

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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Display Date	10.1.98
Publication Date	10.2
Certifier	W.M. DAY

21 CFR Part 558

New Animal Drugs For Use In Animal Feeds; Monensin and Bacitracin Methylene Disalicylate

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, A Division of Eli Lilly & Co. The supplemental NADA provides for using approved single ingredient monensin and bacitracin methylene disalicylate (BMD) Type A medicated articles to make an additional approved combination for a monensin/BMD Type C medicated turkey feed.

EFFECTIVE DATE: *(Insert date of publication in the Federal Register.)*

FOR FURTHER INFORMATION CONTACT: Estella Z. Jones, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-594-1 643.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, A Division of Eli Lilly & Co., Lilly Corporate Center, Indianapolis, IN 46285, filed supplemental NADA 140-937 that provides for combining approved Coban® (45 and 60 grams per pound (g/lb) monensin) and BMD® (25, 30, 40, 50, 60, or 75 g/lb BMD) Type A medicated articles to make Type C medicated turkey feeds containing 54 to 90 g/ton (t) monensin and 200 g/t BMD. The monensin/BMD Type C turkey feeds are used for the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagridis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to BMD. The supplemental NADA is approved as of August 13, 1998, and 21 CFR

558.355(f)(2)(iii) is added to reflect the approval. The basis for approval is discussed in the freedom of information summary.

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.

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 redelegate 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 by adding paragraph (f)(2) (iii) to read as follows:

§ 558.355 Monensin.

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(f) * * *

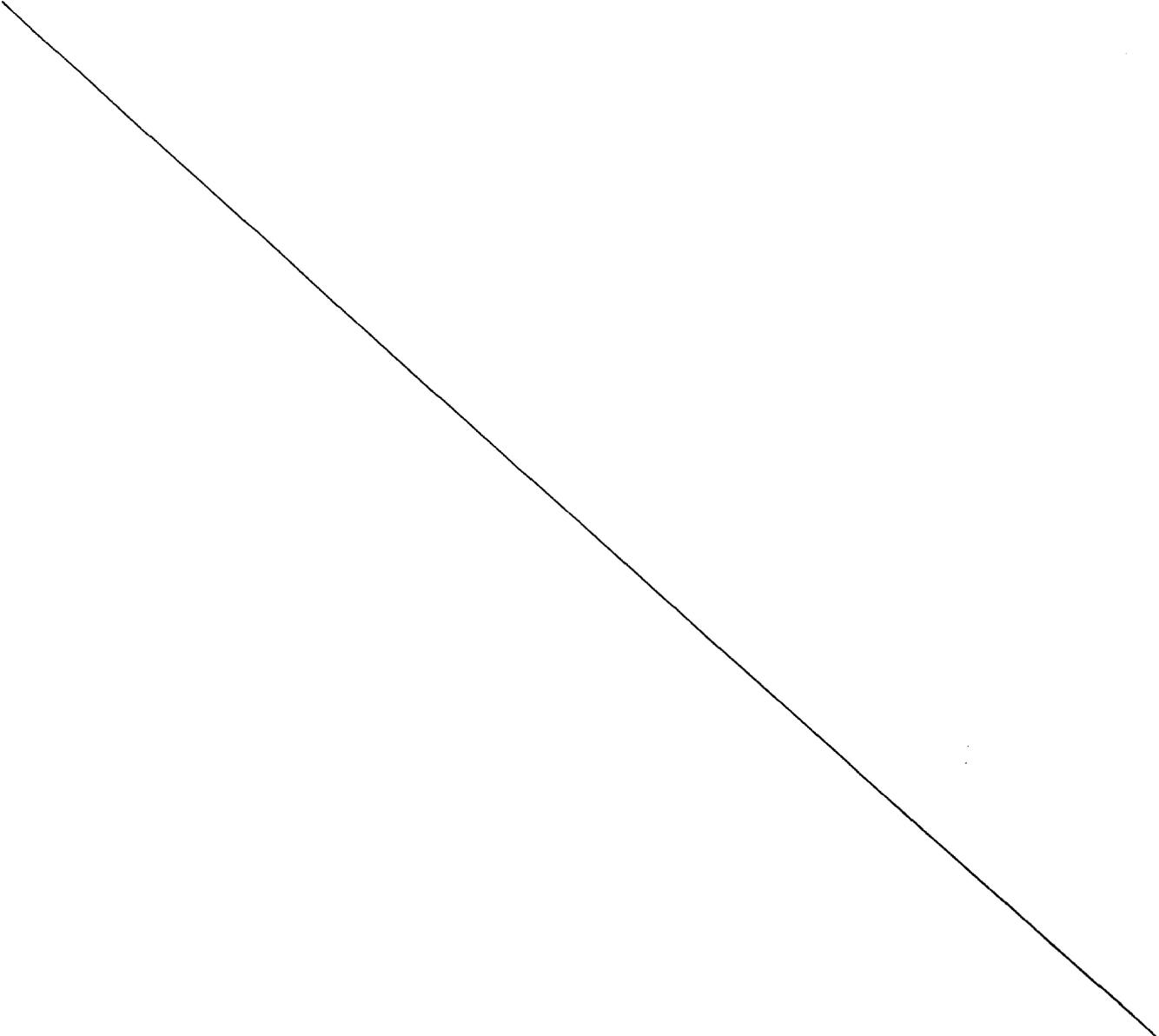
(2) * * *

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(iii) *Amount per ton.* Monensin, 54 to 90 grams, and bacitracin methylene disalicylate, 200 grams.

(a) *Indications for use.* For the prevention of coccidiosis caused by *Eimeria adenoides*, *E. meleagritidis*, and *E. gallopavonis*, and as an aid in the control of transmissible enteritis complicated by organisms susceptible to bacitracin methylene disalicylate.

(b) *Limitations.* For growing turkeys only; as monensin sodium; feed continuously as sole ration. Do not allow horses, other equines, mature turkeys or guinea fowl access to feed containing monensin. Ingestion of monensin by horses and guinea fowl has been fatal. Some strains of turkey coccidia may be monensin tolerant or resistant. Monensin may interfere with development of



immunity to turkey coccidiosis. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(C) of this chapter.

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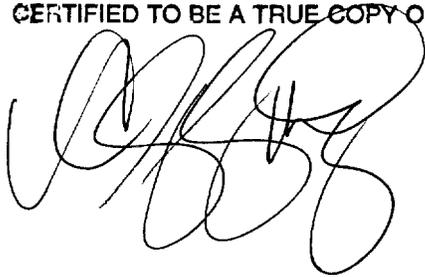
Dated: 09/20/98
September 20, 1998

Margaret Ann Miller
Margaret Ann Miller
Acting Director
Office of New Animal Drug Evaluation
Center for Veterinary Medicine

[FR Dec. 98-???? Filed ??-??-98; 8:45 am]

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