that include subcutaneous ports must include the following:

(A) Labeling must include the recommended type of needle for access as well as detailed instructions for care and maintenance of the port, subcutaneous pocket, and skin overlying the port.

(B) Performance testing must include results on repeated use of the ports that simulates use over the intended life of the device.

(C) Clinical performance testing must demonstrate safe and effective use and capture any adverse events observed during clinical use.

(vii) In addition to Special Controls in paragraphs (b)(1)(i) through (v) of this section, implanted blood access devices with coatings or additives must include the following:

(A) A description and material characterization of the coating or additive material, the purpose of the coating or additive, duration of effectiveness, and how and where the coating is applied.

(B) An identification in the labeling of any coatings or additives and a summary of the results of performance testing for any coating or material with special characteristics, such as decreased thrombus formation or antimicrobial properties.

(C) A Warning Statement in the labeling for potential allergic reactions including anaphylaxis if the coating or additive contains known allergens.

(D) Performance data must demonstrate efficacy of the coating or additive and the duration of effectiveness.

(viii) The following must be included for A–V shunt cannulae (with vessel tips):

(A) The device must comply with Special Controls in paragraphs (b)(1)(i) through (v) of this section with the exception of paragraphs (b)(1)(ii)(B), (b)(1)(ii)(C), (b)(1)(v)(B), and (b)(1)(v)(C), which do not apply.

(B) Labeling must include Warning Statements to address the potential for vascular access steal syndrome, arterial stenosis, arterial thrombosis, and hemorrhage including exsanguination given that the device accesses the arterial circulation.

(C) Clinical performance testing must demonstrate safe and effective use and capture any adverse events observed during clinical use.

(2) Class II (performance standards) for the nonimplanted blood access device.

(3) Class II (performance standards) for accessories for both the implanted and the nonimplanted blood access devices not listed in paragraph (b)(4) of this section.

(4) Class I for the cannula clamp, disconnect forceps, crimp plier, tube plier, crimp ring, and joint ring, accessories for both the implanted and nonimplanted blood access device. The devices subject to this paragraph (b)(4) are exempt from the premarket notification procedures in subpart E of part 807 of this chapter subject to the limitations in § 876.9.

Dated: July 18, 2014.

Leslie Kux,

Assistant Commissioner for Policy.

[FR Doc. 2014–17477 Filed 7–24–14; 8:45 am]

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DEPARTMENT OF STATE

22 CFR Part 13

[Public Notice: 8808]

RIN 1400–AD61

Personnel; Changes in Statutory Authority; Technical Corrections; Liability for Neglect of Duty or for Malfeasance Generally; Repeal of Regulation

AGENCY: Department of State.

ACTION: Final rule.

SUMMARY: The Department of State is repealing the regulation that provides for personal liability for Consular Officers in cases of malfeasance, and provides updates to citations of authorities. The deleted regulation, which was promulgated in 1957 and last amended in 1984, is no longer authorized by statute.

DATES: This rule is effective July 25, 2014.

FOR FURTHER INFORMATION CONTACT: Daniel Klimow, Office of Legal Affairs, Overseas Citizen Services, U.S. Department of State, 2201 C Street NW., SA–17, Washington, DC 20520, (202) 485–6224, *klimowda1@state.gov.*

SUPPLEMENTARY INFORMATION: This rule removes 22 CFR 13.3 from the Code of Federal Regulations. 22 CFR 13.3 provides that consular officers who willfully neglect or fail to perform any duty imposed on them by law shall be found liable to all persons injured by any such neglect, or omission, malfeasance, abuse, or corrupt conduct. 22 CFR 13.3 also provides for criminal penalties for consular officers found guilty for malfeasance and corrupt conduct in office. The Department is removing 22 CFR 13.3 because the rule's authorizing statute has been repealed.

22 CFR 13.3 implemented *22 U.S.C. 1199,* which explicitly provided for civil and criminal liability against consular officers for willful neglect or omission in the performance of their assigned duties. Section 1199 was repealed in 1977, and the legislative history for the repeal of Section 1199 reflected a desire by Congress to treat consular officers the same as other federal employees with respect to personal liability for acts taken within the scope of their official duties. Foreign Relations Authorization Act, Fiscal Year 1978, Public Law 95–105, title I, section 111, 91 Stat. 848 (1977); H.R. Rep. No. 95–231, at 17, 21 (1977); H.R. Rep. No. 95–537 at 33 (1977) (Conf. Rep.).

22 CFR 13.3 was also promulgated under the authority of 22 U.S.C. 2658 and *22 U.S.C. 3926.* However, 22 U.S.C. 2658 was repealed in 1994. 22 U.S.C. 3926 is still in effect and is a general authorization for the Secretary of State to prescribe such regulations as are necessary to administer the foreign service in conformity with federal law; however, it does not grant the Secretary specific authority to provide for the civil and criminal liability of consular officers in 22 CFR 13.3.

