

Dated: July 9, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-17318 Filed 7-13-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-D-2148]

Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices; Draft Guidance for Industry and Food and Drug Administration Staff; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing the availability of a draft guidance entitled "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices." This draft guidance provides a detailed description of the information that should be included in a premarket notification for a magnetic resonance diagnostic device (MRDD). This draft guidance is not final nor is it in effect at this time.

DATES: Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by October 13, 2015.

ADDRESSES: 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 Submit written requests for a single hard copy of the draft guidance document entitled "Guidance for the Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices" to the Office of the Center Director,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.

Submit electronic comments on the draft guidance to 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: Jana Delfino, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4236, Silver Spring, MD 20993-0002, 301-796-6503; or Sunder Rajan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 1113, Silver Spring, MD 20993-0002, 301-796-4194.

SUPPLEMENTARY INFORMATION:

I. Background

The purpose of this document is to provide a detailed description of the information that should be included in a premarket notification for an MRDD. This document is an elaboration of the general requirements contained in 21 CFR 807.87 and is intended to be used in conjunction with general information regarding the content and format of a 510(k) premarket notification. The approach outlined in this guidance document is intended to facilitate the timely review and marketing clearance of MRDDs.

This draft guidance is applicable to MRDDs as defined in 21 CFR 892.1000. An MRDD is intended for general diagnostic use to present images that reflect the spatial distribution and/or magnetic resonance spectra that reflect frequency and distribution of nuclei exhibiting nuclear magnetic resonance. Other physical parameters derived from the images and/or spectra may also be produced. The device includes hydrogen-1 (proton) imaging, sodium-23 imaging, hydrogen-1 spectroscopy, phosphorus-31 spectroscopy, and chemical shift imaging (preserving simultaneous frequency and spatial information). MRDDs are class II medical devices that require premarket notification and an agency determination of substantial equivalence prior to marketing.

The principal components of current MRDDs include the main magnet, shim and gradient systems, radiofrequency transmitter and receiver, transmit and receive coils, power supplies, computer, and software. This draft guidance document is applicable to premarket notifications for new magnetic resonance imaging (MRI) and magnetic resonance spectroscopy systems, new components, and modifications to systems and components that have a significant impact on safety or effectiveness of the magnetic resonance

diagnostic device. The information in this draft guidance document is also applicable to the MRI system components of dual-modality devices, such as positron emission tomography/MRI systems.

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 "Submission of Premarket Notifications for Magnetic Resonance Diagnostic Devices." 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 "Submission of Premarket Notifications for Magnetic Resonance Diagnostic 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 340 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 807, subpart E, have been approved under OMB control number 0910-0120, and the collections of information in 21 CFR part 801 have been approved under OMB control number 0910-0485.

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: July 8, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-17250 Filed 7-13-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Environmental Health Sciences Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Institute of Environmental Health Sciences Special Emphasis Panel; Undergraduate Research Training in Environmental Health Sciences.

Date: August 6, 2015.

Time: 1:00 p.m. to 2:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institute of Environmental Health Sciences, Keystone Building, 530 Davis Drive, Room 3118, Research Triangle Park, NC 27709. (Telephone Conference Call).

Contact Person: Leroy Worth, Ph.D., Scientific Review Officer Scientific Review Branch, Division of Extramural Research and Training, Nat. Institute of Environmental Health Sciences, P.O. Box 12233, MD EC-30/Room 3171, Research Triangle Park, NC 27709, 919/541-0670, worth@niehs.nih.gov. (Catalogue of Federal Domestic Assistance Program Nos. 93.115, Biometry and Risk Estimation—Health Risks from Environmental Exposures; 93.142, NIEHS Hazardous Waste Worker Health and Safety Training; 93.143, NIEHS Superfund Hazardous Substances—Basic Research and Education; 93.894, Resources and Manpower Development in the Environmental Health Sciences; 93.113, Biological Response to Environmental Health Hazards; 93.114, Applied Toxicological Research and Testing, National Institutes of Health, HHS)

Dated: July 7, 2015.

