II. Analysis of Environmental Impact

The Agency has determined under 21 CFR 25.34(b) that this action is of a type that does not individually or cumulatively have a significant effect on the human environment. Therefore, neither an environmental assessment nor an environmental impact statement is required.

III. Paperwork Reduction Act of 1995

This final order establishes special controls that refer to previously approved collections of information found in other FDA regulations. These collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (44 U.S.C. 3501–3520). The collections of information in part 807, subpart E, regarding premarket notification submissions, have been approved under OMB control number 0910–0120, and the collections of information in 21 CFR part 801, regarding labeling, have been approved under OMB control number 0910–0485.

List of Subjects in 21 CFR Part 882

Medical devices, Neurological devices.

Therefore, under the Federal Food, Drug, and Cosmetic Act and under authority delegated to the Commissioner of Food and Drugs, 21 CFR part 882 is amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for part 882 continues to read as follows:

Authority: 21 U.S.C. 351, 360, 360c, 360e, 360j, 360l, 371.

■ 2. Add § 882.5600 to subpart F to read as follows:

§ 882.5600 Neurovascular mechanical thrombectomy device for acute ischemic stroke treatment.

(a) *Identification.* A neurovascular mechanical thrombectomy device for acute ischemic stroke treatment is a prescription device used in the treatment of acute ischemic stroke to improve clinical outcomes. The device is delivered into the neurovasculature with an endovascular approach, mechanically removes thrombus from the body, and restores blood flow in the neurovasculature.

(b) *Classification.* Class II (special controls). The special controls for this device are:

(1) The patient contacting components of the device must be demonstrated to be biocompatible.

(2) Non-clinical performance testing must demonstrate that the device performs as intended under anticipated conditions of use, including:

(i) Mechanical testing to demonstrate the device can withstand anticipated tensile, torsional, and compressive forces.

(ii) Mechanical testing to evaluate the radial forces exerted by the device.

(iii) Non-clinical testing to verify the dimensions of the device.

(iv) Non-clinical testing must demonstrate the device can be delivered to the target location in the neurovasculature and retrieve simulated thrombus under simulated use conditions.

(v) Non-clinical testing must demonstrate the device is radiopaque and can be visualized.

(vi) Non-clinical testing must evaluate the coating integrity and particulates under simulated use conditions.

(vii) Animal testing must evaluate the safety of the device, including damage to the vessels or tissue under anticipated use conditions.

(3) Performance data must support the sterility and pyrogenicity of the patient contacting components of the device.

(4) Performance data must support the shelf-life of the device by demonstrating continued sterility, package integrity, and device functionality over the specified shelf-life.

(5) Clinical performance testing of the device must demonstrate the device performs as intended for use in the treatment of acute ischemic stroke and must capture any adverse events associated with the device and procedure.

(6) The labeling must include:

(i) Information on the specific patient population for which the device is intended for use in the treatment of acute ischemic stroke, including but not limited to, specifying time from symptom onset, vessels or location of the neurovasculature that can be accessed for treatment, and limitations on core infarct size.

(ii) Detailed instructions on proper device preparation and use for thrombus retrieval from the neurovasculature.

(iii) A summary of the clinical testing results, including a detailed summary of the device- and procedure-related complications and adverse events.

(iv) A shelf life.

Dated: December 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–31007 Filed 12–22–16; 8:45 am]

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DEPARTMENT OF JUSTICE

Bureau of Prisons

28 CFR Parts 500 and 553

[Docket No. BOP–1163]

RIN 1120–AB63

Contraband and Inmate Personal Property: Technical Change

AGENCY: Bureau of Prisons, Justice.

ACTION: Final rule.

SUMMARY: In this document, the Bureau of Prisons makes a minor technical change to its regulations on contraband and inmate personal property to maintain consistency in language which describes the purpose of the regulations as ensuring the safety, security, or good order of the facility or protection of the public.

DATES: This rule will be effective on January 23, 2017.

FOR FURTHER INFORMATION CONTACT: Sarah Qureshi, Office of General Counsel, Bureau of Prisons, phone (202) 307–2105.

SUPPLEMENTARY INFORMATION:

In this document, the Bureau of Prisons (Bureau) finalizes a minor technical change to its regulations on contraband and inmate personal property to maintain consistency in language which describes the purpose of the regulations as ensuring the ''safety, security, or good order of the facility or protection of the public.''

Variations on this phrase appear throughout the Bureau's regulations in 28 CFR Chapter V. *See* 28 CFR 500.1(h), 501.2(b), 501.3(b), 511.10(a), 511.11(a), 511.12(a), 511.15(b), 511.17(b), 540.12(a), 540.14(c) and (d), 540.15(d), 540.40, 540.44(c), 540.51(h), 540.70, 540.71(b) and (d), 540.100(a), 540.101(a), 541.12, 541.43(b), 541.63(c), 543.11(f), 543.14(a) and (c), 543.15(c), 543.16(b), 544.20, 544.21(b), 548.10, 548.16–548.18, 549.13(b), 549.50, 549.51(b), 551.1, 551.10, 551.12(d), 551.16(a), 551.31(b), 551.34(b), 551.35, 551.71(d), 551.110(a), 551.112(b), 551.113(a), 551.115(a), 552.13(b), 552.20, 552.21(a) and (d), 553.11(h), 553.12(b).

The Bureau has conformed the phrase in all revised regulations since approximately 2005. This rule likewise conforms this phrase in the Bureau's regulations on contraband. An interim rule on this subject was published on August 3, 2015 (80 FR 45883), and became effective on September 2, 2015, although public comments were accepted until October 2, 2015.

