Proposed Rules

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This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

21 CFR Part 820

[Docket No. FDA–2016–N–0436]

Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notification; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or we) is extending the comment period for the document entitled ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers'' that appeared in the **Federal Register** of March 4, 2016. In the document, FDA requested comments about the quality, safety, and continued effectiveness of medical devices that have been subject to one or more of these activities that are performed by both original equipment manufacturers (OEM) and third parties, including health care establishments. The Agency is taking this action due to the unanticipated high-level of interest from interested persons.

DATES: FDA is extending the comment period on the document published March 4, 2016 (81 FR 11477). Submit either electronic or written comments by June 3, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: http://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *http://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *http://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

Written/Paper Submissions

Submit written/paper submissions as follows:

- *Mail/Hand delivery/Courier (for written/paper submissions):* Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

Instructions: All submissions received must include the Docket No. FDA–2016–N–0436 for ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers; Request for Comments.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *http://www.regulations.gov* or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *http://www.regulations.gov.* Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *http://www.fda.gov/regulatoryinformation/dockets/default.htm.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *http://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Valerie Flournoy, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993–0002, 301–796–5495.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of March 4, 2016, FDA published a document with a 60-day comment period to request comments on the medical device industry and healthcare community that refurbish, recondition, rebuild, remarket, remanufacture, service, and

repair medical devices (hereafter termed ''third-party entity or entities''), including radiation-emitting devices subject to the electronic product radiation control (EPRC) provisions of the Federal Food, Drug, and Cosmetic Act (the FD&C Act). Comments on the service, maintenance, refurbishment, and alteration of medical devices, by third-party entities as well as challenges third-party entities face in maintaining or restoring devices to their original or current specifications will inform FDA when we hold a public meeting later in 2016 to further engage this segment of the device industry and healthcare community.

The Agency has received requests for a 30-day extension of the comment period for the document. Each request conveyed concern that the current 60-day comment period does not allow sufficient time to develop meaningful or thoughtful response to the document on ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers.''

FDA has considered the requests and is extending the comment period for the document on ''Refurbishing, Reconditioning, Rebuilding, Remarketing, Remanufacturing, and Servicing of Medical Devices Performed by Third-Party Entities and Original Equipment Manufacturers'' for 30 days, until June 3, 2016. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying future workshop on these important issues.

Dated: April 19, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–09443 Filed 4–22–16; 8:45 am]

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OFFICE OF THE DIRECTOR OF NATIONAL INTELLIGENCE

32 CFR Part 1704

Mandatory Declassification Review Program

AGENCY: Office of the Director of National Intelligence.

ACTION: Proposed rule.

SUMMARY: The Office of the Director of National Intelligence (ODNI) is publishing this proposed rule pursuant to Executive Order 13526, relating to classified national security information. It provides procedures for members of the public to request from ODNI a Mandatory Declassification Review (MDR) of information classified under the provisions of Executive Order 13526 or predecessor orders such that the agency may retrieve it with reasonable effort. This rule also informs requesters where to send requests for an MDR.

DATES: Submit comments on or before May 25, 2016.

ADDRESSES: You may submit comments by any of the following methods: By mail to the Office of the Director of National Intelligence, Director of the Information Management Division, Washington, DC 20511, by facsimile at (703) 874–8910, or by email at *dni-FOIA@dni.gov.*

FOR FURTHER INFORMATION CONTACT: Jennifer L. Hudson, 703–874–8085.

SUPPLEMENTARY INFORMATION: It is the policy of the ODNI to act in matters relating to national security information in accordance with Executive Order 13526 and directives issued thereunder by the Information Security Oversight Office (ISOO). The purpose of this rule is to assist in implementing specific sections of Executive Order 13526 concerning the Mandatory Declassification Review (MDR).

Regulatory Impact

This proposed rule is not a significant regulatory action for the purposes of Executive Order 12866. This rule is not a major rule as defined in 5 U.S.C. Chapter 8, Congressional Review of Agency Rulemaking. As required by the Regulatory Flexibility Act, we certify that this proposed rule will not have a significant impact on a substantial number of small entities because it applies only to Federal agencies.

List of Subjects in 32 CFR Part 1704

Declassification, Information, Intelligence, National security information.

■ For the reasons set forth in the preamble, ODNI proposes to add 32 CFR part 1704 to read as follows:

PART 1704—MANDATORY DECLASSIFICATION REVIEW PROGRAM

Sec.

1704.1 Authority and purpose.
1704.2 Definitions.
1704.3 Contact information.
1704.4 MDR program feedback.
1704.5 Guidance.
1704.6 Exceptions.
1704.7 Requirements.
1704.8 Fees.
1704.9 Determination by originator or interested party.
1704.10 Appeals.

Authority: 50 U.S.C. 3001; E.O. 13526, 75 FR 707, 3 CFR, 2009 Comp, p. 298.

§ 1704.1 Authority and purpose.

(a) *Authority.* This part is issued under the authority of 32 CFR 2001.33; Section 3.5 of Executive Order 13526 (or successor Orders); the National Security Act of 1947, as amended (50 U.S.C. 3001 *et seq.*).

(b) *Purpose.* This part prescribes procedures, subject to limitations set forth below, for requesters to request a mandatory declassification review of information classified under Executive Order 13526 or predecessor or successor orders. Section 3.5 of Executive Order 13526 and these regulations are not intended to and do not create any right or benefit, substantive or procedural, enforceable at law by a party against the United States, its agencies, officers, employees, or agents, or any other person.

§ 1704.2 Definitions.

For purposes of this part:

Control means the authority of the agency that originates information, or its successor in function, to regulate access to the information. (32 CFR 2001.92)

Day means U.S. Federal Government working day, which excludes Saturdays, Sundays, and federal holidays. Three (3) days may be added to any time limit imposed on a requester by this part if responding by U.S. domestic mail; ten (10) days may be added if responding by international mail.

D/IMD means the Director of the Information Management Division and the leader of any successor organization, who serves as the ODNI's manager of the information review and release program.

Federal agency means any *Executive agency,* as defined in 5 U.S.C. 105; any *Military department,* as defined in 5 U.S.C. 102; and any other entity within the executive branch that comes into the possession of classified information.

Information means any knowledge that can be communicated or documentary material, regardless of its physical form that is owned by, produced by or for, or under the control of the U.S. Government; it does not include information originated by the incumbent President, White House Staff, appointed committees, commissions or boards, or any entities within the Executive Office that solely advise and assist the incumbent President.

Interested party means any official in the executive, military, congressional, or judicial branches of government, or U.S. Government contractor who, in the sole discretion of the ODNI, has a subject