

Inc. The NADA provides for use of approved, single-ingredient chlortetracycline (CTC) and bacitracin methylene disalicylate Type A medicated articles to make two-way combination Type C medicated feeds used for control of porcine proliferative enteropathies (ileitis) and for increased rate of weight gain and improved feed efficiency in swine.

DATES: This rule is effective September 8, 2000.

FOR FURTHER INFORMATION CONTACT:

Diane D. Jeang, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-827-7574.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-059 that provides for use of ChlorMax™ (50, 65, or 70 grams per pound (g/lb) chlortetracycline as chlortetracycline hydrochloride) and BMD® (10, 25, 30, 40, 50, 60, or 75 g/lb bacitracin methylene disalicylate) Type A medicated articles to make combination Type C medicated feeds for use in growing and finishing swine. The Type C medicated feeds contain approximately 400 g/ton CTC (to provide 10 milligrams/lb body weight)

and 10 to 30 g/ton bacitracin methylene disalicylate, and they are used for the control of porcine proliferative enteropathies (ileitis) caused by *Lawsonia intracellularis* susceptible to chlortetracycline and for increased rate of weight gain and improved feed efficiency. The NADA is approved as of July 7, 2000, and the regulations in 21 CFR 558.76 are amended 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 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.

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 558.76 is amended in the table in paragraph (d)(1) by adding an entry under item (iv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *
(d) * * *
(1) * * *

Bacitracin methylene disalicylate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
*	*	*	*	*
(iv) *	***	***	***	***
*	*	Swine; for control of porcine proliferative enteropathies (ileitis) caused by <i>Lawsonia intracellularis</i> susceptible to chlortetracycline.	Feed for not more than 14 days; chlortetracycline and BMD® as provided by 046573 in § 510.600(c) of this chapter.	046573
*	*	*	*	*

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Dated: August 23, 2000.

Claire M. Lathers,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 00-23054 Filed 9-7-00; 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; Monensin and Roxarsone

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 Alpharma, Inc. The NADA provides for use of approved single-ingredient monensin and roxarsone Type A medicated articles to make two-way combination drug Type C medicated feed used as an aid in the prevention of coccidiosis and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in replacement chickens.

DATES: This rule is effective September 8, 2000.

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: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141-139 that provides for use of Coban® (45 or 60 grams per pound (g/lb) of monensin as monensin sodium) and 3-Nitro® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make combination Type C medicated feeds for replacement chickens intended for use as caged layers. The Type C medicated feeds contain 90 to 110 g/ton monensin and 22.7 to 45.4 g/ton roxarsone, and they are used as an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation. The NADA is approved as of June 28, 2000, and the regulations in 21 CFR 558.355 are amended to reflect the approval. The basis of approval is discussed in the freedom of information summary.

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.

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 558.355 is amended by adding paragraph (f)(4)(iv) to read as follows:

§ 558.355 Monensin.

* * * * *

(f) * * *

(4) * * *

(iv) *Amount per ton.* Monensin, 90 to 110 grams, plus roxarsone, 22.7 to 45.4 grams.

(a) *Indications for use.* As an aid in the prevention of coccidiosis caused by *Eimeria necatrix*, *E. tenella*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

(b) *Limitations.* Feed continuously as sole ration. Use as sole source of organic arsenic. Withdraw 5 days before slaughter. Do not feed to laying chickens. Do not feed to chickens over 16 weeks of age. Poultry should have access to drinking water at all times.

Drug overdosage or lack of water may result in leg weakness or paralysis. As monensin sodium provided by 000986; roxarsone as provided by 046573 in § 510.600(c) of this chapter.

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Dated: July 25, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00-23053 Filed 9-7-00; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Parts 40 and 42

[Public Notice 3377]

Documentation of Immigrants and Nonimmigrants Under the Immigration and Nationality Act, as Amended—Change in Procedures for Payment of Immigrant Visa Fees

AGENCY: Department of State.

ACTION: Interim Rule.

SUMMARY: This rule adopts a proposed rule published October 28, 1999 [64 FR 58004] to the extent of clarifying that the new requirement that immigrant visa applicants must pay the application processing fee prior to the time of formal application for a visa will be phased-in to ensure that unanticipated problems are resolved prior to worldwide applicability.

DATES: Effective September 8, 2000. Comments must be received by November 7, 2000.

ADDRESSES: Comments may be sent to Chief, Legislation and Regulations

Division, Visa Services, Department of State, Washington, DC 20520-0106, e-mail, *odomhe@state.gov* or FAX: (202) 663-3898.

FOR FURTHER INFORMATION CONTACT: H. Edward Odom, Chief, Legislation and Regulations Division, Visa Services, Department of State, Washington, D.C. 20520-0106, (202) 663-1204.

SUPPLEMENTARY INFORMATION: The Department received no comments relating to the original proposed rule and assumes, therefore, that the rationale for the change was accepted by all parties. Most new programs, of every variety, have experienced problems at the initial stage, however. The Department believes it prudent, under those circumstances, to apply this new rule initially only with respect to applicants at certain posts which are already participating in a special program at the National Visa Center. Applicants at all other posts will continue to pay fees in accordance with current procedures until such time as the Department is satisfied the system is effective and those other posts are phased into this program.

The ten posts selected for the special program together represent about 40% of all immigrant visa applicants. The program is thus both large enough in terms of volume and small enough in terms of applicability as to be a feasible test. Additional posts will be phased in based on the size of their overall operations beginning with the next largest. It is anticipated that all posts will be included in this new procedure within the next two, possibly three, years.

The 10 posts at which advanced payment of the application processing fee must be paid are: Manila, Ciudad Juarez, Santo Domingo, Guangzhou, Bogota, Port au Prince, Georgetown, Freetown, Tirana, and Montreal. As noted above, at all other posts that fee will continue to be paid immediately prior to formal application for a visa until each such post is designated by the Deputy Assistant Secretary for the new procedure.

No further changes are being made in the rule proposed on October 26, 1999.

List of Subjects in 22 CFR Parts 40 and 42

Aliens, Immigration, Passports and visas.

Accordingly, the Department of State amends 22 CFR Chapter I as set forth below.

PART 40—[AMENDED]

1. The authority citation for Part 40 is amended to read: