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[FR Doc. 04–5902 Filed 3–15–04; 8:45 am]
BILLING CODE 7535–01–P

DEPARTMENT OF HOMELAND SECURITY

Bureau of Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 04–08]

RIN 1505–ABS0

Import Restrictions Imposed on Archaeological Material Originating in Honduras


ACTION: Final rule.

SUMMARY: This document amends the Customs and Border Protection (CBP) Regulations to reflect the imposition of import restrictions on certain archaeological material originating in the Republic of Honduras (Honduras). These restrictions are being imposed pursuant to an agreement between the United States and Honduras that has been entered into under the authority of the Convention on Cultural Property Implementation Act in accordance with 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. The document amends the CBP Regulations by adding Honduras to the list of countries for which an agreement has been entered into for imposing import restrictions. The document also contains the Designated List of Pre-Colombian Archaeological Material from Honduras that describes the types of articles to which the restrictions apply.


SUPPLEMENTARY INFORMATION:

Background

The value of cultural property, whether archaeological or ethnological in nature, is immeasurable. Such items often constitute the very essence of a society and convey important information concerning a people’s origin, history, and traditional setting. The importance and popularity of such items regrettably make them targets of theft, encourage clandestine looting of archaeological sites, and result in their illegal export and import.

The United States shares in the international concern for the need to protect endangered cultural property. The appearance in the United States of stolen or illegally exported artifacts from other countries where there has been pillage has, on occasion, strained our foreign and cultural relations. This situation, combined with the concerns of museum, archaeological, and scholarly communities, was recognized by the President and Congress. It became apparent that it was in the national interest for the United States to join with other countries to control illegal trafficking of such articles in international commerce.

The United States joined international efforts and actively participated in deliberations resulting in the 1970 UNESCO Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property (823 U.N.T.S. 231 (1972)). U.S. acceptance of the 1970 UNESCO Convention was 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”). This was done to promote U.S. leadership in achieving greater international cooperation towards preserving cultural treasures that are of importance to the nations from where they originate and contribute to greater international understanding of mankind’s common heritage.

During the past several years, import restrictions have been imposed on archaeological and ethnological
archaeological materials from Honduras. Importation of these materials, described in the designated list below, are subject to the restrictions of 19 U.S.C. 2606 and §12.104(ga) of the Customs and Border Protection (CBP) Regulations (19 CFR 12.104(ga)) and will be restricted from entry into the United States unless the conditions set forth in 19 U.S.C. 2606 and §12.104c of the regulations (19 CFR 12.104c) are met. CBP is amending §12.104(ga) of the CBP Regulations (19 CFR 12.104(ga)) to indicate that these import restrictions have been imposed.

Material Encompassed in Import Restrictions

The bilateral agreement between Honduras and the United States covers the categories of artifacts described in a Designated List of Pre-Colombian Archaeological Material from Honduras that is set forth below. (Regarding parenthetical references to authors in the list below, see bibliography immediately after the list.)

Designated List of Pre-Colombian Archaeological Material From Honduras

I. Ceramic

Materials made from ceramic (e.g., terracotta/fired clay) include a full range of surface treatments and appendages on various shapes of vessels, lids, figurines, and other ceramic objects (e.g., tools). Decorative techniques used on these materials include, but are not limited to, flattening, dentate-stamping, incised designs, modeled sculpting, polishing/burning, differentially fired areas, and polychrome, bichrome and/or monochrome designs of human and animal figures, mythological scenes and/or geometric motifs. Vessels and figurines may include sculpted and/or applique appendages, such as handles, knobs, faces, fillets, and tripod, quadruped, or ring supports.

Examples include, but are not limited to, polychromes (e.g., Copador, lxcanrio, Gualpopa, Ejar, Cancique and other Copan styles, Ulu-Yojoa (e.g., Red, Maroon, Black, and Tonampua groups), Chichicastenango, Fiopo, Las Flores, Sulaco, Chameleón, Naco, and Bay Island), incised and punctuated designs (e.g., Selin, Gualjiquito, and Escondido groups), Usulutan styles, Mammiform vessels, monochromes (e.g., Cuymal, Limon, Higuerito, Talgua), incense burners (Coner ceramics), Yaba-ding-ding, Playa de los Muertos, Olmec style, and Formative period pottery. Ceramics may also have post-fire pigment and/or stucco.


