Instrument	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Case Component	25	1	150	3,750
Estimated Total Annual Burden Hours				5,718

With respect to the collection of information via NAMRS, ACL specifically requests comments on:

(a) Whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility;

(b) the accuracy of the agency's estimate of the burden of the proposed collection of information;

(c) the quality, utility, and clarity of the information to be collected; and

(d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication. The proposed collection of information tools may be found in the NAMRS section of the ACL Web site.

Dated: March 16, 2016.

Kathy Greenlee,

Administrator and Assistant Secretary for Aging.

[FR Doc. 2016–06342 Filed 3–21–16; 8:45 am]

BILLING CODE 4154–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2015–D–2104]

Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance Environment for Multi-Configuration Passive Medical Devices; Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of the guidance entitled ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices.'' FDA is confronted with an increasing number of premarket submissions that include an MR Conditional labeling claim for multiconfiguration passive medical devices. The assessment of radiofrequency (RF)-induced heating of such devices, typically comprised of many parts, strongly depends on the specific device geometry and can therefore lead to a prohibitively large number of test cases. This guidance provides an approach to reduce the number of possible device configurations to a manageable number, and it provides guidance on how to assess the RF-induced device heating for an individual configuration.

DATES: Submit either electronic or written comments on this guidance at any time. General comments on Agency guidance documents are welcome at any time.

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–2015–D–2104 for ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices.'' 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.

An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the guidance document entitled ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices'' to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your request.

FOR FURTHER INFORMATION CONTACT: Wolfgang Kainz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1115, Silver Spring, MD 20993–0002, 301–661–7595.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance to provide an assessment paradigm for RF-induced heating on or near multicomponent or multiconfiguration passive medical devices in the MR environment. During MR scanning, applied RF excitation pulses induce currents that can cause heating of electrically conductive materials. RF-induced heating of medical devices made with conductive materials may lead to patient burns. To minimize the risk of patient burns during MR scanning, sponsors should comprehensively assess devices in all configurations and combinations. However, multicomponent passive devices, such as orthopedic fixation devices, may permit a very large number of possible device configurations and combinations of individual components. Testing all possibilities may be impractical and unnecessary. This guidance provides an approach to identify a manageable number of device configurations or combinations for the testing of RF-induced heating in the MR environment. Additionally, this guidance provides recommendations on how to assess the RF-induced device heating for multiconfiguration passive medical devices.

In the **Federal Register** of June 29, 2015 (80 FR 36996), the Agency announced the issuance of the draft guidance entitled ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices.'' Interested persons were invited to comment by August 28, 2015.

II. Significance of Guidance

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on the assessment of RF-induced heating of multicomponent, or multiconfiguration, passive medical devices in the MR environment. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

III. Electronic Access

Persons interested in obtaining a copy of the guidance may do so by downloading an electronic copy from the Internet. A search capability for all Center for Devices and Radiological Health guidance documents is available at *http://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/default.htm.* Guidance documents are also available at *http://www.regulations.gov.* Persons unable to download an electronic copy of ''Assessment of Radiofrequency-Induced Heating in the Magnetic Resonance (MR) Environment for Multi-Configuration Passive Medical Devices'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500001 to identify the guidance you are requesting.

IV. Paperwork Reduction Act of 1995

This draft guidance refers to previously approved collections of information found in FDA regulations and guidance. 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 21 CFR part 814, subparts B and E, are approved under OMB control number 0910–0231; the collections of information in 21 CFR part 814, subpart H, are approved under OMB control number 0910–0332; the collections of information in 21 CFR part 807, subpart E, are approved under OMB control number 0910–0120; the collections of information in 21 CFR part 812 are approved under OMB control number 0910–0078; the collections of information in 21 CFR parts 801 and 809 are approved under OMB control number 0910–0485; and the collections of information in the guidance document entitled ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' are approved under OMB control number 0910–0756.

Dated: March 16, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–06361 Filed 3–21–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–N–0001]

2016 Parenteral Drug Association/Food and Drug Administration Joint Conference: Aligning Manufacturing Goals With Patient Needs Through Successful Innovation and Compliance

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public conference.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public conference, to be held in cosponsorship with the Parenteral Drug Association (PDA), entitled ''Aligning Manufacturing Goals with Patient Needs through Successful Innovation and Compliance.'' The conference will cover current issues affecting the industry as well as explore strategies to facilitate the development and continuous improvement of safe and effective medical products. The conference establishes a unique forum to discuss the foundations, emerging technologies, and innovations in regulatory science, as well as the current quality and compliance areas of concerns. Meeting participants will hear from FDA and industry speakers about the requirements and best practices to consider while implementing robust quality systems in order to deliver the best quality product.

DATES: The public conference will be held on September 12, 2016, from 7 a.m. to 7:30 p.m.; September 13, 2016, from