§ 1702.2 Procedural requirements and recommendations.

(a) * * *

(1) Be mailed to the Office of the Secretary, Consumer Product Safety Commission, Washington, DC 20207, or delivered to the Office of the Secretary, Consumer Product Safety Commission, 4330 East West Highway, Bethesda, MD 20814.

* * * * *

Sadye E. Dunn,

Secretary, Consumer Product Safety Commission.

[FR Doc. 97–23498 Filed 9–3–97; 8:45 am]

BILLING CODE 6355–01–F

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Tetracycline Hydrochloride Soluble Powder

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 an abbreviated new animal drug application (ANADA) filed by Med-Pharmex, Inc. The ANADA provides for oral use of tetracycline hydrochloride soluble powder in the drinking water of swine and calves for control and treatment of certain diseases caused by pathogens susceptible to tetracycline, and of chickens and turkeys for control of certain diseases caused by pathogens susceptible to tetracycline.

EFFECTIVE DATE: September 4, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center For Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Med-Pharmex, Inc., 2727 Thompson Creek Rd., Pomona, CA 91767–1861, filed ANADA 200–234, which provides for oral use of tetracycline hydrochloride soluble powder in the drinking water of calves, swine, chickens, and turkeys, as follows: (1) For calves for control and treatment of bacterial enteritis (scours) caused by *Escherichia coli*, and bacterial pneumonia (shipping fever complex) associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp. susceptible to tetracycline; (2) for swine for control and treatment of bacterial enteritis (scours) caused by *E. coli*, and bacterial pneumonia associated with *Pasteurella* spp., *Actinobacillus pleuropneumoniae* (*Hemophilus* spp.), and *Klebsiella* spp. susceptible to tetracycline; (3) for chickens for control of chronic respiratory disease (CRD or air-sac disease) caused by *Mycoplasma gallisepticum* and *E. coli*; infectious synovitis caused by *M. synoviae* susceptible to tetracycline; and (4) for turkeys for control of infectious synovitis caused by *M. synoviae* and bluecomb (transmissible enteritis or coronaviral enteritis) complicated by bacterial organisms susceptible to tetracycline.

Approval of Med-Pharmex's ANADA 200–234 tetracycline hydrochloride soluble powder is as a generic copy of Fermenta's NADA 65–496 tetracycline hydrochloride soluble powder. ANADA 200–234 is approved as of July 22, 1997, and the regulations are amended in 21 CFR 520.2345d(a)(1) 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 21 CFR 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday through Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

§ 520.2345d [Amended]

2. Section 520.2345d *Tetracycline hydrochloride soluble powder* is amended in paragraph (a)(1) by removing ''047864, 000010, 057561, and 059130'' and adding in its place ''047864, 051259, 054273, 057561, and 059130''.

Dated: August 22, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–23372 Filed 9–3–97; 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; Clindamycin Hydrochloride Liquid

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 an abbreviated new animal drug application (ANADA) filed by Phoenix Scientific, Inc. The ANADA provides for veterinary prescription use in dogs of clindamycin hydrochloride liquid for therapy of wounds, abscesses, and dental infections, and therapy of osteomyelitis.

EFFECTIVE DATE: September 4, 1997.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–102), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 301–827–0209.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed ANADA 200–193 that provides for veterinary prescription use in dogs of clindamycin hydrochloride liquid for therapy of wounds, abscesses, and dental infections when administered orally at 2.5 milligrams per pound (mg/lb) every 12 hours, and for therapy of osteomyelitis when administered orally at 5.0 mg/lb every 12 hours.

Phoenix Scientific, Inc.'s, ANADA 200–193 clindamycin hydrochloride liquid is approved as a generic copy of Pharmacia & Upjohn's NADA 135–940 Antirobe Aquadrops®. The ANADA is approved as of August 1, 1997, and the regulations are amended in 21 CFR 520.447(b) 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, 12420 Parklawn Dr., rm. 1–23, Rockville, MD 20857, between 9 a.m. and 4 p.m., Monday to Friday.

