonchus placei*''.

Dated: February 26, 1999.

Margaret Ann Miller,

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

[FR Doc. 99–6670 Filed 3–18–99; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Propofol 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 new animal drug application (NADA) filed by Schering-Plough Animal Health Corp. The supplemental NADA provides for expanding the indications to include the use of propofol in cats.

EFFECTIVE DATE: March 19, 1999.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, filed supplemental NADA 141–070 that provides for intravenous use in cats of Rapinovet Anesthetic Injection (each milliliter contains 10 milligrams of propofol). The product was previously approved for use in dogs. The drug is used as a single injection to provide general anesthesia for short procedures, for induction and maintenance of general anesthesia using incremental doses to affect, and for induction of general anesthesia where maintenance is provided by inhalant anesthetics. The drug is limited to use by or on the order of a licensed veterinarian. The supplemental NADA is approved as of January 14, 1999, and the regulations are amended in 21 CFR 522.2005 by revising paragraph (b) and by adding paragraph (c)(2) to reflect the approval. The basis of approval is provided 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, this approval qualifies for a 3-year period of marketing exclusivity beginning January 14, 1999, because the supplement application contains substantial evidence of the effectiveness of the drug involved, or any studies of animal safety, required for the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the new species (cats) for which the supplemental application was approved.

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.

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