A. Ceremonial Vessels

1. Cylinders
2. Bowls
3. Dishes and plates
4. Jars

B. Common Vessels

1. Cylindrical vessels
2. Bowls
3. Dishes and plates
4. Jars

C. Special Forms

1. Drums—polychrome painted and plain
2. Figurines—human and animal forms
3. Whistles—human and animal forms
4. Rattles—human and animal forms
5. Miniature vessels
6. Stamps and seals—engraved geometric designs, various sizes and shapes
7. Effigy vessels—in human or animal form
8. Incense burners—elaborate painted, applied and modeled decoration in form of human figures
9. Architectural elements

II. Stone/Stucco (marble, jade, obsidian, flint, alabaster/calcite, limestone, slate, and other, including stucco materials)

The range of stone materials includes, but is not limited to, sculpture, vessels, figurines, masks, jewelry, stelae, tools, and weapons.


A. Figurines—human and animal
B. Masks—incised decoration and inlaid with shell, human and animal faces
C. Jewelry—various shapes and sizes
1. Pendants
2. Ear spools
3. Necklaces
4. Pectoral
D. Stelae, Ritual Objects, Architectural Elements, Petroglyphs—Carved in low relief with scenes of war, ritual,
or political events, portraits of rulers or nobles, often inscribed with glyptic texts. Sometimes covered with stucco and painted. The size of steles and architectural elements, such as lintels, posts, steps, and decorative building blocks, range from .5 meters to 2.5 meters in height; hachas, yokes, and other carved ritual objects are under 1 meter in length or height but vary in size.

E. Tools and Weapons
1. Arrowheads
2. Axes, adzes, celts
3. Blades
4. Chisels
5. Spearpoints
6. Eccentric shapes
7. Grinding stones (manos and metates)
8. Maceheads

F. Vessels and Containers
1. Bowls
2. Plates/Dishes
3. Vases

III. Metal (gold, silver, or other)
These objects are cast or beaten into the desired form, decorated with engraving, inlay, punctured design, or attachments. Often in human or stylized animal forms (for examples, consult: Healy 1984; Stone 1941, 1957, 1972, 1977).

A. Jewelry—various shapes and sizes
1. Necklaces
2. Bracelets
3. Disks
4. Ear spools
5. Pendants
6. Pectorals

B. Figurines
C. Masks
D. Disks
E. Axes
F. Bells

IV. Shell
These objects are worked and unworked and include, but are not limited to, conch, snail, spiny oyster, sting-ray, and sea urchin spines. Shell may be decorated with cinnabar and incised lines, sometimes with inlaid jade (for examples, consult: Baudez 1983; Fash 1991).

A. Figurines—human and animal
B. Jewelry—various shapes and sizes
1. Necklaces
2. Bracelets
3. Disks
4. Ear spools
5. Pendants

C. Natural Forms—often with incised designs, various shapes and sizes

V. Bone
These objects are carved or incised with geometric and animal designs and glyphs (for examples, consult: Baudez 1983; Coggins 1988; Fash 1991).

A. Tools—various sizes
1. Needles
2. Scrapers

B. Jewelry—various shapes and sizes
1. Pendants
2. Beads
3. Ear spools

Bibliography


1991 Cerro Palenque: Power and Identity on the Maya Periphery. University of Texas Press, Austin, TX.

303. British Archaeological Reports, Oxford, UK.
1978 Maya Design Features of Mayoid Vessels of the Ulúa Yojoa Polychromes. MA, thesis, Department of Anthropology, Tulane University, New Orleans, LA.
1957 The Archaeology of Central and Southern Honduras. Papers of the Peabody Museum of Archaeology and Ethnology 29 (3). Harvard University, Cambridge, MA.
1938 Masters in Marble, Middle American Research Series, Pub. 6, Pt. 1. Tulane University, New Orleans, LA.

CBP Decision 03–24: Delegations of Authority
This amendment to the regulations is being issued in accordance with § 0.1(a)(1) of the CBP Regulations (19 CFR 0.1(a)(1)) as a regulation the subject of which the Secretary of the Treasury has retained the sole authority to approve. Accordingly, the document is signed by the Commissioner of Customs and Border Protection as the delegate of the Department of Homeland Security and the Deputy Assistant Secretary of the Treasury as the delegate of the Secretary of the Treasury to indicate approval. (see CBP Dec. 03–24; 68 FR 51686).

