Cylicocyclus spp., *Cylicodontophorus* spp., (*Cylicostephanus* spp.), pinworms (adult and fourth-stage larvae) (*Oxyuris equi*); ascarids (third- and fourth-stage larvae and adults) (*Parascaris equorum*); hairworms (adult) (*Trichostrongylus axei*); large-mouth stomach worms (adult) (*Habronema muscae*); stomach bots (oral and gastric stages) (*Gastrophilus* spp.); lungworms (adults and forth-stage larvae) (*Dictyocaulus arnfieldi*); intestinal threadworms (adults) (*Strongyloides westeri*); summer sores caused by *Habronema* and *Draschia* spp. cutaneous third-stage larvae; and dermatitis caused by neck threadworm microfilariae (*Onchocerca* spp.).

Approval of ANADA 200–202 for Phoenix Scientific, Inc.'s, ivermectin oral liquid is as a generic copy of Merial Ltd.'s, NADA 140–439 Eqvalan ® (ivermectin) liquid for horses. The ANADA is approved as of June 5, 1998, and the regulations are amended in 21 CFR 520.1195(b) 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)(1) 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 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

§ 520.1195 [Amended]

2. Section 520.1195 *Ivermectin liquid* is amended in paragraph (b) by removing ''No. 050604'' and adding in its place ''Nos. 050604 and 059130''.

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19028 Filed 7–16–98; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Bacitracin Methylene Disalicylate Soluble

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 Alpharma Inc. The supplemental NADA provides for using soluble bacitracin methylene disalicylate (BMD) powder to make a medicated drinking water for growing quail for prevention of ulcerative enteritis.

EFFECTIVE DATE: July 17, 1998.

FOR FURTHER INFORMATION CONTACT: William T. Flynn, Center for Veterinary Medicine (HFV–133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1644.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 65–470 that provides for use of BMD® Soluble (BMD soluble powder) to make a medicated drinking water for growing quail containing the equivalent of 400 milligrams of bacitracin per gallon used for prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to BMD. The supplemental NADA is approved as of May 27, 1998, and the regulations in 21 CFR 520.154a 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(d)(4) 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 520

Animal drugs.

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 520 is amended as follows:

PART 520—ORAL DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 520 continues to read as follows:

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

2. Section 520.154a is amended in paragraph (a) by removing the phrase ''paragraph (d)(3)'' and by adding in its place the phrase ''paragraphs (d)(3) and (d)(4)'' and by adding paragraph (d)(4) to read as follows:

§ 520.154a Soluble bacitracin methylene disalicylate.

* * * * *

(d) * * *

(4) *Growing quail*—(i) *Amount.* 400 milligrams per gallon in drinking water.

(ii) *Indications for use.* For prevention of ulcerative enteritis due to *Clostridium colinum* susceptible to bacitracin methylene disalicylate.

(iii) *Limitations.* Prepare fresh solution daily. Use as sole source of drinking water.

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19026 Filed 7–16–98; 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; Bacitracin Methylene Disalicylate, Decoquinate, 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 using approved bacitracin methylene disalicylate, decoquinate, and roxarsone Type A medicated articles to make combination drug Type C medicated broiler chicken feeds.

EFFECTIVE DATE: July 17, 1998.

FOR FURTHER INFORMATION CONTACT: Charles J. Andres, Center for Veterinary Medicine (HFV–128), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–594–1638.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, is sponsor of NADA 141–100 that provides for combining approved Type A medicated articles containing BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate) with Deccox® (6 percent or 27.2 g/lb decoquinate), and 3-Nitro® (45.4, 90, or 227 g/lb roxarsone) to make Type C medicated broiler feeds containing 50 g/ton (g/t) bacitracin methylene disalicylate, 27.2 g/t decoquinate, and 22.7 to 45.4 g/t roxarsone. The Type C medicated broiler feeds are used as an aid in the prevention of necrotic enteritis, for the prevention of coccidiosis, and for increased rate of weight gain, improved feed efficiency, and improved pigmentation in broiler chickens. The NADA is approved as of June 2, 1998, and the regulations are amended in 21 CFR 558.76(d)(3) and 558.195(d) by adding new entries, and 558.530(d)(5)(x) is revised 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.

