

Administrative Procedure Act (APA) because this action is administrative in nature. This action postpones the effectiveness of the discharge requirements in the regulations for CBNMS and GFNMS in the areas added to the sanctuaries' boundaries in 2015 (subject to notice and comment review) with regard to USCG activities for six months to provide adequate time for public scoping, completion of an environmental assessment, and subsequent rulemaking, as appropriate. Should NOAA decide to amend the regulations governing discharges in CBNMS and GFNMS, it would publish a proposed rule followed by an appropriate public comment period as required by the APA. The substance of the underlying regulations remains unchanged. Therefore, providing notice and opportunity for public comment under the APA would serve no useful purpose. The delay in effectiveness provided by this action will also enable NOAA to fully implement its statutory responsibilities under the NMSA to protect resources of a national marine sanctuary. For the reasons above, the Assistant Administrator also finds good cause under 5 U.S.C. 553(d) to waive the 30-day delay in effectiveness and make this action effective immediately upon publication.

Authority: 16 U.S.C. 1431 *et seq.*

Dated: May 30, 2017.

W. Russell Callender,

Assistant Administrator for Ocean Services and Coastal Management.

[FR Doc. 2017-11794 Filed 6-6-17; 8:45 am]

BILLING CODE 3510-NK-P

DEPARTMENT OF HOMELAND SECURITY

U.S. Customs and Border Protection

DEPARTMENT OF THE TREASURY

19 CFR Part 12

[CBP Dec. 17-03]

RIN 1515-AE29

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

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 extension of import restrictions on

certain archaeological and ethnological materials from Peru. The restrictions, which were originally imposed by Treasury Decision (T.D.) 97-50 and last extended by CBP Dec. 12-11, are due to expire on June 9, 2017, unless extended. The Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, has determined that conditions continue to warrant the imposition of import restrictions. The Designated List of archaeological and ethnological materials described in T.D. 97-50 is revised in this document to reflect the addition of Colonial period documents and manuscripts. Accordingly, the restrictions will remain in effect for an additional 5 years, and the CBP regulations are being amended to indicate this fourth extension. 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, which implements 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.

DATES: *Effective Date:* June 9, 2017.

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, lisa.burley@cbp.dhs.gov. 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 Convention on Cultural Property Implementation Act (Pub. L. 97-446, 19 U.S.C. 2601 *et seq.*), which implements the 1970 United Nations Educational, Scientific and Cultural Organization (UNESCO) Convention, in U.S. law, the United States entered into a bilateral agreement with the Republic of Peru on June 9, 1997, concerning the imposition of import restrictions on archaeological material from the Pre-Hispanic cultures and certain ethnological material from the Colonial period of Peru (“the Memorandum of Understanding between the United States and the Republic of Peru”). On June 11, 1997, the former United States Customs Service published T.D. 97-50 in the **Federal Register** (62 FR 31713), which amended 19 CFR 12.104g(a) to reflect

the imposition of these restrictions, and included a list designating the types of archaeological and ethnological materials covered by the restrictions. These restrictions continued the protection of archaeological materials from the Sipán Archaeological Region forming part of the remains of the Moche culture that were first subject to emergency import restriction on May 7, 1990 (T.D. 90-37).

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 may be extended for additional periods no more than 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 June 6, 2002, the former United States Customs Service published T.D. 02-30 in the **Federal Register** (67 FR 38877), which amended 19 CFR 12.104g(a) to reflect the extension of these import restrictions for an additional period of five years until June 9, 2007.

On June 6, 2007, U.S. Customs and Border Protection (CBP), published CBP Dec. 07-27 in the **Federal Register** (72 FR 31176), which amended 19 CFR 12.104g(a) to reflect the extension of these import restrictions for an additional period of five years until June 9, 2012.

On June 7, 2012, CBP published CBP Dec. 12-11 in the **Federal Register** (77 FR 33624), which amended 19 CFR 12.104g(a) to reflect the extension of these import restrictions for an additional period of five years until June 9, 2017.

On January 11, 2017, after reviewing the findings and recommendations of the Cultural Property Advisory Committee, the Acting Assistant Secretary for Educational and Cultural Affairs, United States Department of State, concluding that the cultural heritage of Peru continues to be in jeopardy from pillage of archaeological and certain ethnological materials, made the necessary statutory determinations and decided to extend the import restrictions for an additional five-year period. Diplomatic notes have been exchanged reflecting the extension of those restrictions for an additional five-year period and amendment of their coverage to include Colonial manuscripts and documents. CBP is amending 19 CFR 12.104g(a) accordingly.

Amended Designated List

The Designated List of Archaeological and Ethnological Materials from Peru is amended to include Colonial period documents and manuscripts. For the reader's convenience, the Designated List from T.D. 97–50 is reproduced below with the additional category of Colonial manuscripts and documents. Note that the Designated List also subsumes those categories of Moche objects from the Sipán Archaeological Region of Peru for which import restrictions have been in place since 1990 (see T.D. 90–37).

The Designated List includes archaeological materials known to originate in Peru, ranging in date from approximately 12,000 B.C. to A.D. 1532, and including, but not limited to, objects comprised of textiles, metals, ceramics, lithics, perishable remains,

and human remains that represent cultures that include, but are not limited to, the Chavín, Paracas, Vicús, Moche, Virú, Lima, Nazca, Recuay, Tiahuanaco, Huari, Chimú, Chancay, Cuzco, and Inca cultures. The Designated List also includes certain categories of ethnological materials from Peru dating to the Colonial period (A.D. 1532–1821), limited to: (1) Objects directly related to the pre-Columbian past, whose pre-Columbian design and function are maintained with some Colonial characteristics and may include textiles, metal objects, and ceremonial wood, ceramic and stone vessels; (2) objects used for religious evangelism among indigenous peoples and including Colonial paintings and sculpture with distinct indigenous iconography; and (3) Colonial manuscripts and documents. The Designated List may also be found

online at: <https://eca.state.gov/cultural-heritage-center/cultural-property-protection/bilateral-agreements/peru>.

