

materials from Bolivia to which the restrictions apply.

DATES: Effective December 2, 2016.

FOR FURTHER INFORMATION CONTACT: For legal aspects, Lisa L. Burley, Chief, Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325-0215. For operational aspects, William R. Scopa, Branch Chief, Partner Government Agency Branch, Trade Policy and Programs, Office of Trade, (202) 863-6554, *William.R.Scopa@cbp.dhs.gov*.

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 Bolivia¹ on December 4, 2001, concerning the imposition of import restrictions on certain archaeological and ethnological materials from Bolivia. On December 7, 2001, the U.S. Customs Service (U.S. Customs and Border Protection's predecessor agency) published Treasury Decision (T.D.) 01-86 in the **Federal Register** (66 FR 63490), 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 October 11, 2016, 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 Bolivia continues to be in jeopardy from pillage of certain archaeological and ethnological materials, made the necessary determination to extend the import restrictions for an additional five years. Diplomatic notes have been

exchanged reflecting the extension of those restrictions for an additional five-year period. Accordingly, CBP is amending 19 CFR 12.104g(a) to reflect the extension of the import restrictions. The Designated List of Archaeological and Ethnological Material from Bolivia covered by these import restrictions is set forth in T.D. 01-86. The Designated List may also be found at the following Web site address: <https://eca.state.gov/cultural-heritage-center/cultural-property-protection/bilateral-agreements/bolivia>.

The restrictions on the importation of these archaeological and ethnological materials from Bolivia are to continue in effect through December 4, 2021. 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 under 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 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;

* * * * *

§ 12.104g [Amended]

■ 2. In § 12.104g, paragraph (a), the table is amended in the entry for Bolivia by removing the words “CBP Dec. 11-24” in the column headed “Decision No.” and adding in their place the words “CBP Dec. 16-24.”

R. Gil Kerlikowske,

Commissioner, U.S. Customs and Border Protection.

Approved: December 1, 2016.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2016-29279 Filed 12-2-16; 11:15 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 16-23]

RIN 1515-AE19

Import Restrictions Imposed on Certain Archaeological Material From Egypt

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

ACTION: Final rule.

SUMMARY: This final rule amends the U.S. Customs and Border Protection (CBP) regulations to reflect the imposition of import restrictions on certain archaeological material from the Arab Republic of Egypt (Egypt). These restrictions are being imposed pursuant to an agreement between the United States and Egypt that has been 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

¹In 2009, the new constitution of Bolivia changed the country's official name from the “Republic of Bolivia” to the “Plurinational State of Bolivia.”

(UNESCO) Convention on the Means of Prohibiting and Preventing the Illicit Import, Export and Transfer of Ownership of Cultural Property. The final rule amends CBP regulations by adding Egypt to the list of countries for which a bilateral agreement has been entered into for imposing cultural property import restrictions. The final rule also contains the designated list that describes the types of archaeological material to which the restrictions apply.

DATES: Effective December 5, 2016.

FOR FURTHER INFORMATION CONTACT: For legal aspects, Lisa L. Burley, Chief, Cargo Security, Carriers and Restricted Merchandise Branch, Regulations and Rulings, Office of Trade, (202) 325-0030. For operational aspects, William Scopa, Branch Chief, Partner Government Agency Branch, Trade Policy and Programs, Office of Trade, (202) 863-6554, William.R.Scopa@cbp.dhs.gov.

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 makes them targets of theft, encourages clandestine looting of archaeological sites, and results 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 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 (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 our common heritage.

Since the Act entered into force, import restrictions have been imposed on the archaeological and ethnological materials of a number of State Parties to the 1970 UNESCO Convention. These restrictions have been imposed as a result of requests for protection received from those nations. More information on import restrictions can be found on the Cultural Property Protection Web site (<http://eca.state.gov/cultural-heritage-center/cultural-property-protection>).

This rule announces that import restrictions are now being imposed on certain archaeological material from Egypt.

