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 556.275 is amended by redesignating paragraph (b)(3) as paragraph (b)(4) and by adding new paragraph (b)(3) to read as follows:

§ 556.275 Fenbendazole.

* * * * *

(b) * * *

(3) *Turkeys*—(i) *Liver (the target tissue*). The tolerance for fenbendazole sulfone (the marker residue) is 6 ppm.

(ii) *Muscle*. The tolerance for fenbendazole sulfone (the marker residue) is 2 ppm.

* * * * *

PART 558—NEW ANIMAL DRUGS FOR USE IN ANIMAL FEEDS

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

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

4. Section 558.258 is amended by redesignating paragraphs (d)(1), (d)(2), (d)(3), and (d)(4) as paragraphs (d)(2), (d)(3), (d)(4), and (d)(5) and by adding new paragraph (d)(1) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(d) * * *

(1) *Turkeys*—(i) *Amount*. Fenbendazole, 14.5 grams per ton (16 parts per million).

(A) *Indications for use*. For the removal and control of gastrointestinal worms: Round worms, adult and larvae (*Ascaridia dissimilis*); cecal worms, adult and larvae (*Heterakis gallinarum*), an important vector of *Histomonas meleagridis* (Blackhead).

(B) *Limitations*. Feed continuously as the sole ration for 6 days. For growing turkeys only.

(ii) [Reserved]

* * * * *

Dated: July 25, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–21413 Filed 8–21–00; 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; Bacitracin Methylene Disalicylate, Robenidine Hydrochloride, 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 bacitracin methylene disalicylate (BMD), robenidine hydrochloride, and roxarsone Type A medicated articles to make three-way combination Type C medicated broiler chicken feeds used for prevention of coccidiosis; as an aid in the prevention and control of necrotic enteritis; and for increased rate of weight gain, improved feed efficiency, and improved pigmentation.

DATES: This rule is effective August 22, 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 141–155 that provides for use of BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) BMD), ROBENZ® (30 g/lb robenidine hydrochloride), and 3-NITRO® (45.4, 90, 227, or 360 g/lb roxarsone) Type A medicated articles to make three-way combination Type C medicated feeds containing 30 g/ton robenidine hydrochloride, 22.7 to 45.4 g/ton roxarsone, and 50 or 100 to 200 g/ton BMD for use in broiler chickens.

The combination Type C medicated feeds containing 50 g/ton BMD are used for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens; and as an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. The combination Type C medicated feeds containing 100 to 200 g/ton BMD are used for prevention of coccidiosis caused by *E. tenella*, *E. necatrix*, *E. acervulina*, *E. brunetti*, *E. mivati*, and *E. maxima*; for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens; and as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. The NADA is approved as of July 3, 2000, and the regulations are amended in §§ 558.76 and 558.515 (21 CFR 558.76 and 558.515) to reflect the approval. The basis of approval is discussed in the freedom of information summary.

Section 558.76 is also amended editorially to consolidate the cross-references for approved combinations in paragraph (d)(3) and list them in alphabetical order. Section 558.515 is amended editorially to display the conditions of use in paragraph (d) in a table format.

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 by revising paragraph (d)(3) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) Bacitracin methylene disalicylate may also be used with:

(i) Amprolium as in § 558.55.

(ii) Amprolium and ethopabate as in § 558.58.

(iii) Carbarsone (not USP) as in § 558.120.

(iv) Decoquinate alone and with roxarsone as in § 558.195.

(v) Fenbendazole as in § 558.258.

(vi) Halofuginone hydrobromide alone and with roxarsone as in § 558.265.

(vii) Hygromycin B as in § 588.274.

(viii) Ivermectin as in § 558.300.

(ix) Lasalocid sodium alone and with roxarsone as in § 558.311.

(x) Monensin alone and with roxarsone as in § 588.355.

(xi) Narasin alone and with roxarsone as in § 558.363.

(xii) Nicarbazin alone and with narasin and roxarsone as in § 558.366.

(xiii) Nitarsone as in § 558.369.

(xiv) Robenidine alone and with roxarsone as in § 558.515.

(xv) Salinomycin alone and with roxarsone as in § 558.550.

(xvi) Semduramicin alone and with roxarsone as in § 558.555.

(xvii) Zoalene alone and with arsanilic acid as in § 558.680.

3. Section 558.515 is amended by revising paragraphs (c) and (d) to read as follows:

§ 558.515 Robenidine hydrochloride.

* * * * *

(c) *Related tolerances.* See § 556.580 of this chapter.

(d) *Conditions of use.* It is used in feed for chickens as follows:

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
30 (0.0033 pct)		For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*.	Feed continuously as sole ration. Do not feed to layers. Withdraw 5 days prior to slaughter.	063238
	Bacitracin (as bacitracin methylene disalicylate) 4 to 30	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For increased rate of weight gain.	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	046573
	Bacitracin (as bacitracin methylene disalicylate) 27 to 50	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	046573
	Bacitracin (as bacitracin methylene disalicylate) 50 and roxarsone 22.7 to 45.4	For broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. As an aid in the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	Feed continuously as sole ration. Use as the sole source of organic arsenic; poultry should have access to water at all times; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	046573