The list is divided into seven categories of objects:

- I. Pre-Columbian Textiles
- II. Pre-Columbian Metals
- III. Pre-Columbian Ceramics
- IV. Pre-Columbian Lithics
- V. Pre-Columbian Perishable Remains
- VI. Pre-Columbian Human Remains
- VII. Ethnological Objects
 - A. Objects Directly Related to the Pre-Columbian Past
 - B. Objects Used for Religious Evangelism Among Indigenous Peoples
 - C. Colonial Manuscripts and Documents.

What follows immediately is a chart of chronological periods and cultural classifications currently widely used for identifying archaeological remains in Peru. All dates are approximate.

	Rowe	Lumbreras
1440–1532 A.D	Late Horizon	Inca Empire.
1100–1440 A.D	Late Intermediate Period	Regional states and kingdoms.
600–1100 A.D	Middle Horizon	Huari Empire.
200 B.C.–600 A.D	Early Intermediate Period	Regional Cultures.
1000–200 B.C	Early Horizon	Middle and Late Formative.
1700–1000 B.C	Initial Period	Early Formative.
2500–1800 B.C	Late Pre-ceramic	Late Archaic.
4500–2500 B.C	Middle Pre-ceramic	Middle Archaic.
6000–4500 B.C	Early Pre-ceramic	Early Archaic.
12000–6000 B.C	Early Pre-ceramic	Hunter-Gatherers.

The following Designated List is representational and may be amended as appropriate.

I. Pre-Columbian Textiles

Textiles representing these principal cultures and main classes of objects:

A. Chimú

Pillow—Piece of cloth sewn into a bag shape and stuffed with cotton or vegetal fibers. Generally the cloth is made in tapestry technique. 60 cm. x 40 cm.

Painted Cloth—Flat cloth of cotton on which designs are painted. Range between 20 cm. and 6.1 m.

Headdress—Headdresses are usually made of feathers, especially white, green, and dark brown, which are attached to cloth and fitted to a cane or basketry frame. Feathers on the upper part are arranged to stand upright.

Feather Cloth—decorated with bird feathers, especially panels and tunics. They vary in shape and size; generally they depict geometric motif and volutes. Vary from 20 cm.–3 m. in length, and may be up to 1.5 m. in width.

Panels—Chimú panels may be of two types: Tapestry weave or plain-weave cotton. Isolated anthropomorphic designs predominate and may be associated with zoomorphic motifs.

Vary from 20 cm. x 20 cm. to 2.0 m. x 1.8 m.

Belts and Sashes—Generally made in tapestry technique, and predominantly of red, white, ocher, and black. As with other Chimú textiles, they generally depict human figures with rayed headdresses. Up to 2.20 m. in length.

B. Chancay

Loom—Looms are commonly found in Chancay culture, sometimes with pieces of the textile still on the loom. Often these pieces of cloth show varied techniques and are referred to as “samples.” 50 cm. x 20 cm.

Loincloth—Triangular panels of cloth with tapestry woven borders.

Dolls—Three dimensional human figures stuffed with vegetal fiber to which hair and other decorations are added. Sometimes they depict lone females; in other cases they are arranged in groups. Most important, the eyes are woven in tapestry technique; in fakes, they have embroidered features. Usually 20 cm. tall and 8 cm. wide.

False Head—In Chancay culture, false heads are made on a cotton or vegetal fiber cushion covered with plain-weave cloth, decorated with shells, beads, metal, wood, or painting to depict facial

features. They sometimes have real hair. Usually 30 cm. x 35 cm.

Unku/Tunic—Varied sizes and styles. Some are in plain weave, others in gauze, still others are in tapestry technique or brocade. They are recognized by their iconography, which includes geometric motifs, birds, fish, plants, and human figures. Miniatures are tiny; regular size examples are about 50 cm. x 50 cm.

Belt—Chancay belts are multicolored, with geometric motifs rendered in tapestry technique. Sometimes the ends are finished in faux-velour technique. 2 m. x 5 cm.

Panels—Chancay panels may be made in tapestry technique or may be painted on plain weave cloth. In these latter cases, the panels may depict fish, parrots, monkeys, viszcachas, felines, foxes, and human figures. Vary in size from miniatures to 4 m. x 2 m.

Standards—Chancay standards are supported on a frame of straight reeds covered with cotton cloth which is painted in anthropomorphic designs in ochers and black. Sometimes they have a handle. 20 cm. x 20 cm.

Gauze—Pieces of cloth made in openwork gauze technique, with very fine cotton threads. May have

embroidered designs in the same thread that depict birds or other flora and fauna. Usually 80 cm. x 80 cm.; some are smaller.

C. Nazca

Three-Dimensional Cloth—Cloth made in three dimensions, using needles. Of many and bright colors, knitted in long strips. Each figure is approx. 5 cm. long x 2 cm. wide.

Unku/Tunic—These include miniature and regular-sized tunics. They are generally of one color, mostly light brown. The neck edges, hem, and fringes have multicolored geometric designs. Fringes end in woven braids. Vary in size from miniatures up to approx. 1.5 m. x .8 m.

Bags—There are bags of many sizes, from miniatures to large ones, generally with a narrow opening and a wide pouch. Some are decorated with fringe. Their iconography resembles the unku (tunic), stylized designs in yellow, red, and dark and light blue.

Sash—Nazca sashes are made on special looms. Their ends are decorated with plied fringe.

Tie-Dye (Painted) Cloth—Most common are those made in the tie-dye technique, in which the textile is knotted and tied before it is dyed, so that when it is untied, there are negative images of diamonds, squares, and concentric dots. Most common are orange, red, blue, green, and yellow colors. Vary from approx. 20 cm. x 20 cm. to 2.0 m. x 1.8 m.

Patchwork Cloth—Variant of the Tie-Dye cloth, in which little panels are made and later sewn together so that the resulting textile includes rectangles of tie-dyed panels of different colors. The cloth may have a decorative fringe. Vary from 20 cm. x 20 cm. to 2.0 m. x 1.8 m.

Wara/Loincloth—Generally made of a flat piece of cloth with colorful borders depicting stylized geometric motifs. They terminate in fringe. 50 cm. x 30 cm.

