

# Rules and Regulations

Federal Register

Vol. 76, No. 50

Tuesday, March 15, 2011

This section of the FEDERAL REGISTER contains regulatory documents having general applicability and legal effect, most of which are keyed to and codified in the Code of Federal Regulations, which is published under 50 titles pursuant to 44 U.S.C. 1510.

The Code of Federal Regulations is sold by the Superintendent of Documents. Prices of new books are listed in the first FEDERAL REGISTER issue of each week.

## DEPARTMENT OF HOMELAND SECURITY

### U.S. Customs and Border Protection

## DEPARTMENT OF THE TREASURY

### 19 CFR Part 12

[CBP Dec. 11–06]

RIN 1515–AD73

### Extension of Import Restrictions Imposed on Certain Archaeological and Ethnological Materials From Colombia

**AGENCY:** Customs and Border Protection, Department of Homeland Security; Department of the Treasury.

**ACTION:** Final rule.

**SUMMARY:** This document amends the U.S. Customs and Border Protection (CBP) regulations to reflect an extension of import restrictions on certain archaeological and ethnological materials from Colombia. The restrictions, which were originally imposed by CBP Decision (CBP Dec.) 06–09, are due to expire on March 15, 2011. The Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has determined that factors 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 through March 15, 2016. 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 that implemented the 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. 06–09 contains the Designated List of archaeological and ethnological materials of Colombia to which the restrictions apply.

**DATES:** *Effective Date:* March 15, 2011.

**FOR FURTHER INFORMATION CONTACT:** For legal aspects, Charles Steuart, Chief, Intellectual Property Rights and Restricted Merchandise Branch, Regulations and Rulings, Office of International Trade, (202) 325–0020. 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, implemented by 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 Colombia on March 15, 2006, concerning the imposition of import restrictions on certain archeological and ethnological materials from Colombia. On March 17, 2006, CBP published CBP Dec. 06–09 in the **Federal Register** (71 FR 13757), which amended 19 CFR 12.104g(a) to reflect the imposition of these restrictions and included a list designating the types of articles 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)). On July 22, 2010, the Department of State received a request by the Government of Colombia to extend the Agreement. Subsequently, after the Department of State proposed to extend the Agreement and reviewed the findings and recommendations of the Cultural Property Advisory Committee, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, determined that the cultural heritage of Colombia

continues to be in jeopardy from pillage of archaeological and ethnological resources and made the necessary determinations to extend the import restrictions for an additional five years. Diplomatic notes have been exchanged on March 1, 2011, reflecting the extension of those restrictions for an additional five-year period. Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect this extension of the import restrictions.

The Designated List of archaeological and ethnological materials from Colombia covered by these import restrictions is set forth in CBP Dec. 06–09. The Designated List and accompanying image database may also be found at the following Internet Web site address: <http://exchanges.state.gov/heritage/culprop/cofact.html>.

The restrictions on the importation of these archaeological and ethnological materials from Colombia are to continue in effect through March 15, 2016. 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)). In addition, CBP has determined that such notice or public procedure would be impracticable and contrary to the public interest because the action being taken is essential to avoid interruption of the application of the existing import restrictions (5 U.S.C. 553(b)(B)). For the same reasons, 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;

\* \* \* \* \*

**§ 12.104g [Amended]**

■ 2. In § 12.104g, paragraph (a), the table is amended in the entry for Colombia by adding, after the reference to “CBP Dec. 06–09”, the words “extended by CBP Dec. 11–06”.

**Alan Bersin,**

*Commissioner, U.S. Customs and Border Protection.*

Approved: March 9, 2011.

**Timothy E. Skud,**

*Deputy Assistant Secretary of the Treasury.*

[FR Doc. 2011–5879 Filed 3–14–11; 8:45 am]

**BILLING CODE 9111–14–P**

**DEPARTMENT OF HEALTH AND HUMAN SERVICES****Food and Drug Administration****21 CFR Parts 312 and 314**

[Docket No. FDA–2011–N–0130]

**Investigational New Drug Applications and Abbreviated New Drug Applications; Technical Amendment**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Final rule; technical amendment.

