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 and Fenbendazole

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 and fenbendazole Type A medicated articles to make combination Type B and C medicated feeds for growing and finishing swine and pregnant sows for the removal of various internal parasites, for increased rate of weight gain and improved feed efficiency, for control of swine dysentery associated with *Treponema hyodysenteriae*, and for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens*. Technical corrections are also being made.

DATES: This rule is effective July 6, 2000.

FOR FURTHER INFORMATION CONTACT: Janis R. Messenheimer, Center for Veterinary Medicine (HFV–135), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–7578.

SUPPLEMENTARY INFORMATION: Alpharma, Inc., One Executive Dr., P.O. Box 1399, Fort Lee, NJ 07024, filed NADA 141–144 that provides for use of BMD® (10, 25, 30, 40, 50, 60, or 75 grams per pound (g/lb) bacitracin methylene disalicylate) and SafeGuard® (18.1, 36.2, or 90.7 g/lb fenbendazole) Type A medicated articles to make combination Type B and C medicated feeds for growing and finishing swine and pregnant sows.

For growing and finishing swine, the Type A medicated articles are used to make combination Type B medicated feeds that contain 300 to 1,780 grams per ton (g/ton) of bacitracin methylene disalicylate and 300 to 17,740 g/ton of fenbendazole and combination Type C medicated feeds that contain 10 to 30 g/ton of bacitracin methylene disalicylate and 10 to 300 g/ton of fenbendazole. The combination Type C medicated feeds are used for increased rate of weight gain and improved feed efficiency; and for the removal of adult-stage lungworms (*Metastrongylus apri* and*M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, and intestinal forms) large roundworms (*Ascaris suum*); adult-stage nodular worms (*Oesophagostomum dentatum*, *O. quadrispinulatum*); small stomach worms (*Hyostrongylus rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*Trichuris suis*); and adult and larvae kidneyworms (*Stephanurus dentatus*).

For growing and finishing swine and for pregnant sows, the Type A medicated articles are used to make Type B medicated feeds that contain 7,460 to 14,837 g/ton of bacitracin methylene disalicylate and 300 to 17,740 g/ton of fenbendazole and Type C medicated feeds that contain 250 g/ton of bacitracin methylene disalicylate and 10 to 300 g/ton of fenbendazole.

The combination Type C medicated growing and finishing swine feeds are used for the control of swine dysentery associated with *T. hyodysenteriae* in growing and finishing swine on premises with a history of swine dysentery but where signs of disease have not yet occurred, or following an approved treatment of the disease; and for the removal of adult-stage lungworms (*M. apri* and*M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, and intestinal forms) large roundworms (*A. suum*); adult-stage nodular worms (*O. dentatum*,*O. quadrispinulatum*); small stomach worms (*H. rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*T. suis*); and adult and larvae kidneyworms (*S. dentatus*).

The combination Type C medicated sow feeds are used for the control of clostridial enteritis in suckling pigs caused by *C. perfringens*; and for the removal of adult stage lungworms (*M. apri* and *M. pudendotectus*); adult and larvae (L3, 4 stages—liver, lung, and intestinal forms) large roundworms (*A. suum*); adult-stage nodular worms (*O. dentatum*, *O. quadrispinulatum*); small stomach worms (*H. rubidus*); adult and larvae (L2, 3, 4 stages—intestinal mucosal forms) whipworms (*T. suis*); and adult and larvae kidneyworms (*S. dentatus*).

The NADA is approved as of April 7, 2000, and 21 CFR 558.76 and § 558.258 (21 CFR 558.258) are amended to add new entries to reflect the approval. The basis for approval is discussed in the freedom of information summary.

Also, § 558.258 is amended to redesignate paragraph (c) as paragraph (d) and add paragraph (c) to reflect a newer 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 adding paragraph (d)(3)(xxii) to read as follows:

§ 558.76 Bacitracin methylene disalicylate.

* * * * *

(d) * * *

(3) * * *

(xxii) Fenbendazole as in § 558.258.

3. Section 558.258 is amended by redesignating paragraph (c) as paragraph (d) and reserving paragraph (c), and by adding paragraphs (d)(1)(vi) and (d)(1)(vii) to read as follows:

§ 558.258 Fenbendazole.

* * * * *

(c) [Reserved]

(d) * * *

(1) * * *

(vi) *Amount.* Fenbendazole, 10 to 300 grams per ton (to provide 9 milligrams per kilogram body weight), and bacitracin methylene disalicylate, 10 to 30 grams per ton.

(A) *Indications for use.* As an anthelmintic (as provided in paragraph

(d)(1)(i)(A) of this section) and for increased rate of weight gain and improved feed efficiency in growing/finishing swine.

(B) *Limitations.* Feed as sole ration. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(vii) *Amount.* Fenbendazole, 10 to 300 grams per ton, and bacitracin methylene disalicylate, 250 grams per ton.

