**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

# New Animal Drugs for Use in Animal Feeds; Lasalocid and Virginiamycin

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule.

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**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 use of approved lasalocid and virginiamycin Type A medicated articles to make Type C medicated feeds used for prevention of coccidiosis 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, filed NADA 141–150 that provides for use of Avatec® (90.7 grams per pound (g/lb) of lasalocid as lasalocid sodium) and Stafac® (20 or 227 g/lb of virginiamycin) Type A medicated articles to make Type C medicated feeds for growing turkeys. The Type C medicated feeds are used for prevention of coccidiosis caused by *Eimeria meleagrimitis*, *E. gallopavonis*, and *E. adenoeides*, and for increased rate of weight gain and improved feed efficiency in growing turkeys. The NADA is approved as of August 6, 1999, and the regulations are amended in 21 CFR 558.311 to reflect the approval. The basis of 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.

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. Section 558.311 is amended in the table in paragraph (e)(1)(xiv), under the ''Combination in grams per ton'' column, by alphabetically adding an entry for ''Virginiamycin 10 to 20'' 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). | | | | |
| * * * | * | * | * * | * |
| | Virginiamycin 10 to 20 | Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis*, *E. gallopavonis*, and *E. adenoeides*, and for increased rate of weight gain and improved feed efficiency. | Feed continuously as sole ration. As lasalocid sodium provided by 063238 and virginiamycin provided by 000069. | 063238 |
| * * * | * | * | * * | * |

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Dated: 8/30/99
August 30, 1999

S7 S.V.M.
Stephen F. Sundlof
Director
Center for Veterinary Medicine

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

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Lizette N Rose