Fans—The frame is of vegetal fiber provided with twisted cord into which feathers are inserted. Commonly two colors of feathers are attached in this way, such as orange and green, or yellow and blue. 30 cm. x 20 cm.

D. Huari

Panel—Characterized by a complex and abstract iconography. Made in tapestry technique with a range of colors, including browns, beiges, yellows, reds, oranges, and greens. Vary from 20 cm. x 20 cm. to 2.0 m. x 1.8 m.

Unku/tunic—Large with an abstract and geometric iconography. Commonly the designs repeat in vertical bands. Generally these tunics have a cotton

warp and camelid fiber weft. Some are so finely woven that there are 100 threads per cm². Vary in size from miniatures up to 1.5 m. x 80 cm.

Caps—Most common are the so-called “four-corner hats” made in a faux-velour technique that results in a velvety texture. On the base cloth, small tufts of brightly-colored wool are inserted.

Vincha/headband or sashes—These garments are made in tapestry weave or faux-velour technique and depict geometric motifs.

Bags—Bags have an opening which is somewhat narrower than the body, with designs depicting felines, camelids, human faces, and faces with animal attributes.

E. Paracas

Esclavina/Small shoulder poncho—Paracas esclavinas are unique for their decoration with brightly colored images in Paracas style such as birds, flowers, animals, and human figures. Vary in size from miniatures up to 60 cm. x 30 cm.

Mantle—Paracas mantles can be divided into five types, based on their decoration. All are approximately 2.5 m. x 1.6 m.

- a. Mantles with a plain field and woven borders;
- b. Mantles with decorative (embroidered) borders and plain field;
- c. Mantles with decorative (embroidered) borders and a decorative stripe in the center field;
- d. Mantles with embroidered borders and center field embroidered in checkerboard-fashion;
- e. Mantles with embroidered borders and alternating diagonals of embroidered figures in the center field.

Gauzes—Paracas gauzes are made of one color, such as lilac, yellow, red, or grey. They are generally rectangular and have a soft and delicate texture. Approx. 1 m. x 1 m.

Panels—Paracas panels are generally of cloth and may have been used for utilitarian purposes. They are generally undecorated. Vary from 20 cm. x 20 cm. to 2 m. x 1.8 m.

Skirts—Paracas skirts are of two types: Some are plain, made of cotton with decoration reserved for the ends; there are others that are elaborately embroidered with colorful images rendered in wool. These often form sets with mantles and other garments. Skirts are rectangular and very wide, with two fringed ties. 3 m. long and 70 cm. wide.

Wara/Loincloth—Made of cotton, not as large as skirts, and may have embroidered edges.

Slings—Paracas slings are decorated in Cavernas style, made of vegetal fiber,

and are of small size, generally 1.5 m. x 5 cm.

Furs—There are numerous examples of animal skins reported from Paracas contexts, including the skins of the fox, vizcacha, guinea pig. Most are poorly preserved.

F. Moche

Bags—Moche bags are usually square, small, and have a short handle. They are made in tapestry technique with brightly-woven designs. Principal colors used are white, black, red, light blue, and ocher.

Panels—Recognizable by their iconography, these tapestry-technique panels may show people on balsareed rafts surrounded by a retinue. They are rendered in a geometric fashion, and are outlined in black and shown in profile. Scenes of marine life and fauna predominate. Vary from 20 cm. x 20 cm. to 2 m. x 1.8 m.

Ornamental canes—Small canes are “woven” together in a twill technique using colorful threads that depict anthropomorphic designs. Approx. 10 cm. x 10 cm.

G. Lambayeque

Panels—Lambayeque panels are small, made in tapestry technique, of cotton and wool. Vary from 20 cm. x 20 cm. to 2 m. x 1.8 m.

H. Inca

Sling—There are two types of Inca slings. Ceremonial ones are oversize and elaborately decorated with geometric motifs, with long fringes. The other type is smaller and utilitarian, almost always with decoration only on the pouch and far ends. The decoration is geometric and the slings have fringed ends.

Unku/tunic—Inca tunics are well-made and colorful, mostly in red, olive green, black, and yellow. Decorative elements may be arrayed checkerboard fashion and are found on the upper and lower part of the garment. Vary in size from miniatures up to approx. 1.5 m. x 80 cm.

Bags—Recognized by their bright colors, they have an opening that is narrower than the body and a wide pouch with long fringe and handle. Vary in size from miniatures up to 30 cm. x 20 cm.

Panels—Some are made in cotton using the double-cloth technique, based on light brown and beige. Lines of geometrically-rendered llamas predominate. Vary in size from 20 cm. x 20 cm. to 2 m. x 1.8 m.

Mantles—Inca mantles are of standard dimensions, sometime more than a meter long, generally rectangular. They are multi-colored and made of cotton

warp and wool weft. Most common colors are dark red, olive green, white, and black. Generally 2.5 m. x 1.6 m.

Kipu/quipu—Inca quipus (knotted string mnemonic devices) are made of cotton and wool cords, sometimes with the two fibers plied together. Rarely is their original color preserved, though sometime one sees light blues and browns. Some are wrapped with colorful threads on the ends of the cords. 80 cm. x 50 cm.

II. Pre-Columbian Metal Objects

A. Idols

Anthropomorphic or zoomorphic figures, some of which are hollow and others which are solid. They may be of gold and silver, they may be gilded, or of copper, or bronze. Sizes vary from 2 cm.—20 cm. in height.

B. Small Plaques

Thin sheets of gold, silver, copper, or gilded copper, used to cover the body and made in pieces. They have repoussé or punched designs on the edge and middle of the sheet. Average .6 cm in height.

C. Axes

Almost always T-shaped and solid. There are also axes in a traditional axe head shape. May be of bronze or copper.

D. Mace Heads

These come in a great variety of shapes, including star-shaped, flat, or of two or three levels. They may be made of copper or bronze. Most have a central hole through which a wooden handle was affixed.

E. Musical Instruments

Trumpets: Wind instrument with a tubular body and flaring end, fastened at the joint. May be of copper or bronze.

Bells: Of varying shapes and materials (including gold, silver, copper, and silver-plated copper).

Conos: Instrument shaped from a sheet of hammered metal, with or without a clapper. Can be of copper or silver. Up to .5 m. in height.