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 November 14, 2014, the Assistant Secretary for Educational and Cultural Affairs, Department of State, made the determinations required under the statute with respect to certain archaeological material originating in Egypt that are described in the designated list set forth below in this document. These determinations include the following: (1) That the cultural patrimony of Egypt is in jeopardy from the pillage of archaeological material representing Egypt's cultural heritage dating from the Predynastic period (5,200 B.C.) through 1517 A.D. (19 U.S.C. 2602(a)(1)(A)); (2) that the Egyptian government has taken measures consistent with the Convention to protect its cultural patrimony (19 U.S.C. 2602(a)(1)(B)); (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 (19 U.S.C. 2602(a)(1)(C)); and (4) that the application of import restrictions as set forth in this final rule is consistent with the general interests of the international community in the interchange of cultural property among nations for scientific, cultural, and educational purposes (19 U.S.C. 2602(a)(1)(D)). The Assistant Secretary also found that the material described in the determinations meets the statutory

definition of "archaeological material of the state party" (19 U.S.C. 2601(2)).

The Agreement

The United States and Egypt entered into a bilateral agreement on November 30, 2016, pursuant to the provisions of 19 U.S.C. 2602(a)(2). The agreement enables the promulgation of import restrictions on categories of archaeological material representing Egypt's cultural heritage dating from the Predynastic period (5,200 B.C.) through 1517 A.D. A list of the categories of archaeological material subject to the import restrictions is set forth later in this document.

Restrictions and Amendment to the Regulations

In accordance with the Agreement, importation of material designated below is subject to the restrictions of 19 U.S.C. 2606 and § 12.104g(a) of the 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 CBP 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.

Designated List of Archaeological Material of Egypt

The bilateral agreement between the United States and Egypt includes, but is not limited to, the categories of objects described in the designated list set forth below. These categories of objects are subject to the import restrictions set forth above, in accordance with the above explained applicable law and the regulation amended in this document (19 CFR 12.104g(a)). The import restrictions include complete examples of objects and fragments thereof.

The archaeological material represent the following periods and cultures dating from 5,200 B.C. through 1517 A.D.: Predynastic, Pharaonic, Greco-Roman, Coptic, and Early Islamic through the Mamluk Dynasty. Many of the ancient place-names associated with the region of Egypt can be found in J. Baines and J. Malek, *Cultural Atlas of Ancient Egypt* (New York, 2000).

I. Stone

A. Sculpture

1. Architectural elements, from temples, tombs, palaces, commemorative monuments, and domestic architecture, including columns, capitals, bases, lintels, jambs, friezes, pilasters, engaged columns, mihrabs (prayer niches), fountains, and blocks from walls, floors, and ceilings.

Often decorated in relief with ornamental Pharaonic, Greco-Roman, and Coptic motifs and inscriptions. The most common architectural stones are limestone, sandstone and granite.

2. Statues, large- and small-scale, including human, animal, and hybrid figures with a human body and animal head. Human figures may be standing, usually with the left foot forward, seated on a block or on the ground, kneeling, or prone. Figures in stone may be supported by a slab of stone at the back. Greco-Roman examples use traditional Egyptian poses with Hellenistic modeling. The most popular stones are limestone, granite, basalt, sandstone, and diorite, and many other types of stone are used as well.

3. Relief sculpture, large- and small-scale, including Predynastic greywacke cosmetic palettes, limestone wall reliefs depicting scenes of daily life and rituals, and steles and plaques in a variety of stones for funerary and commemorative purposes.

4. Greco-Roman and Coptic tombstones.

B. Vessels and Containers

Includes conventional shapes such as bowls, cups, jars, and lamps, and vessels having the form of human, animal, hybrid, plant, hieroglyphic sign, and combinations or parts thereof.

C. Funerary Objects and Equipment

1. Sarcophagi and coffins, with separate lid, either in the form of a large rectangular box, or human-shaped and carved with modeled human features. Both types are often decorated inside and outside with incised images and inscriptions.

2. Canopic shrines, in the form of a box with space inside for four canopic jars.

3. Canopic jars with lids in the form of human or animal heads. A full set includes four jars. Sometimes these jars are dummies, carved from a single piece of stone with no interior space.

D. Objects of Daily Use

Including chests and boxes, headrests, writing and painting equipment, games and game pieces.

E. Tools and Weapons

Chipped stone includes large and small blades, borers, scrapers, sickles, awls, harpoons, cores, loom weights, and arrow heads. Ground stone types include mortars, pestles, millstones, whetstones, choppers, axes, hammers, molds, and mace heads.

F. Jewelry, Amulets, and Seals

1. Jewelry of colored and semi-precious stones for personal adornment,

including necklaces, chokers, pectorals, pendants, crowns, earrings, bracelets, anklets, belts, girdles, aprons, and rings.

2. Amulets of colored and semi-precious stones in the form of humans, animals, hybrids, plants, hieroglyphic signs, and combinations or parts thereof.

