facility, or other appropriate arbitration forum.

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Issued in Washington, DC, on May 30, 2002, by the Commission.

Jean A. Webb,

Secretary of the Commission.

[FR Doc. 02–14027 Filed 6–5–02; 8:45 am]

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DEPARTMENT OF THE TREASURY

Customs Service

19 CFR Part 12

[T.D. 02–30]

RIN 1515–AD12

Extension of Import Restrictions Imposed on Archaeological and Ethnological Materials From Peru

AGENCY: Customs Service, Treasury.

ACTION: Final rule.

SUMMARY: In T.D. 97–50, the Customs Regulations were amended to reflect the imposition of import restrictions on certain archaeological and ethnological materials originating in Peru. These restrictions were imposed pursuant to an agreement between the United States and Peru that was entered into under the authority 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. Recently, the Assistant Secretary for Educational and Cultural Affairs, United States Department of State, determined that conditions continue to warrant the imposition of these import restrictions for a period of five years from June 9, 2002. Thus, this document amends the Customs Regulations to reflect that the import restrictions continue. T.D. 97–50 contains the Designated List of Archaeological and Ethnological Materials that describes the articles to which the restrictions and this extension of restrictions apply.

EFFECTIVE DATE: This regulation becomes effective on June 6, 2002.

FOR FURTHER INFORMATION CONTACT: (Regulatory Aspects) Joseph Howard, Intellectual Property Rights Branch (202) 927–2336; (Operational Aspects) Al Morawski, Trade Operations (202) 927–0402.

SUPPLEMENTARY INFORMATION:

Background

Pursuant to the provisions of the 1970 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 Act), the United States entered into a bilateral agreement with the Republic of Peru on June 9, 1997, concerning the imposition of import restrictions on certain pre-Columbian archaeological materials of Peru dating to the Colonial period and certain Colonial ethnological material from Peru. The U.S. Customs Service issued T.D. 97–50 (62 FR 31713, June 11, 1997) amending § 12.104g(a) of the Customs Regulations (19 CFR 12.104g(a)) to reflect the imposition of these restrictions for a period of five years.

Prior to the issuance of T.D. 97–50, Customs issued T.D. 90–37 (55 FR 19029, May 7, 1990) imposing emergency import restrictions on certain archaeological materials of Peru from the Sipan Archaeological Region forming part of the remains of the Moche culture. Under T.D. 90–37, § 12.104g(b) (19 CFR 12.104g(b)) of the regulations pertaining to emergency restrictions was amended accordingly. This emergency protection was extended in T.D. 94–54 (59 FR 32902, June 27, 1994). Subsequently, the archaeological materials covered by T.D. 90–37 were subsumed in T.D. 97–50 when it was published in 1997, at which time the emergency restrictions of T.D. 90–37 (as extended by T.D. 94–54) were removed from § 12.104g(b).

On March 5, 2002, the Assistant Secretary of Educational and Cultural Affairs, Department of State, after considering the findings and recommendations of the Cultural Property Advisory Committee and concluding that the cultural heritage of Peru continues to be in jeopardy from pillage of the archaeological and ethnological materials subject of the import restrictions of T.D. 97–50, made the necessary determinations to extend the import restrictions for an additional five years (in the Determination to Extend the Memorandum of Understanding Between the United States of America and the Government of Peru Concerning the Imposition of Import Restrictions on Archaeological Material from the Prehispanic Cultures and Certain Ethnological Material from the Colonial Period of Peru, Signed on June 9, 1997). Accordingly, Customs is amending § 12.104g(a) to reflect the extension of the import restrictions.

The Designated List of Archaeological and Ethnological Materials from Peru describing the materials covered by these import restrictions is set forth in T.D. 97–50. The list and accompanying image database may also be found at the following internet Web site address: *http://e.usia.gov/education/culprop.*

It is noted that the materials identified in T.D. 97–50 as ''certain pre-Columbian archaeological materials of Peru dating to the Colonial period and certain Colonial ethnological material from Peru'' are referred to in the Determination to Extend as ''Archaeological Material from the Prehispanic Cultures and Certain Ethnological Material from the Colonial Period of Peru.'' The materials identified in T.D. 97–50 and those identified in the Determination to Extend are one and the same materials.

The restrictions on the importation of these archaeological and ethnological materials from Peru are to continue in effect for five years from June 9, 2002. Importation of these materials continues to be restricted unless the conditions set forth in 19 U.S.C. 2606 and 19 CFR 12.104c are met. For example, these materials may be permitted entry if accompanied by appropriate export certification issued by the Government of Peru, or documentation showing that exportation from Peru occurred on or before June 11, 1997, or, with respect to materials from the Sipan archaeological region, on or before May 7, 1990. *See* 19 U.S.C. 2606(b)(1) and (2)(B); 19 CFR 12.104c(a) and (c).