Finally, this rule updates all of the statutory authorities cited in Part 13, and updates one regulatory reference (from Section 22.4 to Section 22.6).

Regulatory Analysis and Notices

Administrative Procedure Act

This action is being taken as a final rule pursuant to the ''good cause'' provision of 5 U.S.C. 553(b). It is the position of the Department that notice and comment are not necessary in light of the fact that 22 CFR 13.3 implements a repealed statute; thus, it is no longer authorized. In addition, there were only technical edits to the remaining three sections of Part 13. This rulemaking is effective immediately in accordance with 5 U.S.C. 553(d)(3). Finally, this rulemaking is exempt from the notice and comment pursuant to 5 U.S.C. 553(a)(2), as it is a matter relating to agency management of personnel.

Regulatory Flexibility Act

The Department hereby certifies that this rulemaking will not have a significant economic impact on a substantial number of small entities under the Regulatory Flexibility Act, 5 U.S.C. 605(b).

Unfunded Mandates Reform Act

Section 202 of the Unfunded Mandates Reform Act of 1995, 2 U.S.C. 1532, generally requires agencies to prepare a statement before proposing

any rule that may result in an annual expenditure of $100 million or more by State, local, or tribal governments, or by the private sector. This rulemaking will not result in any such expenditure, nor will it significantly or uniquely affect small governments.

Executive Orders 12866 and 13563

The Department of State has reviewed this rule to ensure its consistency with the regulatory philosophy and principles set forth in Executive Order 12866 and has determined that the benefits of this rule seeking repeal of 22 CFR 13.3 and updates to Part 13 justify its costs. The Department does not consider this rule to be a significant rule as defined by E.O. 12866. The Department has considered this rule in light of Executive Order 13563, and affirms that this regulation is consistent with the guidance therein.

Federalism

This rule will not have substantial direct effects on the States, on the relationship between the national government and the States, or the distribution of power and responsibilities among the various levels of government. Nor will the rule have federalism implications warranting the application of Executive Orders 12372 and 13132.

Civil Justice Reform

The Department has reviewed this rulemaking in light of sections 3(a) and 3(b)(2) of Executive Order 12988 to eliminate ambiguity, minimize litigation, establish clear legal standards, and reduce burden.

Consultations With Tribal Governments

The Department has determined that this rulemaking will not have Tribal implications, will not impose substantial direct compliance costs on Indian Tribal governments, and will not pre-empt Tribal law. Accordingly, the requirements of Executive Order 13175 do not apply to this rulemaking.

Paperwork Reduction Act

This rule does not impose information collection requirements under the provisions of the Paperwork Reduction Act, 44 U.S.C. Chapter 35.

List of Subjects in 22 CFR Part 13

Consular services, Crime, Government employees.

Accordingly, 22 CFR part 13 is amended as follows:

PART 13—PERSONNEL

■ 1. The authority citation for Part 13 is revised to read as follows:

Authority: 22 U.S.C. 2651a; 22 U.S.C. 4198–4199, 4209, and 4217–4218.

§ 13.1 [Amended]

■ 2. Section 13.1 is amended by removing ''(22 U.S.C. 1189)'' and adding ''(22 U.S.C. 4209)'' in its place, by removing ''§ 22.4'' and adding ''§ 22.6'' in its place in the Note, and by removing the sectional authority citation.

§ 13.2 [Amended]

■ 3. Section 13.2 is amended by removing ''(22 U.S.C. 1198)'' and adding ''(22 U.S.C. 4217'') in its place, and by removing ''(22 U.S.C. 1178 and 1179)'' adding ''(22 U.S.C. 4198 and 4199)'' in its place, and by removing the sectional authority citation.

§ 13.3 [Removed and Reserved]

■ 4. Section 13.3 is removed and reserved.

§ 13.4 [Amended]

■ 5. Section 13.4 is amended by removing ''(22 U.S.C. 1200)'' and adding ''(22 U.S.C. 4218)'' in its place, and by removing the sectional authority citation.

Dated: July 18, 2014.

Michele T. Bond,

Acting Assistant Secretary, Bureau of Consular Affairs, U.S. Department of State.

[FR Doc. 2014–17428 Filed 7–24–14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 876

[Docket No. FDA–2014–M–0966]

Medical Devices; Gastroenterology-Urology Devices; Classification of the Implantable Transprostatic Tissue Retractor System

AGENCY: Food and Drug Administration, HHS.

ACTION: Final Order.

SUMMARY: The Food and Drug Administration (FDA) is classifying the implantable transprostatic tissue retractor system 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. 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 August 25, 2014. The classification was applicable beginning September 13, 2013.

FOR FURTHER INFORMATION CONTACT: Mark Kreitz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. G270, Silver Spring, MD 20993–0002, 301–796–7019.

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 postamendments 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