

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

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Certifier	S. Reese

**New Animal Drugs for Use in Animal Feeds; Ractopamine and Tylosin**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 Elanco Animal Health. The NADA provides for use of ractopamine and tylosin single-ingredient Type A medicated articles to make combination drug Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, increased carcass leanness, and prevention and/or control of porcine proliferative enteropathies (ileitis) in swine.

**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:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-172 that provides for use of Paylean® (9 grams per pound (g/lb) ractopamine hydrochloride) and Tylan® (10, 40, or 100 g/lb tylosin phosphate) Type A medicated article to make combination drug 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* in swine. The NADA is approved as of February 20, 2001, and the regulations are amended in 21 CFR 558.500 and 558.625 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 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 558.500 is amended by revising paragraph (d)(1) to read as follows:

**§ 558.500 Ractopamine.**

\* \* \* \* \*

(d) *Conditions of use.*

(1) *Swine.*

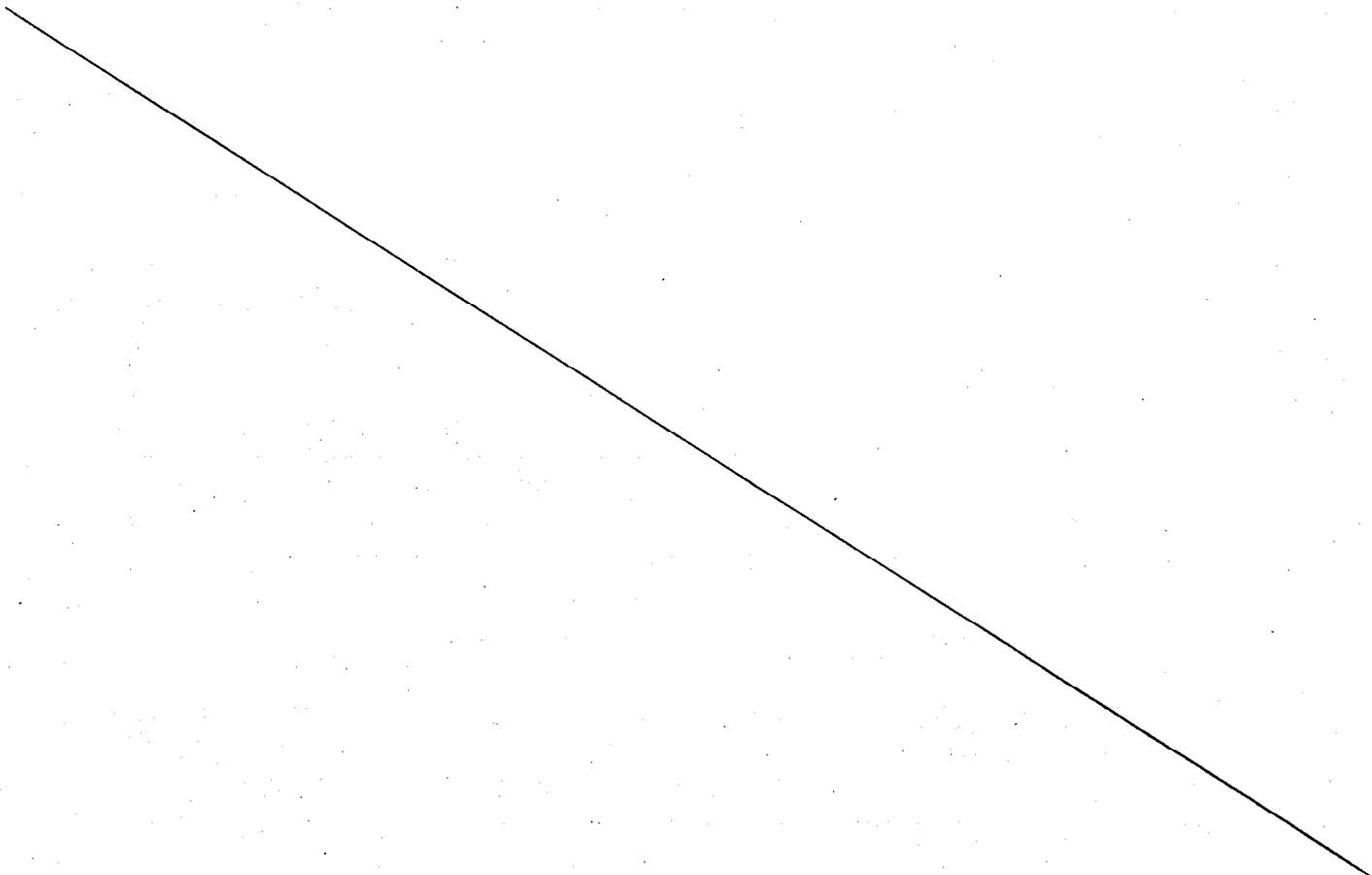
Ractopamine in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(i) 4.5 .....	.....	For increased rate of weight gain, improved feed efficiency, and increased carcass leanness.	Feed continuously as sole ration. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986
(ii) 4.5 to 18 .....	.....	For improved feed efficiency and increased carcass leanness.	Feed continuously as sole ration. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986
(iii) 4.5 .....	Tylosin 100 .....	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 <i>Lawsonia intracellularis</i> .	Feed continuously as sole ration for 21 days. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986
(iv) 4.5 to 18 .....	Tylosin 100 .....	For improved feed efficiency and increased carcass leanness; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with <i>Lawsonia intracellularis</i> .	Feed continuously as sole ration for 21 days. Feed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight. Not for use in breeding swine.	000986

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3. Section 558.625 is amended by adding paragraph (f)(2)(vii) to read as follows:

**§ 558.625 Tylosin.**

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(f) \* \* \*

(2) \* \* \*

(vii) Ractopamine hydrochloride as in § 558.500.

Dated: 4/16/01  
April 16, 2001.

S F Sundlof

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

[FR Doc. 01-????? Filed ??-??-01; 8:45 am]

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Suzette N. Reece