

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

comments. A delay in publication and the lengthy comment period associated with the process of rulemaking in the **Federal Register** does not allow time to publish a NPRM followed by a final rule as these events would occur before the rulemaking process was complete. The sponsors are unable to reschedule these events due to other activities being held in conjunction with the fireworks displays and the Fourth of July holiday. Many community members have made holiday plans based on these fireworks events, and changing the date would cause numerous cancellations and hurt small businesses. Rescheduling would not be a viable option because most event venues, entertainers and vendors have fully booked summer schedules making rescheduling nearly impossible.

Due to the dangers posed by the pyrotechnics used in these fireworks displays, the safety zones are necessary to provide for the safety of event participants, spectator craft, and other vessels transiting the event areas. For the safety concerns noted, it is in the public interest to have these regulations in effect during the events.

Under 5 U.S.C. 553(d)(3), the Coast Guard finds that good cause exists for making this rule effective less than 30 days after publication in the **Federal Register**. Any delay in the effective date of this rule would expose spectators, vessels and other property to the hazards associated with pyrotechnics used in the fireworks displays.

Basis and Purpose

The legal basis for the temporary rule is 33 U.S.C. 1226, 1231, 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; Public Law 107–295, 116 Stat. 2064; and Department of Homeland Security Delegation No. 0170.1, which collectively authorize the Coast Guard to define safety zones.

The safety zones are being issued to establish temporary regulated areas within the Sector Boston Captain of the Port (COTP) Zone for various fireworks displays.

Discussion of Rule

This temporary rule is necessary to ensure the safety of spectators, vessels and other property from the hazards associated with fireworks displays. The COTP Boston has determined that fireworks displays in close proximity to watercraft and waterfront structures pose a significant risk to public safety and property. Such hazards include obstructions to the waterway that may cause marine casualties and the explosive danger of fireworks and debris falling into the water that may cause death or serious bodily harm.

Establishing safety zones around the locations of these fireworks events will help ensure the safety of spectators, vessels and other property and help minimize the associated risks.

The Coast Guard has implemented safety zones for past events and has not received public comments or concerns regarding the impact to waterway traffic from these events.

Regulatory Analyses

We developed this rule after considering numerous statutes and executive orders related to rulemaking. Below we summarize our analyses based on 13 of these statutes or executive orders.

Executive Order 12866 and Executive Order 13563

This rule is not a significant regulatory action under section 3(f) of Executive Order 12866, Regulatory Planning and Review, as supplemented by Executive Order 13563, 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.

The Coast Guard determined that this rule is not a significant regulatory action for the following reasons: The safety zones will be of limited duration, are located in waterways that have no deep draft commercial traffic and are designed to avoid, to the extent possible, fishing and recreational boating traffic routes.

Small Entities

Under the Regulatory Flexibility Act (5 U.S.C. 601–612), we have considered whether this rule would have a significant economic impact on a substantial number of small entities. The term “small entities” comprises small businesses, not-for-profit organizations that are independently owned and operated and are not dominant in their fields, and governmental jurisdictions with populations of less than 50,000.

The Coast Guard certifies under 5 U.S.C. 605(b) that this rule would not have a significant economic impact on a substantial number of small entities.

This rule will affect the following entities, some of which may be small entities: the safety zones during the enforcement periods stated for each event in the List of Subjects.

These safety zones will not have a significant economic impact on a substantial number of small entities because of the minimal amount of time in which the safety zones will be enforced and vessels will be able to

transit around the safety zones. Before the effective periods, we will issue maritime advisories widely available to users of the waterway.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), we offer to assist small entities in understanding the rule so that they can better evaluate its effects on them and participate in the rulemaking process. If the rule would affect your small business, organization, or governmental jurisdiction and you have questions concerning its provisions or options for compliance, please contact MST1 David Labadie at the telephone number or e-mail address indicated under the **FOR FURTHER INFORMATION CONTACT** section of this notice.

Small businesses may send comments on the actions of Federal employees who enforce, or otherwise determine compliance with, Federal regulations to the Small Business and Agriculture Regulatory Enforcement Ombudsman and the Regional Small Business Regulatory Fairness Boards. The Ombudsman evaluates these actions annually and rates each agency’s responsiveness to small business. If you wish to comment on actions by employees of the Coast Guard, call 1–888–REG–FAIR (1–888–734–3247). The Coast Guard will not retaliate against small entities that question or complain about this rule or any policy or action of the Coast Guard.

