Food and Drug Administration

21 CFR Part 510

Animal Drugs, Feeds, and Related Products; Change of Sponsor Address

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 address for Bioproducts, Inc.

EFFECTIVE DATE: February 7, 1995.

FOR FURTHER INFORMATION CONTACT: Judith M. O'Haro, Center for Veterinary Medicine (HFV–238), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1737.

SUPPLEMENTARY INFORMATION: Bioproducts, Inc., has informed FDA of a change of address from 8221 Brecksville Rd., Cleveland, OH 44141, to 320 Springside Dr., suite 300, Fairlawn, OH 44333–2435. Accordingly, the agency is amending the regulations in 21 CFR 510.600(c)(1) and (c)(2) to reflect the new address.

List of Subjects in 21 CFR Part 510

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

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 510 is amended as follows:

PART 510—NEW ANIMAL DRUGS

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

Authority: Secs. 201, 301, 501, 502, 503, 512, 701, 721 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 331, 351, 352, 353, 360b, 371, 379e).

§ 510.600 [Amended]

2. Section 510.600 *Names, addresses, and drug labeler codes of sponsors of approved applications* is amended in the table in paragraph (c)(1) in the entry for ''Bioproducts, Inc.,'' and in the table in paragraph (c)(2) in the entry for ''051359'' by removing ''8221 Brecksville Rd., Cleveland, OH 44141'' and adding in its place ''320 Springside Dr., suite 300, Fairlawn, OH 44333–2435''.

Dated: January 31, 1995.

George A. Mitchell,

Director, Office of Surveillance and Compliance, Center for Veterinary Medicine.

[FR Doc. 95–2992 Filed 2–6–95; 8:45 am]

BILLING CODE 4160–01–F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Tylosin

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 Premiere Agri Technologies, Inc., providing for making a 20-gram-per-pound (g/lb) tylosin Type A medicated article in addition to existing approvals for 40- and 100-g/lb Type A medicated articles.

EFFECTIVE DATE: February 7, 1995

FOR FURTHER INFORMATION CONTACT: David R. Newkirk, Center for Veterinary Medicine (HFV–142), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1700.

SUPPLEMENTARY INFORMATION: Premiere Agri Technologies, Inc. (Premiere), P.O. Box 2508, Fort Wayne, IN 46801–2508, filed a supplement to NADA 91–582 (formerly sponsored by Central Soya Co., Inc.) that provides for making a new 20-g/lb tylosin Type A medicated article used to make Type C medicated feeds for cattle, chickens, and swine for use as in § 558.625(f)(1)(i) through (f)(1)(vi) (21 CFR 558.625(f)(1)(i) through (f)(1)(vi)). Premiere currently has approval for 40- and 100-g/lb Type A medicated articles. The supplemental NADA is approved and the regulations are amended in § 558.625(b)(10) to reflect the approval.

Approval of this supplemental NADA is an administrative action that did not require the generation of new safety or effectiveness data. Therefore, a freedom of information summary is not required for this action.

The agency has determined under 21 CFR 25.24(d)(1)(iii) 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.625 is amended by revising paragraph (b)(10) to read as follows:

§ 558.625 Tylosin.

* * * * *

(b) * * *

(10) To 012286: 0.4, 0.8, and 1.6 grams per pound, paragraph (f)(1)(vi)(*a*) of this section; 20, 40, and 100 grams per pound, paragraphs (f)(1)(i) through (f)(1)(vi) of this section.

* * * * *

Dated: January 11, 1995.

Andrew J. Beaulieau,

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

[FR Doc. 95–2990 Filed 2–6–95; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 117

[CGD02–94–016]

RIN 2115–AE47

Drawbridge Operation Regulation; Red River, AR

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is separating the regulations governing drawbridges on the Red River into two sections, one for Louisiana and one for Arkansas. Currently, the entire length of the Red River in both Arkansas and Louisiana in regulated in one CFR Section. The completion of U.S. Army Corps of Engineer projects at locks and dams 4 and 5 in December 1994 is expected to result in an increase of commercial traffic on the Red River in Louisiana, necessitating a change in drawbridge openings only for the portion of the river flowing in Louisiana. This amendment allows the drawbridge on the Red River in Louisiana and Arkansas to be regulated under separate CFR sections but makes no substantive changes to the regulations for