Rattles: Musical instrument with a central hold to accommodate a handle. May be of copper or bronze. Vary from 6 cm.—25 cm. in height.

Jingle Bells: Spherical bells with an opening on the lower part and a handle on the upper part so they can be suspended from a sash or other garment. They contain a small stone or a little ball of metal. The handles may be decorated. Jingle bells may decorate another object, such as rhythm sticks, and may be of gold, silver, or bronze. Used in all pre-Columbian cultures of Peru.

Chalchachas: Instruments shaped like a bivalve with repoussé decoration. Made of copper.

Quenas (flutes): Tubular instruments, generally of silver, with perforations to vary the tone.

F. Knives

Knives vary depending on their provenance. They can have little or no decoration and can be of different metals or made of two metals. The best known are the *tumis* from the Sicán culture, which have a straight or trapezoidal handle and a half-moon blade. The solid handle may have carved or stamped designs. Generally made of gold, silver, or copper. In ceremonial examples, the blade and upper part may depict an anthropomorphic figure standing or seated, or simply a face or mask with an elaborate headdress, ear spools, and inset semi-precious stones. *Tumi* handles can be triangular, rectangular, or trapezoidal, and blades can be ovaloid or shaped like a half-moon.

G. Pins

With a straight shaft and pointed end, pins can be flat or cylindrical in cross-section. Most are hammered, and some are hollow. They can be of gold, silver, copper, bronze, gold-plated silver or may be made of two metals. Some pins are zoomorphic; others have floral images, and still others depict fish. Some have a round head; others have a flat, circular head; still others have the shape of a half-moon. There are hollow-headed rattle pins; others have solid anthropomorphic images. Most are up to 50 cm. in length, with heads that are up to 10 cm. in diameter. The small pins are about 5 cm. in length.

H. Vessels

There are a variety of metal vessels; they may be made of gold, silver, gilded silver, gilded copper, silver-covered copper, and bronze. There are miniatures, as well as full-size vessels. Such vessels are known from all cultures. Forms include beakers, bowls, open plates, globular vessels, and stirrup-spout bottles. The exact form and surface decoration varies from culture to culture. Shapes include beakers, bowls, and plates. Average .5 m.—.3 m. in height.

I. [Reserved]

J. Masks

May be made of gold, silver, gilded silver, copper, gilded copper, silver-covered copper, or may be made of two metals. They vary greatly in shape and design. The best known examples come from the following cultures: Moche,

Sicán, Chimú, Huari, Inca, Nazca, and Chíncha. The northern coast examples often have insets of shell, precious or semi-precious stones, and may have plant resins to depict the eyes and teeth. Almost all examples that have not been cleaned have a surface coloring of red cinnabar. Examples from Sicán measure up to 49 cm. in width by 29 cm. in height. Miniature examples can measure 7 cm. x 5 cm. Miniature masks are also used as decorations on other objects. Copper examples generally show heavy oxidation.

K. Crowns

Thin or thick sheets of metal made to encircle the head. They may be of silver, gold, copper, gilded silver, silver-covered copper, or may be made of two metals. Some examples have a curved central part, and may be decorated with pieces of metal and real or artificial feathers that are attached with small clamps. Found in all cultures.

L. Penachos (Stylized Metal Feathers)

Stylized metal feathers used to decorate crowns. May be made of gold, silver, copper, or silver-covered copper.

M. Tocados (Headdresses)

Headdress ornaments which may be simple or complex. They may be made of one part, or may include many pieces. Found in all cultures. They may take the form of crowns, diadems, or small crowns. They may have two stylized feathers to decorate the crown and to hold it to the hair (especially the Chimú examples). Paracas examples generally have rayed appendages, with pierced disks suspended from the ends of the rays.

N. Turbans

Long pieces of cloth that are wrapped around the head. Metal ornaments may be sewn on turbans. Found in all cultures; the metal decorations and the cloth vary from culture to culture.

O. Spoons

Utilitarian object of gold, silver, or copper.

P. Lime Spatulas

Miniature spatula: A straight handle has a slightly spoon-shaped end. The handle may have an anthropomorphic figure. Made of gold, silver, or copper.

Q. Ear Spools

Ear spools are generally made of a large cylinder which fits through the earlobe and an even larger disk or decorative sheet on one side. The disk may be decorated with repoussé, stamped, or engraved designs, or may

have inset stone or shell. May be made of gold, silver, copper, or made of two metals. Ear spools are found in all cultures. The largest measure up to 15 cm. height; typical diameter: 5 cm.–14 cm.

R. Nose Ornaments

Of varied shapes, nose ornaments can be as simple as a straight tube or as complex as a flat sheet with repoussé design. In the upper part, there are two points to attach the ornament to the septum. They may be of gold, silver, or copper or may be made of two metals.

S. Earrings

Decoration to be suspended from the earlobes.

T. Rings

Simple bands with or without designs. Some are two bands united by filigree spirals. Some have inset stones. May be of silver, gold, copper, or alloys.

U. Bracelets

Bracelets are made of sheets of metal with a straight or slightly trapezoidal shape, with stamped or repoussé designs. Some are simple, narrow bands. Found in all cultures and with varied designs. May be of gold, silver, bronze, or alloys of copper. Generally 4 cm.–14 cm. in width.

V. Necklaces

Necklaces are made of beads and/or small carved beads. May be of shell, bone, stone, gold, silver, copper, or bronze. The beads are of varied shapes. All beads have two lateral perforations to hold the cord.

W. Tweezers

Made in one piece, with two identical ends and a flexed central handle. They are of varied shapes, including triangular, trapezoidal, and ovaloid. The middle of the handle may have a hole so the tweezers can be suspended from a cord.

X. Feather Carrier

Conical objects with a pointed, hollow end, into which feathers, llama skin, or monkey tails are inserted and held in place with tar. They may be made of gold, silver, or gilded or silver-plated copper.

III. Pre-Columbian Ceramics

A. Chavín

Date: 1200–200 B.C.

Characteristics

Decoration: A grey-black color. Incised, modeled, and high and low-relief are combined to work out designs

in grays and browns. The surface may also juxtapose polishing and matte finish in different design zones.

