

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 tutelar 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]

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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

changes that are now in effect. Specifically, section 3052 of the 21st Century Cures Act amended section 520(m) of the FD&C Act to allow for HDE approval for devices that, among other things, treat or diagnose a disease or condition that affects “not more than 8,000” individuals in the United States; this threshold had been “fewer than 4,000” individuals in the United States (amending 21 U.S.C. 360j(m), *passim*). This final rule amends part 814 (21 CFR part 814) in several places to accurately reflect the threshold recently enacted into law.

In addition, section 3056 of the 21st Century Cures Act amended section 520 of the FD&C Act to remove the requirement for institutional review committees, *i.e.*, IRBs, for devices to be “local”, (amending 21 U.S.C. 360j, *passim*). This final rule amends 21 CFR 814.124(a), “IRB approval”, to remove the term “local” and related language in order to accurately reflect the requirements recently enacted into law.

FDA finds good cause for issuing this amendment as a final rule without notice and comment because this amendment only updates the implementing regulation to restate the statute in light of amendments recently enacted into law (see 5 U.S.C. 553(b)(B), relating to notice and comment procedures): “[W]hen regulations merely restate the statute they implement, notice-and-comment procedures are unnecessary”. *Gray Panthers Advocacy Committee v. Sullivan*, 936 F.2d 1284, 1291 (D.C. Cir. 1991); see also *Komjathy v. Nat. Trans. Safety Bd.*, 832 F.2d 1294, 1296 (D.C. Cir. 1987) (when a rule “does no more than repeat, virtually verbatim, the statutory grant of authority”, notice-and-comment procedures are not required). Therefore, we are issuing these amendments as a final rule, and publication of this document constitutes final action on this change under the Administrative Procedure Act (APA) (5 U.S.C. 553).

In addition, FDA finds good cause for these amendments to become effective on the date of publication of this action. The APA allows an effective date less than 30 days after publication as “provided by the agency for good cause found and published with the rule” (5 U.S.C. 553(d)(3)). A delayed effective date is unnecessary in this case because the new requirements are already effective as a matter of law. Furthermore, this rule does not establish additional regulatory obligations or impose additional burden on regulated entities. As a result, affected parties do not need time to prepare before the rule takes effect. Therefore, FDA finds good

cause for these amendments to become effective on the date of publication of this action.

List of Subjects in 21 CFR Part 814

Administrative practice and procedure, Confidential business information, Medical devices, Medical research, Reporting and recordkeeping requirements.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 814 is amended as follows:

PART 814—PREMARKET APPROVAL OF MEDICAL DEVICES

1. The authority citation for part 814 continues to read as follows:

Authority: 21 U.S.C. 351, 352, 353, 360, 360c–360j, 371, 372, 373, 374, 375, 379, 379e, 381.

§ 814.3 [Amended]

■ 2. Amend § 814.3(n) by removing the words “fewer than 4,000” and adding in their place the words “not more than 8,000”.

§ 814.100 [Amended]

■ 3. Amend § 814.100(b) introductory text by removing the words “fewer than 4,000” and adding in their place the words “not more than 8,000”.

§ 814.102 [Amended]

- 4. Amend § 814.102 as follows:
- a. In paragraph (a)(5), remove the words “fewer than 4,000” in both occurrences and add in their places the words “not more than 8,000” for both occurrences;
 - b. In paragraph (b)(3)(i), remove the words “fewer than 4,000” and add in their place the words “not more than 8,000”; and
 - c. In paragraph (b)(3)(ii), remove the words “4,000 or more” and add in their place the words “more than 8,000”.
- 5. In § 814.124, revise paragraph (a) to read as follows:

§ 814.124 Institutional Review Board requirements.

(a) *IRB approval.* The HDE holder is responsible for ensuring that a HUD approved under this subpart is administered only in facilities having oversight by an Institutional Review Board (IRB) constituted and acting pursuant to part 56 of this chapter, including continuing review of use of the device. In addition, a HUD may be administered only if such use has been approved by an IRB. If, however, a physician in an emergency situation determines that approval from an IRB

cannot be obtained in time to prevent serious harm or death to a patient, a HUD may be administered without prior approval by an IRB. In such an emergency situation, the physician shall, within 5 days after the use of the device, provide written notification to the chairman of the IRB of such use. Such written notification shall include the identification of the patient involved, the date on which the device was used, and the reason for the use.

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§ 814.126 [Amended]

■ 6. Amend § 814.126(b)(1)(iii) by removing the number “4,000” and adding in its place the number “8,000”.

Dated: June 1, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–11816 Filed 6–6–17; 8:45 am]

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DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–413]

Schedules of Controlled Substances: Placement of Acetyl Fentanyl Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.
ACTION: Final order.

SUMMARY: With the issuance of this final order, the Administrator of the Drug Enforcement Administration will maintain the placement of the substance acetyl fentanyl (*N*-(1-phenethylpiperidin-4-yl)-*N*-phenylacetamide), including its isomers, esters, ethers, salts, and salts of isomers, esters and ethers, in schedule I of the Controlled Substances Act. This scheduling action is pursuant to the Controlled Substances Act and is required in order for the United States to discharge its obligations under the Single Convention on Narcotic Drugs, 1961. This action continues to impose the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances on persons who handle (manufacture, distribute, import, export, engage in research or conduct instructional activities with, or possess), or propose to handle, acetyl fentanyl.

DATES: Effective June 7, 2017.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control