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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, it is proposed that 21 CFR part 882 be amended as follows:

PART 882—NEUROLOGICAL DEVICES

■ 1. The authority citation for 21 CFR part 882 continues to read as follows:

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

■ 2. Revise § 882.5800 to read as follows:

§ 882.5800 Cranial electrotherapy stimulator.

(a) *Identification.* A cranial electrotherapy stimulator is a

prescription device that applies electrical current that is not intended to induce a seizure to a patient's head to treat psychiatric conditions.

(b) *Classification.* (1) Class II (special controls) when intended to treat insomnia and/or anxiety. The special controls for this device are:

(i) A detailed summary of the clinical testing pertinent to use of the device to demonstrate the effectiveness of the device when intended to treat insomnia and/or anxiety.

(ii) Components of the device that come into human contact must be demonstrated to be biocompatible.

(iii) The device must be designed and tested for electrical safety and electromagnetic compatibility (EMC) in its intended use environment.

(iv) Appropriate software verification, validation, and hazard analysis must be performed.

(v) The technical parameters of the device, including waveform, output mode, pulse duration, frequency, train delivery, maximum charge and energy, must be fully characterized and verified.

(vi) The labeling for the device must include the following:

(A) The intended use population and the intended use environment.

(B) A warning that patients should be monitored by their physician for signs of worsening.

(C) A warning that instructs patients on how to mitigate the risk of headaches, and what to do should a headache occur.

(D) A warning that instructs patients on how to mitigate the risk of dizziness, and what to do should dizziness occur.

(E) A detailed summary of the clinical testing, which includes the clinical outcomes associated with the use of the device, and a summary of adverse events and complications that occurred with the device.

(F) Instructions for use that address where to place the electrodes, what stimulation parameters to use, and duration and frequency of treatment sessions. This information must be based on the results of clinical studies for the device.

(G) A detailed summary of the device technical parameters, including waveform, output mode, pulse duration, frequency, train delivery, and maximum charge and energy.

(H) Information on validated methods for reprocessing any reusable components between uses.

(vii) Cranial electrotherapy stimulator devices marketed prior to the effective date of this reclassification must have an amendment submitted to the previously cleared premarket notification (510(k)) demonstrating compliance with these special controls.

(2) Class III (premarket approval) when intended to treat depression.

(c) *Date premarket approval application (PMA) or notice of completion of product development protocol (PDP) is required.* A PMA or notice of completion of a PDP is required to be filed with the Food and Drug Administration on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE FEDERAL REGISTER], for any cranial electrotherapy stimulator device with an intended use described in (b)(3) of this section, that was in commercial distribution before May 28, 1976, or that has, on or before [A DATE WILL BE ADDED 90 DAYS AFTER DATE OF PUBLICATION OF A FUTURE FINAL ORDER IN THE FEDERAL REGISTER], been found to be substantially equivalent to any cranial electrotherapy stimulator device with an intended use described in paragraph (b)(3) of this section, that was in commercial distribution before May 28, 1976. Any other cranial electrotherapy stimulator device with an intended use described in paragraph (b)(3) of this section shall have an approved PMA or declared completed PDP in effect before being placed in commercial distribution.

Dated: January 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–01173 Filed 1–21–16; 8:45 am]

BILLING CODE 4164–01–P

POSTAL SERVICE

39 CFR Part 551

Semipostal Stamp Program

AGENCY: Postal Service™.

ACTION: Proposed rule.

SUMMARY: This proposed rule would remove certain restrictions on the commencement date for the Postal Service's discretionary Semipostal Stamp Program, and clarify how many semipostal stamps issued under that program may be on sale at any one time.

DATES: Comments must be received on or before February 22, 2016.

FOR FURTHER INFORMATION CONTACT: Lori Mazzone, Manager, Stamp Products & Exhibitions, 202–268–6711, lori.l.mazzone@usps.gov.

SUPPLEMENTARY INFORMATION:

Pursuant to the Semipostal Authorization Act, Public Law 106–253, the Postal Service has been granted discretionary authority to issue and sell semipostal stamps to advance such

causes as it considers to be “in the national public interest and appropriate.” See 39 U.S.C. 416(b). On June 12, 2001, the Postal Service published a final rule establishing the regulations in 39 CFR part 551 for the discretionary Semipostal Stamp Program (66 FR 31826). Minor revisions were made to these regulations to implement Public Law 107–67, 115 Stat. 514 (2001), and to reflect minor organizational changes in the Postal Service (67 FR 5215 (February 5, 2002)). On February 19, 2004, the Postal Service published a final rule clarifying the cost-offset policy for semipostal stamps (69 FR 7688), and on February 9, 2005, the Postal Service also published an additional minor clarifying revision to these cost-offset regulations (70 FR 6764).

The Postal Service now proposes to revise paragraphs (a) and (b) of 39 CFR 551.5. A brief description of each proposed change follows.

