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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

Display Date 11-21-07
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Certifier A. Corbin

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 a supplemental new animal drug application (NADA) filed by Elanco Animal Health. The supplemental NADA provides for an increased level of monensin in two-way combination Type B and Type C medicated feeds containing ractopamine hydrochloride and monensin for cattle fed in confinement for slaughter.

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

FOR FURTHER INFORMATION CONTACT: Daniel A. Benz, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0223, e-mail: daniel.benz@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 141 225 that provides for use of OPTAFLEXX (ractopamine hydrochloride) and RUMENSIN (monensin USP) Type A medicated articles to make dry and liquid two-way combination medicated feeds for cattle fed in confinement for slaughter. The supplemental NADA provides for an increased level of monensin in combination Type B and Type C medicated feeds. The

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supplemental NADA is approved as of October 30, 2007, and the regulations in 21 CFR 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 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 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. In § 558.500, in the table in paragraph (e)(2), revise paragraphs (e)(2)(ii) and (e)(2)(vii) to read as follows:

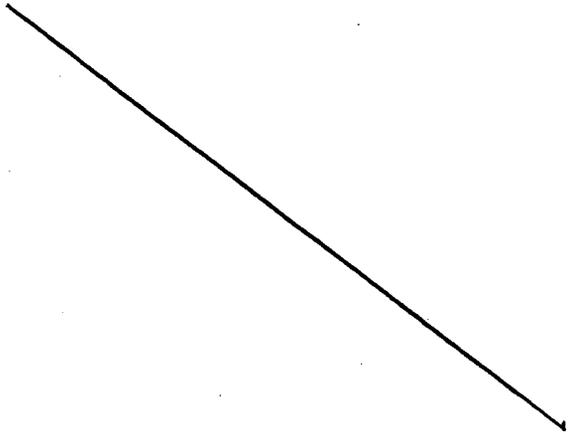
§ 558.500 Ractopamine.

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(e) * * *

(2) * * *

Ractopamine grams/ton	Combination grams/ton	Indications for use	Limitations	Sponsor
(ii) 8.2 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(i) of this section; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E zuernii</i> .	As in paragraph (e)(2)(i) of this section; see paragraph §§ 558.355(d) of this chapter.	000986
(vii) 9.8 to 24.6	Monensin 10 to 40 to provide 0.14 to 0.42 mg monensin/lb of body weight, depending on severity of coccidiosis challenge, up to 480 mg/head/day	Cattle fed in confinement for slaughter: As in paragraph (e)(2)(vi) of this section; for prevention and control of coccidiosis due to <i>Eimeria bovis</i> and <i>E zuernii</i> .	As in paragraph (e)(2)(vi) of this section; see paragraph §§ 558.355(d) of this chapter.	000986



Dated: 11/08/07
November 8, 2007.

Dr. Bernadette Dunham

Bernadette Dunham,
Deputy Director,
Center for Veterinary Medicine.

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11-19-07

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