DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–D–2837]

Testing and Labeling Medical Devices for Safety in the Magnetic Resonance Environment; Draft Guidance for Industry and Food and Drug Administration Staff; Availability; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA or the Agency) is extending the comment period for the notice of availability that appeared in the **Federal Register** of August 2, 2019. In the notice of availability, FDA requested comments on draft guidance for industry and FDA staff entitled ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.'' The Agency is taking this action in response to a request for an extension to allow interested persons additional time to submit comments.

DATES: FDA is extending the comment period on the document published August 2, 2019 (84 FR 37886). Submit either electronic or written comments on the draft guidance by October 31, 2019, to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

Electronic Submissions

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://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 *https://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):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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–2019–D–2837 for ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment; Draft Guidance for Industry and Food and Drug Administration Staff.'' Received comments will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff 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 *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. 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: *https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

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 ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment'' to the Office of Policy, 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: Terry Woods, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 62, Rm. 2116, Silver Spring, MD 20993–0002, 301–796–2503.

SUPPLEMENTARY INFORMATION:

I. Background

In the **Federal Register** of August 2, 2019, FDA published a notice of availability with a 60-day comment period to request comments on the draft guidance for industry and FDA staff entitled ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment.''

The Agency has received a request for a 30-day extension of the comment period. The request conveyed concern that the current 60-day comment period does not allow sufficient time to develop a meaningful or thoughtful response.

FDA has considered the request and is extending the comment period for the notice of availability for 30 days, until October 31, 2019. The Agency believes that a 30-day extension allows adequate time for interested persons to submit comments without significantly delaying guidance on these important issues.

II. Significance of Guidance

FDA is issuing this draft guidance 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 this topic. 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. This guidance is not subject to Executive Order 12866.

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 *https://www.fda.gov/medical-devices/device-advice-comprehensive-regulatory-assistance/guidance-documents-medical-devices-and-radiation-emitting-products.* This guidance document is also available at *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Testing and Labeling Medical Devices for Safety in the Magnetic Resonance (MR) Environment'' may send an email request to *CDRH-Guidance@fda.hhs.gov* to receive an electronic copy of the document. Please use the document number 1500059 to identify the guidance you are requesting.

Dated: August 28, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–18929 Filed 8–30–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Mental Health Services Research Committee, November 7, 2019, 8:00 a.m. to November 7, 2019 p.m., 05:00 p.m., The Dupont Hotel, 1500 New Hampshire Avenue NW, Washington, DC 20036 which was published in the **Federal Register** on August 201, 2019, 84 FR 43150.

This notice is to amend the date of the Mental Health Service Research Committee (SERV) meeting from November 7, 2019 to November 8, 2019. The meeting times and location remain the same. The meeting is closed to the public.

Dated: August 27, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–18901 Filed 8–30–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Office of the Director, National Institutes of Health; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Council of Councils, September 6, 2019, 08:15 a.m. to 04:00 p.m., National Institutes of Health, The Natcher Building, Building 45, Room E, 45 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on February 08, 2019, 84 FR 2890.

The meeting notice is amended to change the open and closed session meeting times as follows: The morning open session will change from 8:15 a.m.–12:00 p.m. to 8:00 a.m.–12:00 p.m.; the closed session will change from 12:00 p.m.–1:30 p.m. to 12:00 p.m.–12:45 p.m.; and the afternoon open session will change from 1:30 p.m.–4:00 p.m. to 12:45 p.m.–4:15 p.m. The meeting is partially closed to the public.

Dated: August 27, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–18902 Filed 8–30–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Center for Advancing Translational Sciences; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the Cures Acceleration Network Review Board, September 19, 2019, 11:00 a.m. to 4:30 p.m., PORTER NEUROSCIENCE RESEARCH CENTER, Building 35A, 35 Convent Drive, Bethesda, MD 20892 which was published in the **Federal Register** on June 27, 2019, 84 FR 30744 Pg. 30744.

This meeting notice is amended to change the start time from 11:00 a.m. to 10:00 a.m. The meeting is open to the public.

Dated: August 27, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019–18895 Filed 8–30–19; 8:45 am]

BILLING CODE 4140–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meetings.

The meetings 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: Biological Chemistry and Macromolecular Biophysics Integrated