Forms: Bottles, plates, and bowls.

Size: 5 cm.–30 cm.

Identifying: Characteristic traits of Cupisnique and Chavín ceramics include: Globular body with a flat base and stirrup spout; thick neck with an obvious and everted lip. Chavín style also includes long-necked bottles, bowls with flaring walls, and highly-polished relief-decorated surfaces.

Styles: Chavín influence is seen in Cupisnique, Chongoyape, Poemape, Tembladera, Patapo, and Chilete.

B. Vicús

Date: 900 B.C.–A.D. 500.

Characteristics

Decoration: Geometric designs in white on red, made using negative technique. There are also monochrome examples.

Forms: Anthropomorphic, zoomorphic and plant-shaped vessels. Some have a double body linked by a tube or common opening.

Size: 30 cm.–40 cm. tall.

C. Virú or Gallinazo

Characteristics

Decoration: Negative technique over orange background.

Forms: Faced anthropomorphic and zoomorphic vessels, face bottles for daily use in dwellings, “cancheros” (type of pot without a neck and with a horn-shaped handle).

Size: Up to 15 cm. high.

Identifying: The surface is basically orange; the vessels have a truncated spout, an arched bridge (like a tube) as handle, and geometric symbols in negative technique (concentric circles, frets and wavy lines). When the vessels represent a face, the eyes are like “coffee beans,” applied on the surface and with a transverse cut.

D. Pucara

Date: 300 B.C.–300 A.D.

Characteristics

Decoration: Slip-painted and incised. Modeled elements include stylized felines and camelids, along with an anthropomorphic image characteristically depicted with a staff in each hand. Vessels are typically decorated in yellows, black, and white on the red background of the vessel. Designs are characteristically outlined by incision. There may be modeled decoration, such as feline heads, attached to the vessels.

Shapes: Tall bowls with annular ring bases predominate, along with vessels that depict anthropomorphic images.

Size: Bowls are up to 20 cm. in diameter and 20 cm. in height.

E. Paracas

Date: Developed around 200 B.C.

Characteristics

Vessels are typically incised, with post-fired resin painting on a black background.

Size: 10 cm.–15 cm. high.

F. Nazca

Date: A.D. 100–600.

Characteristics

Color: Typically very colorful, with a range of slips including cream, black, red, violet, orange, gray, all in a range of tones.

Slip: Background slip is generally cream or orange.

Shapes: Cups, bowls, beakers, plates, double-spout-and-bridge bottles, anthropomorphic figures, and musical instruments.

Decoration: Realistic drawings of fantastic creatures, including the “Flying God.” In late Nazca, bottles are broader and flatter and the designs are arrayed in broad bands. Typically have decorations of trophy heads, geometric motifs, and painted female faces.

Size: 5 cm.–20 cm.

G. Recuay

Date: A.D. 100–700.

Characteristics

Slip: Both positive and negative slip-painting is found, generally in colors of black, cream and red.

Shapes: Sculptural, especially ceremonial jars known as “Paccha” which have an elaborate outlet to serve a liquid.

Decoration: Usually show groups of religious or mythical personages.

Size: 20 cm.—35 cm. in height.

H. Pashash

Date: A.D. 1–600.

Characteristics

Decoration: Positive decoration in black, red, and orange on a creamy-white background. Some show negative painting.

Shapes: Anthropomorphic vessels, bottles in the form of snakes, bowls with annular base, and large vessels with lids.

Size: The anthropomorphic vessels are up to 20 cm. in height, serpent bottles are around 25 cm. wide x 10 cm. tall, and lidded vessels are more than 30 cm. in height.

Motifs: The decorations are rendered in positive or negative painting in zones that depict profile-face images of zoomorphic figures, serpents, or worms, seen from above and with trapezoidal heads.

I. Cajamarca

Date: A.D. 500–900.

Characteristics

Decoration: Pre-fired slip painting with geometric designs, including stepped triangles, circles, lines, dots, and rows of volutes. They may include stylized birds, felines, camelids, batrachians, and serpents. Spiral figures may include a step-fret motif in the base of the bowls.

Shapes: Pedestal base bowls, tripod bowls, bottles with annular ring base, goblets, spoons with modeled handles, bowls with carinated edges.

J. Moche

Date: A.D. 200–700.

Characteristics

Forms: Stirrup-spout vessels, vessels in the shape of humans, animals, or plants.

Colors: Generally red and white.

Manufacture: Often mold-made.

Size: 15 cm.–25 cm. in height.

Decoration: Wide range of images showing scenes of real life or mythical scenes depicting gods, warriors, and other images.

K. Tiahuanaco

Date: A.D. 200–700.

Characteristics

Decoration: Pre-fired slip painting on a highly polished surface. Background is generally a red-orange, with depictions of human, animal, and geometric images, generally outlined in black and white lines.

Shapes: Plates, cups, jars, beakers, open-backed incense burners on a flat base.

L. Lima

Date: A.D. 200–700.

Characteristics

Decoration: Pre-fired slip painting with interlocking fish and snake designs, geometric motifs, including zig-zags, lines, circles, and dots.

Shapes: Breast-shaped bottles, cups, plates, bowls, and cook pots.

Styles: Related to Playa Grande, Nievera, and Pachacamac styles.

M. Huari

Date: A.D. 500–1000.

Characteristics

Colors: Orange, cream, violet, white, black, and red.

Motifs: Anthropomorphic, zoomorphic, and plant shapes, both stylized and realistic. In Pachacamac style one finds vessels with a globular body and long, conical neck. In Atarco style, there is slip painting that retains Nazca motifs, especially in the full-body felines shown running.

Slip: Background slip is commonly cream, red, or black.

Styles: Related to Vinaque, Atarco, Pachacamac, Qosqopa, Robles Moqo, Conchopata, and Caquipampa styles.

Size: Most are around 25 cm. tall. Robles Moqo urns may be up to 1 m. in height.

N. Santa

Date: Derived from Huari style, around A.D. 800.

Characteristics

Decoration: Slip painted with figures and designs in black and white on a red background. There are also face-neck jars.