Prior to the September 2, 2015, effective date of the interim rule, the definition of contraband in § 500.1(h) read as follows: ''Contraband is material prohibited by law, or by regulation, or material which can reasonably be expected to cause physical injury or adversely affect the security, safety, or good order of the institution.'' The interim rule conformed the ''security, safety, or good order'' phrase to the language we have used in recent years, to read as follows: ''Contraband is material prohibited by law, regulation, or policy that can reasonably be expected to cause physical injury or adversely affect the safety, security, or good order of the facility or protection of the public.''

Likewise, to conform the phrase and underscore the importance of prohibiting contraband, we added the phrase to the end of the first sentence of § 553.10, regarding inmate personal property, to read as follows: ''It is the policy of the Bureau of Prisons that an inmate may possess ordinarily only that property which the inmate is authorized to retain upon admission to the institution, which is issued while the inmate is in custody, which the inmate purchases in the institution commissary, or which is approved by staff to be mailed to, or otherwise received by an inmate, *that does not threaten the safety, security, or good order of the facility or protection of the public.*'' [Emphasis added.] Further, § 543.12(b) contained another description/definition of contraband, categorizing it as either ''hard contraband'' or ''nuisance contraband.'' The interim rule added the ''safety, security'' phrase to this regulation as well.

It is important to note that neither the interim nor this final rule change the substantive requirements or obligations relating to petitions for commutation of sentence, nor do they seek to alter the Bureau's responsibilities in this regard.

Public Comments

We received two comments on the August 3, 2015 interim rule via the publicly-accessible *regulations.gov* Web site.

One commenter requested that the Bureau of Prisons ''plainly spell out the changes that are being put out for public notice,'' indicating confusion with regard to the interim rule changes.

The interim rule contained an explanation of the changes made by the interim rule. It is possible that the commenter may have read only the summary available on the *regulations.gov* Web site, rather than the entire interim rule document. However, for the benefit of any who may have been confused by the interim rule, we offer the following explanation.

The interim rule document made a minor technical change to the Bureau of Prisons regulations on contraband and inmate personal property: We added the phrase ''safety, security, or good order of the facility or protection of the public.'' We did this to show that this is the purpose of the contraband regulations—to ensure the ''safety, security, or good order of the facility or protection of the public.'' We also did this because this phrase appears, for the same purpose, throughout the Bureau's other regulations, and we have used this phrase in new regulations, when possible, since 2005. The addition of the phrase did not change the meaning or requirements of the regulations to which it was added, and did not alter the Bureau's responsibilities.

The second commenter stated as follows: ''So many times inmates come to facilities and mix with wrong crowds out of fear or intimidation. Leaving lockers unlocked due to [comfort] and many other reasons. These things should be [taken into account] if this happens three times in one year they should be further reviews on the inmates. This is not tolerated but common for Camps.'' This comment is not relevant to the current regulation change, which does not discuss inmate lockers or storage of personal property. The Bureau will take this comment into consideration when developing new policy with regard to inmates in federal prison camps.

For the aforementioned reasons, the Bureau now finalizes the interim rule published on August 2, 2015, without change.

Executive Order 12866. This regulation falls within a category of actions that the Office of Management and Budget (OMB) has determined not to constitute ''significant regulatory actions'' under section 3(f) of Executive Order 12866 and, accordingly, it was not reviewed by OMB.

Executive Order 13132. This regulation will not have substantial direct effect on the States, on the relationship between the national government and the States, or on distribution of power and responsibilities among the various levels of government. Therefore, under Executive Order 13132, we determine that this regulation does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

Regulatory Flexibility Act. The Director of the Bureau of Prisons, under the Regulatory Flexibility Act (5 U.S.C. 605(b)), reviewed this regulation and by approving it certifies that it will not have a significant economic impact upon a substantial number of small entities for the following reasons: This regulation pertains to the correctional management of offenders committed to the custody of the Attorney General or the Director of the Bureau of Prisons, and its economic impact is limited to the Bureau's appropriated funds.

Unfunded Mandates Reform Act of 1995. This regulation will not result in the expenditure by State, local and tribal governments, in the aggregate, or by the private sector, of $100,000,000 or more in any one year, and it will not significantly or uniquely affect small governments. Therefore, no actions were deemed necessary under the provisions of the Unfunded Mandates Reform Act of 1995.

Small Business Regulatory Enforcement Fairness Act of 1996. This regulation is not a major rule as defined by section 804 of the Small Business Regulatory Enforcement Fairness Act of 1996. This regulation will not result in an annual effect on the economy of $100,000,000 or more; a major increase in costs or prices; or significant adverse effects on competition, employment, investment, productivity, innovation, or on the ability of United States-based companies to compete with foreign-based companies in domestic and export markets.

List of Subjects in 28 CFR Parts 500 and 553

Prisoners.

Kathleen M. Kenney,

Assistant Director/General, Counsel, Federal Bureau of Prisons.

■ Under rulemaking authority vested in the Attorney General in 5 U.S.C. 301; 28 U.S.C. 509, 510 and delegated to the Director, Bureau of Prisons in 28 CFR 0.96, the interim rule amending 28 CFR parts 500 and 553, which was published at 80 FR 45883, on August 3, 2015, is adopted as a final rule without change.

[FR Doc. 2016–30998 Filed 12–22–16; 8:45 am]

BILLING CODE 4410–05–P

DEPARTMENT OF THE TREASURY

Office of Foreign Assets Control

31 CFR Part 560

Iranian Transactions and Sanctions Regulations

AGENCY: Office of Foreign Assets Control, Treasury.

ACTION: Final rule.