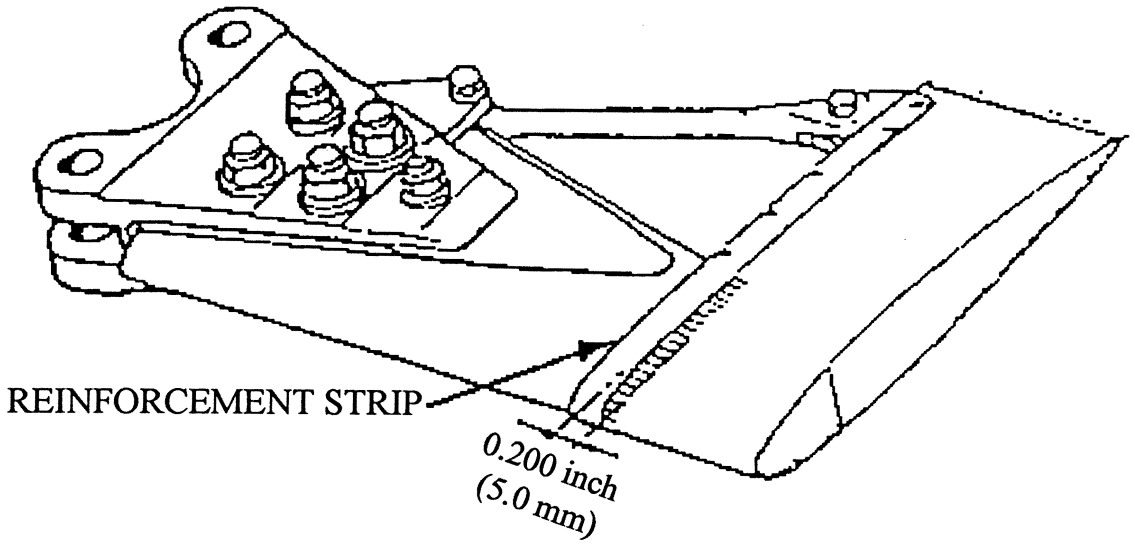

Figure 1

BILLING CODE 4910–13–C

Issued in Fort Worth, Texas, on November 14, 1997.

Eric Bries,

Acting Manager, Rotorcraft Directorate, Aircraft Certification Service.

[FR Doc. 97–30603 Filed 11–20–97; 8:45 am]

BILLING CODE 4910–13–U

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 522

New Animal Drugs; Change of Sponsor

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect a change of sponsor for an approved new animal drug application (NADA) from Schering-Plough Animal Health Corp. to Sioux Biochemical, Inc.

EFFECTIVE DATE: November 21, 1997.

FOR FURTHER INFORMATION CONTACT: Thomas J. McKay, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0213.

SUPPLEMENTARY INFORMATION: Schering-Plough Animal Health Corp., 1095 Morris Ave., Union, NJ 07083, has informed FDA that it has transferred ownership of, and all rights and interests in NADA 9–505 (follicle stimulating hormone) to Sioux Biochemical, Inc., 204 Third St. NW., Sioux Center, IA 51250. Accordingly, the agency is amending the regulations in 21 CFR 522.1002 to reflect the transfer of ownership. The agency is also amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) by alphabetically adding a new listing for Sioux Biochemical, Inc.

List of Subjects

21 CFR Part 510

Administrative practice and procedure, Animal drugs, Labeling, Reporting and recordkeeping requirements.

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 parts 510 and 522 are amended as follows:

PART 510—NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 510 continues to read as follows:

Authority: 21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 376e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Sioux Biochemical, Inc.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''063112'' to read as follows:

§ 510.600 Names, addresses, and drug labeler codes of sponsors of approved applications.

* * * * *

(c) * * *

(1) * * *

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

(2) * * *

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.