example, if your soft tissue injuries are under continuing surgical management (as defined in 101.00M), we will evaluate your impairment under 101.08. However, if your burns do not meet the requirements of 101.08 and you have extensive skin lesions that result in a very serious limitation (as defined in 108.00C1) that has lasted or can be expected to last for a continuous period of at least 12 months, we will evaluate them under 108.08.

G. *How do we determine if your skin disorder(s) will continue at a disabling level of severity in order to meet the duration requirement?* For all of these skin disorder listings except 108.07 and 108.08, we will find that your impairment meets the duration requirement if your skin disorder results in extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed. By *persist*, we mean that the longitudinal clinical record shows that, with few exceptions, your lesions have been at the level of severity specified in the listing. For 108.07A, we will presume that you meet the duration requirement. For 108.07B and 108.08, we will consider all of the relevant medical and other information in your case record to determine whether your skin disorder meets the duration requirement.

H. *How do we assess your skin disorder(s) if your impairment does not meet the requirements of one of these listings?*

1. These listings are only examples of common skin disorders that we consider severe enough to result in marked and severe functional limitations. For most of these listings, if you do not have continuing treatment as prescribed, if your treatment has not lasted for at least 3 months, or if you do not have extensive skin lesions that have persisted for at least 3 months, your impairment cannot meet the requirements of these skin disorder listings. (This provision does not apply to 108.07 and 108.08.) However, we may still find that you are disabled because your impairment(s) meets the requirements of a listing in another body system, medically equals (see §§ 404.1526 and 416.926 of this chapter) the severity of a listing, or functionally equals the severity of the listings.

2. If you have not received ongoing treatment or do not have an ongoing relationship with the medical community despite the existence of a severe impairment(s), or if your skin lesions have not persisted for at least 3 months but you are undergoing continuing treatment as prescribed, you may still have an impairment(s) that meets a listing in another body system or that medically equals a listing. If you do not have an impairment(s) that meets or medically equals a listing, we will consider whether your impairment(s) functionally equals the listings. (See § 416.924 of this chapter.) When we decide whether you continue to be disabled, we use the rules in § 416.994a of this chapter.

108.01 Category of Impairments, Skin Disorders

108.02 *Ichthyosis*, with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.03 *Bullous disease* (for example, pemphigus, erythema multiforme bullosum, epidermolysis bullosa, bullous pemphigoid, dermatitis herpetiformis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.04 *Chronic infections of the skin or mucous membranes*, with extensive fungating or extensive ulcerating skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.05 *Dermatitis* (for example, psoriasis, dyshidrosis, atopic dermatitis, exfoliative dermatitis, allergic contact dermatitis), with extensive skin lesions that persist for at least 3 months despite continuing treatment as prescribed.

108.06 *Hidradenitis suppurativa*, with extensive skin lesions involving both axillae, both inguinal areas, or the perineum that persist for at least 3 months despite continuing treatment as prescribed.

108.07 *Genetic photosensitivity disorders*, established by clinical and laboratory findings as described in 108.00E.

A. Xeroderma pigmentosum. Consider the individual disabled from birth.

B. Other genetic photosensitivity disorders, with:

1. Extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months, or

2. Inability to function outside of a highly protective environment for a continuous period of at least 12 months (see 108.00E2).

108.08 *Burns*, with extensive skin lesions that have lasted or can be expected to last for a continuous period of at least 12 months. (See 108.00F).

* * * * *

[FR Doc. 04–12895 Filed 6–8–04; 8:45 am]

BILLING CODE 4191–02–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

Oral Dosage Form New Animal Drugs; Clindamycin Capsules and Tablets

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 two supplemental abbreviated new animal drug applications (ANADAs) filed by Phoenix Scientific, Inc. One supplemental ANADA provides for an expanded dose range and revised indications wording for the oral use of clindamycin hydrochloride capsules in dogs for the treatment of certain bacterial diseases. The other supplemental ANADA provides for use of a 300-milligram capsule size.

DATES: This rule is effective June 9, 2004.

FOR FURTHER INFORMATION CONTACT: Lonnie W. Luther, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7519 Standish Pl., Rockville, MD 20855, 301–827–8549, e-mail: *lluther@cvm.fda.gov*.

SUPPLEMENTARY INFORMATION: Phoenix Scientific, Inc., 3915 South 48th St. Terrace, P.O. Box 6457, St. Joseph, MO 64506–0457, filed two supplements to ANADA 200–298 for Clindamycin Hydrochloride Capsules. One supplemental ANADA provides for an expanded dose range and revised indications wording for the oral use of clindamycin hydrochloride capsules in dogs for the treatment of certain bacterial diseases. The other supplemental ANADA provides for use of a 300-milligram capsule size. The supplemental applications are approved as of April 21, 2004, and the regulations are amended in 21 CFR 520.446 to reflect their 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), summaries of safety and effectiveness data and information submitted to support approval of these applications may be seen in the Division of Dockets Management (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 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 for either.

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 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.

§ 520.446 [Amended]

■ 2. Section 520.446 is amended by removing paragraphs (a)(2) and (b)(2); by redesignating paragraphs (a)(3) and (b)(3) as paragraphs (a)(2) and (b)(2); in paragraph (b)(1) by removing ''No. 000009'' and by adding in its place ''Nos. 000009 and 059130''; and in newly redesignated paragraph (b)(2) by removing ''(a)(3)'' and by adding in its place ''(a)(2).''

Dated: May 19, 2004.