Collection of Information

This rule calls for no new collection of information under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520).

Federalism

A rule has implications for federalism under Executive Order 13132, Federalism, if it has a substantial direct effect on State or local governments and would either preempt State law or impose a substantial direct cost of compliance on them. We have analyzed this rule under that Order and have determined that it does not have implications for federalism.

Unfunded Mandates Reform Act

The Unfunded Mandates Reform Act of 1995 (2 U.S.C. 1531–1538) requires Federal agencies to assess the effects of their discretionary regulatory actions. In particular, the Act addresses actions that may result in the expenditure by a State, local, or tribal government, in the aggregate, or by the private sector of \$100,000,000 (adjusted for inflation) or

more in any one year. Though this rule will not result in such expenditure, we do discuss the effects of this rule elsewhere in this preamble.

Taking of Private Property

This rule will not cause a taking of private property or otherwise have taking implications under Executive Order 12630, Governmental Actions and Interference with Constitutionally Protected Property Rights.

Civil Justice Reform

This rule meets applicable standards in sections 3(a) and 3(b)(2) of Executive Order 12988, Civil Justice Reform, to minimize litigation, eliminate ambiguity, and reduce burden.

Protection of Children

We have analyzed this rule under Executive Order 13045, Protection of Children from Environmental Health Risks and Safety Risks. This rule is not an economically significant rule and does not create an environmental risk to health or risk to safety that may disproportionately affect children.

Indian Tribal Governments

This rule does not have tribal implications under Executive Order 13175, Consultation and Coordination with Indian Tribal Governments, because it does not have a substantial direct effect on one or more Indian tribes, on the relationship between the Federal Government and Indian tribes, or on the distribution of power and responsibilities between the Federal Government and Indian tribes.

Energy Effects

We have analyzed this rule under Executive Order 13211, Actions Concerning Regulations That Significantly Affect Energy Supply, Distribution, or Use. We have determined that it is not a "significant energy action" under that order because it is not a "significant regulatory action" under Executive Order 12866 and is not likely to have a significant adverse effect on the supply, distribution, or use of energy. The Administrator of the Office of Information and Regulatory Affairs has not designated it as a significant energy action. Therefore, it does not require a Statement of Energy Effects under Executive Order 13211.

Technical Standards

The National Technology Transfer and Advancement Act (NTTAA) (15 U.S.C. 272 note) directs agencies to use voluntary consensus standards in their regulatory activities unless the agency provides Congress, through the Office of

Management and Budget, with an explanation of why using these standards would be inconsistent with applicable law or otherwise impractical. Voluntary consensus standards are technical standards (e.g., specifications of materials, performance, design, or operation; test methods; sampling procedures; and related management systems practices) that are developed or adopted by voluntary consensus standards bodies.

This rule does not use technical standards. Therefore, we did not consider the use of voluntary consensus standards.

Environment

We have analyzed this rule under Department of Homeland Security Management Directive 023-01 and Commandant Instruction M16475.ID, which guide the Coast Guard in complying with the National Environmental Policy Act of 1969 (NEPA) (42 U.S.C. 4321-4370f), and have concluded that this action is one of a category of actions that do not individually or cumulatively have a significant effect on the human environment. This rule is categorically excluded, under figure 2-1, paragraph (34)(g), of the Instruction. This rule involves the establishment of safety zones. An environmental analysis checklist and a categorical exclusion determination are available in the docket where indicated under **ADDRESSES**.

List of Subjects in 33 CFR Part 165

Marine safety, Navigation (water), Reporting and recordkeeping requirements, Waterways.

For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 165 as follows:

PART 165—REGULATED NAVIGATION AREAS AND LIMITED ACCESS AREAS

- 1. The authority citation for part 165 continues to read as follows:

Authority: 33 U.S.C. 1226, 1231; 46 U.S.C. Chapter 701, 3306, 3703; 50 U.S.C. 191, 195; 33 CFR 1.05-1(g), 6.04-1, 6.04-6, and 160.5; Public Law 107-295, 116 Stat. 2064; Department of Homeland Security Delegation No. 0170.1.

