

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

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■ 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.*

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## 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]

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## 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](mailto:john.harshman@fda.hhs.gov).

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