Shapes: Effigy vessels, face-neck jars, double-body vessels.

Sizes: 12 cm.–20 cm. tall.

Shapes: Jars have a globular body and face on the neck. The border may have black and white checkerboard. The body sometimes takes the shape of a stylized llama head. Common are white lines dotted with black. Double-body vessels generally have an anthropomorphic image on the front vessel, and a plain back vessel.

O. Chancay

Date: A.D. 1000–1300.

Characteristics

Treatment: Rubbed surface.

Slip: White or cream with black or dark brown designs.

Molds: Molds are commonly used, especially for the anthropomorphic figures called “cuchimilcos,” which represent naked male and female figures with short arms stretched to the sides.

Size: 3 cm.–1 m.

P. Ica-Chincha

Date: Began to be developed in A.D. 1200.

Characteristics

Decoration: Polychrome painting in black and white on red.

Designs: Geometric motifs combined with fish and birds.

Shapes: Bottles with globular bodies and tall necks and with flaring rims. Cups and pots.

Size: 5 cm.–30 cm. high.

Q. Chimú

Date: A.D. 900–1500.

Characteristics

Slip: Monochrome. Usually black or red.

Shapes: Varied shapes. Commonly made in molds. They may represent fish, birds, animals, fruit, people, and architectural forms. One sees globular bodies with a stirrup spout and a small bird or monkey at the base of the neck.

Size: Between 30 cm.–40 cm. in height.

R. Lambayeque

Date: A.D. 700–1100.

Characteristics

Color: Generally black; a few are cream with red decoration.

Shapes: Double spout and bridge vessels on a pedestal base are common. At the base of the spout one sees modeled heads and the bridge also often has modeled heads.

Size: 15 cm.–25 cm. in height.

S. Inca

Date: A.D. 1300–1500.

Characteristics

Decoration: Slip painted in black, red, white, yellow, and orange.

Designs: Geometric designs (rhomboids and triangles) and stylized bees, butterflies, and animals.

Sizes: 1 cm. to 1.5 m. in height.

IV. Pre-Columbian Lithics

A. Chipped Stone: Projectile Points

Paiján Type Points

Size: 8 cm.–18 cm.

Shape: Triangular or heart-shaped.

Color: Generally reddish, orange, or yellow. Can be made of quartz.

Leaf-Shaped Points

Size: 2.5 cm.–15 cm.

Shape: Leaf-shaped. Can be ovaloid or lanceolate.

Color: Generally bright reds, yellows, ochers, quartz crystals, milky whites, greens and blacks.

Paracas Type Points

Size: .3 cm.–25 cm.

Shape: Triangular and lanceolate. Show marks of pressure-flaking. Often they are broken.

Color: Generally black.

Chivateros-Type Blanks

Size: .8 cm.–18 cm.

Shape: Concave indentations on the surface from working.

Color: Greens, reds, and yellows.

B. Polished Stone

Bowl—Vessels of dark colored-stone, sometimes streaked. They have a highly polished, very smooth surface. Some show external carved decoration. Diameters range from 12 cm–55 cm.

Cups—Also vessels of dark-colored stone. Generally have flaring sides. Typical of the Late Horizon. They are highly polished and may have external carved designs or may be in the shape of heads. 18 cm.–28 cm. in height.

Conopas—Small vessels in the form of camelids with a hollow opening on the back. They are black to greenish-black and highly polished. .8 cm.–16 cm. in length.

Idols—Small anthropomorphic figurines, frequently found in Middle Horizon contexts. The almond-shaped eyes with tear-bands are characteristic of the style. Larger examples tend to be of lighter-colored stone while the smaller ones are of dark stones. 12 cm.–28 cm. in height.

Mace head—Varying shapes, most commonly are doughnut-shaped or star-shaped heads, generally associated with Late Intermediate Period and Inca cultures. Commonly black, gray, or white, .8 cm.–20 cm. in diameter.

Metal-working hammer—Elongated shapes, frequently with one flat surface; highly polished. Generally of dark-colored stone, 3 cm.–12 cm.

C. Carved Material

Tenon head—These heads have an anthropomorphic face, prominent lips, and enormous noses. Some, especially those carved of diorite, have snake-like traits. The carved surface is highly polished.

Tablets—with high-relief design. The upper surface has a patina. They range from 20 cm. to more than 1 m. in length.

V. Pre-Columbian Perishable Remains

A. Wood

Keros (Beakers)—The most common form is a bell-shaped beaker with a flat base, though some have a pedestal like a goblet. Decoration varies with the period:

Pre-Inca: Very rare, they have straight sides and incised or high-relief decoration. Some have inset shells.

Inca: Generally they are incised with geometric designs on the entire exterior.

Colonial Inca: Lacquer painted on the exterior to depict scenes of daily life, nature, and war.

Staffs—Objects of ritual or ceremonial use made of a single piece of wood. They can be distinguished on the basis of two or three of the following traits:

On the lower third, the staff may have a metal decoration.

The body itself is cylindrical and of variable length.

The upper third may have decorations, including inset shell, stone, or metal. Some staffs function as rattles, and in these cases, the rattle is in the upper part.

Carvings—Worked blocks of wood, such as wooden columns (orcones) to support the roofs of houses: Chinchá, Chimú, and Chancay cultures. Individuals may be depicted standing or seated on a pedestal. In the upper part there is a notch to support the beams, which generally has a face, sometimes painted, at the base of the notch. Their length varies, but they are generally at least a meter or more.

Box—Small lidded boxes, carved of two pieces of wood. Generally the outer surface of box and lid are carved in relief. Chimú-Inca cultures. They measure approximately 20 cm. x 10 cm.

Mirror—Wooden supports for a reflective surface of polished anthracite or pyrite. In some cases the upper part of backs of mirrors are worked in relief or have inset of shell. Moche culture.

Paddle and rudder—Large carvings made of a single piece of wood. Paddles have three parts: The blade and the handle (sometimes decorated), and an upper decorated part, which can have metal plaques or decorative painting. Rudders have two parts: The blade and a handle which may be carved in relief. Chinchá culture. Paddles can be 2.30 m. in length and rudders are up to 1.4 m.