This approval is for use of single ingredient Type A medicated articles to make combination drug Type C medicated feeds. One ingredient, roxarsone, is a Category II drug as defined in 21 CFR 558.3(b)(1)(ii). Prior to enactment of the Animal Drug Availability Act of 1996 (Pub. L. 104–250) (ADAA), an approved medicated feed application (MFA) was required for feed mills to make Type C medicated feeds from Type A medicated articles containing Category II drugs. The ADAA revised the Federal Food, Drug, and Cosmetic Act to replace the requirement for MFA's with a requirement for feed mill licenses.

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 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 adding paragraph (d)(3)(xv) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xv) Decoquinate and roxarsone as in § 558.195.

3. Section 558.195 is amended in the table in paragraph (d) by adding an entry for ''27.2 (0.003 pct)'' following the entry for ''Bacitracin 10 to 50'' and before the entry for ''Chlortetracycline 100 to 200'' to read as follows:

§ 558.195 Decoquinate.

* * * * *

(d) * * *

Decoquinate in grams per ton	Combination in grams per ton	Indications for use	Limitations	Sponsor
* *	*	* *	*	*
27.2 (0.003 pct)	Bacitracin methylene disalicylate 50 and roxarsone 22.7–45.4.	Broiler chickens; for prevention of coccidiosis caused by *Eimeria tenella*, *E. necatrix*, *E. mivati*, *E. acervulina*, *E. maxima*, *E. brunetti*; 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. Withdraw 5 days before slaughter. Do not feed to laying chickens. Not for use in breeder chickens. Use as sole source of organic arsenic. Poultry should have access to drinking water at all times. Drug overdosage or lack of drinking water may result in leg weakness or paralysis. Decoquinate, bacitracin methylene disalicylate, and roxarsone, as provided by No. 046573 in § 510.600(c) of this chapter.	046573
* *	*	* *	*	*

3. Section 558.530 is amended by removing and reserving paragraph (c), and by revising paragraph (d)(5)(x) to read as follows:

§ 558.530 Roxarsone.

* * * * *

(c) [Reserved]
(d) * * *
(5) * * *
(x) Decoquinate alone or in combination as in § 558.195.
* * * * *

Dated: July 9, 1998.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

[FR Doc. 98–19025 Filed 7–16–98; 8:45 am]
BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD07–98–006]

RIN 2115–AE46

Security Zone; Coast Waters Adjacent to Florida

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: Pursuant to Presidential Proclamation No. 6867, declaring a national emergency, the Coast Guard, after consultation with the Department of Justice, established a security zone, restricting the operation of certain vessels within the internal waters and territorial seas of the United States, adjacent to or within the coastal waters around southern Florida. The Coast Guard is revising the security zone to encompass all of the internal waters and territorial seas of the United States adjacent to or within the State of Florida and within the boundaries of the Seventh Coast Guard District (defined in 33 CFR 3.35–1); that is, all the described waters in and off Florida with the exception of those waters west of 083–50 W. The Coast Guard Captain of the Port (COTP) may exercise complete control over all vessel operations and movements within the security zone. Non-public vessels of less than 50 meters (165 feet) in length, may not get underway in or depart the security zone with the intent to enter Cuban territorial waters, absent express authorization from the COTP. These vessels control measures are necessary to provide for the safety of the United States citizens and residents and to prevent threatened disturbances of the international relations of the United States.

DATES: This rule is effective July 14, 1998 and will terminate when the National Emergency as declared by the President in Presidential Proclamation No. 6867 terminates. The Coast Guard will publish a separate document in the **Federal Register** announcing termination of this rule.

