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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration
21 CFR Part 558

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**New Animal Drugs for Use in Animal Feeds; Lasalocid; 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 approval of a supplemental new animal drug application (NADA) filed by Alpharma, Inc. The supplemental NADA provides for the use of a lasalocid Type A medicated article to make free-choice, loose mineral Type C medicated feeds used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). The regulations are also being revised to provide current references for the amounts of selenium and ethylenediamine dihydroiodide (EDDI) permitted in other free-choice cattle feeds.

DATES: This rule is effective [*insert date of publication in the Federal Register*].

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; 301-827-0232; e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed a supplement to NADA 96-298 that provides for use of BOVATEC 68 (lasalocid) Type A medicated article to make a free-choice high phosphorus loose mineral Type C medicated feed containing 1088

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grams lasalocid per ton of feed. The free-choice medicated feed is used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers). The NADA is approved as of April 9, 2003, and the regulations are amended in 21 CFR 558.311 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 558.311 is also being revised to reflect publication of an updated compliance policy guide (CPG) on permitted levels of EDDI in animal feed (CPG 7125.18, May 1, 2000).

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning April 9, 2003.

The agency has determined under 21 CFR 25.33(a)(1) 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 Subject 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 558.311 is amended:

- a. In paragraph (b)(4) by removing “(e)(2) and (e)(3)” and by adding in its place “(e)(2), (e)(3), and (e)(4)”;
- b. In paragraphs (e)(2)(i) and (e)(3)(i) by revising footnote 1;
- c. By redesignating paragraph (e)(4) as paragraph (e)(5); and
- d. By adding new paragraph (e)(4).

The revisions and addition read as follows:

§ 558.311 Lasolocid.

* * * * *

(e) * * *

(2) * * *

(i) * * *

¹ Content of this vitamin and trace mineral premixes may be varied; however, they should be comparable to those used by the firm for other free-choice feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with § 573.920 of this chapter.

Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).

(3) * * *

(i) * * *

¹Content of vitamin and trace mineral premixes may be varied; however, they should be comparable to those used for other free-choice liquid feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with § 573.920 of this chapter. EDDI should comply with FDA Compliance Policy Guide Sec. 651.100 (CPG 7125.18).

* * * * *

(4) It is used as a free-choice, loose mineral Type C feed as follows:

(i) *Specifications.*

Ingredient	Percent	International feed No.
Monocalcium Phosphate (21% P)	57.50	6-01-082
Salt	17.55	6-04-152
Distillers Dried Grains w/Solubles	5.40	5-28-236
Dried Cane Molasses (46% Sugars)	5.20	4-04-695
Potassium Chloride	4.90	6-03-755
Trace Mineral/Vitamin Premix ¹	3.35
Calcium Carbonate (38% Ca)	2.95	6-01-069
Mineral Oil	1.05	8-03-123
Magnesium Oxide (58% Mg)	1.00	6-02-756
Iron Oxide (52% Fe)	0.10	6-02-431
Lasalocid Type A Medicated Article (68 g per pound)	0.80

¹ Content of vitamin and trace mineral premixes may be varied. However, they should be comparable to those used for other free-choice loose mineral feeds. Formulation modifications require FDA approval prior to marketing. Selenium must comply with § 573.920 of this chapter. EDDI should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