Utensils—Bowls and spoons made of wood decorated with zoomorphic or anthropomorphic motifs.

Musical instruments—Trumpets and whistles. Trumpets can be up to 1.2 m. long and are generally decorated on the upper third of the instrument. Whistles vary a great deal from the undecorated to those decorated with human forms. Moche, Huari, and Inca cultures.

B. Bone

Worked bone—Most interesting are Chavín pieces with incised decorations. The bones are generally the long bones of mammals. They vary from 10 cm.–25 cm. in length.

Balance weights—Flat rectangles of bone about 10 cm. in length. Chinchá culture.

Musical instruments—Quenas (flutes) and antaras (panpipes) in various shapes. Paracas, Chinchá, and Ancon cultures.

C. Gourds

Vessels—Bowls, pots, and holders for lime (for coca chewing). Most interesting are those which are carved or pyroengraved. Produced from the Pre-ceramic onward.

Musical instruments—Ocarinas, small flutes, and whistles. Inca examples may have incised decoration, or decoration with cords and feathers.

D. Cane

Musical instruments—Flutes (especially in Chancay culture), panpipes, and whistles. Flutes are often pyroengraved. Panpipes can have one or two tiers of pipes, which may be lashed together with colored thread. Nazca culture.

E. Straw

Weaving baskets—Basketry over a cane armature, in the shape of a lidded box. Sometimes the basketry is made of several colors of fiber to work out geometric designs. Some still hold their original contents: Needles, spindle whorls, spindles, balls of thread, loose thread, etc. Chancay culture.

F. Shell

Musical instruments—Marine shells (*Strombus galeatus*, *Malea ringens*, etc.), some, especially those from the Formative Period, with incised decoration.

Jewelry—Small beads and charms worked of shell, chiefly *Spondylus princeps*, used mainly in necklaces and pectorals. Moche, Chimú, and Inca cultures.

VI. Pre-Columbian Human Remains

The human remains included in this listing demonstrate modifications of the remains due to ritualistic practices or other intentional treatment of the deceased.

A. Mummies

Peruvian mummies were formed by natural mummification due to the conditions of burial; they have generally not been eviscerated. Usually found in flexed position, with extremities tied together, resulting in a fetal position. In many cases the cords used to tie the body in this position are preserved.

B. Deformed Skulls

Many ancient Peruvian cultures practiced cranial deformation. Such skulls are easily recognized by their unnatural shapes.

C. Skulls Displaying Trepanation

Trepanation is an operation performed on a skull; the resulting cuts, easily visible on a bare skull, take various forms. Cuts may be less easily distinguished if skin and hair are present:

Principal Techniques

a. Straight cuts: These cuts are pointed at the ends and wider in the

center. Openings made this way have a polygonal shape.

b. Cylindrical-conical openings: The openings form a discontinuous line. The resulting opening has a serrated edge.

c. Circular: Generally made by a file. The resulting hole is round or elliptical, with beveled or straight edges. This is the most common form of trepanation.

D. Pre-Columbian Trophy Heads

Trophy heads can be identified by the hole made in the forehead to accommodate a carrying cord. When the skin is intact, the eyes and the mouth are held shut with cactus thorns. Finally, the occiput is missing since that is how the brain was removed when the trophy head was prepared.

E. Shrunken Trophy Heads From the Amazon

These heads have had the bones removed and then have been cured to shrink them. They are recognizable because they conserve all the traits of the original skin, including hair and hair follicles. The mouth is sewn shut and generally there are carrying cords attached. There may be an obvious seam to repair the cuts made when the skin was removed from the skull. Finally, the skin is thick (up to 2.5 mm.) and has a dark color. Trophy heads vary between 9.5 cm. and 15.5 cm. in height.

F. Tattoos

Tattooing in pre-Columbian Peru was practiced mainly on the wrists. Most common are geometric designs, including bands of triangles and rhomboids of a bluish color.

G. False Shrunken Heads

False shrunken heads can be recognized because they are made of the skin of a mammal, with some of the fur left where the human hair would be. The skin is first smoked, then pressed into a mold to give it a face-like shape. The eyes, nose, mouth and ears are simple bumps without real holes. Further, the skin is very thin and yellowish in color. Often the "heads" have eyebrows and moustaches formed by leaving some of the animal hair, but these features are grotesque because they appear to grow upside down.

VII. Ethnological Objects

A. *Objects directly related to the pre-Columbian past, whose pre-Columbian design and function are maintained with some Colonial modifications or additions in technique and/or iconography.*

Colonial Indigenous Textiles

Predominant materials: Cotton and wool.

Description: These textiles are characterized by the cut of the cloth, with the four borders or selvages finished on the same loom. Clothes are untailed and made from smaller pieces of convenient sizes which were then sewn together. Colonial indigenous textiles of the period are differentiated by their decoration: Western motifs such as lions, heraldic emblems, and Spanish personages are incorporated into the designs; sometimes fibers distinct from cotton or wool (threads of silver, gold, and silk) are woven into the cloth; and the colors tend to be more vivid because the fabrics were made more recently. Another important characteristic of the clothing is the presence of tocapus or horizontal bands of small squares with anthropomorphic, zoomorphic, phytomorphic and geometric ideographs and designs. Characteristic textiles include:

Panels: Rectangular or square pieces of various sizes.

Anacus: Untailored woman's dress consisting of two or three long horizontal pieces of cloth sewn together that was wound around the body and held in place with "tupus" (pins).

Unku/Tunic: Man's shirt with an opening for the head. Sometimes has sleeves.

Lliclla/Shoulder Mantle: Rectangular piece of cloth that women put over their shoulders and held in place by a tupu; standard size: 40" x 45". Generally has a tripartite design based on contrasting panels that alternate bands with decoration and bands with solid colors.

Chumpi/Belt: A woven belt, generally using tapestry technique.

Tupus

Material: Silver, gilded silver, copper, bronze. May have inlays of precious or semi-precious stones.

Description: Tupus were used to hold in place llicllas and ancus. They are pins with a round or elliptical head, with piercing, repoussé, and incised decorations. The difference between pre-Columbian and ethnological tupus can be seen in the introduction of Western designs, for example bi-frontal eagles and heraldic motifs.

