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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; Nicarbazin 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 nicarbazin and bambermycins Type A medicated articles to make Type C medicated broiler chicken feeds to be used as an aid in preventing outbreaks of cecal and intestinal 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-128), 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 140-339 that provides for combining approved single ingredient Nicarb® (nicarbazin) and Flavomycin® (bambermycins) Type A medicated articles to make Type C medicated broiler chicken feeds containing 113.5 grams per ton (g/t) nicarbazin and 1 to 2 g/t bambermycins. The Type C medicated broiler chicken feeds are used as an aid in preventing outbreaks of cecal (*Eimeria tenella*) and intestinal (*E. acervulina*, *E. maxima*, *E. necatrix*, and *E. brunetti*) coccidiosis, 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 § 558.95 (21 CFR 558.95) by adding paragraph (d)(5)(iv), and in 21 CFR 558.366 in the table in paragraph (c) by adding an entry, to reflect the approval. Also, the introductory text of § 558.95(d)(5) is revised to better reflect the combination approvals.

In accordance with the freedom of information provisions of 21 CFR parts 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.

This approval is for use of single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, nicarbazin, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). As provided in 21 CFR 558.4(b), an approved form FDA 1900 is required to make Type C medicated feed from a Category II drug. Under section 512(m) of the act (21 U.S.C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Public Law 104-250), medicated feed applications have been replaced by a requirement for feed mill licenses. Therefore, use of Type A medicated articles to make Type C medicated feeds as provided in NADA 140-339 is limited to manufacture in a licensed feed mill.

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 revising the introductory text of paragraph (d)(5) and by adding paragraph (d)(5)(iv) to read as follows:

**§ 558.95 Bambermycins.**

\* \* \* \* \*

(d) \* \* \*

(5) Bambermycins may be used in chickens as in paragraph (d)(1) of this section in combination with:

\* \* \* \* \*

(iv) Nicarbazin as in § 558.366.

3. Section 558.366 is amended in the table in paragraph (c) under the entry for “113.5 (0.0125 pct)” by alphabetically adding an item for “Bambermycins 1 to 2” and <sup>revising</sup> ~~republishing~~ the item for “Lincomycin 2” to read as follows:

**§ 558.366 Nicarbazin.**

\* \* \* \* \*

(c) \* \* \*

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
113.5 (0.0125 pct)		...	...	...

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
	Bambermycins 1 to 2	Broiler chickens; aid in preventing outbreaks of cecal ( <i>Eimeria tenella</i> ) and intestinal ( <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i> ) coccidiosis, for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter. Nicarbazin as provided by 063271.	012799
	Lincomycin 2 (0.00044 pct)	Broiler chickens; aid in preventing outbreaks of cecal ( <i>Eimeria tenella</i> ) and intestinal ( <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. necatrix</i> , and <i>E. brunetti</i> ) coccidiosis; for increased rate of weight gain.	Feed continuously as sole ration from time chicks are placed on litter until past the time when coccidiosis is ordinarily a hazard; do not use as a treatment for coccidiosis; do not use in flushing mashers; do not feed to laying hens; withdraw 4 days before slaughter.	060728 063271

Dated: 8/30/99  
August 30, 1999

*SFS*

Stephen F. Sandlof  
Director  
Center for Veterinary Medicine

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*W. H. Bryant*