

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

DMB

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New Animal Drugs for Use in Animal Feeds; Monensin and Tylosin

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 supplemental new animal drug applications (NADA's) filed by Elanco Animal Health. These supplemental NADA's provide for using tylosin or monensin and tylosin single-ingredient Type A medicated articles to make tylosin liquid Type B medicated feeds or combination drug liquid Type B medicated feeds. The liquid Type B medicated feeds are used to make dry Type C medicated feeds for cattle.

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.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 12-491 that provides for use of TYLAN® (40 or 100 grams per pound (g/lb) tylosin phosphate) Type A medicated articles to make liquid Type B medicated feeds. The tylosin liquid Type B medicated feeds are, in turn, used to make dry Type C medicated feeds for reduction of the incidence of liver abscesses caused by *Fusobacterium necrophorum* and *Actinomyces (Corynebacterium) pyogenes* in beef cattle. Elanco Animal Health also filed supplemental NADA 104-646 that provides for use of RUMENSIN® (20, 30, 45, 60, 80, or 90.7 g/lb monensin activity as monensin sodium) and TYLAN® Type A medicated articles to make liquid combination drug Type B medicated feeds.

The combination drug liquid Type B medicated feeds are, in turn, used to make dry Type C medicated feeds used for improved feed efficiency and reduction of the incidence of liver abscesses caused by *F. necrophorum* and *A. (Corynebacterium) pyogenes* in cattle fed in confinement for slaughter. The supplemental NADA's are approved as of February 2, 2001, and the regulations are amended in 21 CFR 558.355 and 558.625 to reflect the approval.

The agency has determined under 21 CFR 25.33(a)(1) 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 an 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 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 558.355 is amended in paragraph (f)(3)(ii)(b) by adding a new sentence after the second sentence to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(3) * * *

(ii) * * *

(b) * * * 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).

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3. Section 558.625 is amended by adding paragraph (c) to read as follows:

§ 558.625 Tylosin.

* * * * *

(c) *Special considerations.* (1) Type C medicated feeds for cattle may be manufactured from tylosin liquid Type B medicated feeds which have a pH between 4.5 and 6.0 and which bear appropriate mixing directions as follows:

(i) For liquid Type B feeds stored in recirculating tank systems: Recirculate immediately prior to use for no fewer than 10 minutes, moving not less than 1 percent of the tank contents per minute from the bottom of the tank to the top. Recirculate daily as described even when not used.

(ii) For liquid Type B feeds stored in mechanical, air, or other agitation-type tank systems: Agitate immediately prior to use for no fewer than 10 minutes, creating a turbulence at the bottom of the tank that is visible at the top. Agitate daily as described even when not used.

(2) Tylosin liquid Type B medicated feeds used to make Type C medicated feeds for cattle may be manufactured from tylosin Type A medicated articles according to the following mixing directions:

(i) Presolubilize tylosin in 50 percent urea for approximately 1 hour prior to adding any feed components or other active ingredients.

(ii) Maintain a pH between 4.5 and 6.0.

(3) Tylosin liquid Type B medicated feeds must bear an expiration date of 8 weeks after the date of manufacture.

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Dated: March 8, 2001
March 8, 2001.

Claire M. Lathers

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