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

the Type C medicated feeds of 75 to 125 percent of the labeled amount. The assay limits for the halofuginone Type A medicated articles of 90 to 115 percent of labeled amount in the approved NADA were not published at that time.

In the **Federal Register** of March 3, 1986 (51 FR 7382 at 7393), FDA added § 558.4 (21 CFR 558.4) providing for the regulation of medicated feed applications. In § 558.4, FDA incorrectly published the assay limits for Type A articles of 80 to 120 percent of the labeled amount. At this time, FDA is amending the assay limits for Type A medicated articles to reflect those levels in the approved application. Accordingly, FDA is correcting § 558.4(d) to provide for an assay limit for halofuginone hydrobromide Type A medicated articles of 90 to 115 percent of the labeled amount instead of 80 to 120 percent.

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

§ 558.4 [Amended]

2. Section 558.4 *Medicated feed applications* is amended in paragraph (d), in the table entitled ''Category II'', in the entry ''Halofuginone hydrobromide'' in the second column by removing ''80–120'' and adding in its place ''90–115''.

Dated: February 26, 1998.

Steven D. Vaughn,

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

[FR Doc. 98–6077 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; Chlortetracycline, Sulfathiazole, Penicillin; Correction

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule, correction.

SUMMARY: The Food and Drug Administration (FDA) is correcting a final rule that appeared in the **Federal Register** of January 15, 1998 (63 FR 2306). The document amended the animal drug regulations to reflect approval of Hoffmann-La Roche, Inc.'s, abbreviated new animal drug regulation (ANADA). ANADA 200-167 provides for use of Aureozol®, a Type A medicated article containing chlortetracycline, sulfathiazole, and penicillin to make Type C medicated swine feeds. The amendment to § 558.155(a)(2) (21 CFR 558.155(a)(2)), reflecting the approval, incorrectly provided for sponsor No. 054273 when it should have provided for Nos. 000004 and 000010. This document corrects that error.

EFFECTIVE DATE: January 15, 1998.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 15, 1998 (63 FR 2306), FDA published a document reflecting approval of Hoffmann-La Roche, Inc.'s, ANADA 200–167. The approval was for Aureozol®, a Type A medicated article containing chlortetracycline calcium complex equivalent to 40 grams (g) of chlortetracycline hydrochloride, 8.8 percent (40 g) sulfathiazole, and procaine penicillin equivalent in activity to 20 g of penicillin per pound, to make Type C medicated swine feeds containing 100 g of chlortetracycline, 100 g of sulfathiazole, and 50 g of penicillin per ton of feed. Hoffmann-La Roche's ANADA 200–167 was approved as a generic copy of Boehringer Ingelheim Animal Health, Inc.'s, NADA 39–077 CSP 500 Fermazole Brand (chlortetracycline (as hydrochloride), sulfathiazole, penicillin (from procaine penicillin)). The regulations that were amended in § 558.155(a)(2) to reflect the approval provided the incorrect drug labeler number. This document corrects the error by providing for ''Nos. 000004 and 000010''.

In FR Doc. 98–703, appearing on page 2306 in the **Federal Register** of Thursday, January 15, 1998, the following correction is made:

§ 558.155 [Corrected]

1. On page 2307, in the second column, amendment no. 2 is corrected to read ''Section 558.155 *Chlortetracycline, sulfathiazole, penicillin* is amended in paragraph (a)(2) by removing '000010' and adding in its place 'Nos. 000004 and 000010'''.

Dated: February 26, 1998.

Steven D. Vaughn,

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

[FR Doc. 98–6078 Filed 3–9–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF DEFENSE

Office of the Secretary

32 CFR Part 220

RIN 0790–AG50

Collection From Third Party Payers of Reasonable Costs of Healthcare Services

AGENCY: Office of the Assistant Secretary of Defense (Health Affairs), DoD.

ACTION: Final rule with request for comments.

SUMMARY: This final rule implements, without embellishment or additional requirement, the recently enacted statutory authority to collect Social Security account numbers from all DoD beneficiaries as part of the program to identify third party payer situations.

DATES: This rule is effective April 9, 1998. Comments are requested by May 11, 1998.

ADDRESSES: Forward comments to: Third Party Collection Program, Office of the Assistant Secretary of Defense (Health Affairs), Health Services Operations and Readiness, 1200 Defense Pentagon, Washington, DC 20301–1200.

FOR FURTHER INFORMATION CONTACT: LTC Michael Montgomery, 703–681–8910.

SUPPLEMENTARY INFORMATION:

Final Rule Regarding Collection of Social Security Account Numbers

As part of the program to identify third party payer situations, Congress authorized DoD to require mandatory disclosure of Social Security account numbers of all covered beneficiaries. Based on this statutory revision, we are adding the final rule, § 220.9(d), that every covered beneficiary eligible for care in facilities of the Uniformed Services is, as a condition of eligibility, required to disclose to authorized personnel his or her Social Security account number. This is essential to the conduct of the program to identify third party payer situations.

Executive Order 12866, ''Regulatory Planning and Review''

It has been determined that this rule is not a significant rule as defined under section 3(f)(1) through 3(f)(4) of Executive Order 12866.