

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(xiii) 113 (0.0125 pct).	Chukar partridges; for prevention of coccidiosis caused by <i>Eimeria leionensis</i> .	Feed continuously as sole ration up to 8 weeks of age.	000004

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 Dated: May 24, 1995.

Stephen F. Sundlof,
 Director, Center for Veterinary Medicine.
 [FR Doc. 95-13636 Filed 6-2-95; 8:45 am]
 BILLING CODE 4160-01-F

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid

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 Hoffmann-La Roche, Inc. The supplemental NADA provides for the use of a 20-percent lasalocid Type A medicated article in making Type C medicated feed used for growing turkeys as a coccidiostat.

EFFECTIVE DATE: June 5, 1995.

FOR FURTHER INFORMATION CONTACT: Melanie R. Berson, Center for Veterinary Medicine (HFV-135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1643.

SUPPLEMENTARY INFORMATION: Hoffmann-La Roche, Inc., Nutley, NJ 07110, is the sponsor of NADA 96-298, which currently provides for the use of a Type A medicated article containing 20 percent (90.7 grams per pound (g/lb)) of lasalocid sodium activity in making a 68- to 113-g-per-ton (g/t) Type C medicated feed for broiler or fryer

chickens and chukar partridges. The firm has filed a supplemental NADA that expands the use of the article to making a 68- to 113-g/t Type C medicated feed for growing turkeys for the prevention of coccidiosis caused by *Eimeria meleagrimitis*, *E. gallopavonis*, and *E. adenoeides*.

The supplemental NADA is approved as of April 28, 1995, and the regulations are amended in 21 CFR 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 part 20 (21 CFR part 20) and § 514.11(e)(2)(ii) (21 CFR 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, rm. 1-23, 12420 Parklawn Dr., Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this approval qualifies for 3 years of marketing exclusivity beginning April 28, 1995, because the supplemental application contains reports of new clinical or field investigations (other than bioequivalence or residue studies) essential to the approval of the application and conducted or sponsored by the applicant. The 3 years of marketing exclusivity applies only to the described use of lasalocid sodium in growing turkeys for which the supplemental application was approved.

The agency has carefully considered the potential environmental effects of

this action. FDA has concluded that the action will not have a significant impact on the human environment, and that an environmental impact statement is not required. The agency's finding of no significant impact and the evidence supporting that finding, contained in an environmental assessment, may be seen in the Dockets Management Branch (address above) between 9 a.m. and 4 p.m., Monday through Friday.

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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.311 is amended in paragraph (b) by revising paragraph (b)(7) and in the table in paragraph (e)(1) by adding new entry "(xiv)" to read as follows:

§ 558.311 Lasalocid.

* * * * *
 (b) * * *

(7) 20 percent activity to No. 000004 for use in chukar partridges as in paragraph (e)(1)(xiii) and for use in turkeys as in paragraph (e)(1)(xiv) of this section.

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 (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).	Growing turkeys; for prevention of coccidiosis caused by <i>E. meleagrimitis</i> , <i>E. gallopavonis</i> , and <i>E. adenoeides</i> .	Feed continuously as sole ration.	000004

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Dated: May 24, 1995.

Stephen F. Sundlof,
 Director, Center for Veterinary Medicine.
 [FR Doc. 95-13637 Filed 6-2-95; 8:45 am]
 BILLING CODE 4160-01-F

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Nicarbazin 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 codify a previously approved new animal drug application (NADA) held by Merck Research Laboratories, Division of Merck & Co., Inc. The NADA provides for use of nicarbazin and bacitracin methylene disalicylate in Type C broiler feeds for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency.

EFFECTIVE DATE: June 5, 1995.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1623.

SUPPLEMENTARY INFORMATION: Merck Research Laboratories, Division of Merck & Co., Inc., P.O. Box 2000, Rahway, NJ 07065, is sponsor of NADA 98-378 which provides for the use of approved nicarbazin and bacitracin methylene disalicylate Type A medicated articles to make Type C medicated broiler feeds containing

113.5 grams per ton (g/t) nicarbazin with 30 g/t bacitracin methylene disalicylate. The NADA was approved by letter of March 15, 1955, for prevention of certain forms of coccidiosis and for increased rate of weight gain and improved feed efficiency. This document amends the regulations in 21 CFR 558.76(d) and in the table in 21 CFR 558.366(c) to reflect the approval.

Also, the table in § 558.366(c) contains two entries in the first column for "113.5 (0.0125 pct)." The second entry in the first column is unnecessary, and is being removed at this time. In addition, the entry for "113.5 (0.0125)" contains an outdated footnote to the approval for use of 113.5 g/t nicarbazin. Because the National Academy of Sciences/National Research Council (NAS/NRC) status was changed by enactment of the Generic Animal Drug and Patent Term Restoration Act of 1988, the footnote is hereby removed.

NADA 98-378 provides for use of nicarbazin and bacitracin methylene disalicylate Type A medicated articles to make Type C medicated feeds. Nicarbazin is a Category II drug which, as provided in 21 CFR 558.4, requires an approved Form FDA 1900 for making Type C medicated feeds. Therefore, use of nicarbazin Type A medicated articles in making Type C medicated feeds as in this NADA requires an approved Form FDA 1900.

Because this NADA was approved prior to July 1, 1975, the freedom of information (FOI) summary specified in 21 CFR part 20 and 21 CFR 514.11(e)(2)(ii) is not required.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Secs. 512, 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b, 371).

2. Section 558.76 is amended by adding paragraph (d)(3)(v) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(v) Nicarbazin as in § 558.366.

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3. Section 558.366 is amended in the table in paragraph (c) by removing footnote "1" for the entry "113.5 (0.0125 pct)," by removing the second entry "113.5 (0.0125 pct)," and by adding a new item before the entry for "Lincomycin 2 (0.00044 pct)," to read as follows:

§ 558.366 Nicarbazin.

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(c) * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
	Bacitracin methylene disalicylate 30	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.do	000006
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