**SUMMARY:** The Food and Drug Administration (FDA) is amending its investigational new drug application (IND) regulations and abbreviated new drug application regulations to correct inaccurate cross-references to the IND regulations and the Federal Food, Drug, and Cosmetic Act (the FD&C Act). This

action is being taken to ensure accuracy and clarity in the Agency’s regulations.

**DATES:** This rule is effective March 15, 2011.

**FOR FURTHER INFORMATION CONTACT:**

Olivia A. Pritzlaff, Center for Drug Evaluation and Research, Food and Drug Administration, Bldg. 51, Rm. 6308, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–3506.

**SUPPLEMENTARY INFORMATION:** FDA is amending its regulation in 21 CFR 312.83 to correct an inaccurate cross-reference to other sections of the IND regulations. FDA is amending its regulation in 21 CFR 314.94 to correct an inaccurate cross-reference to a section of the FD&C Act.

Publication of this document constitutes final action on these changes under the Administrative Procedure Act (5 U.S.C. 553). FDA has determined that notice and public comment are unnecessary because this amendment to the regulations provides only technical changes to correct inaccurate cross-references to the IND regulations and the FD&C Act.

**List of Subjects***21 CFR Part 312*

Drugs, Exports, Imports, Investigations, Labeling, Medical research, Reporting and recordkeeping requirements, Safety.

*21 CFR Part 314*

Administrative practice and procedure, Confidential business information, Drugs, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR parts 312 and 314 are amended as follows:

**PART 312—INVESTIGATIONAL NEW DRUG APPLICATION**

■ 1. The authority citation for 21 CFR part 312 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 360bbb, 371; 42 U.S.C. 262.

**§ 312.83 [Amended]**

■ 2. Section 312.83 is amended by removing “312.34 and 312.35” and by adding in its place “312.305 and 312.320”.

**PART 314—APPLICATIONS FOR FDA APPROVAL TO MARKET A NEW DRUG**

■ 3. The authority citation for 21 CFR part 314 continues to read as follows:

**Authority:** 21 U.S.C. 321, 331, 351, 352, 353, 355, 356, 356a, 356b, 356c, 371, 374, 379e.

**§ 314.94 [Amended]**

■ 4. Section 314.94 is amended in paragraph (a)(8)(iv) by removing “505(j)(4)(D)” and by adding in its place “505(j)(5)(F)”.

Dated: March 9, 2011.

**Leslie Kux,**

*Acting Assistant Commissioner for Policy.*

[FR Doc. 2011–5946 Filed 3–14–11; 8:45 am]

**BILLING CODE 4160–01–P**

**DEPARTMENT OF THE TREASURY****Internal Revenue Service****26 CFR Part 301**

[TD 9516]

**RIN 1545–BG73**

**Disclosure of Return Information in Connection With Written Contracts Among the IRS, Whistleblowers, and Legal Representatives of Whistleblowers**

**AGENCY:** Internal Revenue Service (IRS), Treasury.

**ACTION:** Final regulations and removal of temporary regulations.

**SUMMARY:** This document contains final regulations relating to the disclosure of return information by an officer or employee of the Treasury Department, to a whistleblower and, if applicable, the legal representative of the whistleblower, to the extent necessary in connection with a written contract among the IRS, the whistleblower and, if applicable, the legal representative of the whistleblower, for services relating to the detection of violations of the internal revenue laws or related statutes. The final regulations will affect officers and employees of the Treasury Department who disclose return information to whistleblowers or their legal representatives in connection with written contracts among the IRS, whistleblowers and, if applicable, their legal representatives, for services relating to the detection of violations of the internal revenue laws or related statutes. The final regulations will also affect any whistleblower or legal representative of a whistleblower who receives return information in connection with a written contract among the IRS, the whistleblower and, if applicable, the legal representative of the whistleblower, for services relating to the detection of violations of the internal revenue laws or related statutes.