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.

Submit electronic comments on the draft guidance to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Wolfgang Kainz, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1129, Silver Spring, MD 20993–0002, 301–661–7595.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance to provide an assessment paradigm for RF-induced heating on or near multi-component or multi-configuration passive medical devices in the MR environment.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, multi-component 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 impracticable and unnecessary. This draft guidance provides an approach to identify a manageable number of device configurations or combinations for the testing of RF-induced heating in the MR environment. Additionally, this draft guidance provides recommendations on how to assess RF-induced device heating for multi-configuration passive medical devices.

II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the current thinking of FDA on the assessment of RF-induced heating of multi-component, or multi-configuration, passive medical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 draft 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. 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 have been approved under OMB control number 0910–0231.

V. Comments

Interested persons may submit either electronic comments regarding this document to *http://www.regulations.gov* or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

Dated: June 23, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015–15833 Filed 6–26–15; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Notice of Publication of the Revised Guidebook for the National Practitioner Data Bank (NPDB)

AGENCY: Health Resources and Services Administration (HRSA), HHS.

ACTION: Notice.

SUMMARY: The National Practitioner Data Bank (NPDB) announces the release of the revised user Guidebook. The NPDB is a confidential information clearinghouse created by Congress and intended to facilitate a comprehensive review of the professional credentials of health care practitioners, entities, and suppliers. The Guidebook is the primary policy document explaining the statutes and regulations behind and operation of the NPDB. It serves as an essential reference for NPDB users, offering reporting and querying examples, explanations, definitions, and frequently asked questions. The new Guidebook incorporates legislative and regulatory changes adopted since its last edition, including the NPDB's merger with the Healthcare Integrity and Protection Data Bank.

In November 2013, the Health Resources and Services Administration (HRSA) released a draft Guidebook to the public for review and comment by NPDB stakeholders and other interested parties. It announced the draft Guidebook's availability in the **Federal Register**. HRSA received more than 360 separate comments, consisting of analyses of issues raised by the draft Guidebook. The NPDB carefully studied all comments received, and many led to detailed analyses of how NPDB explains its policies to its audiences. The final Guidebook is now available at *www.npdb.hrsa.gov* and replaces previous Guidebooks.

FOR FURTHER INFORMATION CONTACT: Ernia P. Hughes, MBA, Director of the Division of Practitioner Data Bank, Bureau of Health Workforce, Health Resources and Services Administration at: *NPDBPolicy@hrsa.gov* or 301–443–2300.

Dated: June 18, 2015.

James Macrae,

Acting Administrator.

[FR Doc. 2015–15802 Filed 6–26–15; 8:45 am]

BILLING CODE 4165–15–P