

Commenters wishing the FAA to acknowledge receipt of their comments submitted in response to this rule must submit a self-addressed, stamped postcard on which the following statement is made: "Comments to Docket Number 98-NM-305-AD." The postcard will be date stamped and returned to the commenter.

Regulatory Impact

The regulations adopted herein will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 12612, it is determined that this final rule does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

The FAA has determined that this regulation is an emergency regulation that must be issued immediately to correct an unsafe condition in aircraft, and that it is not a "significant regulatory action" under Executive Order 12866. It has been determined further that this action involves an emergency regulation under DOT Regulatory Policies and Procedures (44 FR 11034, February 26, 1979). If it is determined that this emergency regulation otherwise would be significant under DOT Regulatory Policies and Procedures, a final regulatory evaluation will be prepared and placed in the Rules Docket. A copy of it, if filed, may be obtained from the Rules Docket at the location provided under the caption ADDRESSES.

List of Subjects in 14 CFR Part 39

Air transportation, Aircraft, Aviation safety, Incorporation by reference, Safety.

Adoption of the Amendment

Accordingly, pursuant to the authority delegated to me by the Administrator, the Federal Aviation Administration amends part 39 of the Federal Aviation Regulations (14 CFR part 39) as follows:

PART 39—AIRWORTHINESS DIRECTIVES

1. The authority citation for part 39 continues to read as follows:

Authority: 49 U.S.C. 106(g), 40113, 44701.

§ 39.13 [Amended]

2. Section 39.13 is amended by adding the following new airworthiness directive:

98-22-07 Dornier Luftfahrt GMBH:

Amendment 39-10854. Docket 98-NM-305-AD.

Applicability: All Model 328-100 series airplanes, certificated in any category.

Compliance: Required as indicated, unless accomplished previously.

To prevent an uncommanded retraction of the flaps during takeoff, which could result in an aborted takeoff and consequent potential for runway overrun, accomplish the following:

(a) Within 14 days after the effective date of this AD, accomplish the requirements of paragraphs (a)(1) and (a)(2) of this AD.

(1) Revise the Normal Procedures Section of the Dornier 328 FAA-approved Airplane Flight Manual (AFM) to include the information specified in pages 6 and 7 of Dornier 328 All Operators Telefax (AOT) AOT-328-27-016, dated July 31, 1998. This may be accomplished by inserting a copy of pages 6 and 7 of the AOT into the AFM.

(2) Revise the Abnormal Procedures Section of the Dornier 328 FAA-approved AFM to include the information specified in page 4 of Dornier 328 AOT-328-27-016, dated July 31, 1998. This may be accomplished by inserting a copy of page 4 of the AOT into the AFM.

(b) An alternative method of compliance or adjustment of the compliance time that provides an acceptable level of safety may be used if approved by the Manager, International Branch, ANM-116, FAA, Transport Airplane Directorate. Operators shall submit their requests through an appropriate FAA Principal Operations Inspector, who may add comments and then send it to the Manager, International Branch, ANM-116.

Note 1: Information concerning the existence of approved alternative methods of compliance with this AD, if any, may be obtained from the International Branch, ANM-116.

(c) Special flight permits may be issued in accordance with sections 21.197 and 21.199 of the Federal Aviation Regulations (14 CFR 21.197 and 21.199) to operate the airplane to a location where the requirements of this AD can be accomplished.

(d) The actions shall be done in accordance with Dornier 328 All Operators Telefax (AOT) AOT-328-27-016, dated July 31, 1998. This incorporation by reference was approved by the Director of the Federal Register in accordance with 5 U.S.C. 552(a) and 1 CFR part 51. Copies may be obtained from Fairchild Dornier, Dornier Luftfahrt GmbH, P.O. Box 1103, D-82230 Wessling, Germany. Copies may be inspected at the FAA, Transport Airplane Directorate, 1601 Lind Avenue, SW., Renton, Washington; or at the Office of the Federal Register, 800 North Capitol Street, NW., suite 700, Washington, DC.

Note 2: The subject of this AD is addressed in German airworthiness directive 1998-359, dated September 10, 1998.

(e) This amendment becomes effective on November 12, 1998.

Issued in Renton, Washington, on October 19, 1998.

Darrell M. Pederson,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 98-28539 Filed 10-26-98; 8:45 am]

BILLING CODE 4910-13-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 556 and 558

New Animal Drugs for Use in Animal Feeds; Chlortetracycline

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 Roche Vitamins, Inc. The supplemental NADA provides for use of a chlortetracycline (CTC) Type A medicated article in Type C medicated feeds for chickens producing eggs for human consumption, a tolerance for residues in eggs, and an acceptable daily intake (ADI) for total tetracycline residues in humans.

EFFECTIVE DATE: October 27, 1998.

FOR FURTHER INFORMATION CONTACT: Dianne T. McRae, Center for Veterinary Medicine (HFV-102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-0212.

SUPPLEMENTARY INFORMATION: Roche Vitamins, Inc., 45 Waterview Blvd., Parsippany, NJ 07054-1298, filed supplemental NADA 48-761 that provides for use of Aureomycin® (50, 90, and 100 grams per pound CTC) Type A medicated article in Type C medicated feeds for chickens laying eggs for human consumption. The supplemental NADA is approved as of July 31, 1998, and the regulations are amended in 21 CFR 558.128(d)(1) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In approving the use of chlortetracycline Type C medicated feeds for chickens laying eggs for human consumption, a tolerance is established for chlortetracycline residues in eggs. At this time, FDA is also establishing the ADI for total tetracycline residues (the total drug residues from chlortetracycline, oxytetracycline, and tetracycline, that can safely be

consumed each day by humans). The regulations in 21 CFR 556.150, 556.500, and 556.720 are amended to establish a tetracycline ADI, and in § 556.150 to provide for a tolerance for chlortetracycline residues in eggs.

