

been filed, unless an exclusion is issued in final form by the Commission after notice and comment, materials or products subject to the lead limits under section 101 of the CPSIA are considered to be banned hazardous substances if they do not meet the lead limits as provided under paragraph (a) of this section.

Dated: March 5, 2009.

**Todd A. Stevenson,**

Secretary, Consumer Product Safety Commission.

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## DEPARTMENT OF HOMELAND SECURITY

### Bureau of Customs and Border Protection

## DEPARTMENT OF THE TREASURY

### 19 CFR Part 12

[CBP Dec. 09-05]

RIN 1505-AC11

### Extension of Import Restrictions Imposed on Archaeological Material From Honduras

**AGENCIES:** U.S. Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document amends Customs and Border Protection (CBP) regulations to reflect the extension of import restrictions on certain categories of archaeological material from the Pre-Columbian cultures of the Republic of Honduras (Honduras) that were imposed by CBP Decision (Dec.) 04-08 and expire on March 12, 2009. The Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has determined that conditions continue to warrant the imposition of import restrictions. Accordingly, these import restrictions will remain in effect for an additional 5 years, and the CBP regulations are being amended to reflect this extension until March 12, 2013. These restrictions are being extended pursuant to determinations of the United States Department of State made under the terms of the Convention on Cultural Property Implementation Act in accordance with the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural

Property. CBP Dec. 04-08 contains the Designated List of archaeological material that describes the articles to which the restrictions apply.

**DATES:** *Effective Date:* March 11, 2009.

**FOR FURTHER INFORMATION CONTACT:** For legal aspects, George Frederick McCray, Esq., Chief, Intellectual Property Rights and Restricted Merchandise Branch, Regulations and Rulings, Office of International Trade, (202) 325-0082. For operational aspects, Michael Craig, Chief, Interagency Requirements Branch, Trade Policy and Programs, Office of International Trade, (202) 863-6558.

#### SUPPLEMENTARY INFORMATION:

##### Background

Pursuant to the provisions of the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention, codified into U.S. law as the Convention on Cultural Property Implementation Act (Pub. L. 97-446, 19 U.S.C. 2601 *et seq.*), the United States entered into a bilateral agreement with the Republic of Honduras (Honduras) on March 12, 2004, concerning the imposition of import restrictions on certain categories of archaeological material from Honduras. The archaeological materials subject to the bilateral agreement represent the Pre-Columbian cultures of Honduras and range in date from approximately 1200 B.C. to 1500 A.D. On March 16, 2004, CBP published CBP Decision (Dec.) 04-08 in the **Federal Register** (69 FR 12267), which amended 19 CFR 12.104g(a) to reflect the imposition of these restrictions and included a list designating the types of archaeological material covered by the restrictions.

Import restrictions listed in 19 CFR 12.104g(a) are “effective for no more than five years beginning on the date on which the agreement enters into force with respect to the United States. This period can be extended for additional periods not to exceed five years if it is determined that the factors which justified the initial agreement still pertain and no cause for suspension of the agreement exists” (19 CFR 12.104g(a)).

After reviewing the findings and recommendations of the Cultural Property Advisory Committee, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, concluding that the cultural heritage of Honduras continues to be in jeopardy from pillage of certain archaeological materials, made the necessary determinations to extend the import restrictions for an additional five years on December 4, 2008.

Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions. The Designated List of Pre-Columbian Archaeological Material from Honduras covered by these import restrictions is set forth in CBP Dec. 04-08. The Designated List and accompanying image database may also be accessed from the following Internet Web site address: <http://exchanges.state.gov/heritage/culprop.html>. The restrictions on the importation of these archaeological materials from Honduras are to continue in effect for an additional five years. Importation of such material continues to be restricted unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met.

##### Inapplicability of Notice and Delayed Effective Date

This amendment involves a foreign affairs function of the United States and is, therefore, being made without notice or public procedure (5 U.S.C. 553(a)(1)). For the same reason, a delayed effective date is not required under 5 U.S.C. 553(d)(3).

##### Regulatory Flexibility Act

Because no notice of proposed rulemaking is required, the provisions of the Regulatory Flexibility Act (5 U.S.C. 601 *et seq.*) do not apply.

##### Executive Order 12866

Because this rule involves a foreign affairs function of the United States, it is not subject to Executive Order 12866.

##### Signing Authority

This regulation is being issued in accordance with 19 CFR 0.1(a)(1).

##### List of Subjects in 19 CFR Part 12

Cultural property, Customs duties and inspection, Imports, Prohibited merchandise.

##### Amendment to CBP Regulations

■ For the reasons set forth above, part 12 of Title 19 of the Code of Federal Regulations (19 CFR part 12), is amended as set forth below:

#### PART 12—SPECIAL CLASSES OF MERCHANDISE

■ 1. The general authority citation for part 12 and the specific authority citation for § 12.104g continue to read as follows:

**Authority:** 5 U.S.C. 301; 19 U.S.C. 66, 1202 (General Note 3(i), Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

\* \* \* \* \*

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]

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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