Keros

Material: Wood.

Description: The most common form is a beaker like cup with truncated base. After the Conquest, keros started to be decorated with pictorial scenes. The most frequently used techniques include incision, inlaying pigments in wood, and painting. Ideography includes geometric designs, figures under a rainbow (an Inca symbol),

ceremonial rituals, scenes of war, and agricultural scenes. Sometimes are in the form of human or zoomorphic heads.

Cochas or Cocchas

Material: Ceramic.

Description: Ceremonial vessels with two or more concentric interior compartments which are linked. Often decorated with volutes representing reptiles.

Aribalos

Material: Ceramic.

Description: The post-Conquest aribalos have a flat base, often using a glaze for finishing, and the decoration includes Inca and Hispanic motifs.

Pacchas

Material: Stone, ceramic.

Description: One of the characteristics of pacchas is that they have a drain which is used to sprinkle an offering on the ground. They have pictorial or sculpted relief decorations symbolizing the benefits hoped for from the ritual.

B. *Objects that were used for religious evangelism among indigenous peoples.*

In Colonial paintings and sculptures Western religious themes were reinterpreted by indigenous and mestizo artists who added their own images and other characteristics to create a distinct iconography.

Specific types of objects used for religious evangelism during the Colonial period include the following:

Sculpture

Types of statues include:

A three-dimensional sculpted image: In the Peruvian Colonial period these were made of maguey (a soft wood) and occasionally of cedar or walnut.

Images made of a dough composed of sawdust, glue and plaster: After they are sculpted, figures are dressed with cloth dipped in plaster.

Images to be dressed: These are wooden frames resembling mannequins, with only the head and arms sculpted in wood (cedar or maguey). The images are dressed with embroidered clothes and jewelry. Frequently other elements were added, such as teeth and false eyelashes, wigs of real hair, eyes of colored glass, and palates made of glass.

Paintings

Catholic priests provided indigenous and mestizo artists with canvases and reproductions of Western works of art, which the artists then "interpreted" with their own images and other indigenous characteristics. These may include symbolically associating Christian religious figures with

indigenous divinities, or rendering the figures with Andean facial characteristics or in traditional Andean costume. In addition, each church, convent, monastery, and town venerated an effigy of its patron or tutelary saint, some of them native to Peru.

Retables

Retables (*retablos*) are architectonic structures made of stone, wood, or other material that are placed behind the altar and include attached paintings, sculptures or other religious objects.

Liturgical Objects

Objects Used for Mass Ritual:

Chalices, cibaries, candelabras, vials for christening or consecrated oil, reliquaries, vessels for wine and water, incense burners, patens, monstrances, pelicans and crucifixes. Made out of silver, gold or gilded silver, often inlaid with pearls or precious stones. Techniques: Casting, engraving, piercing, repoussé, filigree.

Fixtures for sculpted images: Areoles, crowns, scepters, halo, halos in the form of rays, and books carried by religious scholars and founders of religious orders.

Ecclesiastical vestments: Some ecclesiastical vestments were commissioned by indigenous individuals or communities for the celebrations of their patron saint and thus are part of the religious legacy of a particular town. In such cases, the vestment has the name of the donor and of the town or church as well as the date.

Votive Offerings: These are representations of miracles or favors received from a particular saint. They can be made of different materials, usually metal or wood, and come in a variety of forms according to the type of favor received, usually representing parts of the human body in reference to the organ healed or agricultural products in recognition of a good harvest or increase in a herd.

C. Colonial Manuscripts and Documents

Predominant materials: Paper, parchment, vellum

Description: Original handwritten texts or printed texts of limited circulation dating to the Colonial period (AD 1532–1821). These include but are not limited to notary documents (wills, bill of sales, contracts), ecclesiastical materials, and documents of the city councils, Governorate of New Castile, the Governorate of New Toledo, the Vice Royalty of Peru, the Real Audiencia and Chancery of Lima, or the Council of the Indies. These can include books, single folios, or collections of

related documents bound with string. Documents may contain a seal or ink stamp denoting a public or ecclesiastical institution. Because many of these documents are of institutional or official nature, they may have multiple signatures, denoting scribes, witnesses, and other authorities. Documents are generally written in Spanish, but may be composed in an indigenous language such as Quechua or Aymara.

The restrictions on the importation of these archaeological and ethnological materials from Peru are to continue in effect through June 9, 2022. 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)). For the same reasons, pursuant to 5 U.S.C. 553(d)(3), 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.

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

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;

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§ 12.104g [Amended]

■ 2. In § 12.104g(a), the table of the list of agreements imposing import restrictions on described articles of cultural property of State Parties is amended in the entry for Peru by removing the words “T.D. 97–50 extended by CBP Dec. 12–11” and adding in their place “CBP Dec. 17–03” in the column headed “Decision No.”.

Kevin K. McAleenan,

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

Approved: June 2, 2017.

Timothy E. Skud,

Deputy Assistant Secretary of the Treasury.

[FR Doc. 2017–11841 Filed 6–6–17; 8:45 am]

BILLING CODE 9111–14–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 814

[Docket No. FDA–2017–N–0011]

Humanitarian Use Devices; 21st Century Cures Act; Technical Amendment

AGENCY: Food and Drug Administration, HHS.

ACTION: Final rule; technical amendment.

SUMMARY: The Food and Drug Administration (FDA) is amending regulations to reflect changes recently enacted into law by the 21st Century Cures Act. Specifically, certain requirements related to humanitarian device exemptions (HDEs) and institutional review boards (IRBs) for devices have changed. This action is being taken to align the regulations with the Federal Food, Drug, and Cosmetic Act (the FD&C Act) as amended.

DATES: This rule is effective June 7, 2017.

FOR FURTHER INFORMATION CONTACT: Ian Ostermiller, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5515, Silver Spring, MD 20993–0002, 301 796–5678.

SUPPLEMENTARY INFORMATION: On December 13, 2016, the 21st Century Cures Act (Pub. L. 114–255) was signed into law, amending certain provisions of the FD&C Act. FDA is updating regulations to reflect some of those