(A) *Indications for use*—(*1*) *Growing/finishing swine.* As an anthelmintic (as provided in paragraph (d)(1)(i)(A) of this section) and for control of swine dysentery associated with *Treponema hyodysenteriae* on premises with a history of swine dysentery, but where signs of disease have not yet occurred; or following an approved treatment of the disease condition.

(*2*) *Pregnant sows.* As an anthelmintic (as provided in paragraph (d)(1)(i)(A) of this section) and for control of clostridial enteritis in suckling pigs caused by *Clostridium perfringens.*

(B) *Limitations*—(*1*)*Growing/finishing swine.* Feed as sole ration. Not for use in growing and finishing swine that weigh more than 250 pounds. Diagnosis of swine dysentery should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

(*2*) *Pregnant sows.* Feed as sole ration. Diagnosis of clostridial enteritis should be confirmed by a veterinarian when results are not satisfactory. Under conditions of continued exposure to parasites, retreatment may be needed after 4 to 6 weeks. Consult your veterinarian for assistance in the diagnosis, treatment, and control of parasitism. Bacitracin methylene disalicylate as provided by 046573 in § 510.600(c) of this chapter.

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Dated: June 19, 2000.

Stephen F. Sundlof,

Director, Center for Veterinary Medicine.

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DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 165

[CGD13–00–022]

RIN 2115–AA97

Safety Zone Regulations, Seafair Blue Angels Performance, Lake Washington, WA

AGENCY: Coast Guard, DOT.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing a temporary safety zone on the waters of Lake Washington, Seattle, Washington. The Coast Guard is taking this action to safeguard the participants and spectators from the safety hazards associated with Seafair Blue Angels Performance. Entry into this zone is prohibited unless authorized by the Captain of the Port, Puget Sound or his designated representatives.

DATES: This is effective from 8:30 a.m. Pacific Daylight Time on August 3 through 3 p.m. on August 6, 2000.

ADDRESSES: Documents as indicated in this preamble are available for inspection or copying at the U.S. Coast Guard Marine Safety Office Puget Sound, 1519 Alaskan Way South, Building 1, Seattle, Washington 98134. Normal office hours are between 7 a.m. and 5 p.m., Monday through Friday, except federal holidays.

FOR FURTHER INFORMATION CONTACT: LT Paul Stocklin, c/o Captain of the Port Puget Sound, 1519 Alaskan Way South, Seattle, Washington 98134, (206) 217–6232.

SUPPLEMENTARY INFORMATION:

Background and Purpose

Pursuant to 5 U.S.C. 553, a notice of proposed rulemaking has not been published for this regulation and good cause exists for making it effective less than 30 days from date of publication in the **Federal Register**. Due to complex planning and coordination requirements, the Coast Guard was not able to obtain details of the event thirty days prior to its occurrence. Because of this, following normal rulemaking procedures would be impracticable and contrary to the public interest. Prompt regulatory action is needed in order to provide for the safety of spectators and participants during the event. If normal notice and comment procedures were followed, this rule would not become effective until after the date of the event. For this reason, following normal rulemaking procedures in this case would be impracticable and contrary to the public interest.

Discussion of Proposed Rule

The Coast Guard is adopting a temporary safety zone regulation on the waters of Lake Washington, Seattle, Washington, for the Seafair Blue Angels Performance. The Coast Guard has determined it is necessary to close the area in the vicinity of the air show in order to minimize the dangers that low-flying aircraft present to persons and vessels. These dangers include, but are not limited to excessive noise and the risk of falling objects from any accidents associated with low flying aircraft. In the event that aircraft require emergency assistance, rescuers must have immediate and unencumbered access to the craft. The Coast Guard, through this action, intends to promote the safety of personnel, vessels, and facilities in the area. Entry into this zone will be prohibited unless authorized by the Captain of the Port. This safety zone will be enforced by Coast Guard personnel. The Captain of the Port may be assisted by other federal, state, or local agencies.

Regulatory Evaluation

This proposed rule is not a ''significant regulatory action'' under section 3(f) of Executive Order 12866 and does not require an assessment of potential costs and benefits under section 6(a)(3) of that Order. The Office of Management and Budget has not reviewed it under that Order. It is not significant under the regulatory policies and procedures of the Department of Transportation (DOT)(44 FR 11040, February 26, 1979). We expect the economic impact of this proposed rule to be so minimal that a full Regulatory Evaluation under paragraph 10(e) of the regulatory policies and procedures of DOT is unnecessary. This expectation is based on the fact that the regulated area established by the proposed regulation would encompass an area near the middle of Lake Washington, not frequented by commercial navigation. The regulation is established for the benefit and safety of the recreational boating public, and any recreational boating impact is offset by the benefits of allowing the Blue Angels to fly. For the above reasons, the Coast Guard does not anticipate any significant economic impact.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard considered whether this rule would have a significant economic impact on a substantial number of small entities.