

believes this rule amendment does not contain information collection requirements that require the approval of the Office of Management and Budget.

#### List of Subjects in 17 CFR Part 143

Civil monetary penalty, Claims.

In consideration of the foregoing and pursuant to authority contained in sections 6(c), 6b and 6c of the Act, 7 U.S.C. 9, 13a, and 13a-1(d), and 28 U.S.C. 2461 note as amended by Pub. L. No. 104-134, the Commission hereby amends part 143 of Chapter I of Title 17 of the Code of Federal Regulations as follows:

#### PART 143—COLLECTION OF CLAIMS OWED THE UNITED STATES ARISING FROM ACTIVITIES UNDER THE COMMISSION'S JURISDICTION

1. The authority of citation for part 143 is revised to read as follows:

**Authority:** 7 U.S.C. 9 and 15, 9a, 12a(5), 13a, 13a-1(d) and 13(a); 31 U.S.C. 3701-3719; 28 U.S.C. 2461 note.

2. Section 143.8 is amended by revising paragraphs (a) and (c) to read as follows:

##### § 143.8 Inflation-adjusted civil monetary penalties.

(a) Unless otherwise amended by an act of Congress, the inflation-adjusted maximum civil monetary penalty for each violation of the Commodity Exchange Act or the rules or orders promulgated thereunder that may be assessed or enforced by the Commission under the Commodity Exchange Act pursuant to an administrative proceeding or a civil action in Federal court will be:

(1) For each violation for which a civil monetary penalty is assessed against any person (other than a contract market) pursuant to section 6(c) of the Commodity Exchange Act, 7 U.S.C. 9:

(i) For violations committed between November 27, 1996 and October 22, 2000, not more than the greater of \$110,000 or triple the monetary gain to such person for each such violation; and

(ii) For violations committed on or after October 23, 2000, not more than the greater of \$120,000 or triple the monetary gain to such person for each such violation;

(2) For each violation for which a civil monetary penalty is assessed against any contract market or other person pursuant to section 6c of the Commodity Exchange Act, 7 U.S.C. 13a-1:

(i) For violations committed between November 27, 1996 and October 22, 2000, not more than the greater of

\$110,000 or triple the monetary gain to such person for each such violation; and

(ii) For violations committed on or after October 23, 2000, not more than the greater of \$120,000 or triple the monetary gain to such person for each such violation; and

(3) For each violation for which a civil monetary penalty is assessed against any contract market or any director, officer, agent, or employee of any contract market pursuant to section 6b of the Commodity Exchange Act, 7 U.S.C. 13a:

(i) For violations committed between November 27, 1996 and October 22, 2000, not more than \$550,000 for each such violation; and

(ii) For violations committed on or after October 23, 2000, not more than \$575,000 for each such violation.

\* \* \* \* \*

(c) Unless otherwise amended by an act of Congress, the penalties set forth in this section or any penalty adjusted for inflation in the future pursuant to paragraph (b) of this section shall be applicable only to violations of the Commodity Exchange Act, Commission rules, or Commission orders which occur after the date on which such future inflation adjustments become effective.

Issued in Washington, DC on July 19, 2000 by the Commission.

**Jean A. Webb,**

*Secretary of the Commission.*

[FR Doc. 00-18728 Filed 7-24-00; 8:45 am]

**BILLING CODE 6351-01-U**

#### DEPARTMENT OF HEALTH AND HUMAN SERVICES

##### Food and Drug Administration

##### 21 CFR Part 558

##### New Animal Drugs for Use in Animal Feeds; Halofuginone and Roxarsone

**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 Alpharma, Inc. The NADA provides for use of approved, single-ingredient halofuginone hydrobromide and roxarsone Type A medicated articles to make two-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, improved feed efficiency, and

improved pigmentation in broiler and replacement chickens.

**DATES:** This rule is effective July 25, 2000.

##### FOR FURTHER INFORMATION CONTACT:

Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-157 that provides for use of STENOROL® (2.72 grams per pound (g/lb) of halofuginone hydrobromide) and 3-NITRO® (45.4, 90, 227, or 360 g/lb of roxarsone) Type A medicated articles to make combination Type C medicated feeds for broiler chickens, replacement broiler breeder chickens, and replacement caged laying chickens prior to sexual maturity. The combination Type C medicated feeds contain 2.72 grams per ton (g/ton) halofuginone hydrobromide and 22.7 to 45.4 g/ton roxarsone and are used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of July 3, 2000, and the regulations are amended in 21 CFR 558.265 and § 558.530 (21 CFR 558.530) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Also, § 558.530 is editorially amended in paragraphs (a) and (d)(5) to simplify the regulation.

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.

The agency has determined under 21 CFR 25.33(a)(2) 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 558**

Animal drugs, Animal feeds.

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 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.