- 2. Add § 165.T01-0507 to read as follows:

§ 165.T01-0507 Safety Zones; Fireworks within the Sector Boston Captain of the Port Zone.

(a) *General.* Temporary safety zones are established for the fireworks display as follows:

- (1) *Surfside Fireworks, Salisbury Beach, MA.*

(i) *Location.* All waters of the Atlantic Ocean near Salisbury Beach, MA from surface to bottom, within a 350-yard radius of the fireworks barge located at position 42°50.6' N, 070°48.4' W (NAD 83).

(ii) *Enforcement Period.* This safety zone will be enforced every Saturday evening from 9:30 p.m. through 10:30 p.m. during the effective period. This safety zone will also be enforced from 9:30 p.m. through 10:30 p.m. on Sunday July 3, 2011.

(2) *Weymouth Fireworks, Weymouth, MA.*

(i) *Location.* All waters of Weymouth Fore River, within a 350-yard radius of the fireworks launch site located at position 42°15.5' N, 070°56.1' W (NAD 83).

(ii) *Enforcement Period.* This safety zone will be enforced from 9 p.m. to 11 p.m. on July 3, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 9 p.m. to 11 p.m. on July 9, 2011.

(3) *Lynn 4th of July Fireworks, Lynn, MA.*

(i) *Location.* All waters of Nahant Bay, within a 350-yard radius of the fireworks barge located at position 42°27.62' N, 070°55.58' W (NAD 83).

(ii) *Enforcement Period.* This safety zone will be enforced from 9 p.m. to 11 p.m. on July 3, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 9 p.m. to 11 p.m. on July 5, 2011.

(4) *Marblehead 4th of July Fireworks, Marblehead, MA.*

(i) *Location.* All waters of Marblehead Harbor within a 350-yard radius of the fireworks launch site located at position 42°30.34' N, 070°50.13' W (NAD 83).

(ii) *Enforcement Period.* This safety zone will be enforced from 8:30 p.m. to 10 p.m. on July 4, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 8:30 p.m. to 10 p.m. on July 5, 2011.

(5) *Beverly Farms 4th of July Celebration Fireworks, Beverly, MA.*

(i) *Location.* All waters of Manchester Bay within a 350-yard radius of the fireworks launch site near West Beach located at position 42°33.84' N, 070°48.5' W (NAD 83).

(ii) *Enforcement Period.* This safety zone will be enforced from 9 p.m. to 11 p.m. on July 3, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 9 p.m. to 11 p.m. on July 5, 2011.

(6) *Boston Pops Fireworks Spectacular, Boston, MA.*

(i) *Location*. All waters of the Charles River within a 350-yard radius of the fireworks barges located in the vicinity of position 42°21.47' N, 071°05.00' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 9 p.m. to 11 p.m. on July 4, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 9 p.m. to 11 p.m. on July 5, 2011.

(7) *Town of Nahant Fireworks, Nahant, MA.*

(i) *Location*. All waters of Nahant Harbor within a 350-yard radius of the fireworks launch site on Bailey's Hill Park located at position 42°25.1' N, 070°55.8' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 9 p.m. to 11 p.m. on July 4, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 9 p.m. to 11 p.m. on July 5, 2011.

(8) *City of Salem Fireworks, Salem, MA.*

(i) *Location*. All waters of Salem Harbor, within a 350-yard radius of the fireworks launch site located on Derby Wharf at position 42°31.15' N, 070°53.13' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 9 p.m. to 10 p.m. on July 4, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 9 p.m. to 10 p.m. on July 5, 2011.

(9) *Plymouth 4th of July Celebration Fireworks, Plymouth, MA.*

(i) *Location*. All waters of Plymouth Harbor within a 350-yard radius of the fireworks launch site located at position 42°57.3' N, 070°38.3' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 9 p.m. to 10 p.m. on July 4, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 9 p.m. to 10 p.m. on July 5, 2011.

(10) *Beverly Homecoming Fireworks.*

(i) *Location*. All waters of Beverly Harbor within a 350-yard radius of the fireworks barge located at position 42°32.62' N, 070°52.15' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 9 p.m. to 11 p.m. on August 7, 2011.