The proposed revision of § 551.5(a) would remove certain restrictions on the commencement date of the discretionary Semipostal Stamp Program. Under current regulations, the 10-year period for the discretionary semipostal stamp program commences on a date determined by the Office of Stamp Services, but that date must be after the sales period of the Breast Cancer Research Stamp (BCRS) is concluded. Most recently, Public Law 114–99 (December 11, 2015) extended that sales period to December 31, 2019.

The proposed revision of § 551.5(a) would specify that the 10-year period will commence on a date determined by the Office of Stamp Services, but this date need not be after the BCRS sale period concludes.

The proposed revision of § 551.5(b) would clarify that although only one semipostal stamp under the discretionary Semipostal Stamp Program under 39 U.S.C. 416 (a “discretionary program semipostal stamp”) will be offered for sale at any one time, other semipostal stamps required to be issued by Congress (such as the BCRS) may be on sale when a discretionary program semipostal stamp is on sale. Current regulations state that the Postal Service will offer only one semipostal stamp for sale at any given time during the 10-year period (not specifying whether it is a discretionary program semipostal stamp or a semipostal stamp required by Congress).

The proposed revision of § 551.5(b) would clarify that the one-at-a-time limitation on the sale of semipostal stamps applies only to discretionary program semipostal stamps.

We will publish an appropriate amendment to 39 CFR part 551 to reflect these changes if the proposal is adopted.

List of Subjects in 39 CFR Part 551

Administrative practice and procedure.

In accordance with 39 U.S.C. 416(e)(2), the Postal Service invites public comment on the following proposed amendments to the *Code of Federal Regulations*. For the reasons stated in the preamble, the Postal Service proposes to revise 39 CFR part 551 as follows:

PART 551—SEMIPOSTAL STAMP PROGRAM

■ 1. The authority citation for 39 CFR part 551 continues to read as follows:

Authority: 39 U.S.C. 101, 201, 203, 401, 403, 404, 410, 414, 416.

■ 2. In § 551.5, revise paragraphs (a) and (b) to read as follows:

§ 551.5 Frequency and other limitations.

(a) The Postal Service is authorized to issue semipostal stamps for a 10-year period beginning on the date on which semipostal stamps are first sold to the public under 39 U.S.C. 416. The Office of Stamp Services will determine the date of commencement of the 10-year period.

(b) The Postal Service will offer only one semipostal stamp pursuant to the discretionary semipostal stamp program under 39 U.S.C. 416 for sale at any given time during the 10-year period.

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Stanley F. Mires,

Attorney, Federal Compliance.

[FR Doc. 2016–01070 Filed 1–21–16; 8:45 am]

BILLING CODE 7710–12–P

DEPARTMENT OF DEFENSE

GENERAL SERVICES ADMINISTRATION

NATIONAL AERONAUTICS AND SPACE ADMINISTRATION

48 CFR Parts 3, 4, and 52

[FAR Case 2015–012; Docket No. 2015–0012; Sequence No. 1]

RIN 9000–AN04

Federal Acquisition Regulation: Contractor Employee Internal Confidentiality Agreements

AGENCY: Department of Defense (DoD), General Services Administration (GSA), and National Aeronautics and Space Administration (NASA).

ACTION: Proposed rule.

SUMMARY: DoD, GSA, and NASA are proposing to amend the Federal Acquisition Regulation (FAR) to implement a section of the Consolidated and Further Continuing Appropriations Act, 2015, that prohibits the use of funds, appropriated or otherwise made available, for a contract with an entity that requires employees or subcontractors to sign an internal confidentiality agreement that restricts such employees or subcontractors from lawfully reporting waste, fraud, or abuse to a designated Government representative authorized to receive such information.

DATES: Interested parties should submit written comments to the Regulatory Secretariat at one of the addresses shown below on or before March 22, 2016 to be considered in the formation of the final rule.

ADDRESSES: Submit comments in response to FAR Case 2015–012 by any of the following methods:

- *Regulations.gov:* <http://www.regulations.gov>. Submit comments via the Federal eRulemaking portal by searching for “FAR Case 2015–012”. Select the link “Comment Now” that corresponds with FAR Case 2015–012. Follow the instructions provided on the screen. Please include your name, company name (if any), and “FAR Case 2015–012” on your attached document(s).

- *Mail:* General Services Administration, Regulatory Secretariat (MVCB), ATTN: Ms. Flowers, 1800 F Street NW., 2nd Floor, Washington, DC 20405–0001.

Instructions: Please submit comments only and cite “FAR Case 2015–012” in all correspondence related to this case. All comments received will be posted without change to <http://www.regulations.gov>, including any personal and/or business confidential information provided. To confirm receipt of your comment(s), please check www.regulations.gov, approximately two to three days after submission to verify posting (except allow 30 days for posting of comments submitted by mail).

FOR FURTHER INFORMATION CONTACT: Ms. Cecelia L. Davis, Procurement Analyst, at 202–219–0202 for clarification of content. For information pertaining to status or publication schedules, contact the Regulatory Secretariat at 202–501–4755. Please cite FAR Case 2015–012.

SUPPLEMENTARY INFORMATION:

I. Background

This proposed rule revises the FAR to implement section 743 of Division E,