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
	Bacitracin (as bacitracin methylene disalicylate) 100 to 200 and roxarsone 22.7 to 45.4	For broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. As an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to bacitracin. For increased rate of weight gain, improved feed efficiency, and improved pigmentation.	To control necrotic enteritis, start medication at first clinical signs of disease; vary bacitracin dosage based on the severity of infection; administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce bacitracin to prevention level (50 g/ton). Use as the sole source of organic arsenic; poultry should have access to water at all times; drug overdose or lack of water intake may result in leg weakness or paralysis. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	046573
	Bacitracin (as bacitracin zinc) 4 to 30	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For increased rate of weight gain.	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	046573 063238
	Bacitracin (as bacitracin zinc) 27 to 50	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For improved feed efficiency.	Feed continuously as sole ration. Do not feed to laying chickens. Withdraw 5 days prior to slaughter.	046573 063238
	Chlortetracycline 100 to 200	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For control of infectious synovitis caused by *Mycoplasma synoviae* susceptible to chlortetracycline.	Feed continuously as sole ration up to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter.	
	Chlortetracycline 200 to 400	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For control of chronic respiratory disease (CRD) and air sac infection caused by *M. gallisepticum* and *E. coli* susceptible to chlortetracycline.	Feed continuously as sole ration up to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter.	
	Chlortetracycline 500	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. As an aid in the reduction of mortality due to *E. coli* susceptible to chlortetracycline.	Feed continuously as sole ration up to 5 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days prior to slaughter.	063238

Robenidine hydrochloride in grams/ton	Combination in grams/ton	Indications for use	Limitations	Sponsor
	Lincomycin 2	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For increase in rate of weight gain and improved feed efficiency.	Feed continuously as the sole ration. Do not feed to laying hens. Withdraw 5 days before slaughter.	000009
	Oxytetracycline 400	For broiler chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For control of CRD and air sac infection caused by *Mycoplasma gallisepticum* and *E. coli* susceptible to oxytetracycline.	Feed continuously for 7 to 14 days. Do not feed to chickens producing eggs for human consumption. Withdraw 5 days before slaughter.	000069
	Roxarsone 22.5 to 45.4 (0.005 percent)	For broiler and fryer chickens: As an aid in the prevention of coccidiosis caused by *E. mivati*, *E. brunetti*, *E. tenella*, *E. acervulina*, *E. maxima*, and *E. necatrix*. For increased rate of weight gain.	Feed continuously as the sole ration. Use as sole source of organic arsenic. Do not feed to layers. Withdraw 5 days prior to slaughter.	046573

Dated: July 25, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 00–21412 Filed 8–21–00; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD01–00–204]

RIN 2115–AA97

Safety Zone: Fireworks Display, Hudson River, Pier 84, NY

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone for a fireworks display located on the Hudson River. This action is necessary to provide for the safety of life on navigable waters during the event. This action is intended to restrict vessel traffic in a portion of the Hudson River.

DATES: This rule is effective from 8:30 p.m. on August 27, 2000 to 10 p.m. on August 28, 2000.

ADDRESSES: Material received from the public, as well as documents indicated in this preamble as being available in the docket, are part of docket (CGD01–00–204) and are available for inspection or copying at Coast Guard Activities New York, 212 Coast Guard Drive, room 204, Staten Island, New York 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: Lieutenant M. Day, Waterways Oversight Branch, Coast Guard Activities New York (718) 354–4012.

SUPPLEMENTARY INFORMATION:

Regulatory Information

We did not publish a notice of proposed rulemaking (NPRM) for this regulation. Under 5 U.S.C. 553(b)(8), the Coast Guard finds that good cause exists for not publishing an NPRM. Good cause exists for not publishing an NPRM due to the date the Application for Approval of Marine Event was received; there was insufficient time to draft and publish an NPRM. Further, it is a local event with minimal impact on the waterway; vessels may still transit through the western 385 yards of the 900-yard wide Hudson River during the event. The zone is only in effect for 1½ hours and vessels can be given permission to transit the zone except for about 15 minutes during this time. Additionally, vessels would not be precluded from mooring at or getting underway from commercial or recreational piers in the vicinity of the zone. Any delay encountered in this regulation's effective date would be unnecessary and contrary to public interest since immediate action is needed to close the waterway and protect the maritime public from the hazards associated with this fireworks display.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. This is due to the following reasons: it is a local event with minimal impact on the waterway, vessels may still transit through the western 385 yards of the 900-yard wide Hudson River during the event, the zone is only in effect for 1½ hours and vessels can be given permission to transit the zone except for about 15 minutes during this time. Additionally, vessels would not be precluded from mooring at or getting underway from commercial or recreational piers in the vicinity of the zone.

Background and Purpose

The Coast Guard has received an application to hold a fireworks program on the waters of the Hudson River. This rule establishes a safety zone in all waters of the Hudson River within a 240-yard radius of the fireworks barge in approximate position 40°45′56.2″N 074°00′21.6″W (NAD 1983), about 300 yards west of Pier 84, Manhattan. The safety zone is in effect from 8:30 p.m. (e.s.t.) until 10 p.m. (e.s.t.) on Sunday, August 27, 2000. If the event is cancelled due to inclement weather, then this zone is effective from 8:30 p.m. (e.s.t.) until 10 p.m. (e.s.t.) on Monday, August 28, 2000. The safety zone prevents vessels from transiting a portion of the Hudson River and is needed to protect boaters from the hazards associated with fireworks launched from a barge in the area. Marine traffic will still be able to transit through the western 385 yards of the 900-yard wide Hudson River during this