3. Stamp and cylinder seals. The most common type is the scarab, in the form of a beetle with an inscription on the flat base.

G. Ostraca

Chips of stone used as surface for writing or drawing.

II. Metal

A. Sculpture

1. Statues, large- and small-scale, including human, animal, and hybrid figures similar to those in stone. Metal statues usually lack the support at the back. The most common material is bronze and copper alloys, and gold and silver are used as well.

2. Relief sculpture, including plaques, appliques, and mummy masks.

B. Vessels and Containers

Includes conventional shapes such as bowls, cups, jars, plates, cauldrons, and lamps, and vessels in the form of humans, animals, hybrids, plants, hieroglyphic signs, and combinations or parts thereof.

C. Objects of Daily Use

Musical instruments, including trumpets, clappers, and sistra.

D. Tools

Including axes, adzes, saws, drills, chisels, knives, hooks, needles, tongs, tweezers, and weights. Usually in bronze and copper alloys, later joined by iron.

E. Weapons and Armor

1. Weapons include mace heads, knives, swords, curved swords, axes, arrows, and spears. Usually in bronze and copper alloys, later joined by iron.

2. Early armor consisted of small metal scales, originally sewn to a backing of cloth or leather, later augmented by helmets, body armor, shields, and horse armor.

F. Jewelry, Amulets, and Seals

1. Jewelry of gold, silver, copper, and iron for personal adornment, including necklaces, pectorals, pendants, crowns, earrings, bracelets, anklets, belts, and rings.

2. Amulets in the form of humans, animals, hybrids, plants, hieroglyphic signs, and combinations or parts thereof.

G. Coptic Liturgical Objects

In metal, including censers, crosses, Bible caskets, and lamps.

H. Coins

In copper or bronze, silver, and gold.

1. General—There are a number of references that list Egyptian coin types. Below are some examples. Most Hellenistic and Ptolemaic coin types are listed in R.S. Poole, *A Catalogue of Greek Coins in the British Museum: Alexandria and the Nomes* (London, 1893); J.N. Svoronos, *Τὰ Νομισματὰ τοῦ Κρατοῦς τῶν Πτολεμαίων* (*Münzen der Ptolemäer*) (Athens 1904); and R.A. Hazzard, *Ptolemaic Coins: An Introduction for Collectors* (Toronto, 1985). Examples of catalogues listing the Roman coinage in Egypt are J.G. Milne, *Catalogue of Alexandrian Coins* (Oxford, 1933); J.W. Curtis, *The Tetradrachms of Roman Egypt* (Chicago, 1969); A. Burnett, M. Amandry, and P.P. Ripollès, *Roman Provincial Coinage I: From the Death of Caesar to the Death of Vitellius (44 BC–AD 69)* (London, 1998—revised edition); and A. Burnett, M. Amandry, and I. Carradice, *Roman Provincial Coinage II: From Vespasian to Domitian (AD 69–96)* (London, 1999). There are also so-called *nwb-nfr* coins, which may date to Dynasty 30. See T. Faucher, W. Fischer-Bossert, and S. Dhennin, “Les Monnaies en or aux types hiéroglyphiques *nwb nfr*,” *Bulletin de l’institut français d’archéologie orientale* 112 (2012), pp. 147–169.

2. Dynasty 30—*Nwb nfr* coins have the hieroglyphs *nwb nfr* on one side and a horse on the other.

3. Hellenistic and Ptolemaic coins—Struck in gold, silver, and bronze at Alexandria and any other mints that operated within the borders of the modern Egyptian state. Gold coins of and in honor of Alexander the Great, struck at Alexandria and Memphis, depict a helmeted bust of Athena on the obverse and a winged Victory on the reverse. Silver coins of Alexander the Great, struck at Alexandria and Memphis, depict a bust of Herakles wearing the lion skin on the obverse, or “heads” side, and a seated statue of Olympian Zeus on the reverse, or “tails” side. Gold coins of the Ptolemies from Egypt will have jugate portraits on both obverse and reverse, a portrait of the king on the obverse and a cornucopia on the reverse, or a jugate portrait of the king and queen on the obverse and cornucopiae on the reverse. Silver coins of the Ptolemies coins from Egypt tend to depict a portrait of Alexander wearing an elephant skin on the obverse and Athena on the reverse or a portrait

of the reigning king with an eagle on the reverse. Some silver coins have jugate portraits of the king and queen on the obverse. Bronze coins of the Ptolemies commonly depict a head of Zeus (bearded) on the obverse and an eagle on the reverse. These iconographical descriptions are non-exclusive and describe only some of the more common examples. There are other types and variants. Approximate date: ca. 332 B.C. through ca. 31 B.C.

