

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DDM

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Certifier J. Hawkins

New Animal Drugs For Use in Animal Feeds; Monensin

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 revises the concentration of monensin in two-way Type B and Type C medicated feeds containing monensin and tylosin to cattle fed in confinement for slaughter and a revision to bacterial pathogen nomenclature.

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 104-646 that provides for use of RUMENSIN (monensin USP) and TYLAN (tylosin phosphate) 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 and a revision to bacterial pathogen nomenclature. The supplemental NADA is approved as

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of October 30, 2007, and the regulations in 21 CFR 558.355 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 § 558.355, revise paragraphs (f)(3)(ii) and (f)(3)(xii) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(ii) *Amount per ton.* Monensin, 5 to 40 grams; plus tylosin, 8 to 10 grams.

(a) *Indications for use.* Cattle fed in confinement for slaughter: For improved feed efficiency; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. Feed continuously as sole ration at the rate of 50 to 480 milligrams of monensin and 60 to 90 milligrams of tylosin per head per day. Combination drug liquid Type B medicated feeds may be used to manufacture dry Type C medicated feeds and shall conform to mixing instructions as in § 558.625(c) of this chapter.

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(xii) *Amount per ton.* Monensin, 10 to 40 grams; plus tylosin, 8 to 10 grams.

(a) *Indications for use.* Cattle fed in confinement for slaughter: For prevention and control of coccidiosis due to *E. bovis* and *E. zuernii*; and reduction of incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Arcanobacterium (Actinomyces) pyogenes*.

(b) *Limitations.* Feed only to cattle being fed in confinement for slaughter. For prevention and control of coccidiosis, feed at a rate of 0.14 to 0.42 milligrams monensin per pound of body weight per day, depending upon the

severity of challenge, up to maximum of 480 milligrams per head per day; and
60 to 90 milligrams of tylosin per head per day.

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Dated: Nov 20 07

November 20, 2007.

Bernadette Dunham DVM PhD.

Bernadette Dunham,
Deputy Director,
Center for Veterinary Medicine.

[FR Doc. 07-????? Filed ??-??-07; 8:45 am]

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