

DEPARTMENT OF HEALTH AND HUMAN SERVICES

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Food and Drug Administration

21 CFR Part 558

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

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 approved, single ingredient monensin and bambermycins Type A medicated articles to make two-way combination Type C medicated feeds used for prevention of coccidiosis, increased rate of weight gain, and improved feed efficiency in growing turkeys.

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

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140-955 that provides for use of Coban® (45 or 60 grams per pound (g/lb) of monensin as monensin sodium) and Flavomycin® (2, 4, or 10 g/lb of bambermycins activity) Type A medicated articles to make combination Type C medicated feeds. The combination Type C medicated feeds containing 54 to 90 g/ton monensin and 1 to 2 g/ton bambermycins and are used for prevention of coccidiosis caused by *Eimeria adenoeides*, *E. meleagrimitis*, and *E. gallopavonis*; and for improved feed efficiency in growing turkeys. The combination Type C medicated feeds containing 54 to 90 g/ton monensin and 2 g/ton bambermycins and are used for prevention of coccidiosis caused by *E. adenoeides*, *E.*

meleagrimitis, and *E. gallopavonis*; and for increased rate of weight gain and improved feed efficiency in growing turkeys. The NADA is approved as of June 28, 2000, and the regulations in 21 CFR 558.95 and 558.355 are amended to reflect the approval.

In accordance with the freedom of information provisions of 21 CFR part 20 and 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 Dockets Management Branch (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 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 558.95 is amended by redesignating paragraphs (d)(5)(iii) and (d)(5)(iv) as (d)(5)(iv) and (d)(5)(v), and by adding new paragraph (d)(5)(iii) to read as follows:

§ 558.95 Bambermycins.

* * * * *

(d) * * *

(5) * * *

(iii) Monensin as in § 558.355.

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3. Section 558.355 is amended by adding paragraphs (f)(2)(v) and (f)(2)(vi) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(2) * * *

(v) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 1 to 2 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagritidis*, and *E. gallopavonis*, and for improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of immunity to turkey coccidiosis. Bambermycins as provided by No. 012799 in § 510.600(c) of this chapter.

(vi) *Amount per ton.* Monensin, 54 to 90 grams, plus bambermycins, 2 grams.

(a) *Indications for use.* For the prevention of coccidiosis in turkeys caused by *E. adenoeides*, *E. meleagritidis*, and *E. gallopavonis*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

(b) *Limitations.* For growing turkeys only. Feed continuously as sole ration. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development

of immunity to turkey coccidiosis. Bambermycins as provided by No. 012799 in § 510.600(c) of this chapter.

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Dated: 8/23/00
August 23, 2000

Stephen F. Sundlof
Stephen F. Sundlof
Director for Veterinary Medicine

CERTIFIED TO BE A TRUE
COPY OF THE ORIGINAL
Jan W. [Signature]

[FR Doc. 00-???? Filed ??-??-00; 8:45 am]

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