2. Section 558.265 is amended by adding paragraphs (c)(1)(viii) and (c)(3)(ii) to read as follows:

**§ 558.265 Halofuginone hydrobromide.**

\* \* \* \* \*

(c) \* \* \*

(1) \* \* \*

(viii) *Amount per ton.* Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

\* \* \* \* \*

(3) \* \* \*

(ii) *Amount per ton.* Halofuginone hydrobromide, 2.72 grams plus roxarsone, 22.7 to 45.4 grams.

(A) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(B) *Limitations.* Feed continuously as sole ration to replacement cage laying chickens until 20 weeks of age. Feed continuously as sole ration to replacement broiler breeder chickens until 16 weeks of age. Use as the sole source of organic arsenic; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens or waterfowl. Withdraw 5 days before slaughter.

3. Section 558.530 is amended by revising paragraphs (a) and (d)(5) and by removing paragraph (d)(6) to read as follows:

**§ 558.530 Roxarsone.**

(a) *Approvals.* Type A medicated articles: 10, 20, 50, and 80 percent to 046573 in § 510.600(c) of this chapter for use as in paragraphs (d)(1) through (d)(4) of this section.

\* \* \* \* \*

(d) \* \* \*

(5) *Permitted combinations.* It may be used in accordance with this section in combination with:

(i) Akloimide as in § 558.35.

(ii) Amprolium as in § 558.55.

(iii) Amprolium and ethopabate as in § 558.58.

(iv) Bacitracin methylene disalicylate as in § 558.76.

(v) Bacitracin zinc as in § 558.78.

(vi) Bambermycins and bambermycins plus certain anticoccidials as in § 558.95.

(vii) Chlortetracycline as in § 558.128.

(viii) Clopidol as in § 558.175.

(ix) Decoquinatone alone or in combination as in § 558.195.

(x) [Reserved]

(xi) Halofuginone alone or in combination as in § 558.265.

(xii) Lasalocid alone or in combination as in § 558.311.

(xiii) Monensin alone or in combination as in § 558.355.

(xiv) Narasin alone or in combination as in § 558.363.

(xv) Nequinatone as in § 558.365.

(xvi) Nicarbazine alone or in combination as in § 558.366.

(xvii) Nitromide and sulfantran as in § 558.376.

(xviii) Penicillin and zoalene as in § 558.680.

(xix) Robenidine hydrochloride as in § 558.515.

(xx) Salinomycin alone or in combination as in § 558.550.

(xxi) Semduramicin alone or in combination as in § 558.555.

(xxii) Sulfadimethoxine, ormetoprim as in § 558.575.

(xxiii) Zoalene alone or in combination as in § 558.680.

Dated: July 17, 2000.

**Stephen F. Sundlof,**

*Director, Center for Veterinary Medicine.*

[FR Doc. 00-18744 Filed 7-24-00; 8:45 am]

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**DEPARTMENT OF JUSTICE****Drug Enforcement Administration****21 CFR Part 1306**

[DEA-1901]

RIN 1117-AA54

**Facsimile Transmission of Prescriptions for Patients Enrolled in Hospice Programs**

**AGENCY:** Drug Enforcement Administration (DEA), Justice.

**ACTION:** Interim rule.

**SUMMARY:** DEA is amending Title 21, Code of Federal Regulations (CFR) 1306.11(g) to clearly include articulate that prescriptions for Schedule II narcotic substances for patients enrolled in hospice care certified by Medicare under Title XVIII or licensed by the state may be transmitted by facsimile. The regulation as it is currently worded grants this allowance for Schedule II prescriptions for patients "residing in a hospice \* \* \*". This phrase has been perceived by the regulated industry as requiring that the patient reside in a hospice facility to the exclusion of other care settings, such as home hospice care. It was never DEA's intent to omit the significant number of patients receiving hospice care who reside at home. This interim rule clarifies DEA regulations in response to industry questions.

**DATES:** *Effective Date:* July 25, 2000.

*Comments:* Written comments must be submitted on or before September 25, 2000.

**ADDRESSES:** Comments should be submitted in triplicate to the Deputy Assistant Administrator, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, Attention: DEA Federal Register Representative/CCR.

**FOR FURTHER INFORMATION CONTACT:** Patricia M. Good, Chief, Liaison and Policy Section, Office of Diversion Control, Drug Enforcement Administration, Washington, D.C. 20537, telephone (202) 307-7297.

**SUPPLEMENTARY INFORMATION:****What Do DEA Regulations Currently Provide?**

DEA regulations permit a pharmacy to dispense a Schedule II narcotic substance pursuant to a prescription transmitted to the pharmacy via facsimile for a patient residing in a hospice certified by Medicare under Title XVIII or licensed by the state (21 CFR 1306.11(g)). The faxed prescription