Carolyn Baum,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2015-17164 Filed 7-13-15; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Scientific Advisory Committee on Alternative Toxicological Methods; Announcement of Meeting; Request for Comments

SUMMARY: This notice announces a meeting of the Scientific Advisory Committee on Alternative Toxicological Methods (SACATM). SACATM advises the Interagency Coordinating Committee on the Validation of Alternative Methods (ICCVAM), the National Toxicology Program (NTP) Interagency Center for the Evaluation of Alternative Toxicological Methods (NICEATM), and the Director of the National Institute of Environmental Health Sciences (NIEHS) and NTP regarding statutorily mandated duties of ICCVAM and activities of NICEATM. The meeting is open to the public. Registration is requested for both public attendance and oral comment and required to access the webcast. Information about the meeting and registration is available at <http://ntp.niehs.nih.gov/go/32822>.

DATES: Meeting: September 2, 2015, beginning at 8:30 a.m. Eastern Daylight Time (EDT) and continuing until adjournment at approximately 5:00 p.m.

Written Public Comments Submissions: Deadline is August 19, 2015.

Registration for Meeting and/or Oral Comments: Deadline is August 26, 2015.

Registration to View Webcast:

Deadline is September 2, 2015.

Registration to view the meeting via the webcast is required.

ADDRESSES:

Meeting Location: Rodbell Auditorium, Rall Building, NIEHS, 111 T.W. Alexander Drive, Research Triangle Park, NC 27709

Meeting Web page: The preliminary agenda, registration, and other meeting materials will be at <http://ntp.niehs.nih.gov/go/32822>.

Webcast: The meeting will be webcast; the URL will be provided to those who register for viewing.

FOR FURTHER INFORMATION CONTACT: Dr. Lori White, Designated Federal Officer for SACATM, Office of Liaison, Policy and Review, Division of NTP, NIEHS, P.O. Box 12233, K2-03, Research

Triangle Park, NC 27709. Phone: 919-541-9834, fax: (301) 480-3272, email: whitel@niehs.nih.gov. Hand Deliver/Courier address: 530 Davis Drive, Room K2136, Morrisville, NC 27560.

SUPPLEMENTARY INFORMATION:

Preliminary Agenda and Other

Meeting Information: A preliminary agenda, roster of SACATM members, background materials, public comments, and any additional information, when available, will be posted on the SACATM meeting Web site (<http://ntp.niehs.nih.gov/go/32822>) or is available upon request from the Designated Federal Officer. Following the meeting, summary minutes will be prepared and available on the SACATM Web site or upon request.

Meeting and Registration: This meeting is open to the public with time scheduled for oral public comments. The public may attend the meeting at NIEHS, where attendance is limited only by the space available, or view the webcast. Registration is required to view the webcast; the URL for the webcast will be provided in the email confirming registration. Individuals who plan to attend and/or provide oral comments are encouraged to register at <http://ntp.niehs.nih.gov/go/32822> by August 26, 2015, to facilitate planning for the meeting. Individuals interested in the meeting are encouraged to access this Web site to stay abreast of the most current information regarding the meeting. Visitor and security information for those attending in person is available at niehs.nih.gov/about/visiting/index.cfm. Individuals with disabilities who need accommodation to participate in this event should contact Ms. Robbin Guy at phone: (919) 541-4363 or email: guyr2@niehs.nih.gov. TTY users should contact the Federal TTY Relay Service at 800-877-8339. Requests should be made at least five business days in advance of the event.

Request for Comments: Both written and oral public input on the agenda topics is invited. Written comments submitted in response to this notice should be received by August 19, 2015. Comments will be posted on the meeting Web site and persons submitting them will be identified by their name and affiliation and/or sponsoring organization, if applicable. Persons submitting written comments should include their name, affiliation (if applicable), and sponsoring organization (if any) with the document. Time is allotted during the meeting for presentation of oral comments and each organization (sponsoring organization or affiliation) is allowed one time slot per