Steven D. Vaughn,

Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.

[FR Doc. 04–12961 Filed 6–8–04; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 100

[CGD01–04–052]

Special Local Regulation; Harvard-Yale Regatta, Thames River, New London, CT

AGENCY: Coast Guard, DHS.

ACTION: Notice of implementation of regulation.

SUMMARY: The Coast Guard is implementing the permanent regulations for the annual Harvard-Yale Regatta, a rowing competition held on the Thames River in New London, CT. The regulation controls vessel traffic within the immediate vicinity of the event due to the confined nature of the waterway and anticipated congestion at the time of the event, thus providing for the safety of life and property on the affected navigable waters.

DATES: The regulations in 33 CFR 100.101 will be enforced from 9:30 a.m. on June 12, 2004, until 5 p.m on June 13, 2004.

FOR FURTHER INFORMATION CONTACT: Petty Officer Austin Nagle, Office of Search and Rescue, First Coast Guard District, (617) 223–8460.

SUPPLEMENTARY INFORMATION: This notice implements the permanent special local regulation governing the 2004 Harvard-Yale Regatta. The regulations in 33 CFR 100.101 will be enforced from 9:30 a.m. until 5 p.m. on June 12, 2004, with a rain date of June 13, 2004, if the regatta is postponed due to inclement weather.

A portion of the Thames River in New London, Connecticut will be closed during the event to all vessel traffic except participants, official regatta vessels, patrol craft and spectators as prescribed by the regulation. The regulated area is that area of the river between the Penn Central drawbridge, now known as the Thames River Amtrak drawbridge, and Bartlett's Cove. Additional public notification will be made via the First Coast Guard District Local Notice to Mariners and marine safety broadcasts. The full text of this regulation is found in 33 CFR 100.101.

Dated: May 27, 2004.

Vivien S. Crea,

Rear Admiral, U.S. Coast Guard, Commander, First Coast Guard District.

[FR Doc. 04–12964 Filed 6–8–04; 8:45 am]

BILLING CODE 4910–15–P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 52

[NV–040–0075; FRL–7663–4]

Approval and Promulgation of Implementation Plans; Nevada-Las Vegas Valley PM–10 Nonattainment Area; Serious Area Plan for Attainment of the Annual and 24-Hour PM–10 Standards

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is approving the serious area particulate matter (PM–10) plan for the Las Vegas Planning Area that addresses attainment of the annual and 24-hour PM–10 national ambient air quality standards (NAAQS) and includes motor vehicle emissions budgets for transportation conformity. We are also granting Nevada's request to extend the Clean Air Act (CAA or Act) deadline for attaining the 24-hour PM–10 standard in the Las Vegas area from 2001 to 2006. Finally, we are approving into the State Implementation Plan (SIP) fugitive dust rules adopted by Clark County (County).

DATES: *Effective Date:* July 9, 2004.

ADDRESSES: You can inspect copies of the administrative record for this action at EPA's Region IX office during normal business hours by appointment. You can inspect copies of the submitted SIP revisions by appointment at the following locations:

Environmental Protection Agency, Region 9, Air Division, Air Planning Office (AIR–2), 75 Hawthorne Street, San Francisco, CA 94105–3901;

Clark County Department of Air Quality Management, 500 S. Grand Central Parkway, Las Vegas, NV 89155;

Nevada Division of Environmental Protection, 333 West Nye Lane, Carson City, NV 89710.

Electronic Availability

This document and the Response to Comments Document for this action are also available as electronic files on EPA's Region 9 Web Page at *http://www.epa.gov/region09/air.*

FOR FURTHER INFORMATION CONTACT: Karen Irwin, Office of Air Planning (AIR–2), U.S. Environmental Protection Agency, Region 9, 75 Hawthorne Street, San Francisco, CA 94105. (415) 947–4116, *irwin.karen@epa.gov.*

SUPPLEMENTARY INFORMATION: Throughout this document, ''we,'' ''us'' and ''our'' refer to EPA. This supplementary information is organized as follows:

I. Summary of Today's Actions

We are approving the *PM–10 State Implementation Plan for Clark County* (''Clark County Serious Area Plan'' or ''Plan''), submitted on July 23, 2001.[1] The Plan addresses attainment of the annual and 24-hour PM–10 standards.[2] This action is based on our determination that this Plan complies with the CAA requirements for serious PM–10 nonattainment area plans.

First, we are approving the following specific elements of the Plan:

• A demonstration that the Plan provides for implementation of best available control measures (BACM); [3]

[1] On November 19, 2002, the Nevada Division of Environmental Protection submitted to EPA an amendment to the Plan adopted by the Clark County Board of Commissioners on November 19, 2002. The amendment establishes new deadlines for SIP commitments concerning revisions to Sections 90 through 94 and adds documentation on adopted local ordinances for fireplaces and woodstoves as Appendix R of the Plan. EPA approved these ordinances in a separate action. 68 FR 52838 (Sept. 8, 2003).

[2] PM–10 is particulate matter with an aerometric diameter of less than or equal to a nominal 10 micrometers. There are two separate NAAQS for PM–10, an annual standard of 50 μg/m^3 and a 24-hour standard of 150 μg/m^3.

[3] Because the demonstration of BACM subsumes the demonstration of Reasonably Available Control Measures (RACM), a separate analysis to determine if the measures represent a RACM level of control is not necessary. The BACM demonstration, therefore, is also a finding that the Plan provides for the implementation of RACM as required under CAA sections 173(c)(1) and 189(a)(1)(C).