

Street Ter., St. Joseph, MO 64503, filed ANADA 200–463 that provides for the use of Amprolium 9.6% Oral Solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis. IVX Animal Health, Inc.'s Amprolium 9.6% Oral Solution is approved as a generic copy of Huvepharma, AD's AMPROVINE 9.6% Solution, approved under NADA 13–149. The ANADA is approved as of February 12, 2009, and the regulations are amended in 21 CFR 520.100 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(a)(1) 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, revise paragraph (b)(3) to read as follows:

§ 520.100 Amprolium.

* * * * *

(b) * * *

(3) No. 059130 for use of product described in paragraph (a)(1) of this section as in paragraph (d) of this section.

* * * * *

Dated: February 27, 2009.

Bernadette Dunham,

Director, Center for Veterinary Medicine.

[FR Doc. E9–5131 Filed 3–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 529

[Docket No. FDA–2009–N–0665]

Other Dosage Form New Animal Drugs; Sevoflurane

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 supplemental new animal drug application (NADA) filed by Abbott Laboratories, Inc. The supplemental NADA provides for a revised induction dose of sevoflurane inhalant anesthetic in dogs.

DATES: This rule is effective March 11, 2009.

FOR FURTHER INFORMATION CONTACT:

Melanie R. Berson, Center for Veterinary Medicine (HFV–110), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8337, e-mail: melanie.berson@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Abbott Laboratories, North Chicago, IL 60064, has filed a supplement to NADA 141–103 for SEVOFLO (sevoflurane) used for induction and maintenance of general anesthesia in dogs. The supplemental NADA provides for a revised induction dose of sevoflurane. The supplemental NADA is approved as of July 27, 2006, and the regulations are amended in 21 CFR 529.2150 to reflect the approval.

Approval of this supplemental NADA did not require review of additional safety or effectiveness data or information. Therefore, a freedom of information summary is not required.

The agency has determined under 21 CFR 25.33(d)(1) 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 529

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 529 is amended as follows:

PART 529—CERTAIN OTHER DOSAGE FORM NEW ANIMAL DRUGS

■ 1. The authority citation for 21 CFR part 529 continues to read as follows:

Authority: 21 U.S.C. 360b.

§ 529.2150 [Amended]

■ 2. In § 529.2150, in the first sentence in paragraph (c)(1), remove “5 to 7 percent sevoflurane” and in its place add “Up to 7 percent sevoflurane”.

Dated: March 3, 2009.

Steven D. Vaughn,

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

[FR Doc. E9–4879 Filed 3–10–09; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 110

[Docket No. USCG–2008–0155]

RIN 1625–AA01

Anchorage Regulations; Port of New York

AGENCY: Coast Guard, DHS.

ACTION: Final rule.

SUMMARY: This final rule amends the size of Romer Shoal Anchorage Ground in Lower New York Bay. This action is necessary to facilitate safe navigation in the area and to provide safe and secure anchorages for vessels transiting this area. This change to the anchorage is intended to increase the safety of life and property within this area of the Port of New York by providing for greater safety of anchored vessels and to enhance the safe and efficient flow of commercial vessels and commerce.

DATES: This rule is effective April 10, 2009.

ADDRESSES: Comments and material received from the public, as well as documents mentioned in this preamble as being available in the docket, are part of docket USCG–2008–0155 and are available online by going to <http://www.regulations.gov>, selecting the

Advanced Docket Search option on the right side of the screen, inserting USCG–2008–0155 in the Docket ID box, pressing Enter, and then clicking on the item in the Docket ID column. This material is also available for inspection or copying at two locations: 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 and the Waterways Management Division, Coast Guard Sector New York, 212 Coast Guard Drive, room 210, Staten Island, NY 10305, between 8 a.m. and 3 p.m., Monday through Friday, except Federal holidays.

FOR FURTHER INFORMATION CONTACT: If you have questions on this rule, call LT Edward Munoz, Chief, Waterways Management Division, 718–354–2353. If you have questions on viewing the docket, call Renee V. Wright, Program Manager, Docket Operations, telephone 202–366–9826.

SUPPLEMENTARY INFORMATION:

Regulatory Information

On July 16, 2008, we published a notice of proposed rulemaking (NPRM) entitled Anchorage Regulations; Port of New York in the **Federal Register** (73 FR 40800). We received no letters commenting on the proposed rule. No public meeting was requested, and none was held.

Background and Purpose

The Sandy Hook Pilots Association through the New York/New Jersey Harbor Safety Committee requested the Coast Guard reduce the size of federal anchorage ground 27(ii) near Romer Shoal located between Ambrose and Swash Channels. The eastern boundary of anchorage ground 27(ii) is being moved about 2,860 yards to the west (inshore). The revised anchorage ground will be bound by the following points: 40 28°27.21′N, 073 56°45.84′W; thence to 40 29°47.70′N, 073 56°46.23′W; thence to 40 31°25.38′N, 074 00°53.50′W; thence to 40 32°11.38′N, 074 01°39.50′W; thence to 40 32°12.38′N, 074 02°05.50′W; thence to 40 31°27.38′N, 074 02°05.50′W; thence to 40 30°13.38′N, 074 00°05.50′W; thence to the point of origin (NAD 83). These positions are slightly different than those published in the Notice of Proposed Rulemaking. It was determined after publication of the proposed rule that the Anchorage Ground coordinates were never converted from datum NAD 27 to datum

NAD 83. The coordinates in this final rule have been converted to datum NAD 83 to ensure the unchanged portions of the Anchorage Ground boundary remain the same in the regulation and on the navigation charts that are also in datum NAD 83.

