§ 648.10(c)(3) that have utilized "part of a DAS" (less than 24 hours) may land up to an additional 1,000 lb (453.6 kg), or 1,500 lb (680.4 kg) if applicable, of cod for that "part of a DAS"; however, such vessels may not end any subsequent trip with cod on board within the 24-hour period following the beginning of the "part of the DAS" utilized (e.g., a vessel that has called-in to the multispecies DAS program at 3 p.m. on a Monday and ends its trip the next day (Tuesday) at 4 p.m. (accruing a total of 25 hours) may legally land up to 2,000 lb (907.2 kg) of cod on such a trip, but the vessel may not end any subsequent trip with cod on board until after 3 p.m. on the following day (Wednesday)). Cod on board a vessel subject to this landing limit must be separated from other species of fish and stored so as to be readily available for inspection.

(ii) A vessel subject to the cod landing limit restrictions described in paragraph (b)(1)(i) of this section, and subject to the cod landing limit call-in provision specified at § 648.10(f)(3)(ii), may come into port with and offload cod in excess of the landing limit as determined by the number of DAS elapsed since the vessel called into the DAS program, provided that:

(A) The vessel operator does not call-out of the DAS program as described under § 648.10(c)(3) and does not depart from a dock or mooring in port to engage in fishing, unless transiting as allowed in paragraph (b)(3) of this section, until sufficient time has elapsed to account for and justify the amount of cod harvested at the time of offloading regardless of whether all of the cod on board is offloaded (e.g., a vessel that has called-in to the multispecies DAS program at 3 p.m. on Monday that fishes and comes back into port at 4 p.m. on Wednesday of that same week with 4,000 lb (1,814.4 kg) of cod, and offloads some or all of its catch, cannot call out of the DAS program or leave port until 3:01 p.m. the next day, Thursday (i.e., 3 days plus one minute)); and

(B) Upon returning to port and before offloading, the vessel operator notifies the Regional Administrator (see Table 1 to § 600.502 of this chapter for the Regional Administrator's address) and provides the following information: Vessel name and permit number, owner and caller name, DAS confirmation number, phone number, and the hail weight of cod on board and the amount of cod to be offloaded, if any. A vessel that has not exceeded the landing limit and is offloading and ending its trip by calling out of the multispecies DAS program does not have to report under this call-in system.

* * * * *

(2) *Exemption.* A vessel fishing under a NE multispecies DAS is exempt from the landing limit described in paragraph (b)(1) of this section when fishing south of a line beginning at the Cape Cod, MA coastline at 42°00' N. lat. and running eastward along 42°00' N. lat. until it intersects with 69°30' W. long., then northward along 69°30' W. long. until it intersects with 42°20' N. lat., then eastward along 42°20' N. lat. until it intersects with 67°20' W. long., then northward along 67°20' W. long. until it intersects with the U.S.-Canada maritime boundary, provided that it does not fish north of this exemption area for a minimum of 30 consecutive days (when fishing under the multispecies DAS program), and has on board an authorization letter issued by the Regional Administrator. Vessels exempt from the landing limit requirement may transit the GOM/GB Regulated Mesh Area north of this exemption area, provided that their gear is stowed in accordance with one of the provisions of § 648.81(e).

(3) *Transiting.* A vessel that has exceeded the cod landing limit as specified in paragraph (b)(1) of this section and is, therefore, subject to remain in port for the period of time described in paragraph (b)(1)(ii)(A) of this section, may transit to another port during this time, provided that the vessel operator notifies the Regional Administrator (see Table 1 to § 600.502 of this chapter for the Regional Administrator's address) either at the time the vessel reports its hailed weight of cod or at a later time prior to transiting, and provides the following information: Vessel name and permit number, destination port, time of departure, and estimated time of arrival. A vessel transiting under this provision must stow its gear in accordance with one of the methods specified in § 648.81(e), and may not have any fish on board the vessel.

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[FR Doc. 98-5564 Filed 3-9-98; 8:45 am]

BILLING CODE 3510-22-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 14

Advisory Committees; Pharmacy Compounding Advisory Committee; Establishment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is announcing the establishment of the Pharmacy Compounding Advisory Committee in FDA's Center for Drug Evaluation and Research by the Commissioner of Food and Drugs (the Commissioner). Elsewhere in this issue of the **Federal Register**, FDA is publishing a notice requesting nominations for membership on this committee. This document adds the Pharmacy Compounding Advisory Committee to the agency's list of standing advisory committees.

DATES: This rule becomes effective March 10, 1998. Authority for the committee being established will end on February 3, 2000, unless the Commissioner formally determines that renewal is in the public interest.

FOR FURTHER INFORMATION CONTACT: Donna M. Combs, Committee Management Office (HFA-306), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-4820.

SUPPLEMENTARY INFORMATION: Under the Federal Advisory Committee Act of October 6, 1972 (Pub. L. 92-463) (5 U.S.C. app. 2); section 904 of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 394), as amended by the Food and Drug Administration Revitalization Act (Pub. L. 101-635); section 503A of the act (21 U.S.C. 353a) and 21 CFR 14.40(b), FDA is announcing the establishment of the Pharmacy Compounding Advisory Committee by the Commissioner. The committee shall provide advice on scientific, technical, and medical issues concerning drug compounding by pharmacists and licensed practitioners, and make appropriate recommendations to the Commissioner.

Because establishment of this advisory committee is explicitly required by section 503A(d)(1) of the act (21 U.S.C. 353a(d)(1)), the Commissioner finds, under 21 CFR 10.40, that notice and public procedure in § 10.40(b) are unnecessary and contrary to the public interest.

Therefore, the agency is amending 21 CFR 14.100(c) as set forth below.

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.