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 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 June 18, 2001, because the supplemental application contains substantial evidence of the effectiveness of the drug involved, any 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 application and conducted or sponsored by the applicant.

The agency has determined under 21 CFR 25.33(a)(1) that this action is of a type that does not individually or cumulatively have a significant impact on 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 524

Animal drugs.

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 524 is amended as follows:

PART 524—OPHTHALMIC AND TOPICAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 524 continues to read as follows:

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

2. Section 524.1451 is amended by redesignating paragraph (d) as paragraph (e), by removing the last sentence of newly redesignated paragraph (e)(3), by adding new paragraph (d), and by revising newly redesignated paragraph (e)(2) to read as follows.

§ 524.1451 Moxidectin.

* * * * *

(d) *Special considerations.* See § 500.25 of this chapter.

(e) * * *

(2) *Indications for use.* Beef and dairy cattle: For treatment and control of internal and external parasites: gastrointestinal roundworms (*Ostertagia ostertagi* (adult and L4, including inhibited larvae), *Haemonchus placei* (adult and L4), *Trichostrongylus axei* (adult and L4), *T. colubriformis* (adult and L4), *Cooperia oncophora* (adult and L4), *C. pectinata* (adult), *C. punctata* (adult and L4), *C. spatulata* (adult), *C. surnabada* (adult and L4), *Bunostomum phlebotomum* (adult), *Oesophagostomum radiatum* (adult and L4), *Nematodirus helvetianus* (adult and L4)); lungworms (*Dictyocaulus viviparus*, adult and L4); cattle grubs (H*ypoderma bovis*, *H. lineatum*); mites (*Chorioptes bovis*, *Psoroptes ovis* (*P. communis* var. *bovis*)); lice (*Linognathus vituli*, *Haematopinus eurysternus*, *Solenopotes capillatus*, *Bovicola*(*Damalinia*) *bovis*); and horn flies (*Haematobia irritans*). To control infections and to protect from reinfection with *H. placei* for 14 days after treatment, *O. radiatum* and *O. ostertagi* for 28 days after treatment, and *D. viviparus* for 42 days after treatment.

* * * * *

Dated: August 24, 2001.

Claire M. Lathers,

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

[FR Doc. 01–22200 Filed 9–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 556

Tolerances for Residues of New Animal Drugs in Food; Oxytetracycline; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect the tolerance for the sum of residues of the tetracyclines in milk previously established but inadvertently removed in a subsequent amendment and to reflect the correct tolerance of 0.3 part per million oxytetracycline in milk. This action is being taken to improve the accuracy of the agency's regulations.

DATES: This rule is effective September 5, 2001.

FOR FURTHER INFORMATION CONTACT: Lynn G. Friedlander, Center for Veterinary Medicine (HFV–151), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–6985.

SUPPLEMENTARY INFORMATION: FDA is amending the animal drug regulations in § 556.500 (21 CFR 556.500) to reflect the tolerance for the sum of residues of the tetracyclines in milk, which had been established in a final rule published in the **Federal Register** of September 30, 1998 (63 FR 52157 at 52158), but removed in a subsequent amendment to § 556.500 in a final rule published in the **Federal Register** of October 27, 1998 (63 FR 57245 at 57246). At this time, § 556.500 is being amended to reflect the correct tolerance of 0.3 part per million for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline in milk.

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. Publication of this document constitutes final action on this changes under the Administrative Procedure Act (5 U.S.C. 553).

List of Subjects in 21 CFR Part 556

Animal drugs, Foods.

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 556 is 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 556.500 is amended by revising paragraph (b) to read as follows:

§ 556.500 Oxytetracycline.

* * * * *

(b) *Beef cattle, dairy cattle, calves, swine, sheep, chickens, turkeys, catfish, lobster, and salmonids.* Tolerances are established for the sum of residues of the tetracyclines including chlortetracycline, oxytetracycline, and tetracycline, in tissues and milk as follows:

(1) 2 parts per million (ppm) in muscle.

(2) 6 ppm in liver.

(3) 12 ppm in fat and kidney.

(4) 0.3 ppm in milk.

Dated: August 20, 2001.

Claire M. Lathers,

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

[FR Doc. 01–22164 Filed 9–4–01; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 558

New Animal Drugs for Use in Animal Feeds; Lasalocid 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 reflect approval of a new animal drug application (NADA) filed by Alpharma, Inc. The NADA provides for use of approved, single-ingredient lasalocid and bacitracin methylene disalicylate Type A medicated articles to make two-way combination drug Type C medicated feeds. These combination medicated feeds are used for the prevention of coccidiosis, and for increased rate of weight gain and improved feed efficiency in growing turkeys.

DATES: This rule is effective September 5, 2001.

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 141–179 that provides for use of AVATEC® (90.7 grams per pound (g/lb) of lasalocid sodium) and BMD® (50 g/lb of bacitracin methylene disalicylate) Type A medicated articles to make combination drug Type C medicated turkey feeds. The combination Type C medicated feeds are used for prevention of coccidiosis caused by *Eimeria meleagrimitis*, *E. gallopavonis*, *E. adenoeides*, and for increased rate of weight gain and improved feed efficiency in growing turkeys. The NADA is approved as of July 11, 2001, and the regulations are amended in 21 CFR 558.311 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 558.311 is amended in the table in paragraph (e)(1) by alphabetically adding an item under entry (xv) following ''Bacitracin 4 to 50'' to read as follows:

§ 558.311 Lasalocid.

* * * * *

(e) * * *

(1) * * *

Lasalocid sodium activity in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	*	*	*	*
(xv) 68 (0.0075 pct) to 113 (0.0125 pct)				
	Bacitracin 4 to 50	* * *	* * *	* * *
	Bacitracin methylene disalicylate 4 to 50	Growing turkeys; for prevention of coccidiosis caused by *E. meleagrimitis*, *E. gallopavonis*, and *E. adenoeides*; for increased rate of weight gain and improved feed efficiency.	Feed continuously as sole ration. Bacitracin methylene disalicylate as provided by No. 046573 in § 510.600(c) of this chapter.	046573
* *	*	*	*	*