

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

*DUB*  
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Certifier R. VEDESMA

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

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

**ACTION:** Final rule; technical amendment.

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**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 for their ractopamine hydrochloride Type A medicated article. The supplemental NADAs provide for use of a 45-gram-per-pound (g/lb) strength Type A medicated article to make Type B and Type C medicated feeds for finishing swine, for amending the assay limits for Type B and Type C medicated feeds containing ractopamine, and for the addition of cautionary statements to labeling.

**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, e-mail: candres@cvm.fda.gov.

**SUPPLEMENTARY INFORMATION:** Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed two supplemental applications to NADA 140-863 for PAYLEAN (ractopamine hydrochloride), a Type A medicated article used to make Type B and Type C medicated feeds for finishing swine. The first supplemental NADA provides for use of a 45-g/lb strength of PAYLEAN and for amending the assay limits for Type B and Type C medicated feeds containing ractopamine. The second supplemental NADA provides for addition of cautionary statements to labeling. The supplemental NADAs are approved as of February 27

and June 1, 2001, respectively, and the regulations are amended in §§ 558.4 and 558.500 (21 CFR 558.4 and 558.500) to reflect the approval.

In addition, § 558.500 is being revised to correct the wording of the indications for the use of ractopamine alone or in combination with tylosin.

Approval of the first supplemental NADA did not require review of safety or effectiveness data; therefore, a freedom of information summary is not required.

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 submitted to support approval of the second supplemental 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)(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 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.

§ 558.4 [Amended]

2. Section 558.4 *Requirement of a medicated feed mill license* is amended in paragraph (d) in the "Category I" table in the entry for "Ractopamine" in the "Assay limits percent<sup>1</sup> type B/C<sup>2</sup>" column by removing "80-110" and adding in its place "80-110/75-125".

3. Section 558.500 is amended in paragraph (a) by removing "9" and adding in its place "9 or 45" and by revising the table in paragraph (d)(1) to read as follows:

§ 558.500 Ractopamine.

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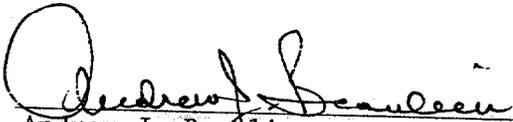
(d) \* \* \*

(1) \* \* \*

Ractopamine grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(i) 4.5		For increased rate of weight gain, improved feed efficiency, and increased carcass leanness in finishing swine fed a complete ration containing at least 16 percent crude protein from 150 pounds (lb) (68 kilograms (kg)) to 240 lb (109 kg) body weight.	Feed continuously as sole ration. Pigs fed PAYLEAN are at an increased risk for exhibiting the downer pig syndrome (also referred to as "slows," "subs," or "suspects"). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of PAYLEAN. Not for use in breeding swine.	000986
(ii) 4.5	Tylosin 100	Finishing swine: As in paragraph (d)(1)(i) of this section; 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. Not for use in breeding swine.	000986
(iii) 4.5 to 18		For improved feed efficiency and increased carcass leanness in finishing swine fed a complete ration containing at least 16 percent crude protein from 150 lb (68 kg) to 240 lb (109 kg) body weight.	Feed continuously as sole ration. Pigs fed PAYLEAN are at an increased risk for exhibiting the downer pig syndrome (also referred to as "slows," "subs," or "suspects"). Pig handling methods to reduce the incidence of downer pigs should be thoroughly evaluated prior to initiating use of PAYLEAN. Not for use in breeding swine.	000986
(iv) 4.5 to 18	Tylosin 100	Finishing swine: As in paragraph (d)(1)(iii) of this section; and for prevention and/or control of porcine proliferative enteropathies (ileitis) associated with <i>L. intracellularis</i> .	Feed continuously as sole ration for 21 days. Not for use in breeding swine.	000986

(2) [Reserved]

Dated: July 9, 2002  
July 9, 2002.

  
Andrew J. Beaulieu,  
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Office of New Animal Drug Evaluation,  
Center for Veterinary Medicine.

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