Inapplicability of Notice and Delayed Effective Date
Because the amendment to the CBP Regulations contained in this document imposing import restrictions on the above-listed cultural property of Honduras is being made in response to a bilateral agreement entered into in furtherance of the foreign affairs interests of the United States, pursuant to 5 U.S.C. 553(a)(1), no notice of proposed rulemaking or public procedure is necessary. For the same reason, a delayed effective date is not required pursuant to 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.
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 E.O. 12866.

Drafting Information
The principal author of this document was Bill Conrad, Regulations Branch, Office of Regulations and Rulings, U.S. Customs and Border Protection. However, personnel from other offices participated in its development.

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—SPECIAL CLASSES OF MERCHANDISE

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:

* * * *

2. In § 12.104g, paragraph (a), containing the list of agreements imposing import restrictions on described articles of cultural property of State Parties, is amended by adding Honduras to the list in appropriate alphabetical order as follows:

§ 12.104(g) Specific items or categories designated by agreements or emergency actions:
(a) * * *
DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 522

Implantation or Injectable Dosage Form New Animal Drugs; Trenbolone and Estradiol

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 abbreviated new animal drug application (ANADA) filed by Ivy Laboratories, Division of Ivy Animal Health, Inc. The supplemental ANADA provides for the addition of tylosin tartrate to an approved subcutaneous implant containing trenbolone acetate and estradiol used for increased rate of weight gain and improved feed efficiency in feedlot steers.

DATES: This rule is effective March 16, 2004.

FOR FURTHER INFORMATION CONTACT: Eric S. Dubbin, Center for Veterinary Medicine, 7500 Standish Pl., Rockville, MD 20855, 301–827–0232, e-mail: edubbin@cvm.fda.gov.

SUPPLEMENTARY INFORMATION: Ivy Laboratories, Division of Ivy Animal Health, Inc., 8857 Bond St., Overland Park, KS 66214, filed a supplement to ANADA 200–221 for COMPONENT TE–IS (trenbolone acetate and estradiol) with TYLAN, a subcutaneous implant used for increased rate of weight gain and improved feed efficiency in steers fed in confinement for slaughter. The supplemental ANADA provides for the addition of a pellet containing 29 milligrams tylosin tartrate to the approved implant.

The supplemental application is approved as of February 13, 2004, and the regulations are amended in 21 CFR 522.2477 to reflect the approval. The basis of approval is discussed in the freedom of information summary.

In accordance with the freedom of information provisions of 21 CFR part 20 and 514.11(e)(2)(ii), a summary of safety and effectiveness data and information submitted to support approval of this supplemental 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.


The agency 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 522

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 522 is amended as follows:

PART 522—IMPLANTATION OR INJECTABLE DOSAGE FORM NEW ANIMAL DRUGS

1. The authority citation for 21 CFR part 522 continues to read as follows:


2. Section 522.2477 is amended by adding paragraph (d)(1)(i)(F) to read as follows:

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

Robert C. Bonner,
Commissioner, Customs and Border Protection.


Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.

FOR FURTHER INFORMATION CONTACT:

[FR Doc. 04–6017 Filed 3–12–04; 2:31 pm]

BILLING CODE 4620–02–M

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 864

[DOCKET No. 2004P–0044]

Medical Devices; Hematology and Pathology Devices; Classification of the Factor V Leiden DNA Mutation Detection Systems Devices

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Factor V Leiden deoxyribonucleic acid (DNA) mutation detection systems device into class II (special controls). The special control that will apply to the device is the guidance document entitled “Class II Special Controls Guidance Document: Factor V Leiden DNA Mutation Detection Systems.” The agency is taking this action in response to a petition submitted under the Federal Food, Drug, and Cosmetic Act (the act) as amended by the Medical Device Amendments of 1976 (the 1976 amendments), the Safe Medical Devices Act of 1990 (SMDA), the Food and Drug Administration Modernization Act of 1997 (FDAMA), and the Medical Device User Fee and Modernization Act of 2002. The agency is classifying this device into class II (special controls) in