List of Subjects in 21 CFR Part 14

Administrative practice and procedure, Advisory committees, Color additives, Drugs, Radiation protection.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 14 is amended as follows:

PART 14—PUBLIC HEARING BEFORE A PUBLIC ADVISORY COMMITTEE

1. The authority citation for 21 CFR part 14 continues to read as follows:

Authority: 21 U.S.C. 41–50, 141–149, 321–394, 467f, 679, 821, 1034; 42 U.S.C. 201, 262, 263b, 264; 15 U.S.C. 1451–1461; 5 U.S.C. app. 2; 28 U.S.C. 2112.

2. Section 14.100 is amended by adding paragraph (c)(18) to read as follows:

§ 14.100 List of standing advisory committees.

* * * * *

(c) * * *

(18) *Pharmacy Compounding Advisory Committee*.

(i) Date established: February 12, 1998.

(ii) Function: Provides advice on scientific, technical, and medical issues concerning drug compounding by pharmacists and licensed practitioners.

Dated: March 3, 1998.

Michael A. Friedman,

Deputy Commissioner for Operations.

[FR Doc. 98–6151 Filed 3–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 104

[Docket No. 97N–0365]

Code of Federal Regulations; Authority Citations; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending its regulations to revise an authority citation that was inadvertently omitted when the agency revised the authority citations for 21 CFR Chapter I. This action is being taken to ensure clarity and consistency in the agency's regulations.

EFFECTIVE DATE: March 10, 1998.

FOR FURTHER INFORMATION CONTACT: LaJuana D. Caldwell, Office of Policy (HF–27), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301–443–2994.

SUPPLEMENTARY INFORMATION: The Office of the Federal Register, in accordance with the procedures of the Administrative Committee of the Federal Register (1 CFR 21.52), has recommended that each citation of authority for Chapter I of Title 21 of the Code of Federal Regulations include only references to the United States Code. Therefore, in the **Federal Register** of October 1, 1997, FDA revised its authority citations in accordance with that recommendation. In that document, the agency inadvertently omitted an amendment to revise the authority citation for 21 CFR part 104. At this time the agency is correcting that error. Publication of this document constitutes final action under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment is nonsubstantive in nature.

Lists of Subjects in 21 CFR Part 104

Food grades and standards, Frozen foods, Nutrition.

Therefore, under the Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 104 is amended as follows:

PART 104—NUTRITIONAL QUALITY GUIDELINES FOR FOODS

1. The authority citation for 21 CFR part 104 is revised to read as follows:

Authority: 21 U.S.C. 321, 343, 371(a).

Dated: March 4, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98–6153 Filed 3–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 510 and 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 new animal drug application (NADA) filed by Biopure Corp. The NADA provides for the use of hemoglobin glutamer-200 (bovine) for the treatment of anemia in dogs.

EFFECTIVE DATE: March 10, 1998.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1612.

SUPPLEMENTARY INFORMATION: Biopure Corp., 11 Hurley St., Cambridge, MA 02141, is the sponsor of NADA 141–067 that provides for the use of Oxyglobin® (hemoglobin glutamer-200 (bovine)) for the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia for at least 24 hours, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis). The drug is limited to use by or on the order of a licensed veterinarian. The NADA is approved as of January 28, 1998, and the regulations are amended by adding § 522.1125 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, Biopure Corp. has not been previously listed in the animal drug regulations as sponsor of an approved application. At this time, 21 CFR 510.600(c) is amended to add entries for the firm.

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, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.33(d)(5) 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act, this approval for nonfood-producing animals qualifies for 5 years of marketing exclusivity beginning January 28, 1998, because no active ingredient of the drug (including any salt or ester of the active ingredient) has been approved in any other application.

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, 379e.

2. Section 510.600 is amended in the table in paragraph (c)(1) by alphabetically adding a new entry for ''Biopure Corp.'' and in the table in paragraph (c)(2) by numerically adding a new entry for ''063075'' 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
* * *	* * * *
Biopure Corp., 11 Hurley St., Cambridge, MA 02141.	063075
* * *	* * * *

(2) * * *

Drug labeler code	Firm name and address
063075	Biopure Corp., 11 Hurley St., Cambridge, MA 02141.
* * *	* * * *

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 522.1125 is added to read as follows:

§ 522.1125 Hemoglobin glutamer-200 (bovine).

(a) *Specifications.* Each 125 milliliter bag contains 13 grams per deciliter of polymerized hemoglobin of bovine origin in modified Lactated Ringer's Solution. It is a sterile, clear, dark purple solution.

(b) *Sponsor.* See No. 063075 in § 510.600(c) of this chapter.

(c) [Reserved]

(d) *Conditions of use*— (1) *Amount.* One-time dose of 30 milliliters per kilogram of body weight administered intravenously at a rate of up to 10 milliliters per kilogram per hour.

(2) *Indications for use.* For the treatment of anemia in dogs by increasing systemic oxygen content (plasma hemoglobin concentration) and improving the clinical signs associated with anemia for at least 24 hours, regardless of the cause of anemia (hemolysis, blood loss, or ineffective erythropoiesis).

(3) *Limitations.* For intravenous use only. Overdosage or an excessive rate of administration (greater than 10 milliliters per kilogram per hour) may result in circulatory overload. Federal law restricts this drug to use by or on the order of a licensed veterinarian.

Dated: February 27, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–6080 Filed 3–9–98; 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; Medicated Feed Applications; Halofuginone Hydrobromide; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the correct assay limits for halofuginone hydrobromide Type A medicated articles. As amended, the regulation reflects the assay limits in the approved new animal drug application (NADA). This action is being taken to ensure the accuracy and consistency of the regulations and to correct an error that occurred because the regulation did not reflect the assay limits approved in the NADA.

EFFECTIVE DATE: March 10, 1998.

FOR FURTHER INFORMATION CONTACT: Mary G. Leadbetter, Center for Veterinary Medicine (HFV–143), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1662.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of August 21, 1985 (50 FR 33718), FDA added § 558.265 (21 CFR 558.265) to reflect approval of Hoechst Roussel Vet's NADA 130–951 for the use of halofuginone hydrobromide Type A medicated articles. Section 558.265 provided for the use of the Type A article to make Type C feed. Section 558.265 also provided the approved assay limits for