

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.

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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