4. Roman coins—Struck in silver or bronze at Alexandria and any other mints that operated within the borders of the modern Egyptian state in the territory of the modern state of Egypt until the monetary reforms of Diocletian. The iconography of the coinage in the Roman period varied widely, although a portrait of the reigning emperor is almost always present on the obverse of the coin. Approximate date: ca. 31 B.C. through ca. A.D. 294.

III. Ceramic and Clay

A. Sculpture

Terracotta statues and statuettes, including human, animal, and hybrid figures.

B. Islamic Architectural Decorations

Including carved and molded brick, and tile wall ornaments and panels.

C. Vessels and Containers

1. Predynastic pottery, typically having a burnished red body with or without a white-painted decoration, or a burnished red body and black top, or a burnished black body sometimes with incised decoration, or an unburnished light brown body with dark red painted decoration, including human and animal figures and boats, spirals, or an abstract design.

2. Dynastic period pottery features primarily utilitarian but also ornate forms, typically undecorated, sometimes burnished. New Kingdom examples may have elaborate painted, incised, and molded decoration, especially floral motifs depicted in blue paint.

3. Roman period pottery includes vessels with rilled decoration, pilgrim flasks and terra sigillata, a high quality table ware made of red to reddish brown clay, and covered with a glossy slip.

4. Coptic pilgrim flasks, and decorated ceramic jars and bowls.

5. Islamic glazed, molded, and painted ceramics.

D. Objects of Daily Use

Including game pieces, loom weights, toys, and lamps.

E. Writing

1. Ostraca, pottery shards used as surface for writing or drawing.

2. Cuneiform tablets, typically small pillow-shaped rectangles of unbaked clay incised with patterns of wedge-shaped cuneiform symbols.

IV. Wood

A. Sculpture

1. Statues, large- and small-scale, including human, animal, and hybrid figures. Shabti statuettes, small mummiform human figures, are especially popular. Wood statues usually lack the support at the back.

2. Relief sculpture, large- and small-scale, including relief plaques for funerary purposes.

B. Architectural Elements

1. Coptic carved and inlaid wood panels, doors, ceilings, and altars, often decorated with floral, geometric, and Christian motifs.

2. Islamic carved and inlaid wood rooms, balconies, stages, panels, ceilings, and doors.

C. Funerary Objects and Equipment

1. Sarcophagi and coffins, with separate lid, either in the form of a large rectangular box, or human-shaped and carved with modeled human features. Both types are often decorated inside and outside with painted, inlaid or incised images, and inscriptions.

2. Mummy masks, often painted, inlaid, and covered with gold foil.

3. Funerary models, including boats, buildings, food, and activities from everyday life.

4. Shrines to house sarcophagi or statuettes of deities.

5. Food containers in the shape of the product they contain, such as bread or a duck.

D. Objects of Daily Use

Including furniture such as chairs, stools, beds, chests and boxes, headrests, writing and painting equipment, musical instruments, game boxes and pieces, walking sticks, chariots and chariot fittings.

E. Tools and Weapons

Including adzes, axes, bow drills, carpenter's levels and squares, bows, arrows, spears.

V. Faience and Glass

A. Egyptian Faience

A glossy, silicate-based fired material, is usually blue or turquoise, but other colors are found as well. It was popular for statuettes, including human, animal, and hybrid figures, vessels and

containers, canopic jars, game pieces, seals, amulets, jewelry, and inlays in all types of objects.

B. Glass

1. Pharaonic glass containers are typically small and often elaborately decorated with multi-colored bands.

2. The Roman period introduced a great variety of hand-blown shapes.

3. Islamic vessels and containers in glass, including glass and enamel mosque lamps.

VI. Ivory, Bone, and Shell

A. Sculpture

Statuettes of ivory, including human, animal, and hybrid figures, and parts thereof. Some of the earliest Egyptian sculpture is in ivory.

B. Objects of Daily Use

Ivory, bone, and shell were used either alone or as inlays in luxury objects including furniture, chests and boxes, writing and painting equipment, musical instruments, games, cosmetic containers, combs, jewelry, amulets, and seals.

