

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DUB
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Certifier R. LEDESMA

New Animal Drugs for Use in Animal Feeds; Lasalocid

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 new animal drug application (NADA) filed by Purina Mills, Inc. The NADA provides for the use of a lasalocid Type A medicated article to make free-choice Type C medicated feed mineral blocks used for increased rate of weight gain in pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers).

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

FOR FURTHER INFORMATION CONTACT: Amey L. Adams, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7560, e-mail: aadams1@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Purina Mills, Inc., P.O. Box 66812, St. Louis, MO 63166-6812, filed NADA 141-171 that provides for use of BOVATEC 68 (lasalocid) Type A medicated article to make Purina Sugar Mag Block 1440 BVT Medicated Mineral Block, a free-choice Type C medicated feed. The free-choice mineral block 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 August 20, 2002, and the regulations are amended

in § 558.311 (21 CFR 558.311) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In addition, § 558.311 is being amended to collocate the entry for another free-choice mineral Type C medicated feed, approved under NADA 138–993, to the new entry created for NADA 141–171. This is being done to improve the readability and clarity of the regulations.

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)(ii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning August 20, 2002.

The agency has determined under 21 CFR 25.33(a)(6) 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 558.311 is amended by adding paragraph (b)(8); in paragraph (d)(7) by adding “and (e)(1)(xviii)” after “(e)(1)(xii)” ; by revising (e)(1)(xii); and by adding paragraph (e)(1)(xviii) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(b) * * *

(8) 15 percent activity to No. 017800 for use as in paragraph (e)(1)(xviii)

of this section.

* * * * *

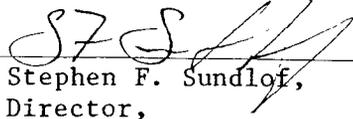
(e) * * *

(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
i)	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.	Feed continuously on a free-choice basis at a rate of not less than 60 mg or more than 300 mg of lasalocid per head per day.	046573
) 1440	Pasture cattle (slaughter, stocker, feeder cattle, and dairy and beef replacement heifers): For increased rate of weight gain.	Feed continuously on a free-choice basis at a rate of not less than 60 mg nor more than 200 mg of lasalocid per head per day.	021930 017800

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Dated: 11/8/02
November 8, 2002



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

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