Discussion of Comments and Changes

The Coast Guard received no comments on the proposed rulemaking. The following changes were made to the Final Rule.

It was determined after publication of the proposed rule that the Anchorage Ground coordinates were never converted from datum NAD 27 to datum NAD 83. The coordinates in the final rule have been converted to datum NAD 83 to ensure the unchanged portions of the Anchorage Ground boundary remain in the same geographic location and correspond with the coordinates provided in the regulation and on the navigation charts. The revised anchorage ground is bound by the following points: 40 28°27.21′N, 073 56°45.84′W; thence to 40 29°47.70′N, 073 56°46.23′W; thence to 40 31°25.38′N, 074 00°53.50′W; thence to 40 32°11.38′N, 074 01°39.50′W; thence to 40 32°12.38′N, 074 02°05.50′W; thence to 40 31°27.38′N, 074 02°05.50′W; thence to 40 30°13.38′N, 074 00°05.50′W; thence to the point of origin (NAD 83).

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.

Regulatory Planning and Review

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

We expect the economic impact of this rule to be so minimal that a full Regulatory Evaluation is unnecessary. The finding is based on the fact that the anchorage change conforms to the current needs of commercial vessels and is designed to better accommodate the increased commercial traffic within the Port of New York and New Jersey while balancing use of the waterway between commercial and recreational vessels.

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 will not have a significant economic impact on a substantial number of small entities. This rule would affect the following entities, some of which might be small entities: The owners or operators of vessels intending to transit through the charted Pilot Area to anchor in the eastern end of anchorage ground 27(ii). This revised anchorage ground would not have a significant economic impact on a substantial number of small entities for the following reason: These vessels are still able to anchor in the northeastern quadrant of the Precautionary Area as they have been for several years now while awaiting orders, dock space, or inshore anchorage for conducting lightering, bunkering, crew transfer or other necessary vessel operations.

Assistance for Small Entities

Under section 213(a) of the Small Business Regulatory Enforcement Fairness Act of 1996 (Pub. L. 104–121), in the NPRM we offered to assist small entities in understanding the rule so that they could better evaluate its effects on them and participate in the rulemaking process.

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

Taking of Private Property

This rule will not effect 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 5100.1 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 under the Instruction that there are no factors in this case that would limit the use of a categorical exclusion under section 2.B.2 of the Instruction. Therefore, this rule is categorically excluded, under figure 2–1, paragraph (34)(f), of the Instruction, from further environmental documentation. The rule fits this category as it reduces the size of an anchorage ground.

Under figure 2–1, paragraph (34)(f) of the Instruction, an environmental analysis checklist and a categorical exclusion determination are not required for this rule.

List of Subjects in 33 CFR Part 110

Anchorage grounds.

■ For the reasons discussed in the preamble, the Coast Guard amends 33 CFR part 110 as follows:

PART 110—ANCHORAGE REGULATIONS

■ 1. The authority citation for part 110 continues to read as follows:

Authority: 33 U.S.C. 471, 1221 through 1236, 2030, 2035, 2071; 33 CFR 1.05–1; Department of Homeland Security Delegation No. 0170.1.

■ 2. Amend § 110.155, by revising paragraph (f)(2)(ii) to read as follows:

§ 110.155 Port of New York.

* * * * *

(f) * * *

(2) * * *

(ii) Romer Shoal. All waters bound by the following points: 40°28′27.21″N, 073°56′45.84″W; thence to 40°29′47.70″N, 073°56′46.23″W; thence to 40°31′25.38″N, 074°00′53.50″W; thence to 40°32′11.38″N, 074°01′39.50″W; thence to 40°32′12.38″N, 074°02′05.50″W; thence to 40°31′27.38″N, 074°02′05.50″W; thence to 40°30′13.38″N, 074°00′05.50″W; thence to the point of origin (NAD 83).

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Dated: February 23, 2009.

Dale G. Gabel,

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

[FR Doc. E9–5095 Filed 3–10–09; 8:45 am]

BILLING CODE 4910–15–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2009–0100]

Drawbridge Operation Regulation; Gulf Intracoastal Waterway, Belle Chasse, LA

AGENCY: Coast Guard, DHS.

ACTION: Notice of temporary deviation from regulations.

SUMMARY: The Commander, Eighth Coast Guard District, has issued a temporary deviation from the regulation governing the operation of the SR 23 bridge across the Gulf Intracoastal Waterway (Algiers Alternate Route), mile 3.8, at Belle Chasse, Plaquemines Parish, Louisiana. This temporary rule is issued to facilitate movement of vehicular traffic for the 2009 N’Awlins Air Show, to be held at the U.S. Naval