VII. Plaster and Cartonnage

A. Plaster

Typically molded and then decorated with paint or gilding for mummy masks, jewelry, and other objects in imitation of expensive materials. Also used by itself for life masks and sculptor's models.

B. Cartonnage

Pieces of papyrus or linen covered with plaster and molded into a shape, similar to papier-mâché, and then painted or gilded. Used for coffins and mummy masks. Today, cartonnage objects are sometimes dismantled in hopes of extracting inscribed papyrus fragments.

C. Stucco

Islamic architectural decoration in stucco.

VIII. Textile, Basketry, and Rope

A. Textile

1. Linen cloth was used in Pharaonic and Greco-Roman times for mummy wrapping, shrouds, garments, and sails.

2. Coptic textiles in linen and wool, including garments and hangings.

3. Islamic textile fragments.

B. Basketry

Plant fibers were used to make baskets and containers in a variety of shapes and sizes, as well as sandals and mats.

C. Rope

Rope and string were used for a great variety of purposes, including binding

planks together in shipbuilding, rigging, lifting water for irrigation, fishing nets, measuring, and stringing beads for jewelry and garments.

IX. Leather and Parchment

A. Leather

Used for shields, sandals, clothing, including undergarments, and horse trappings. It was also used occasionally as an alternative to papyrus as a writing surface, a function later assumed by parchment.

B. Parchment

In the Coptic period, documents such as illuminated ritual manuscripts occur in single leaves or bound as a book or “codex” and are written or painted on specially prepared animal skins (cattle, sheep/goat, camel) known as parchment.

X. Papyrus

Scrolls, books, manuscripts, and documents, including religious, ceremonial, literary, and administrative texts. Scripts include hieroglyphic, hieratic, Aramaic, Hebrew, Greek, Latin, Coptic, and Arabic.

XI. Painting and Drawing

A. Tomb Paintings

Paintings on plaster or stone, either flat or carved in relief. Typical subjects include the tomb owner and family, gods, and scenes from daily life.

B. Domestic Wall Painting

These are painted on mud plaster or lime plaster. Types include simple applied color, bands and borders, landscapes, and scenes of people and/or animals in natural or built settings.

C. Rock Art

Chipped and incised drawings on natural rock surfaces, from prehistoric to Pharaonic periods.

D. Ostraca

Paintings and drawings on stone chips and pottery shards.

E. Mummy Portrait Panels and Funerary Masks

In wood, plaster, and cartonnage, often painted with the head and upper body of the deceased.

F. Coptic Painting

1. Wall and ceiling paintings—On various kinds of plaster and which generally portray religious images and scenes of Biblical events. Surrounding paintings may contain animal, floral, or geometric designs, including borders and bands.

2. Panel Paintings (Icons)—Smaller versions of the scenes on wall paintings, and may be partially covered with gold or silver, sometimes encrusted with semi-precious or precious stones and are usually painted on a wooden panel, often for inclusion in a wooden screen (iconostasis). May also be painted on ceramic.

XII. Mosaics

A. Floor Mosaics

Greco-Roman, including landscapes, scenes of humans or gods, and activities such as hunting and fishing. There may also be vegetative, floral, or decorative motifs. They are made from stone cut into small bits (tesserae) and laid into a plaster matrix.

B. Wall and Ceiling Mosaics

Generally portray religious images and scenes of Biblical events. Surrounding panels may contain animal, floral, or geometric designs. Similar technique to floor mosaics, but may include teserae of both stone and glass.

XIII. Writing

On papyrus, wood, ivory, stone, metal, textile, clay, and ceramic, in hieroglyphic, hieratic, Aramaic, Assyrian, Babylonian, Persian, Hebrew, Greek, Latin, Coptic, and Arabic scripts.

XIV. Human and Animal Remains

Human and animal mummies.

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, Reporting and recordkeeping requirements.

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 by adding the Arab Republic of Egypt to the list in appropriate alphabetical order as follows:

§ 12.104g Specific items or categories designated by agreements or emergency actions.

(a) * * *

State party	Cultural property	Decision No.
*	*	*
Egypt	Archaeological material representing Egypt’s cultural heritage from Predynastic period (5,200 B.C.) through 1517 A.D.	CBP Dec. 16–23.
*	*	*

* * * * *

R. Gil Kerlikowske,
Commissioner, U.S. Customs and Border
Protection.

Approved: December 1, 2016.

