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 Biopure Corp. The supplemental NADA provides for flexible dosing for use of hemoglobin glutamer-200 (bovine) to treat anemia in dogs.

DATES: This rule is effective April 18, 2000.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7540.

SUPPLEMENTARY INFORMATION: Biopure Corp., 11 Hurley St., Cambridge, MA 02141, is the sponsor of NADA 141–067 that provides for the veterinary prescription use of Oxyglobin® (hemoglobin glutamer-200 (bovine)) for the treatment of anemia in dogs. The drug increases systemic oxygen content (plasma hemoglobin concentration) and improves the clinical signs associated with anemia, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis). The supplemental NADA provides for use of 10 to 30 milliliters per kilogram of body weight (mL/kg) administered at 10 mL/kg/hour. The supplemental NADA is approved as of January 11, 2000, and 21 CFR 522.1125(d) is 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.

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 approval for nonfood-producing animals qualifies for 3 years of marketing exclusivity beginning January 11, 2000, because the approval contains substantial evidence of effectiveness of the drug involved, or any studies of animal safety, required for approval of the supplement and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to use of the dosing range of 10 to 30 mL/kg.

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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

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.

§ 522.1125 [Amended]

2. Section 522.1125 *Hemoglobin glutamer-200 (bovine)* is amended in paragraph (d)(1) by removing ''30'' and adding in its place ''10 to 30'' and in paragraph (d)(2) by removing the phrase ''for at least 24 hours''.

Dated: March 17, 2000.

Claire M. Lathers,

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

[FR Doc. 00–9576 Filed 4–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 526

Intramammary Dosage Form New Animal Drugs; Cephapirin Sodium for Intramammary Infusion

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 Fort Dodge Animal Health. The supplemental NADA provides for amending the milk discard statement to state the milk discard time only (i.e., to remove reference to the number of milkings).

DATES: This rule is effective April 18, 2000.

FOR FURTHER INFORMATION CONTACT: Naba K. Das, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7569.

SUPPLEMENTARY INFORMATION: Fort Dodge Animal Health, Division of American Home Products Corp., 800 Fifth Street NW., P.O. Box 518, Fort Dodge, IA 50501, filed supplemental NADA 97–222 that provides for a 96-hour milk-discard time (i.e., removal of the parenthetical reference to an 8-milking milk discard time) for use of CEFA–LAK® and TODAY® (cephapirin sodium) intramammary infusion products for treatment of lactating cows for bovine mastitis. The supplemental NADA is approved as of February 4, 2000, and the regulations are amended in 21 CFR 526.365(d)(3) to reflect the approval.

Approval of this supplemental NADA conforms to the requirements of 21 CFR 510.105. Approval does not require review of the safety or effectiveness data required for approval of the NADA. Therefore, a freedom of information summary is not required.

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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 21 CFR Part 526

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 526 is amended as follows:

PART 526—INTRAMAMMARY DOSAGE FORMS

1. The authority citation for 21 CFR part 526 continues to read as follows:

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

§ 526.365 [Amended]

2. Section 526.365 *Cephapirin sodium for intramammary infusion* is amended in paragraph (d)(3) by removing ''(8 milkings)''.

Dated: March 17, 2000.

Claire M. Lathers,

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

[FR Doc. 00–9572 Filed 4–17–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Fenbendazole

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 Hoechst Roussel Vet. The supplemental NADA provides for establishing tolerances for residues of fenbendazole in edible tissues of swine. Technical corrections are also made.

DATES: This rule is effective April 18, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–130), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010, filed a supplement to NADA 131–675 that provides for use of Safe-Guard® (20 percent fenbendazole) Type A medicated articles to make Type B and C medicated swine feeds. The supplement provides for establishing tolerances for parent fenbendazole in swine liver and muscle. The supplement is approved as of February 10, 2000, and § 556.275 (21 CFR 556.275) is amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 556.275 is further amended by deleting references to safe concentrations and by adding the previously established acceptable daily intake (ADI) of total residues of fenbendazole. The footnote for ''tolerance'' in that section is also removed.

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, rm. 1061, 5630 Fishers Lane, Rockville, MD 20852, from 9 a.m. to 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.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because it is a rule of ''particular applicability.'' Therefore, it is not subject to the congressional review requirements in 5 U.S.C. 801–808.

List of Subjects in 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 part 556 is amended as follows:

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

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

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

2. Section 556.275 is revised to read as follows:

§ 556.275 Fenbendazole.

(a) *Acceptable daily intake (ADI).* The ADI for total residues of fenbendazole is 40 micrograms per kilogram of body weight per day.

(b) *Tolerances*—(1) *Cattle*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 0.8 part per million (ppm).

(ii) [Reserved]

(iii) *Milk.* The tolerance for fenbendazole sulfoxide metabolite (the marker residue in cattle milk) is 0.6 ppm.

(2) *Swine*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 6 ppm.

(ii) *Muscle.* The tolerance for parent fenbendazole (the marker residue) is 2 ppm.

(3) *Goats*—(i) *Liver (the target tissue).* The tolerance for parent fenbendazole (the marker residue) is 0.8 ppm.

(ii) [Reserved]

Dated: March 17, 2000.

Claire M. Lathers,

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

[FR Doc. 00–9578 Filed 4–17–00; 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; Bambermycins; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is updating the animal drug regulations to correctly reflect the previously approved use level for bambermycins Type C medicated cattle feed. This document amends the regulations to state the correct use level is 2 to 40 grams (g) of bambermycins per ton of feed. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective April 18, 2000.

FOR FURTHER INFORMATION CONTACT: Jack Caldwell, Center for Veterinary Medicine (HFV–126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0217.

SUPPLEMENTARY INFORMATION: Hoechst Roussel Vet, Perryville Corporate Park III, P.O. Box 4010, Clinton, NJ 08809–4010, is sponsor of NADA 141–034 that provides for use of GAINPRO® (bambermycins) Type A medicated articles to make Type B and Type C medicated cattle feeds. In its approval letter of October 17, 1994, the Center for Veterinary Medicine approved the use of Type C medicated feeds containing 2 to 40 g of bambermycins per ton of feed, used to provide 10 to 20 milligrams bambermycins per head per day for increased rate of weight gain in pasture cattle. At this time, 21 CFR 558.95(d)(4)(ii) is amended by removing ''4 to 20'' and adding in its place ''2 to 40'' to reflect the correct Type C medicated feed levels.

This rule does not meet the definition of ''rule'' in 5 U.S.C. 804(3)(A) because