(11) *Hingham 4th of July Fireworks.*

(i) *Location*. All waters within a 350-yard radius of the beach on Button Island located at position 42°15.07' N, 070°53.03' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 9:30 p.m. to 10:30 p.m. on July 2, 2011. In the case

this event is rescheduled due to inclement weather, this safety zone will be enforced from 9:30 p.m. to 10:30 p.m. on July 9, 2011.

(12) *Gloucester July 4th Celebration Fireworks.*

(i) *Location*. All waters of Gloucester Harbor, Stage Fort Park, within a 350-yard radius of the fireworks launch site on the beach located at position 42°36.3' N, 070°40.5' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 8 p.m. to 11 p.m. on July 3, 2011.

(13) *Gloucester Schooner Festival Fireworks.*

(i) *Location*. All waters of Gloucester Harbor within a 350-yard radius of the launch site on the beach located at position 42°36.3' N, 070°40.5' W (NAD 83).

(ii) *Enforcement Period*. This safety zone will be enforced from 7 p.m. to 11 p.m. on September 3, 2011. In the case this event is rescheduled due to inclement weather, this safety zone will be enforced from 7 p.m. to 11 p.m. on September 5, 2011.

(b) *Regulations*. (1) In accordance with the general regulations in § 165.23 of this part, entering into, transiting through, mooring or anchoring within these regulated areas is prohibited unless authorized by the Captain of the Port (COTP) Boston, or the designated on-scene representative.

(2) The "on-scene representative" is any Coast Guard commissioned, warrant, or petty officer who has been designated by the COTP Boston to act on his behalf. The on-scene representative will be aboard either a Coast Guard or Coast Guard Auxiliary vessel.

(3) Vessel operators desiring to enter or operate within the regulated areas shall contact the COTP or the designated on-scene representative via VHF channel 16 or 617-223-5750 (Sector Boston command center) to obtain permission to do so.

(4) Vessel operators given permission to enter or operate in the regulated areas must comply with all directions given to them by the Captain of the Port or the designated on-scene representative.

(c) *Effective Period*. 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.

Dated: June 27, 2011.

N.E. Knapp,

Commander, U.S. Coast Guard, Acting Captain of the Port Sector Boston.

[FR Doc. 2011-17393 Filed 7-11-11; 8:45 am]

BILLING CODE 9110-04-P

ENVIRONMENTAL PROTECTION AGENCY

40 CFR Part 180

[EPA-HQ-OPP-2010-0327; FRL-8878-6]

Maneb; Tolerance Actions

AGENCY: Environmental Protection Agency (EPA).

ACTION: Final rule.

SUMMARY: EPA is revoking all the tolerances for the fungicide maneb with expiration/revocation dates that provide sufficient time to use existing stocks of the canceled registrations for the last food uses of maneb in the United States.

DATES: This regulation is effective July 12, 2011. Objections and requests for hearings must be received on or before September 12, 2011 and must be filed in accordance with the instructions provided in 40 CFR part 178 (see also Unit I.C. of the **SUPPLEMENTARY INFORMATION**).

ADDRESSES: EPA has established a docket for this action under docket identification (ID) number EPA-HQ-OPP-2010-0327. All documents in the docket are listed in the docket index available at <http://www.regulations.gov>. Although listed in the index, some information is not publicly available, e.g., Confidential Business Information (CBI) or other information whose disclosure is restricted by statute. Certain other material, such as copyrighted material, is not placed on the Internet and will be publicly available only in hard copy form. Publicly available docket materials are available in the electronic docket at <http://www.regulations.gov>, or, if only available in hard copy, at the OPP Regulatory Public Docket in Rm. S-4400, One Potomac Yard (South Bldg.), 2777 S. Crystal Dr., Arlington, VA. The Docket Facility is open from 8:30 a.m. to 4 p.m., Monday through Friday, excluding legal holidays. The Docket Facility telephone number is (703) 305-5805.

FOR FURTHER INFORMATION CONTACT: Joseph Nevola, Pesticide Re-evaluation Division (7508P), Office of Pesticide Programs, Environmental Protection Agency, 1200 Pennsylvania Ave., NW., Washington, DC 20460-0001; *telephone number:* (703) 308-8037; *e-mail address:* nevola.joseph@epa.gov.

SUPPLEMENTARY INFORMATION:

I. General Information

A. Does this action apply to me?

You may be potentially affected by this action if you are an agricultural