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.

* * * * *

(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.

* * * * *

Dated: November 7, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–19614 Filed 11–20–06; 8:45 am]

BILLING CODE 4160–01–S

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

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 is approved as of October 20, 2006, and the regulations in 21 CFR 558.500 are amended to reflect both approvals. The basis of these approvals is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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.

FDA has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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 the 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. Amend § 558.500 as follows:

a. Revise paragraph (d)(1)(i);

b. Add paragraph (d)(1)(iii);

c. In the table in paragraph (e)(1), revise paragraph (e)(1)(i);

d. In the table in paragraph (e)(1), in paragraphs (e)(1)(ii) and (e)(1)(iii), in the ''Ractopamine in grams/ton'' column, remove ''4.5'' and add in its place ''4.5 to 9''; and

e. In the table in paragraph (e)(1), remove paragraphs (e)(1)(iv), (e)(1)(v), and (e)(1)(vi).

The revisions, addition, and removals read as follows:

§ 558.500 Ractopamine.

* * * * *

(d) * * *

(1) * * *

(i) Ractopamine may increase the number of injured and/or fatigued pigs during marketing.

* * * * *

(iii) No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.5 g/ton.

* * * * *

(e) * * *

(1) * * *

Ractopamine in grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5 to 9		For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine, weighing not less than 150 lbs, fed a complete ration containing at least 16% crude protein for the last 45 to 90 lbs of gain prior to slaughter.	Feed continuously as sole ration.	000986
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Dated: November 7, 2006.

Steven D. Vaughn,

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

[FR Doc. E6–19615 Filed 11–20–06; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[CGD11–06–043]

RIN 1625–AA09

Drawbridge Operation Regulations; Little Potato Slough, Terminous, CA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eleventh Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the Highway 12 Drawbridge across Little Potato Slough, mile 0.1, at Terminous, CA. This deviation allows the bridge to remain in the closed-to-navigation position during the deviation period. The deviation is necessary for the bridge owner, the California Department of Transportation (Caltrans), to perform submarine power and control cable testing.

DATES: This deviation is effective from 10 a.m. to 4 p.m. on November 28, 2006.

ADDRESSES: Materials referred to in this document are available for inspection or copying at Commander (dpw), Eleventh Coast Guard District, Building 50–2, Coast Guard Island, Alameda, CA 94501–5100, between 8 a.m. and 4 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: David H. Sulouff, Chief, Bridge Section, Eleventh Coast Guard District, telephone (510) 437–3516.

SUPPLEMENTARY INFORMATION: On October 25, 2006, Caltrans requested a temporary change to the operation of the Highway 12 Drawbridge, mile 0.1, Little Potato Slough, at Terminous, CA. The Highway 12 Drawbridge navigation span provides a vertical clearance of 34 feet above Mean High Water in the closed-to-navigation position. The draw opens on signal if at least 4 hours notice is given as required by 33 CFR 117.167. Navigation on the waterway is mainly recreational with some commercial traffic hauling materials for levee repair. Caltrans requested the drawbridge be allowed to remain closed to navigation from 10 a.m. to 4 p.m. on November 28, 2006. During this time, submarine power and control cable testing will be conducted to ensure the continuing operation of the drawspan. This temporary deviation has been coordinated with waterway users. No objections to the proposed temporary rule were raised. Vessels that can transit