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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; Narasin and Nicarbazin With Lincomycin

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 Elanco Animal Health, Division of Eli Lilly and Co. The NADA provides for combining approved narasin, nicarbazin, and lincomycin Type A medicated articles to make combination drug Type C medicated broiler chicken feeds 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-128), Food and Drug Administration, 7500 Standish Pi., Rockville, MD 20855, 301-594-1600.

SUPPLEMENTARY INFORMATION: Elanco Animal Health, a Division of Eli Lilly and Co., Lilly Corporate Center, Indianapolis, IN 46285, filed NADA 140-947 that provides for combining approved narasin, nicarbazin, and lincomycin Type A medicated articles to make combination drug Type C medicated broiler chicken feeds containing 27 to 45 grams per ton (g/t) narasin, 27 to 45 g/t nicarbazin, and 2 to 4 g/t lincomycin. The Type C medicated broiler chicken feed is used for the prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. maxima*, *E. brunetti*, and *E. mivati*, and for increased rate of weight gain and improved feed efficiency.

CV9757

NADA-140-947

NFR-1

The NADA is approved as of September 3, 1998, and the regulations are amended in 21 CFR 558.325, 558.363, and 558.366 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.

This approval is for use of approved Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, nicarbazone, is a Category 11 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 for making a Type B or C medicated feed as in this application. Under section 512(m) of the Federal Food, Drug, and Cosmetic Act (the act) (21 U. S. C. 360b(m)), as amended by the Animal Drug Availability Act of 1996 (Pub. L. 104-250), medicated feed applications have been replaced by a requirement for manufacture in a licensed feed mill. Therefore, use of narasin, nicarbazin, and lincomycin Type A medicated articles to make Type C medicated feeds as provided in NADA 140-947 requires a licensed feed mill.

The agency has determined under 21 CFR 25.33(u)(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 the authority delegated to the Commissioner of Food and Drugs and redelegate 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 558.325 is amended by revising paragraph (c)(3)(xii) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(c) * * *

(3)* * *

(xii) Nicarbazin with or without narasin as in §558.366.

* * * * *

3. Section 558.363 is amended by revising paragraph (d)(2) to read as follows:

§ 558.363 Narasin.

* * * * *

(d) * * *

(2) Narasin may also be used for broilers in combination with:

(i) Nicarbazin with lincomycin as in §558.366.

(ii) [Reserved]

4. Section 558.366 is amended in the table in paragraph (c) by revising the entry for “27 to 45” to read as follows:

§ 558.366 Nicarbazin.

* * * * *

Nicarbazin in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
27 to 45	Narasin 27 to 45	Broiler chickens: prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i>	Sec 558.363(d)(1)(iii)	000986
	Narasin 27 to 45 and Lincomycin 2 to 4	Broiler chickens; prevention of coccidiosis caused by <i>Eimeria tenella</i> , <i>E. necatrix</i> , <i>E. acervulina</i> , <i>E. maxima</i> , <i>E. brunetti</i> , <i>E. mivati</i> ; for increased rate of weight gain and improved feed efficiency	Feed continuously as sole ration, Withdraw 5 days before slaughter Do not allow turkey s, horses, or other equines access to formulations containing narasin Ingestion of narasin by these species has been fatal Donotfeed to laying hens. Do not allow rabbits, hamsters, guinea pigs, horses, or ruminants access to feeds containing lincomycin. Ingestion by these species may result in severe gastrointestinal effects. Narasin and nicarbazin as provided by 000986, lincomycin by 000009.	000986

Dated: 10/5/98
October 5, 1998

S F Sundlof

Stephen F. Sundlof
Director
Center for Veterinary Medicine

CERTIFIED TO BE A TRUE COPY OF THE ORIGINAL

Jan Windsor

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