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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Hemoglobin Glutamer-200 (bovine)

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 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 [*insert date of publication in the Federal Register*].

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

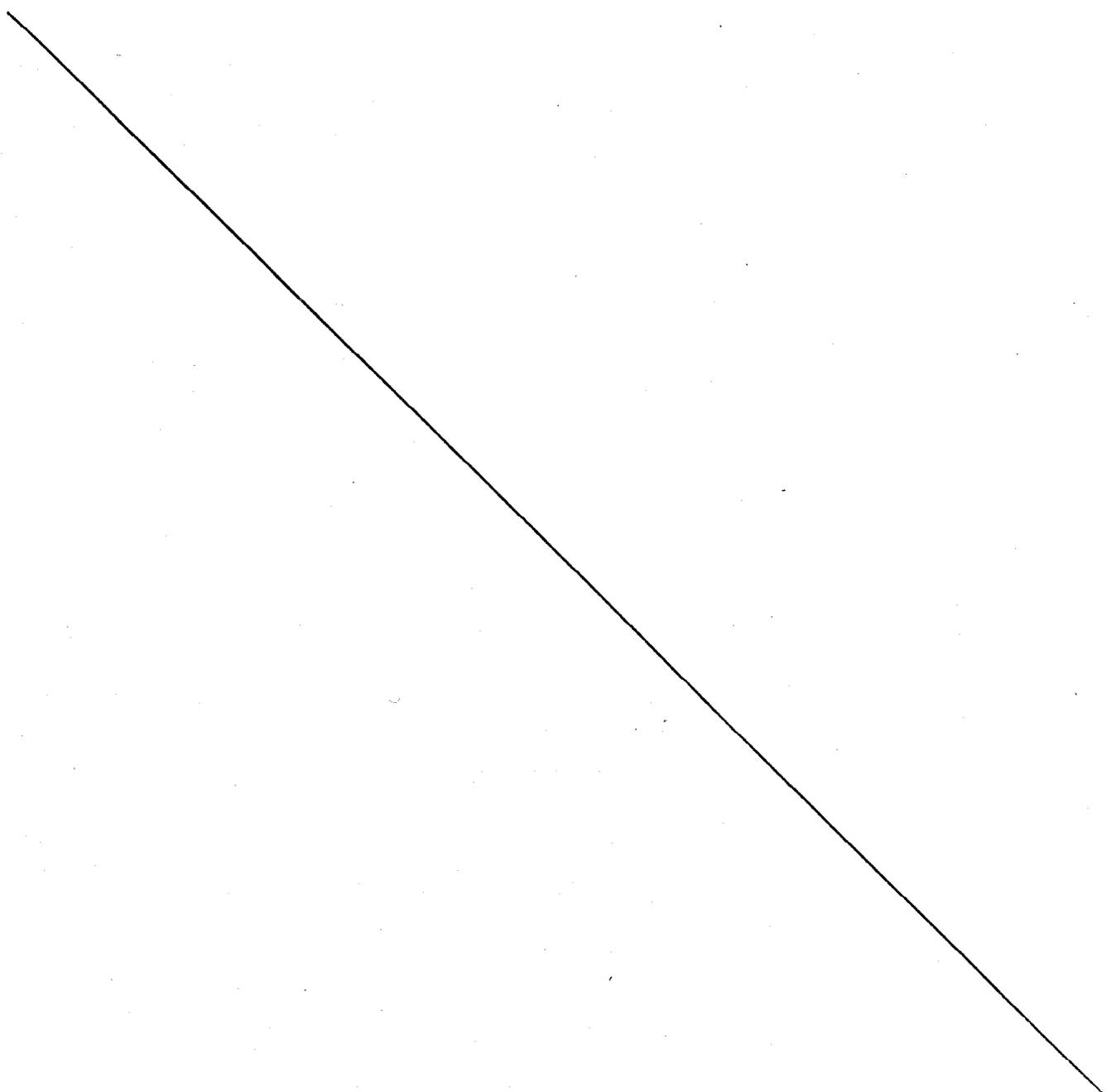
Animal drugs.

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:

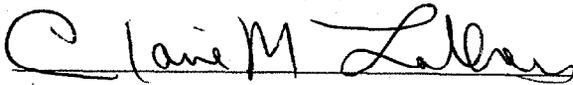
Authority: 21 U.S.C. 360b.



§ 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: 3/17/2000
March 17, 2000



Claire M. Lathers
Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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