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

[FR Doc. 2016-29191 Filed 12-5-16; 8:45 am]

BILLING CODE 9111-14-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 882

[Docket No. FDA-2015-N-2737]

Medical Devices; Neurological Devices; Classification of the Computerized Cognitive Assessment Aid for Concussion

AGENCY: Food and Drug Administration,
HHS.

ACTION: Final order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the Computerized Cognitive Assessment Aid for Concussion into class II (special controls). The special controls that will apply to the device are identified in this order and will be part of the codified language for the computerized cognitive assessment aid for concussion's classification. The Agency is classifying the device into class II (special controls) in order to provide a reasonable assurance of safety and effectiveness of the device.

DATES: This order is effective December 6, 2016. The classification was applicable on August 22, 2016.

FOR FURTHER INFORMATION CONTACT: Stacie Gutowski, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 2656, Silver Spring, MD 20993-0002, 240-402-6032, Stacie.Gutowski@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

In accordance with section 513(f)(1) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 360c(f)(1)), devices that were not in commercial distribution before May 28, 1976 (the date of enactment of the Medical Device Amendments of 1976), generally referred to as post-

amendments devices, are classified automatically by statute into class III without any FDA rulemaking process. These devices remain in class III and require premarket approval, unless and until the device is classified or reclassified into class I or II, or FDA issues an order finding the device to be substantially equivalent, in accordance with section 513(i) of the FD&C Act, to a predicate device that does not require premarket approval. The Agency determines whether new devices are substantially equivalent to predicate devices by means of premarket notification procedures in section 510(k) of the FD&C Act (21 U.S.C. 360(k)) and part 807 (21 CFR part 807) of the regulations.

Section 513(f)(2) of the FD&C Act, as amended by section 607 of the Food and Drug Administration Safety and Innovation Act (Pub. L. 112-144), provides two procedures by which a person may request FDA to classify a device under the criteria set forth in section 513(a)(1). Under the first procedure, the person submits a premarket notification under section 510(k) of the FD&C Act for a device that has not previously been classified and, within 30 days of receiving an order classifying the device into class III under section 513(f)(1) of the FD&C Act, the person requests a classification under section 513(f)(2). Under the second procedure, rather than first submitting a premarket notification under section 510(k) of the FD&C Act and then a request for classification under the first procedure, the person determines that there is no legally marketed device upon which to base a determination of substantial equivalence and requests a classification under section 513(f)(2) of the FD&C Act. If the person submits a request to classify the device under this second procedure, FDA may decline to undertake the classification request if FDA identifies a legally marketed device that could provide a reasonable basis for review of substantial equivalence with the device or if FDA determines that the device submitted is not of "low-moderate risk" or that general controls would be inadequate to control the risks and special controls to mitigate the risks cannot be developed.

In response to a request to classify a device under either procedure provided by section 513(f)(2) of the FD&C Act, FDA shall classify the device by written order within 120 days. This

classification will be the initial classification of the device.

On August 11, 2015, ImPACT Applications, Inc., submitted a request for classification of the ImPACT and ImPACT Pediatric under section 513(f)(2) of the FD&C Act.

In accordance with section 513(f)(2) of the FD&C Act, FDA reviewed the request in order to classify the device under the criteria for classification set forth in section 513(a)(1). FDA classifies devices into class II if general controls by themselves are insufficient to provide reasonable assurance of safety and effectiveness, but there is sufficient information to establish special controls to provide reasonable assurance of the safety and effectiveness of the device for its intended use. After review of the information submitted in the request, FDA determined that the device can be classified into class II with the establishment of special controls. FDA believes these special controls, in addition to general controls, will provide reasonable assurance of the safety and effectiveness of the device.

Therefore, on August 22, 2016, FDA issued an order to the requestor classifying the device into class II. FDA is codifying the classification of the device by adding 21 CFR 882.1471.

Following the effective date of this final classification order, any firm submitting a premarket notification (510(k)) for a computerized cognitive assessment aid for concussion will need to comply with the special controls named in this final order. The device is assigned the generic name computerized cognitive assessment aid for concussion, and it is identified as a prescription device that uses an individual's score(s) on a battery of cognitive tasks to provide an indication of the current level of cognitive function in response to concussion. The computerized cognitive assessment aid for concussion is used only as an assessment aid in the management of concussion to determine cognitive function for patients after a potential concussive event where other diagnostic tools are available and does not identify the presence or absence of concussion. It is not intended as a stand-alone diagnostic device.

FDA has identified the following risks to health associated specifically with this type of device, as well as the mitigation measures required to mitigate these risks in table 1.