

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
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Dated: October 19, 1998.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 98-28635 Filed 10-26-98; 8:45 am]

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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 Nicarbazine 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, nicarbazine, 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: October 27, 1998.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV-128), Food and Drug Administration, 7500 Standish Pl., 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, nicarbazine, 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 nicarbazine, 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. 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, nicarbazine, 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 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, nicarbazine, 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(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.

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 558.325 is amended by revising paragraph (c)(3)(xii) to read as follows:

§ 558.325 Lincomycin.

* * * * *

(c) * * *

(3) * * *

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

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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) Nicarbazine 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 Nicarbazine.

* * * * *

(c) * * *

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 turkeys, horses, or other equines access to formulations containing narasin. Ingestion of narasin by these species has been fatal. Do not feed 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
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Dated: October 5, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF THE INTERIOR

Minerals Management Service

30 CFR Part 203

RIN 1010-AC13

Royalty Relief for Producing Leases and Certain Existing Leases in Deep Water

AGENCY: Minerals Management Service (MMS), Interior.

ACTION: Correcting amendments.

SUMMARY: This document contains corrections to the final regulations which were published in the **Federal Register** of Friday, January 16, 1998 (63 FR 2605-2626), and also in 30 CFR Part 203, Revised as of July 1, 1998. The corrections noted here are in the portion of these regulations related to the Royalty Relief for End-of-Life Leases.

EFFECTIVE DATE: November 1, 1998.

FOR FURTHER INFORMATION CONTACT: Marshall Rose, Chief, Economics Division, (703) 787-1538.

SUPPLEMENTARY INFORMATION:

Background

The final regulations that are the subject of these corrections affect persons requesting reduction of oil and

gas royalty under § 1337(a)(3)(A) of the United States Code.

Need for Correction

As published, the final regulations omit logical implications of the simplified relief approval process. The corrections make explicit when you should apply for royalty relief and the action we may take if we determine that you have not applied properly. The corrections also clarify which costs we consider allowable in the end-of-life circumstance.

List of Subjects in 30 CFR Part 203

Continental shelf, Government contracts, Indians-lands, Minerals royalties, Oil and gas exploration, Public lands-mineral resources, Sulphur.

Accordingly, 30 CFR Part 203 is corrected by making the following correcting technical amendments:

PART 203—RELIEF OR REDUCTION IN ROYALTY RATES

1. The authority citation for Part 203 continues to read as follows:

Authority: 25 U.S.C. 396 *et seq.*; 25 U.S.C. 396a *et seq.*; 25 U.S.C. 2101 *et seq.*; 30 U.S.C. 181 *et seq.*; 30 U.S.C. 351 *et seq.*; 30 U.S.C. 1001 *et seq.*; 30 U.S.C. 1701 *et seq.*; 31 U.S.C. 9701 *et seq.*; 43 U.S.C. 1301 *et seq.*; 43 U.S.C. 1331 *et seq.*; and 43 U.S.C. 1801 *et seq.*

Subpart B—[Corrected]

2. Subpart B is corrected by revising the word “OLS” in the Subpart heading to read “OCS”.

3. Section 203.50 is corrected by adding two sentences at the end of paragraph (a) to read as follows:

§ 203.50 Who may apply for end-of-life royalty relief?

(a) * * * These 12 months should reflect the basic operation you intend to use until your resources are depleted. If you changed your operation significantly (e.g., begin re-injecting rather than recovering gas) during the qualifying months, or if you do so while we are processing your application, we may defer action on your application until you revise it to show the new circumstances.

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§ 203.84 [Corrected]

4. In § 203.84, paragraph (b) is corrected by revising the citation “30 CFR 220.013(a), (b), and (d) through (k)” to read “30 CFR 220.013”.

5. Section 203.84 is corrected by revising paragraphs (b)(7) and (c) to read as follows:

§ 203.84 What is in a net revenue and relief justification report?

* * * * *

(b) * * *

(7) Costs associated with existing obligations (e.g., royalty overrides or other forms of payment for acquiring the lease, depreciation on previously acquired equipment or facilities).

(c) We may, in reviewing and evaluating your application, disallow costs when you have not shown they are necessary to operate the lease, or if they