

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Display Date	5-17-99
Publication Date	5-18-99
Certifier	Michael W. Bell

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid and Bacitracin Zinc

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 Roche Vitamins, Inc. The NADA provides for the use of approved lasalocid Type A medicated articles and bacitracin zinc Type A medicated articles in making Type C medicated feed used for the prevention of coccidiosis caused by *Eimeria meleagridis*, *E. gallopavonis*, and *E. adenoides*, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

EFFECTIVE DATE: (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: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298, is the sponsor of NADA 141-109 that provides for the use of 20 percent of lasalocid Type A medicated articles and bacitracin zinc Type A medicated articles containing 50 grams (g) per pound bacitracin activity in making Type C medicated feed containing 68 to 113 g/ton (t) lasalocid and 4 to 50 g/t bacitracin zinc used for the prevention of coccidiosis caused by *Eimeria meleagridis*, *E. gallopavonis*, and *E. adenoides* and for increased rate of weight gain and improved feed efficiency in growing turkeys. The NADA is approved as of April 15, 1999, and

are amended in 21 CFR 558.78 and 558.311 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 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 558.78 is amended by revising paragraph (d)(3)(xii) to read as follows:

§ 558.78 Bacitracin zinc.

* * * * *

(d) * * *

(3) * * *

(xii) Lasalocid sodium alone or with roxarsone as in § 558.311.

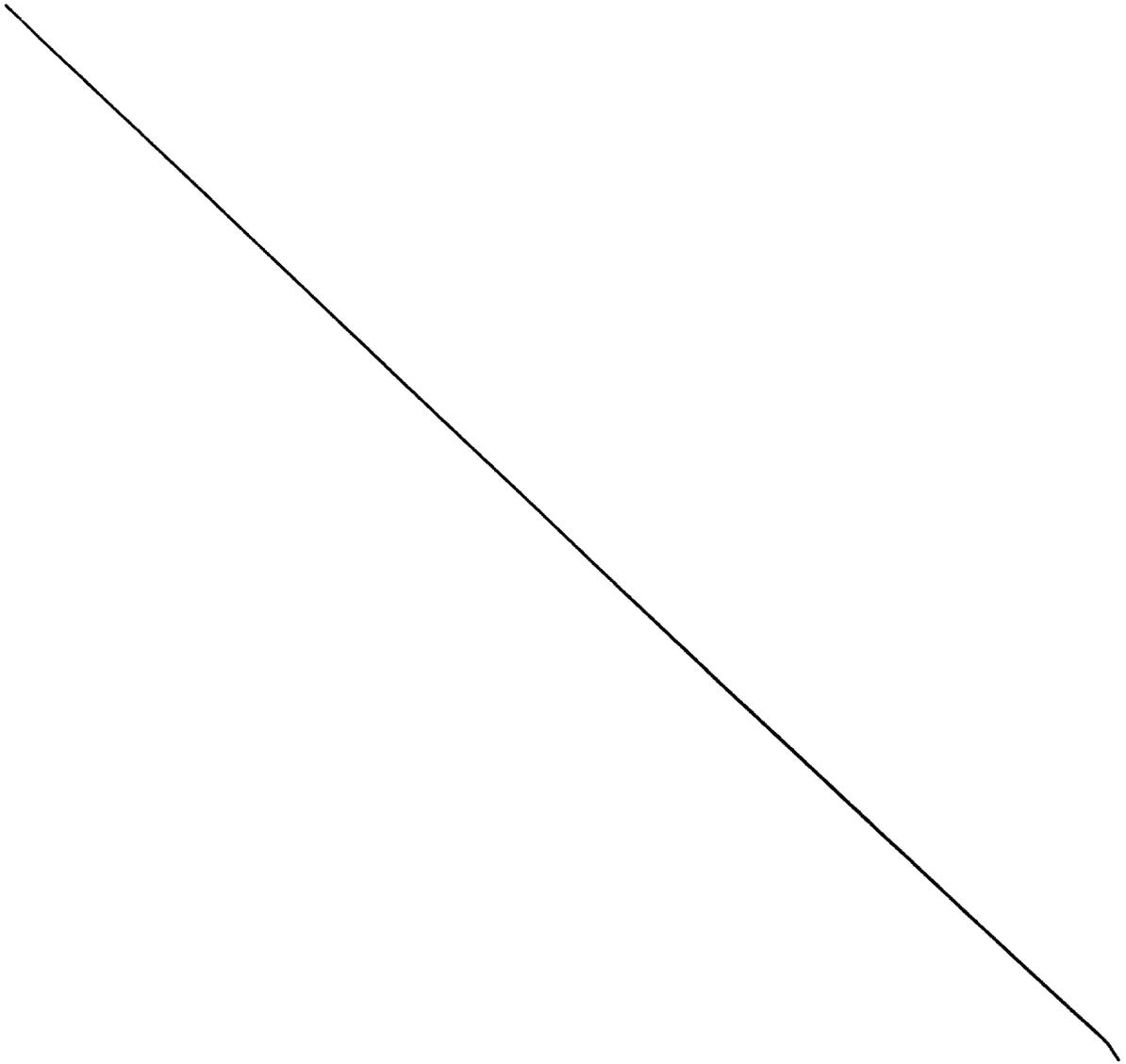
* * * * *

3. Section 558.311 is amended in the table by revising paragraph (e)(1)(xiv) to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e)(1) * * *



Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
(xiv) 68 (0.0075 pct) to 113 (0.0125 pct)	Bacitracin 4 to 50	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> . Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> ; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration Feed continuously as sole ration	000004 063238

* * * * *

Dated: 4/30/99
April 30, 1999



Stephen F. Sundlof
Director
Center for Veterinary Medicine

[FR Doc. 99-???? Filed ??-??-99; 8:45 am]

BILLING CODE 4160-01-F

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Michael W. Bell