Sections 12.104 through 12.104i also issued under 19 U.S.C. 2612;

* * * * *

■ 2. In § 12.104g, paragraph (a), the table is amended in the entry for Honduras by removing the reference to ''CBP Dec. 04–08'' in the column headed ''Dec. No.'' and adding in its place the language ''CBP Dec. 04–08 extended by CBP Dec. 09–05''.

W. Ralph Basham,

Commissioner, U.S. Customs and Border Protection.

Approved: March 5, 2009.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. E9–5001 Filed 3–10–09; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Parts 73 and 101

[Docket No. FDA–1998–P–0032] (formerly Docket No. 1998P–0724)

Listing of Color Additives Exempt From Certification; Food, Drug, and Cosmetic Labeling: Cochineal Extract and Carmine Declaration; Confirmation of Effective Date

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; confirmation of effective date.

SUMMARY: The Food and Drug Administration (FDA) is confirming the effective date of January 5, 2011, for the final rule that appeared in the **Federal Register** of January 5, 2009. The final rule amends the regulations for cochineal extract and carmine by requiring their declaration by name on the label of all food and cosmetic products that contain these color additives. This final rule responds to reports of severe allergic reactions, including anaphylaxis, to cochineal extract-containing food and carmine-containing food and cosmetics and will allow consumers who are allergic to these color additives to identify and thus avoid products that contain these color additives. This action also responds to a citizen petition submitted by the Center for Science in the Public Interest.

DATES: The effective date of the final rule published on January 5, 2009 (74 FR 207), amending 21 CFR 73.100, 73.2087, and 101.22, is confirmed: January 5, 2011.

FOR FURTHER INFORMATION CONTACT: James C. Wallwork, Center for Food Safety and Applied Nutrition (HFS–265), Food and Drug Administration, 5100 Paint Branch Pkwy., College Park, MD 20740–3835, 301–436–1303.

SUPPLEMENTARY INFORMATION: In the **Federal Register** of January 5, 2009 (74 FR 207), FDA amended the color additive regulation in 21 CFR 73.100 that permits the use of cochineal extract and carmine in foods by adding new paragraph (d)(2) to require that all foods (including butter, cheese, and ice cream) that contain cochineal extract or carmine specifically declare the presence of the color additive by its respective common or usual name, ''cochineal extract'' or ''carmine,'' in the ingredient statement of the food label. Because § 101.22(k) (21 CFR 101.22(k)) allows any certification-exempt color additive to be declared with a general phrase, such as ''Artificial Color'' or ''Artificial Color Added,'' rather than by its specific common or usual name, FDA amended § 101.22(k) to disallow generic declaration of color additives for which individual declaration is required by applicable regulations in part 73 (21 CFR part 73).

For cosmetic products, FDA amended the color additive regulation in § 73.2087 (21 CFR 73.2087) permitting the use of carmine in cosmetics by revising paragraph (c) to require that cosmetics containing carmine that are not subject to the requirements of § 701.3 (21 CFR 701.3) specifically declare the presence of carmine prominently and conspicuously at least once in the labeling. This amendment covers all cosmetic products, including those cosmetics that are manufactured and sold for use only by professionals (e.g., makeup used in photography studios and by makeup artists for television, movie, and theater actors/actresses, products intended for use only by professionals in beauty salons, and camouflage makeup dispensed by physicians and aestheticians to clients with skin conditions such as scarring) and those cosmetics that are gifts or free samples. FDA also included in § 73.2087, as an example, the following statement: ''Contains carmine as a color additive.''

FDA gave interested persons until February 4, 2009, to file objections or requests for a hearing. The agency received no objections or requests for a hearing on the final rule. Therefore, FDA finds that the effective date of the final rule that published in the **Federal Register** of January 5, 2009, should be confirmed.

List of Subjects

21 CFR Part 73

Color additives, Cosmetics, Drugs, Medical devices.

21 CFR Part 101

Food labeling, Nutrition, Reporting and recordkeeping requirements.

■ Therefore, under the Federal Food, Drug, and Cosmetic Act (15 U.S.C. 1453, 1454, 1455; 21 U.S.C. 321, 331, 341, 342, 343, 348, 351, 352, 355, 361, 362, 371, 379e; 42 U.S.C. 243, 264, 271) and under the authority delegated to the Commissioner of Food and Drugs (1410.10 of the FDA Staff Manual Guide) notice is given that no objections or requests for a hearing were filed in response to the January 5, 2009, final rule. Accordingly, the amendments issued thereby become effective January 5, 2011.

Dated: March 6, 2009.

Jeffrey Shuren,

Associate Commissioner for Policy and Planning.

[FR Doc. E9–5286 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 520

[Docket No. FDA–2009–N–0665]

Oral Dosage Form New Animal Drugs; Amprolium

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending the animal drug regulations to reflect approval of an abbreviated new animal drug application (ANADA) filed by IVX Animal Health, Inc. The ANADA provides for the use of generic amprolium concentrate solution to make medicated drinking water for chickens and turkeys for the treatment of coccidiosis.

DATES: This rule is effective March 11, 2009.

FOR FURTHER INFORMATION CONTACT: John K. Harshman, Center for Veterinary Medicine (HFV–104), Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240–276–8197, e-mail: *john.harshman@fda.hhs.gov*.

SUPPLEMENTARY INFORMATION: IVX Animal Health, Inc., 3915 South 48th

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