

uplands of Womens Bay and is generally located in Section 21, Township 28 South, Range 20 West, Seward Meridian according to the USGS 1:63360 scale quadrangle maps of Kodiak (C-2 and D-2) Alaska. The Kodiak State Airport site includes the developed and undeveloped lands and is generally located within Section 15, Township 28 South, Range 20 West, Seward Meridian according to the USGS 1:63360 scale quadrangle map of Kodiak (D-2) Alaska.

Inapplicability of Public Notice and Comment and Delayed Effective Date

Because this document relates to agency organization and management and merely corrects the geographical description of a port, the establishment of which was directed by Congress, it is not subject to the notice and public procedure requirements of 5 U.S.C. 553. For the same reasons, pursuant to 5 U.S.C. 553(d)(3), a delayed effective date is not required.

Regulatory Flexibility Act

Because this document is not subject to the notice and public procedure requirements of 5 U.S.C. 553, it is not subject to the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 et seq.).

Executive Order 12866

Agency organization matters such as this are exempt from consideration under Executive Order 12866.

List of Subjects in Part 101

Customs duties and inspection, Customs ports of entry, Exports, Foreign trade, Harbors, Imports, Reporting and recordkeeping requirements, Shipments, Vessels.

Amendments to the Regulations

For the reasons set forth in the preamble, Part 101 of the Customs Regulations is amended as follows:

PART 101—GENERAL PROVISIONS

1. The general authority citation for part 101 and the specific authority citation for §§ 101.3 and 101.4 continue to read as follows:

Authority: 5 U.S.C. 301; 19 U.S.C. 2, 66, 1202 (General Note 20, Harmonized Tariff Schedule of the United States), 1623, 1624.

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Sections 101.3 and 101.4 also issued under 19 U.S.C. 1 and 58b;

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§ 101.3 [Amended]

2. Section 101.3(b)(1) is amended by removing the reference "T.D. 98-24" in the "Limits of port" column adjacent to the entry for "Kodiak" in the "Ports of entry" column under Alaska and adding in its place the reference "T.D. 98-65."

Dated: June 10, 1998.

Samuel H. Banks,

Acting Commissioner of Customs.

John P. Simpson,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 98-20455 Filed 7-30-98; 8:45 am]

BILLING CODE 4820-02-P

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

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 approved bacitracin methylene disalicylate (BMD) Type A medicated articles to make a Type C medicated feed for replacement chickens.

EFFECTIVE DATE: July 31, 1998.

FOR FURTHER INFORMATION CONTACT:

William T. Flynn, Center for Veterinary Medicine (HFV-133), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301-594-1652.

SUPPLEMENTARY INFORMATION: Alpharma Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed supplemental NADA 46-592 that provides for using approved BMD® (10, 25, 30, 40, 50, 60, or 75 grams (g) per pound BMD) Type A medicated articles to make Type C medicated replacement chicken feed. A Type C feed containing 50 g per ton (/ t) BMD is fed continuously as an aid in

the prevention of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD. A Type C feed containing 100 to 200 g/t BMD is fed for 5 to 7 days, or as long as clinical signs persist, as an aid in the control of necrotic enteritis caused or complicated by *Clostridium* spp. or other organisms susceptible to BMD. The supplemental NADA is approved as of June 22, 1998, and the regulations in 21 CFR 558.76(d)(1) are amended in the table in items (vi) and (ix) to add new entries 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 the 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.

FDA has determined under 21 CFR 25.33(a)(1) that these actions are of a type that do 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 in paragraph (d)(1) in the table in items (vi) and (ix) by adding new entries 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 |
|--|------------------------------|--|--|---------|
| (vi) * * * | | Replacement chickens; as an aid in the prevention of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | Feed continuously as sole ration.. | 046573 |
| (ix) * * * | | Replacement chickens; as an aid in the control of necrotic enteritis caused or complicated by <i>Clostridium</i> spp. or other organisms susceptible to bacitracin. | Feed continuously as sole ration. Start at first clinical signs of disease, vary dosage based on severity of infection, administer continuously for 5 to 7 days or as long as clinical signs persist, then reduce medication to prevention level (50 g/t). | 046573 |

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Dated: July 10, 1998.

Margaret Ann Miller,

Acting Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 98-20466 Filed 7-30-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. 98N-0171]

Medical Devices; Humanitarian Use of Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Direct final rule; withdrawal.

SUMMARY: The Food and Drug Administration (FDA) published, in the **Federal Register** of April 17, 1998 (63 FR 19185), a direct final rule to implement the amendments to the humanitarian use devices provision of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The comment period closed July 1, 1998. FDA is withdrawing the direct final rule because the agency received significant adverse comment.

DATES: The direct final rule published at 63 FR 19185, April 17, 1998, is withdrawn effective July 31, 1998.

FOR FURTHER INFORMATION CONTACT: Joanne R. Less, Center for Devices and Radiological Health (HFZ-403), Food and Drug Administration, 9200 Corporate Blvd., Rockville, MD 20857, 301-594-1190.

Therefore, under the Federal Food, Drug, and Cosmetic Act, and under authority delegated to the Commissioner of Food and Drugs, the direct final rule published on April 17, 1998, at 63 FR 19185 is withdrawn.

Dated: July 29, 1998.

William K. Hubbard,

Associate Commissioner for Policy Coordination.

[FR Doc. 98-20594 Filed 7-30-98; 8:45 am]

BILLING CODE 4160-01-F

DEPARTMENT OF THE INTERIOR

Office of Surface Mining Reclamation and Enforcement

30 CFR Part 917

[KY-217-FOR]

Kentucky Regulatory Program

AGENCY: Office of Surface Mining Reclamation and Enforcement (OSM), Interior.

ACTION: Final rule; approval of amendment.

SUMMARY: OSM is approving a proposed amendment to the Kentucky regulatory program (hereinafter referred to as the "Kentucky program") under the Surface Mining Control and Reclamation Act of 1977 (SMCRA). Kentucky requested the removal of 30 CFR 917.17(a) which disapproved Kentucky's proposed revision to its staffing and budget levels (49 FR 50718, December 31, 1984). The amendment is intended to revise the Kentucky program to be consistent with the Federal regulations and SMCRA.

EFFECTIVE DATE: July 31, 1998.

FOR FURTHER INFORMATION CONTACT: William J. Kovacic, Director, Lexington Field Office, 2675 Regency Road, Lexington, Kentucky 40502. Telephone: (606) 233-2494.

SUPPLEMENTARY INFORMATION:

- I. Background on the Kentucky Program
- II. Submission of the Proposed Amendment
- III. Director's Findings
- IV. Summary and Disposition of Comments
- V. Director's Decision
- VI. Procedural Determinations

I. Background on the Kentucky Program

On May 18, 1982, the Secretary of the Interior conditionally approved the Kentucky program. Background information on the Kentucky program, including the Secretary's findings, the disposition of comments, and the conditions of approval can be found in the May 18, 1982 **Federal Register** (47 FR 21404). Subsequent actions concerning conditions of approval and program amendments can be found at