The agency has determined under 21 CFR 25.24(d)(1)(i) 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: Sec. 512 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b).

2. Section 520.447 is amended by revising paragraph (b) to read as follows:

§ 520.447 Clindamycin hydrochloride liquid.

* * * * *

(b) *Sponsor.* See No. 000009 in § 510.600(c) of this chapter for use as in paragraphs (c) and (d) of this section. See No. 059130 for use as in paragraph (c) of this section.

* * * * *

Dated: August 22, 1997.

Michael J. Blackwell,

Deputy Director, Center for Veterinary Medicine.

[FR Doc. 97–23450 Filed 9–3–97; 8:45 am]

BILLING CODE 4160–01–F

DEPARTMENT OF TRANSPORTATION

Coast Guard

33 CFR Part 100

[CGD 05–97–007]

RIN 2115–AE46

Special Local Regulations for Marine Events; Norfolk Harbor, Elizabeth River, Norfolk, Virginia and Portsmouth, Virginia

AGENCY: Coast Guard, DOT.

ACTION: Final rule.

SUMMARY: The Coast Guard is amending permanent special local regulations established for marine events held in the Norfolk Harbor, Elizabeth River, between Norfolk and Portsmouth, Virginia, by identifying specific annual events for which the regulated area will be in effect. This rule updates the regulation in order to enhance the safety of life and property during the events.

EFFECTIVE DATE: This final rule is effective on June 6, 1997.

FOR FURTHER INFORMATION CONTACT: S.L. Phillips, Project Manager, Search and Rescue Branch, at (757) 398–6204.

SUPPLEMENTARY INFORMATION:

Regulatory History

On February 21, 1997, the Coast Guard published a notice of proposed rulemaking entitled Special Local Regulations for Marine Events; Norfolk Harbor, Elizabeth River, Norfolk, Virginia and Portsmouth, Virginia, in the **Federal Register** (62 FR 7969). The Coast Guard received no comments on the proposed rulemaking. No public hearing was requested, and none was held. The final rule was inadvertently published as a quarterly on 8 August 1997 (62 FR 42671).

Background and Purpose

33 CFR 100.501 established special local regulations for marine events held in the Norfolk Harbor, Elizabeth River, between Norfolk and Portsmouth, Virginia. The effect of these regulations is the control of vessel traffic during marine events to enhance the safety of participants, spectators, and transiting vessels. The regulations are implemented at various times, for various events throughout the year by publishing notice in the **Federal Register** and the Fifth Coast Guard District Local Notice to Mariners. This rule updates the regulations to reflect specific events for which the regulated area will be in effect.

Discussion of Comments and Changes

The Coast Guard received no comments on the proposed rulemaking; however, the Coast Guard has learned that the sponsoring organization for the Harborfest event will be Festevents, Ltd. Therefore, Table 1 of the proposed rule has been amended to reflect this change.

Good Cause Statement

This final rule is effective in less than 30 days because it is contrary to the public interest to delay the effective date because timely action is required to protect vessel traffic and event participants during these events.

Regulatory Evaluation

This 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. It has been exempted from review by the Office of Management and Budget 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). The Coast Guard expects the economic impact of this final rule to be so minimal that a full Regulatory Evaluation under paragraph 10e of the regulatory policies and procedures of DOT is unnecessary. This rule merely changes the effective period of an existing regulation and does not impose any new restrictions on vessel traffic.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*), the Coast Guard must consider whether this rule will have a significant economic impact on a substantial number of small entities. ''Small entities'' include independently owned and operated small businesses that are not dominant in their field and that otherwise qualify as ''small business concerns'' under section 3 of the Small Business Act (15 U.S.C. 632). This rule does not impose any new restrictions on vessel traffic, but merely changes the effective period of the regulation. Therefore, the Coast Guard certifies under Section 605(b) of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) that this final rule will not have a significant economic impact on a substantial number of small entities.

Collection of Information

This final rule contains no collection of information requirement under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501 *et seq.*).