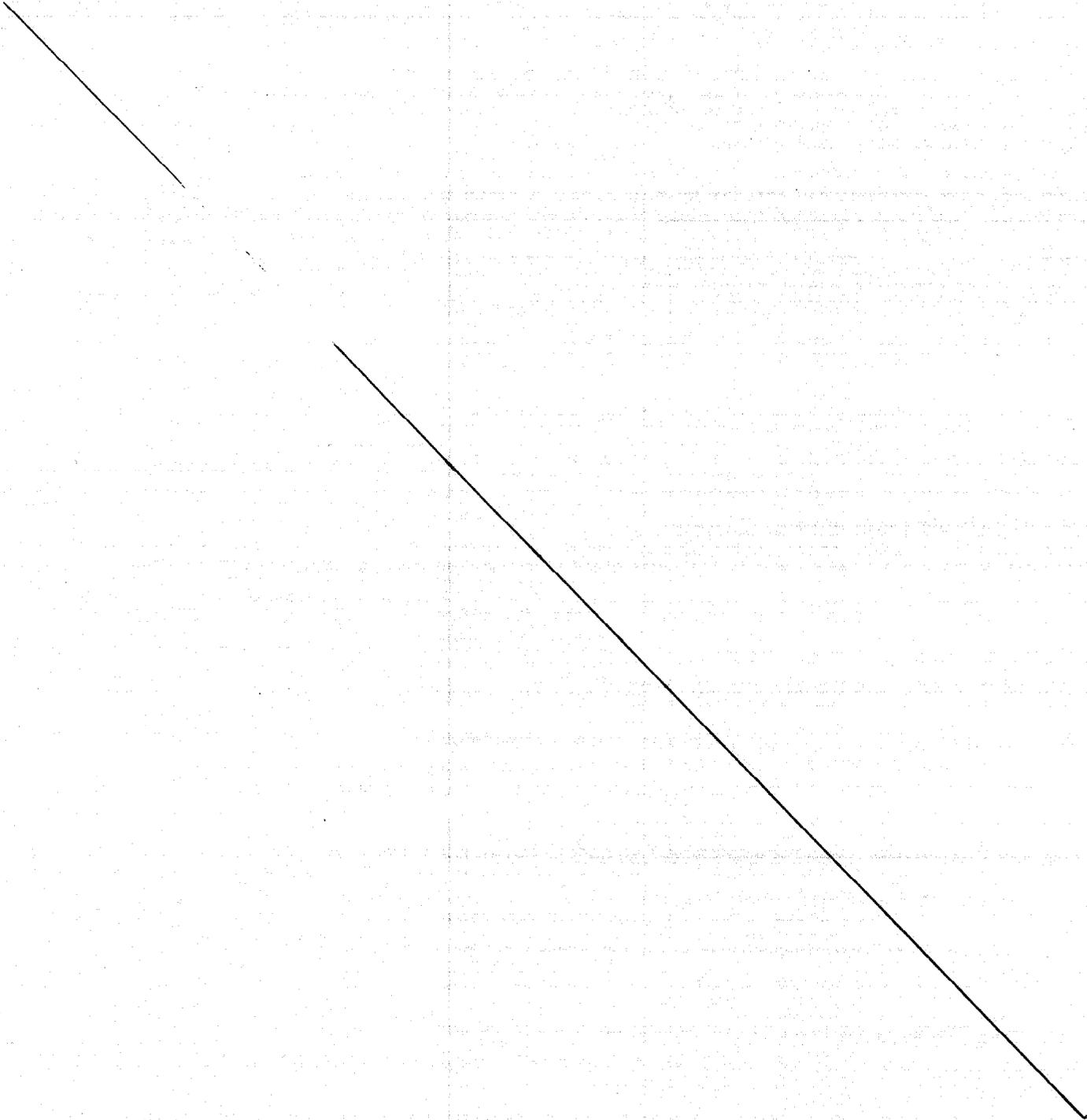
(ii) *Amount.* 1,088 grams per ton.

(iii) *Indications for use.* Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain. Intakes of lasalocid in excess of 200 mg/head/day have not been shown to be more effective than 200 mg/head/day.

(iv) *Limitations.* Feed continuously on a free-choice basis at a rate of 60 to 300 mg lasalocid per head per day.

(v) *Sponsor.* See No. 046573 in § 510.600(c) of this chapter.

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Dated: May 29, 2003
May 29, 2003.

cv02110

Steven D. Vaughn

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Glenn Lantry