

12 CFR part or section where identified and described	Current OMB control No.
702	3133-0154
703	3133-0133
704	3133-0129
706	3133-0165
707	3133-0134
708a	3133-0153
708b	3133-0024
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711	3133-0152
712	3133-0149
714	3133-0151
716	3133-0163
722	3133-0125
723	3133-0101
740.2	3133-0098
740.3	3133-0149
741	3133-0099
	3133-0142
	3133-0163
748	3133-0033
	3133-0108
749	3133-0032
	3133-0057
	3133-0058
	3133-0059
	3133-0080
760	3133-0143
792	3133-0146

[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-AB50

Import Restrictions Imposed on Archaeological Material Originating in Honduras

AGENCY: Customs and Border Protection, Homeland Security.

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-Columbian Archaeological Material from Honduras that describes the types of articles to which the restrictions apply.

EFFECTIVE DATE: March 16, 2004.

FOR FURTHER INFORMATION CONTACT:

(Legal Aspects) Joseph Howard, Intellectual Property Rights Branch (202) 572-8701; (Operational Aspects) Michael Craig, Trade Compliance and Facilitation (202) 927-0370.

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

artifacts/materials of a number of signatory nations. These restrictions have been imposed as a result of requests for protection received from those nations, as well as pursuant to bilateral agreements between the United States and other countries. More information on import restrictions can be found on the International Cultural Property Protection Web site (<http://exchanges.state.gov/education/culprop>).

Import restrictions are now being imposed on certain archaeological materials from the Republic of Honduras (Honduras).

Determinations

Under 19 U.S.C. 2602(a)(1), the United States must make certain determinations before entering into an agreement to impose import restrictions under 19 U.S.C. 2602(a)(2). On July 28, 2003, the Assistant Secretary of State for Educational and Cultural Affairs made the determinations required under the statute with respect to certain archaeological materials originating in Honduras that are described in the designated list set forth further below in this document, including the following:

(1) That the unique cultural patrimony of Honduras is in jeopardy from the pillage of these archaeological materials; (2) that Honduras has taken measures consistent with the Convention to protect its cultural patrimony; (3) that import restrictions imposed by the United States would be of substantial benefit in deterring a serious situation of pillage and remedies less drastic are not available; and (4) that the application of import restrictions is consistent with the general interests of the international community in the interchange of the designated archaeological materials among nations for scientific, cultural, and educational purposes.

The Agreement

On March 12, 2004, the United States and Honduras entered into a bilateral agreement (the Agreement) pursuant to the provisions of 19 U.S.C. 2602(a)(2) covering certain archaeological materials representing its pre-Colombian cultural heritage. Dating from approximately 1200 B.C. to approximately 1500 A.D., these materials include, but are not limited to, objects of ceramic, metal, stone, shell, and animal bone representing, among others, the Maya, Chorti Maya, Lenca, Jicaque, and Pipil cultures.

Restrictions and Amendment to the Regulations

In accordance with the Agreement, import restrictions are now being imposed on these 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 § 12.104g(a) of the Customs and Border Protection (CBP) Regulations (19 CFR 12.104g(a)) 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 § 12.104g(a) of the CBP Regulations (19 CFR 12.104g(a)) 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, fluting, 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, Ixcario, Gualpapa, Ejar, Cancique and other Copan styles, Ulu-Yojoa (*e.g.*, Red, Maroon, Black, and Tenampua groups), Chichicaste, Fiopo, Las Flores, Sulaco, Chameleon, Naco, and Bay Island), incised and punctuated designs (*e.g.*, Selin, Gualijoquito, and Escondido groups), Usulután 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.

For reference, please consult the following: Chapters in Henderson and

Beaudry-Corbett 1993; Baudez 1983; Baudez and Bequelin 1973; Beaudry 1984; Canby 1949, 1951; Fash 1991; Glass 1966; Gordon 1898; Healy 1984; Henderson 1997; Henderson et al 1979; Hirth, Kennedy, and Cliff 1989; Joyce 1985, 1987, 1991, 1993a, 1993b; Joyce and Henderson 2001; Longyear 1952; Robinson 1978; papers in Robinson 1987; Stone 1957, 1941; Strong 1935; Strong, Kidder, and Paul 1938; Urban and Schortman 1988; Veil 1978, 1983, 1993; Willey 1988; Willey et al. 1994; Wonderley 1987; Yde 1938.

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.

For reference, please consult the following: Baudez 1983, 1994; Digby 1972; Doonan 1996; Garber et al. 1993; Gordon 1898, 1920, 1921; Hirth 1988; Hirth and Hirth 1993; Joyce and Henderson 2001; Henderson 1992, 1997; Luke 2002; Luke et al. 2003; Stone 1938, 1941, 1957, 1972, 1977; Strong, Kidder and Paul 1938.

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 glyphic texts. Sometimes covered with stucco and painted. The size of stelae 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
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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 51868).

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) * * *

State party	Cultural property	Decision No.
Honduras	Archaeological Material of Pre-Colombian cultures ranging approximately from 1200 B.C. to 1500 A.D.	CBP Dec. 04—08.

* * * * *

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

Approved: March 12, 2004.

Timothy E. Skud,
Deputy Assistant Secretary of the Treasury.
[FR Doc. 04-6017 Filed 3-12-04; 2:31 pm]

BILLING CODE 4820-02-M

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 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 (HFV-126), Food and Drug Administration, 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.

Under section 512(c)(2)(F)(iii) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360b(c)(2)(F)(iii)), this supplemental approval qualifies for 3 years of marketing exclusivity beginning February 13, 2004.

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:

Authority: 21 U.S.C. 360b.

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

§ 522.2477 Trenbolone acetate and estradiol.

* * * * *

(d) * * *

(1) * * *

(i) * * *

(F) 80 mg trenbolone acetate and 16 mg estradiol (one implant consisting of 5 pellets, each of 4 pellets containing 20 mg trenbolone acetate and 4 mg estradiol, and 1 pellet containing 29 mg tylosin tartrate) per implant dose.

* * * * *

Dated: March 2, 2004.

Steven D. Vaughn,
Director, Office of New Animal Drug Evaluation, Center for Veterinary Medicine.
[FR Doc. 04-5863 Filed 3-15-04; 8:45 am]

BILLING CODE 4160-01-S

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 detections 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