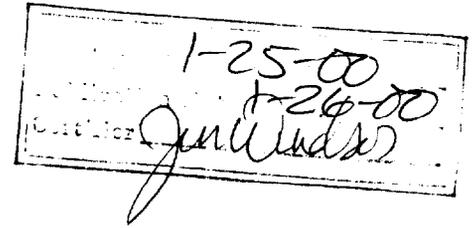


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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Parts 556 and 558**

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

**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, A Division of Eli Lilly and Co. The NADA provides for use of a ractopamine hydrochloride Type A medicated article to make Type B and Type C medicated swine feeds. The Type C medicated finishing swine feeds are used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. The regulations are also amended to provide for an acceptable daily intake (ADI) for ractopamine and tolerances for drug residues in edible products derived from treated 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 and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140-863 that provides for use of Paylean® (ractopamine hydrochloride) Type A medicated article to make Type B and Type C medicated swine feeds. The Type C medicated finishing swine feeds must contain at least 16 percent crude protein. Feeds containing 4.5 grams per ton (g/t) ractopamine hydrochloride are used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness. Feeds containing

4.5 to 18 g/t ractopamine hydrochloride are used for improved feed efficiency and increased carcass leanness. The NADA is approved as of December 22, 1999, and the regulations in part 558 (21 CFR part 558) are amended by adding § 558.500 to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Furthermore, § 558.4(d) is amended in the “Category I” table by adding an entry for “ractopamine” to provide for the assay limits for Type A medicated articles and Type B/C medicated feeds and the maximum Type B medicated feed level.

In addition, part 556 (21 CFR part 556) is amended by adding § 556.570 to establish an ADI for total ractopamine and tolerances for residues of ractopamine in edible tissues of treated swine.

In accordance with the freedom of information provisions of 21 CFR part 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.

Under section 512(c)(2)(F)(i) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(i)), this approval for food-producing animals qualifies for 5 years of marketing exclusivity beginning December 22, 1999, because no active ingredient (including any ester or salt of the active ingredient) has been previously approved for any other application filed under section 512(b)(1).

The agency has carefully considered the potential environmental effects of this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency’s finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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

#### *21 CFR Part 556*

Animal drugs, Foods.

#### *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 parts 556 and 558 are amended as follows:

### **PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD**

1. The authority citation for 21 CFR part 556 continues to read as follows:

**Authority:** 21 U.S.C. 342, 360b, 371.

2. Section 556.570 is added to subpart B to read as follows:

#### **§ 556.570 Ractopamine.**

(a) *Acceptable daily intake (ADI)*. The ADI for total residues of ractopamine is 1.25 micrograms ractopamine hydrochloride per kilogram of body weight per day.

(b) *Tolerances*. Swine—Tolerances are established for residues of ractopamine hydrochloride parent (marker residue) in edible swine tissues of 0.05 part per million (ppm) in muscle, and 0.15 ppm in liver (target tissue). Residues of ractopamine in swine muscle are not indicative of the safety of residues in other edible tissue.

**PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS**

3. The authority citation for 21 CFR part 558 continues to read as follows:

**Authority:** 21 U.S.C. 360b, 371.

4. Section 558.4 is amended in paragraph (d) in the “Category I” table by adding an entry alphabetically for “Ractopamine” to read as follows:

**§ 558.4 Medicated feed applications.**

\* \* \* \* \*

(d) \* \* \*

CATEGORY I

Drug	Assay limits percent <sup>1</sup> type A	Type B maximum (200x)	Assay limits percent <sup>1</sup> type B/C <sup>2</sup>
Ractopamine	85–105	1.8 g/lb (0.4%)	80–110

<sup>1</sup> Percent of labeled amount.

<sup>2</sup> Values given represent ranges for either Type B or Type C medicated feeds. For those drugs that have two range limits, the first set is for a Type B medicated feed and the second set is for a Type C medicated feed. These values (ranges) have been assigned in order to provide for the possibility of dilution of a Type B medicated feed with lower assay limits to make Type C medicated feed.

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5. Section 558.500 is added to subpart B to read as follows:

**§ 558.500 Ractopamine.**

(a) *Approvals.* Type A medicated articles: 9 grams of ractopamine hydrochloride per pound to 000986 in § 510.600(c) of this chapter.

(b) [Reserved]

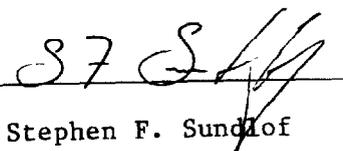
(c) *Related tolerances.* See § 556.570 of this chapter.

(d) *Conditions of use.* (1) *Swine*—(i) *Amount.* 4.5 grams of ractopamine hydrochloride per ton of Type C feed for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; 4.5 to 18 grams per ton for improved feed efficiency and increased carcass leanness; fed in a complete ration containing at least 16 percent crude protein to finishing swine from 150 to 240 pounds body weight.

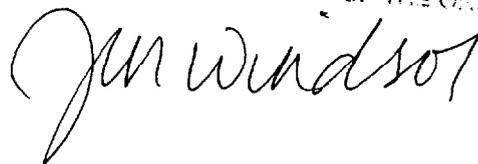
(ii) *Limitations*. Feed continuously as sole ration. Not for use in breeding swine.

(2) [Reserved]

Dated: 1/13/00  
January 13, 2000

  
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Stephen F. Sundlof  
Director  
Center for Veterinary  
Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL.



[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

**BILLING CODE 4160-01-F**