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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

**21 CFR Part 558**

**New Animal Drugs for Use in Animal Feeds; Lasalocid and Bambermycins**

**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 Hoechst Roussel Vet. The NADA provides for combining approved single ingredient lasalocid and bambermycins Type A medicated articles to make Type C medicated broiler feeds to be used for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

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

**FOR FURTHER INFORMATION CONTACT:** Charles J. Andres, Center for Veterinary Medicine (HFV-28), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-1600.

**SUPPLEMENTARY INFORMATION:** Hoechst Roussel Vet, 30 Independence Blvd., P.O. Box 4915, Warren, NJ 07059, filed NADA 141-129 that provides for combining approved single ingredient Avatec® (lasalocid) and Flavomycin® (bambermycins) Type A medicated articles to make Type C medicated broiler feeds containing 68 to 113 grams per ton (g/t) lasalocid and 1 to 2 g/t bambermycins. The Type C medicated broiler feeds are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency in broiler chickens. The NADA is approved as of August 6, 1999, and the regulations are amended in 21 CFR 558.95 by adding paragraph (d)(1)(xiv) and in 21 CFR 558.311 by adding paragraph (e)(4)(ii) 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 adding paragraph (d)(1)(xiv) to read as follows:

**§ 558.95 Bambermycins.**

\* \* \* \* \*

(d) \* \* \*

(1) \* \* \*

(xiv) *Amount per ton.* Bambermycins 1 to 2 grams, plus lasalocid 68 to 113 grams.

(a) *Indications for use.* For prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain and improved feed efficiency in broiler chickens.

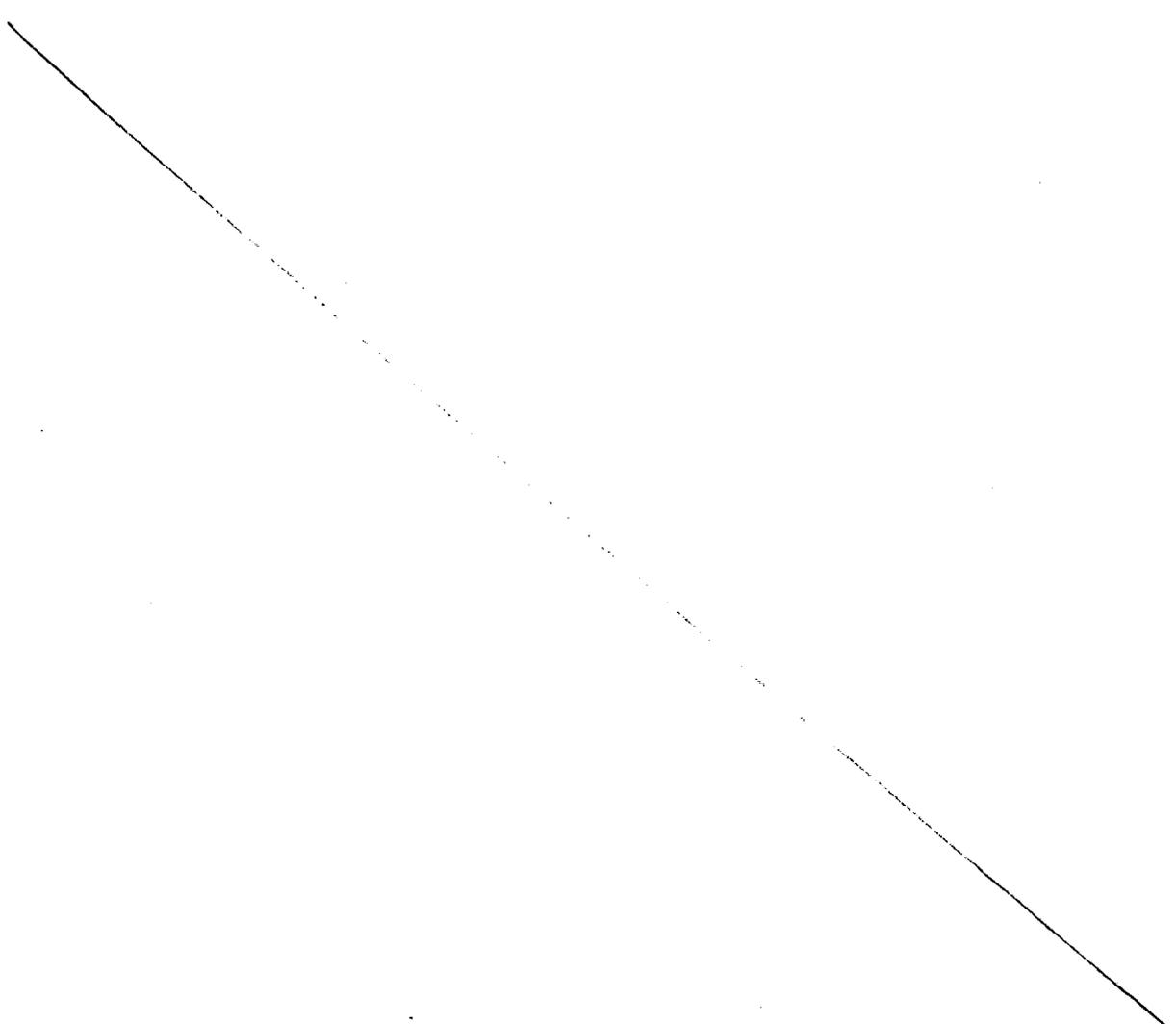
(b) *Limitations.* For broiler chickens only. Feed continuously as sole ration. Lasalocid as provided by No. 063238 in § 510.600(c) of this chapter.

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3. Section 558.311 is amended by adding paragraph (e)(4)(ii) to read as follows:

**§ 558.311 Lasalocid.**

\* \* \* \* \*

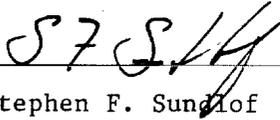


(e) \* \* \*

(4) \* \* \*

(ii) Bambermycins as in § 558.95 of this chapter.

Dated: 8/30/99  
August 30, 1999



Stephen F. Sundlof  
Director  
Center for Veterinary Medicine

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