Drug labeler code	Firm name and address
* * *	* * * *
063112	Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250
* * *	* * * *

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

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

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

§ 522.1002 [Amended]

4. Section 522.1002 *Follicle stimulating hormone* is amended in paragraph (b)(2) by removing ''000061'' and adding in its place ''063112''.

Dated: November 6, 1997.

Robert C. Livingston,

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

[FR Doc. 97–30563 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 522 and 556

Animal Drugs, Feeds, and Related Products; 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 intramuscular use of doramectin in swine for the treatment and control of certain infections of nematode and arthropod parasites.

EFFECTIVE DATE: November 21, 1997.

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1643.

SUPPLEMENTARY INFORMATION: Pfizer, Inc., 235 East 42d St., New York, NY 10017–5755, is sponsor of NADA 141–061, which provides for the subcutaneous and intramuscular use of Dectomax® 1 percent injectable solution (doramectin) for treatment and control of certain gastrointestinal roundworms, lungworms, eyeworms, grubs, lice, and mange mites of cattle, and to control infections and to protect cattle from reinfection with *Ostertagia ostertagi* for 21 days, and *Cooperia punctata* and *Dictyocaulus viviparus* for 28 days after treatment. The firm filed a supplemental NADA that provides for intramuscular use of doramectin in swine for the treatment and control of certain infections of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites. The supplemental NADA is approved as of September 18, 1997, and the regulations are amended in 21 CFR 522.770(d) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, a tolerance for residues of doramectin in edible swine tissues has not been previously established. Section 556.225 (21 CFR 556.225) is amended to provide for a tolerance for residues of doramectin in swine tissues.

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 supplemental application may be seen in the Dockets Management Branch (HFA–305), Food and Drug Administration, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, 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 September 18, 1997, 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 the treatment and control of gastrointestinal roundworms, lungworms, kidneyworms, sucking lice, and mange mites in swine.

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

List of Subjects

21 CFR Part 522

Animal drugs.

21 CFR Part 556

Animal drugs, Foods.

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 parts 522 and 556 are 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 522.770 is amended by revising the heading of paragraph (d) and redesignating paragraphs (d)(1), (d)(2), and (d)(3) as paragraphs (d)(1)(i), (d)(1)(ii), and (d)(1)(iii), respectively, and by adding new paragraph (d)(2) to read as follows:

§ 522.770 Doramectin.

* * * * *

(d) *Conditions of use*—(1) *Cattle.* (i) *Amount.* * * *

* * * * *

(2) *Swine.* (i) *Amount.* 300 micrograms per kilogram (10 milligrams per 75 pounds).

(ii) *Indications for use.* For treatment and control of gastrointestinal roundworms, lungworms, kidney worms, sucking lice, and mange mites.

(iii) *Limitations.* Administer as a single intramuscular injection. Do not slaughter swine within 24 days of treatment. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism.

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

3. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

4. Section 556.225 is revised to read as follows:

§ 556.225 Doramectin.

A tolerance of 0.1 part per million (ppm) is established for parent doramectin (marker residue) in liver (target tissue) of cattle and 0.16 ppm in liver of swine.

Dated: October 22, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–30562 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Clopidol and Bacitracin Zinc With Roxarsone

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 Alpharma Inc. The abbreviated NADA provides for using approved clopidol, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated broiler chicken feeds used for prevention of coccidiosis, improved feed efficiency, improved pigmentation, and increased rate of weight gain.

EFFECTIVE DATE: November 21, 1997.

FOR FURTHER INFORMATION CONTACT: Jeffrey M. Gilbert, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1602.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of ANADA 200–207 that provides for combining approved clopidol, bacitracin zinc, and roxarsone Type A medicated articles to make Type C medicated feeds for broilers containing clopidol 113.5 grams per ton (g/t) and bacitracin zinc 4 to 25 g/t with roxarsone 45.4 g/t. The Type C medicated feed is used as an aid in the prevention of coccidiosis caused by *Eimeria tenella, E. necatrix, E. acervulina, E. brunetti, E. mivati,* and *E. maxima,* and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

Alpharma Inc.'s ANADA 200–207 is approved as a generic copy of Rhone-Poulenc, Inc.'s NADA 44–016. The ANADA is approved as of November 21, 1997 and 21 CFR 558.175 is amended 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, from 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 558

Animal drugs, Animal feeds.

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 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.

§ 558.175 [Amended]

2. Section 558.175 *Clopidol* is amended in paragraph (d)(1)(iii)(*b*) by removing ''No. 000061'' and adding in its place ''Nos. 000061 and 046573.''

Dated: November 7, 1997.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 97–30564 Filed 11–20–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 809 and 864

[Docket No. 96N–0082]

RIN 0910–ZA03

Medical Devices; Classification/ Reclassification; Restricted Devices; Analyte Specific Reagents

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is issuing a final rule to classify/reclassify analyte specific reagents (ASR's) presenting a low risk to public health into class I (general controls), and to exempt these class I devices from the premarket notification (510(k)) requirements. FDA is classifying/reclassifying ASR's used in certain blood banking tests as class II (special controls) because general controls are insufficient to provide a reasonable assurance of safety and effectiveness. Finally, ASR's presenting a high risk are being classified or retained in class III (premarket approval). FDA is also designating all ASR's as restricted devices under the Federal Food, Drug, and Cosmetic Act (the act), and establishing restrictions on their sale, distribution and use. The scope of products covered by this final rule includes both pre-1976 devices, which have not been previously classified, as well as post-1976 devices, which are statutorily classified into class III. The intent of this final rule is to regulate these pre- and post-1976 devices in a consistent fashion. This rulemaking does not affect requirements for reagents that are subject to licensure under the Public Health Service Act (the PHS Act). This rulemaking also does not affect reagents sold to nonclinical settings, including those reagents sold as components to manufacturers of cleared or approved in vitro diagnostic tests.

DATES: This rule is effective November 23, 1998.

FOR FURTHER INFORMATION CONTACT: Steven I. Gutman, Center for Devices and Radiological Health (HFZ–440), Food and Drug Administration, 2098 Gaither Rd., Rockville, MD 20850, 301–594–3084.

SUPPLEMENTARY INFORMATION:

I. Background

The the act (21 U.S.C. 201 *et seq.*), as amended by the Medical Device