DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

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 supplemental new animal drug application (NADA) filed by Alpharma Inc. The supplemental NADA provides for the use of lasalocid Type A medicated articles containing 20 percent lasalocid activity per pound to make free-choice Type C medicated feeds 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 November 21, 2006.

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

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., Fort Lee, NJ 07024, filed a supplement to NADA 96–298 for use of BOVATEC 91 (lasalocid) Type A medicated article (20 percent lasalocid activity per pound) to make free-choice 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 supplemental NADA is approved as of October 20, 2006, 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.

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 Division of Dockets Management (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)(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. In § 558.311, revise paragraphs (e)(2)(i), (e)(2)(ii), (e)(3)(i), (e)(3)(ii), and (e)(4)(i) to read as follows:

§ 558.311 Lasalocid.

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(e) * * *

(2) * * *

(i) *Specification.*

Ingredient	Percent	International feed No.
Defluorinated phosphate (20.5% Ca, 18.5% P)	35.9	6–01–080
Sodium chloride (salt)	20.0	6–04–152
Calcium carbonate (38% Ca)	18.0	6–01–069
Cottonseed meal	10.0	5–01–621
Potassium chloride	3.0	6–03–755
Selenium premix (0.02 percent Se)[1]	3.0	.....
Dried cane molasses (46% sugars)	2.5	4–04–695
Magnesium sulfate	1.7	6–02–758
Vitamin premix[1]	1.4	.....
Magnesium oxide (58% Mg)	1.2	6–02–756
Potassium sulfate	1.2	6–06–098
Trace mineral premix[1]	1.04	.....
Lasalocid Type A medicated article (68 g/lb)[2]	1.06	.....

[1] Content of the 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 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1,440 g lasalocid per ton, use 21.2 lbs (1.06%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 15.88 lbs per ton (0.794%), adding molasses.

(ii) *Amount.* 1,440 grams per ton.

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(3) * * *

(i) *Specification.*

Ingredient	Percent	International feed No.
Cane molasses	55.167	4–13–241
Condensed molasses fermentation solubles	24.0	.....
50% Urea Solution (23% N)	12.0	.....
Ammonium polyphosphate solution	1.0	6–08–42
Phosphoric acid (54%)	3.0	6–03–707
Xanthan gum	0.05	8–15–818

Ingredient	Percent	International feed No.
Water	4.0	
Trace mineral premix[1]	0.5	
Vitamin premix[1]	0.2	
Lasalocid Type A medicated article (90.7 g/lb)[2]	0.083	

[1] Content of the 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 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 150 gm lasalocid per ton, use 1.652 lb (0.083%) of a lasalocid liquid Type A medicated article containing 90.7 g/lb. If using a dry lasalocid Type A medicated article containing 68 g/lb, use, use 2.206 lbs per ton (0.111%), replacing molasses. If using a dry lasalocid Type A medicated article containing 90.7 g/lb, use 1.652 lbs per ton (0.083%), adding molasses.

(ii) *Amount.* 150 grams per ton.

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(4) * * *

(i) *Specification.*

Ingredient	Percent	International feed No.
Monocalcium phosphate (21% P)	57.70	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/lb)[2]	0.80	

[1] Content of the 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 21 CFR 573.920. Ethylenediamine dihydroiodide (EDDI) should comply with FDA Compliance Policy Guides Sec. 651.100 (CPG 7125.18).

[2] To provide 1,088 g lasalocid per ton, use 16 lbs (0.80%) of a lasalocid Type A medicated article containing 68 g/lb. If using a lasalocid Type A medicated article containing 90.7 g/lb, use 12 lbs per ton (0.6%), adding molasses.

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Dated: November 7, 2006.

Steven D. Vaughn,

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

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs For Use in Animal Feeds; Ractopamine

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 two supplemental new animal drug applications (NADAs) filed by Elanco Animal Health. The first supplemental NADA revises the concentrations of ractopamine hydrochloride in single-ingredient Type B and C medicated swine feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. The other supplemental NADA revises the concentrations of ractopamine hydrochloride used with tylosin phosphate in two-way Type C medicated swine feeds to conform with approved single-ingredient ractopamine use.

DATES: This rule is effective November 21, 2006.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–120), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855; tel: 301–827–7561; e-mail: *charles.andres@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed a supplement to NADA 140–863 that provides for use of PAYLEAN (ractopamine hydrochloride) Type A medicated articles in Type B and C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine. The supplement revises the concentrations of ractopamine hydrochloride fed to finishing swine, weighing not less than 150 pounds, fed a complete ration containing at least 16 percent crude protein for the last 45 to 90 pounds of gain prior to slaughter. This supplemental NADA was approved on April 25, 2006. 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 supplemental approval qualifies for 3 years of marketing exclusivity beginning April 25, 2006.

Elanco Animal Health also filed a supplement to NADA 141–172 that provides for use of two-way combination Type C medicated swine feeds formulated with PAYLEAN (ractopamine hydrochloride) and TYLAN (tylosin phosphate) single-ingredient Type A medicated articles. The supplement revises the concentrations of ractopamine hydrochloride in Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with Lawsonia intracellularis and for prevention of swine dysentery (vibrionic) in finishing swine, weighing