

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DDM
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Certifier A. Corbin

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 two new animal drug applications (NADAs) filed by Elanco Animal Health. One NADA provides for use of ractopamine, melengestrol, and monensin Type A medicated articles to make three-way combination Type C medicated feeds for heifers fed in confinement for slaughter. The other NADA provides for use of ractopamine, melengestrol, monensin, and tylosin Type A medicated articles to make four-way combination Type C medicated feeds for heifers fed in confinement for slaughter.

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

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine (HFV-126), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 141-234 that provides for use of OPTAFLEXX (ractopamine hydrochloride), MGA (melengestrol acetate), and RUMENSIN (monensin sodium) Type A medicated articles to make three-way combination Type C medicated feeds used for

increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *Eimeria bovis* and *E. zuernii*; and for suppression of estrus (heat) in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. Elanco Animal Health also filed NADA 141–233 that provides for use of OPTAFLEXX, MGA, RUMENSIN, and TYLAN (tylosin phosphate) Type A medicated articles to make four-way combination Type C medicated feeds used for increased rate of weight gain, improved feed efficiency, and increased carcass leanness; for prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; for suppression of estrus (heat); and for reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes* in heifers fed in confinement for slaughter during the last 28 to 42 days on feed. The NADAs are approved as of July 2, 2004, and the regulations in 21 CFR 558.342, 558.355, 558.500, and 558.625 are amended to reflect the approvals. The basis of approval is discussed in the freedom of information summaries.

In accordance with the freedom of information provisions of 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii), summaries of safety and effectiveness data and information submitted to support approval of these applications 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 these actions are of a type that do not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor environmental impact statement is required for either.

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. Section 558.342 is amended by adding paragraph (e)(2) to read as follows:

§ 558.342 Melengestrol.

* * * * *

(e) * * *

(2) Melengestrol may also be used with ractopamine alone or in combination as in § 558.500 of this chapter.

§ 558.355 [Amended]

■ 3. Section 558.355 is amended in paragraph (f)(7)(iii) by removing “with tylosin” and by adding in its place “in combination”.

■ 4. Section 558.500 is amended by adding paragraphs (e)(2)(viii) and (e)(2)(x) to read as follows:

§ 558.500 Ractopamine.

* * * * *

(e) * * *

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(2) Cattle—

Ractopamine in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
(viii) 9.8 to 24.6	Monensin 10 to 30, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers 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> ; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d) and 558.355(d) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	000986
(x) 9.8 to 24.6	Monensin 10 to 30, plus tylosin 8 to 10, plus melengestrol acetate to provide 0.25 to 0.5 mg/head/day	Heifers 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> ; for reduction of incidence of liver abscesses caused by <i>Fusobacterium necrophorum</i> and <i>Actinomyces (Corynebacterium) pyogenes</i> ; and for suppression of estrus (heat).	As in paragraph (e)(2)(vi) of this section; see §§ 558.342(d), 558.355(d), and 558.625(c) of this chapter. Melengestrol acetate as provided by No. 000009 in § 510.600(c) of this chapter.	000986

§ 558.625 [Amended]

■ 5. Section 558.625 is amended in paragraph (f)(2)(vii) by removing “with monensin” and by adding in its place “in combination”.

Dated: 7/27/04
July 27, 2004.

S F Sundlof

Stephen F. Sundlof,
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Center for Veterinary Medicine.
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