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DEPARTMENT OF HEALTH AND HUMAN SERVICES

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

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) Aklomide 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) Decoquate 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) Nequate as in § 558.365.

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

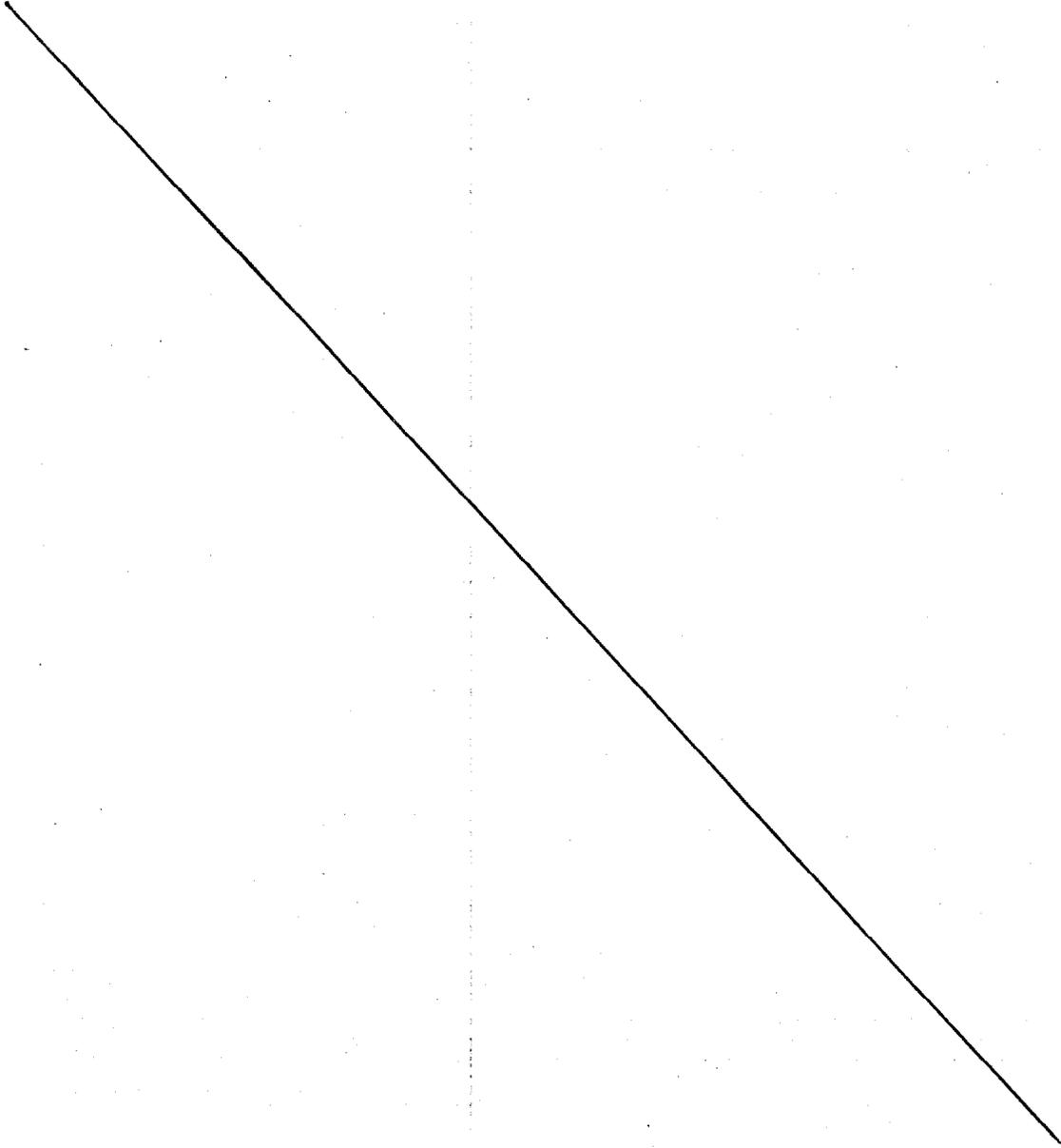
(xvii) Nitromide and sulfanitran as in § 558.376.

(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.

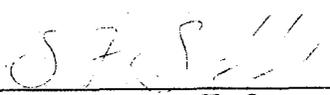
(xxi) Semduramicin alone or in combination as in § 558.555.



(xxii) Sulfadimethoxine, ormetoprim as in § 558.575.

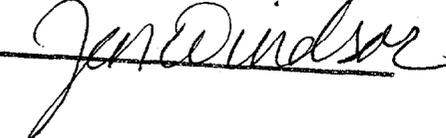
(xxiii) Zoalene alone or in combination as in § 558.680.

Dated: 7/17/00
July 17, 2000



Stephen F. Sundlof,
Director,
Center for Veterinary Medicine.

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL



Jan Windsor

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

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