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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

[Docket No. FDA-2008-N-0039]

New Animal Drugs; 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 a new animal drug application (NADA) filed by Elanco Animal Health. The NADA provides for use of ractopamine hydrochloride Type A medicated articles to make Type B and Type C medicated feeds used for increased rate of weight gain and improved feed efficiency in finishing turkeys.

DATES: This rule is effective [insert date of publication in the **Federal Register**].

FOR FURTHER INFORMATION CONTACT: Timothy Schell, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8116, e-mail: timothy.schell@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-290 that provides for use of TOPMAX 9 (ractopamine hydrochloride) Type A medicated article to make Type B and Type C medicated feeds used for increased rate of weight gain and improved feed efficiency in finishing turkeys. The NADA is approved as of November 12, 2008, and the regulations in 21 CFR

556.570 and 558.500 are amended to reflect the approval.

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 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 Division of Dockets Management (see address in the previous paragraph) between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(ii) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U.S.C. 360b(c)(2)(F)(ii)), this approval qualifies for 3 years of marketing exclusivity beginning on the date of approval.

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 the 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. In § 556.570, add paragraph (b)(3) to read as follows:

§ 556.570 Ractopamine.

* * * * *

(b) * * *

(3) *Turkeys*—(i) *Liver (the target tissue)*. The tolerance for ractopamine (the marker residue) is 0.45 ppm.

(ii) *Muscle*. The tolerance for ractopamine (the marker residue) is 0.1 ppm.

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. In § 558.500:

- a. Revise paragraph (d)(1);
- b. Redesignate paragraphs (d)(2) and (d)(3) as paragraphs (d)(4) and (d)(5);
- c. Add new paragraphs (d)(2) and (d)(3);
- d. In paragraph (e)(2)(i), in the "Limitations" column, remove "Not for animals intended for breeding."; and
- e. Add paragraph (e)(3).

The revisions and additions read as follows:

§ 558.500 Ractopamine.

* * * * *

(d) * * *

(1) Labeling of Type B and Type C feeds shall bear the following: "Not for animals intended for breeding."

(2) Labeling of Type B and Type C swine feeds shall bear the following:

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

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

(3) Labeling of Type B and Type C tom turkey feeds shall bear the following: "No increased benefit has been shown when ractopamine concentrations in the diet are greater than 4.6 g/ton."

* * * * *

(e) * * *

(3) *Turkeys*—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(i) 4.6 to 11.8 (5 to 13 ppm)		Finishing hen turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 7 to 14 days prior to slaughter.	Feed continuously as sole ration during the last 7 to 14 days prior to slaughter.	000986
(ii) 4.6 to 11.8 (5 to 13 ppm)		Finishing tom turkeys: For increased rate of weight gain and improved feed efficiency when fed for the last 14 days prior to slaughter.	Feed continuously as sole ration during the last 14 days prior to slaughter. Feeding ractopamine to tom turkeys during periods of excessive heat can result in increased mortality.	000986

Dated: November 24, 2008.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 08-????? Filed ??-??-08; 8:45 am]

BILLING CODE 4160-01-S