ADDRESSES: Permission of a Captain of the Port (COTP) to depart the security zone with the intent of entering Cuban territorial waters may be obtained from the following U.S. Coast Guard units: Marine Safety Office Miami, 51 S.W. First Avenue, Miami, FL 33130, ph. (305) 536–5693; Marine Safety Office Tampa, 155 Columbia Drive, Tampa, FL 33603, ph. (813) 228–2195; Marine Safety Office Jacksonville, 7802 Arlington Expy., Suite 400, Jacksonville, FL 32211–7445; Station Miami Beach, 100 MacArthur Causeway, Miami Beach, FL 33139, ph. (305) 535–4368; Station Fort Lauderdale, 7000 N. Ocean Dr., FL 33004, ph. (305) 927–1611; Station Marathon, 1800 Overseas Highway, Marathon, FL 33050, ph. (305) 743–1945; Station Islamorada, PO Box 547, 183 Palermo Dr., Islamorada, FL 33036, ph. (305) 292–8862; Station Key West, Key West, FL 33040, ph. (305) 292–8862; Station Fort Myers Beach, 719 San Carlos Drive, Fort Myers Beach, FL 33931, ph. (813) 463–5754. Additional locations may be established.

FOR FURTHER INFORMATION CONTACT: Chief, Marine Safety Division, Seventh Coast Guard District, 909 SE First Avenue, Brickell Plaza Federal Building, Miami, FL 33931, Phone (305) 536–5651.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Regulatory History

On March 1, 1996, the President of the United States signed Proclamation No. 6867 declaring a national emergency following the February 24 1996, shooting down of two Brothers to the Rescue aircraft by Cuban armed forces. The Proclamation, which addressed the disturbances or threatened disturbances of United States international relations, the President authorized the Secretary of Transportation to regulate the anchorage and movement of domestic and foreign vessels. Order No. 96–3–7, signed by the Secretary of Transportation delegated this authority to the Commandant, United States Coast Guard. This authority has been further delegated to the Commander, Seventh Coast Guard District and appropriate Captains of the Port. To secure the rights and obligations of the United States and to protect its citizens and residents from the use of excessive force upon them by foreign powers, the Coast Guard on March 8, 1996 (61 FR 9348), pursuant to its regulatory authority in 50 U.S.C. 191 and as supplemented by the authority delegated to the Secretary of Transportation in the Presidential Proclamation, established a security zone.

This security zone established on March 1, 1996, restricted the operation of vessels within the internal waters and territorial seas of the United States, adjacent to or within the coastal waters around southern Florida. The security zone prohibits private, noncommercial vessels less than 50 meters in length from departing the security zone with the intent to enter Cuban territorial waters, absent express authorization from the Captain of the Port (COTP).

On May 14, 1997 (62 FR 26390) the Coast Guard published a temporary rule revising the security zone by additional security measures that prohibit a similar class of vessels from getting underway in or departing the security zone with the intent to enter Cuban territorial waters without express authorization from the COTP. Additionally, under the revised security zone, commercial vessels less than 50 meters in length became subject to the same restrictions as private, noncommercial vessels less than 50 meters in length.

Discussion of Rule

This temporary rule further amends the security zone by expanding its geographic scope of the Florida peninsula. During the Pope's visit to Cuba in January, 1998, several boaters asserted that they had evaded the requirements of the security zone by departing for Cuba from a port north of Fort Lauderdale, outside the geographic limits of the prior security zone. Expansion of the geographic limits of the security zone around Florida will cure this potential enforcement problem, thereby enhancing boater safety and better preventing a possible disturbance of the foreign relations of the United States.

The Coast Guard has determined that control of the movement of non-public vessels less than 50 meters in length in the security zone, or departure of such vessels from the security zone, with the intent to enter Cuban territorial waters (hereinafter ''subject vessels''), is necessary to protect the safety of United States citizens and residents and prevent threatened disturbance of the international relations of the United States. These controls do not apply to foreign flag vessels in innocent passage in the territorial sea of the United States. Maintaining such control of vessel movement will necessitate some temporary limitations on traditional freedoms of navigation. Efforts will be made to keep these limitations to a minimum.