Inapplicability of Notice and Delayed Effective Date

Because the amendment to the Customs Regulations contained in this document extends import restrictions already imposed on the above-listed cultural property of Peru by the terms of a bilateral agreement entered into in furtherance of a foreign affairs function of the United States, pursuant to the Administrative Procedure Act (5 U.S.C. 553(a)(1)), no notice of proposed rulemaking or public procedure is necessary and a delayed effective date is not required.

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. Accordingly, this final rule is not subject to the regulatory analysis or other requirements of 5 U.S.C 603 and 604.

Executive Order 12866

This amendment does not meet the criteria of a ''significant regulatory action'' as described in Executive Order 12866.

Drafting Information

The principal author of this document was Bill Conrad, Regulations Branch, Office of Regulations and Rulings, U.S. Customs Service.

List of Subjects in 19 CFR Part 12

Customs duties and inspections, Imports, Cultural property.

Amendment to the Regulations

Accordingly, Part 12 of the Customs Regulations (19 CFR part 12) is amended as set forth below:

PART 12—[AMENDED]

1. The general authority and specific authority citations for Part 12, in part, continue to read as follows:

Authority: 5 U.S.C. 301, 19 U.S.C. 66, 1202 (General Note 23, Harmonized Tariff Schedule of the United States (HTSUS)), 1624;

* * * * *

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

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§ 12.104g [Amended]

2. In § 12.104g(a), the list of agreements imposing import restrictions on described articles of cultural property of State Parties is amended in the entry for Peru by adding ''extended by T.D. 02–30'' immediately after ''T.D. 97–50'' in the column headed ''T.D. No.''.

Approved: June 3, 2002

Robert C. Bonner,

Commissioner of Customs.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 02–14219 Filed 6–5–02; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 822

[Docket No. 00N–1367]

Postmarket Surveillance

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is implementing the postmarket surveillance (PS) provisions of the Federal Food, Drug, and Cosmetic Act (the act), as amended by the Food and Drug Administration Modernization Act of 1997 (FDAMA). The purpose of this rule is to provide for the collection of useful data about devices that can reveal unforeseen adverse events or other information necessary to protect the public health.

DATES: This rule is effective July 8, 2002.

FOR FURTHER INFORMATION CONTACT: David L. Daly, Center for Devices and Radiological Health (HFZ–510), Food and Drug Administration, 1350 Piccard Dr., Rockville, MD 20850, 301–594–3060.

SUPPLEMENTARY INFORMATION:

Table of Contents

I. What Is the Background of This Rulemaking?

In the **Federal Register** of August 29, 2000 (65 FR 52376), we (FDA) published a proposed rule implementing the PS provisions in section 522 (21 U.S.C. 360l) of the act, as amended by FDAMA. We provided a period of 90 days for comments from interested parties. We received comments from four entities. We summarize and discuss these comments below, and we have revised the final rule appropriately.

II. What Comments Did FDA Receive on the Proposed Rule? How Did These Comments Affect the Final Rule?

A. Organization and Format

(Comment 1) We received several comments commending the use of plain English, logical formatting, and the question and answer style.

We appreciate the positive comments and will continue to use the plain English concepts.

B. General Comments

(Comment 2) One comment suggested that § 822.1 be revised to include the statutory criteria for imposing PS. This would make the scope of the regulation clearer.

We agree, and have modified § 822.1 accordingly.

(Comment 3) Several comments expressed concern that the proposed rule would impose substantial, unnecessary burdens on device manufacturers, and proposed a number of changes that would reduce the burden. Individual changes are addressed in the appropriate regulation sections. One comment stated that existing systems, such as medical device reports (MDRs), are adequate to provide safety and effectiveness information.

We do not agree. If Congress thought that existing mechanisms were sufficient, it would not have provided for PS. We recognize the potential for PS to be burdensome, but do not agree that any burden imposed by PS would be unnecessary. We intend to impose PS only when necessary to address a postmarket public health question. We also intend to work with the affected manufacturer(s) to identify the least burdensome approach that will adequately address the surveillance question.

(Comment 4) Two comments stated that FDA does not have the authority to require clinical studies, citing the legislative history of FDAMA and the changes in language in the act from ''protocol'' to ''plan'' and ''investigator'' to ''designated person.''

We disagree. As originally enacted in the Safe Medical Devices Act of 1990 (SMDA), PS under section 522 of the act was automatically required for certain devices, and the statutory language allowed little flexibility in designing a PS study. In FDAMA, Congress eliminated this automatic PS, giving FDA discretion to require PS when appropriate, and also gave FDA greater discretion in crafting the form of the surveillance. This broader discretion means that we can accept PS plans that are less rigorous (and less burdensome) than clinical studies, such as literature reviews and analyses of complaint information. The agency expects that it would rarely if ever demand an adequate and well-controlled double-blind clinical trial as the only means of collecting clinical data to satisfy a PS requirement. On the other hand,