

Dated: July 1, 2011.

Matthew S. Borman,

Deputy Assistant Secretary for Export Administration.

[FR Doc. 2011-17494 Filed 7-11-11; 8:45 am]

BILLING CODE 3510-33-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 520

[Docket No. FDA-2011-N-0003]

Oral Dosage Form New Animal Drugs; Amprolium

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 original abbreviated new animal drug application (ANADA) filed by Cross Vetpharm Group Ltd. The original ANADA provides for the use of amprolium soluble powder for the treatment of coccidiosis in chickens and turkeys.

DATES: This rule is effective July 12, 2011.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV-170), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-276-8197, e-mail: john.harshman@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Cross Vetpharm Group Ltd., Broomhill Rd., Tallaght, Dublin 24, Ireland, filed ANADA 200-488 for the use of AMPROMED-P (amprolium) for poultry, a water-soluble powder used for the treatment of coccidiosis in chickens and turkeys. Cross Vetpharm Group Ltd.'s AMPROMED-P for Poultry is approved as a generic copy of Huvapharma AD's AMPROL 128 (amprolium) 20% Soluble Powder, approved under NADA 33-165. The ANADA is approved as of May 23, 2011, and the regulations in 21 CFR 520.100 are amended to reflect the approval.

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 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.

FDA has determined under 21 CFR 25.33 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 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. In § 520.100, paragraph (b)(4) is revised to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(4) No. 061623 for use of product described in paragraph (a)(2) of this section as in paragraphs (d)(1) and (d)(2) of this section.

* * * * *

Dated: June 30, 2011.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. 2011-17465 Filed 7-11-11; 8:45 am]

BILLING CODE 4160-01-P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 165

[Docket No. USCG-2011-0507]

RIN 1625-AA00

Safety Zones; Fireworks Within the Sector Boston Captain of the Port Zone

AGENCY: Coast Guard, DHS.

ACTION: Temporary final rule.

SUMMARY: The Coast Guard is establishing temporary safety zones

within the Sector Boston Captain of the Port (COTP) Zone for various fireworks displays. These safety zones are necessary to provide for the safety of life on navigable waters during these fireworks events. Entering into, transiting through, mooring or anchoring within these zones is prohibited unless authorized by the COTP or the designated on-scene representative.

DATES: This rule is effective in the CFR on July 12, 2011 through 11:59 p.m. September 9, 2011. This rule is effective with actual notice for purposes of enforcement beginning at 8:30 p.m. June 27, 2011.

ADDRESSES: Documents indicated in this preamble as being available in the docket are part of docket USCG-2011-0507 and are available online by going to <http://www.regulations.gov>, inserting USCG-2011-0507 in the "Keyword" box, and then clicking "Search." They are also available for inspection or copying at the Docket Management Facility (M-30), U.S. Department of Transportation, West Building Ground Floor, Room W12-140, 1200 New Jersey Avenue, SE., Washington, DC 20590, between 9 a.m. and 5 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary rule, call or e-mail MST1 David Labadie of the Waterways Management Division, U.S. Coast Guard Sector Boston; telephone 617-223-3010, e-mail david.j.labadie@uscg.mil. If you have questions on viewing material related to the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202-366-9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

The Coast Guard is issuing this temporary final rule without prior notice and opportunity to comment pursuant to authority under section 4(a) of the Administrative Procedure Act (APA) (5 U.S.C. 553(b)). This provision authorizes an agency to issue a rule without prior notice and opportunity to comment when the agency for good cause finds that those procedures are "impracticable, unnecessary, or contrary to the public interest." Under 5 U.S.C. 553(b)(B), the Coast Guard finds that good cause exists for not publishing a notice of proposed rulemaking (NPRM) with respect to this rule. The safety zones listed in this rule are associated with annual fireworks events. The Coast Guard intends to make these safety zones permanent regulations and has submitted a NPRM for submission to the **Federal Register** requesting public