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.

Under 21 U.S.C. 360b(c)(2)(F)(iii), this supplemental NADA for food-producing animals qualifies for 3 years of marketing exclusivity beginning July 31, 1998, because the supplement contains substantial evidence of the effectiveness of the drug involved, studies of animal safety or, in the case of food-producing animals, human food safety studies (other than bioequivalence or residue studies) required for approval of the supplement and conducted or sponsored by the applicant. The 3 years marketing exclusivity is limited to use of this drug in the feed of chickens producing eggs for human consumption.

The agency has determined under 21 CFR 25.33(a)(3) 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

21 CFR Part 556

Animal drugs, Foods.

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 parts 556 and 558 are amended as follows:

PART 556—TOLERANCES FOR RESIDUES OF NEW ANIMAL DRUGS IN FOOD

1. The authority citation for 21 CFR part 556 continues to read as follows:

Authority: 21 U.S.C. 342, 360b, 371.

2. Section 556.150 is amended by revising paragraph (b) to read as follows:

§ 556.150 Chlortetracycline.

(a) * * *

(b) *Tolerances.* (1) Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, nonlactating dairy cows, calves, swine, sheep, chickens, turkeys, and ducks, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

(2) A tolerance is established for residues of chlortetracycline in eggs of 0.4 ppm.

3. Section 556.500 is revised to read as follows:

§ 556.500 Oxytetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total tetracycline residues

(chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances.* Tolerances are established for the sum of tetracycline residues in tissues of beef cattle, beef calves, nonlactating dairy cattle, dairy calves, swine, sheep, chickens, turkeys, catfish, lobsters, and salmonids, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

4. Section 556.720 is revised to read as follows:

§ 556.720 Tetracycline.

(a) *Acceptable daily intake (ADI).* The ADI for total tetracycline residues (chlortetracycline, oxytetracycline, and tetracycline) is 25 micrograms per kilogram of body weight per day.

(b) *Tolerances.* Tolerances are established for the sum of tetracycline residues in tissues of calves, swine, sheep, chickens, and turkeys, of 2 parts per million (ppm) in muscle, 6 ppm in liver, and 12 ppm in fat and kidney.

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

5. The authority citation for 21 CFR part 558 continues to read as follows:

Authority: 21 U.S.C. 360b, 371.

6. Section 558.128 is amended in paragraph (d)(1) in the table by revising entries (i) through (viii) to read as follows:

§ 558.128 Chlortetracycline.

* * * * *

(d)(1) * * *

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(i) 10 to 50 g/t		1. Chickens; increased rate of weight gain and improved feed efficiency.	Do not feed to chickens producing eggs for human consumption.	063238.
		2. Growing turkeys; increased rate of weight gain and improved feed efficiency.	Do not feed to turkeys producing eggs for human consumption.	000069, 017519, 046573, 053389.
		3. Growing swine; increased rate of weight gain and improved feed efficiency.		000069, 017519, 046573, 053389, 063238.
		Growing sheep; increased rate of weight gain and improved feed efficiency.		Do.
(ii) 20 to 50 g/t				000069, 046573, 053389, 063238.

Chlortetracycline amount	Combination	Indications for use	Limitations	Sponsor
(iii) 50 to 100 g/t		Swine; reducing the incidence of cervical lymphadenitis (jowl abscesses) caused by Group <i>E. Streptococci</i> susceptible to chlortetracycline.		000069, 017519, 046573, 053389, 063238.
(iv) 100 to 200 g/t		Chickens; control of infectious synovitis caused by <i>Mycoplasma synoviae</i> susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d.	063238.
(v) 200 g/t		Turkeys; control of infectious synovitis caused by <i>M. synoviae</i> susceptible to chlortetracycline.	2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	000069, 017519, 046573, 053389.
(vi) 200 to 400 g/t		1. Chickens; control of chronic respiratory disease (CRD) and air sac infection caused by <i>M. gallisepticum</i> and <i>E. coli</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	000069, 017519, 046573, 053389, 063238.
		2. Ducks; control and treatment of fowl cholera caused by <i>Pasteurella multocida</i> susceptible to chlortetracycline.	1. Feed continuously for 7 to 14 d.	063238.
			2. Feed continuously for 7 to 14 d; do not feed to chickens producing eggs for human consumption.	000069, 017519, 046573, 053389.
			Feed in complete ration to provide from 8 to 28 milligrams per pound of body weight per day depending upon age and severity of disease, for not more than 21 d. Do not feed to ducks producing eggs for human consumption.	063238.
(vii) 400 g/t		1. Turkeys; control of hexamitiasis caused by <i>Hexamita meleagridis</i> susceptible to chlortetracycline.	Feed continuously for 7 to 14 d; do not feed to turkeys producing eggs for human consumption.	000069, 017519, 046573, 053389, 063238.
		2. Turkey poults not over 4 weeks of age; reduction of mortality due to paratyphoid caused by <i>Salmonella typhimurium</i> susceptible to chlortetracycline.		Do.
		3. Breeding swine; control of leptospirosis (reducing the incidence of abortion and shedding of leptospirae) caused by <i>Leptospira pomona</i> susceptible to chlortetracycline.	Feed continuously for not more than 14 d.	Do.
(viii) 500 g/t		Chickens; reduction of mortality due to <i>E. coli</i> infections susceptible to chlortetracycline.	1. Feed for 5 d; withdraw 24 h prior to slaughter.	063238.
			2. Feed for 5 d; do not feed to chickens producing eggs for human consumption; withdraw 24 h prior to slaughter.	000069, 017519, 046573, 053389.

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]

BILLING CODE 4160-01-F

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.

* * * * *

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) * * *