premarket notifications for new magnetic resonance imaging (MRI) and magnetic resonance spectroscopy systems, components, and accessories, and modifications to systems, components, and accessories that could significantly affect the safety or effectiveness of the MRDD. The information in this guidance document is also applicable to the MRI system components of dual-modality devices, such as positron emission tomography/MRI systems.

In the **Federal Register** of July 14, 2015 (80 FR 41046), FDA announced the availability of the draft guidance and interested persons were invited to comment by October 13, 2015. FDA has considered the comments received, and has incorporated changes suggested by the comments, as appropriate.

This guidance supersedes FDA's guidance entitled ''Guidance for Industry: Guidance for the Submissions of Premarket Notifications for Magnetic Resonance Diagnostic Devices'' dated November 14, 1998.

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 ''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 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 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 (premarket notification), have been approved under OMB control number 0910–0120; the collections of information in 21 CFR part 801 (labeling) have been approved under OMB control number 0910–0485; the collections of information in parts 1002 through 1050 (electronic product requirements) have been approved under OMB control number 0910–0025; and the collections of information in the guidance document ''Requests for Feedback on Medical Device Submissions: The Pre-Submission Program and Meetings with Food and Drug Administration Staff'' have been approved under OMB control number 0910–0756.

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27842 Filed 11–17–16; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2016–D–3004]

Use of The Seafood List To Determine Acceptable Seafood Names; Draft Compliance Policy Guide; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing the availability of a draft guidance for FDA staff entitled ''Compliance Policy Guide Sec. 540.750 Use of *The Seafood List* to Determine Acceptable Seafood Names'' (the draft Compliance Policy Guide (CPG)). The draft CPG, when finalized, will provide guidance for FDA staff regarding use of *The Seafood List* to determine whether a seafood name is acceptable.

DATES: Although you can comment on any CPG at any time (see 21 CFR 10.115(g)(5)), to ensure that we consider your comment on the draft CPG before we begin work on the final version of the CPG, submit either electronic or written comments on the draft CPG by January 17, 2017.

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–D–3004 for ''Compliance Policy Guide Sec. 540.750 Use of *The Seafood List* to Determine Acceptable Seafood Names.'' 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.

Submit written requests for single copies of the draft CPG to the Food and Feed Policy Staff, Office of Policy and Risk Management, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed adhesive labels to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the draft CPG.

FOR FURTHER INFORMATION CONTACT: Spring C. Randolph, Center for Food Safety and Applied Nutrition (HFC–325), Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–1421.

SUPPLEMENTARY INFORMATION:

I. Background

We are announcing the availability of the draft CPG entitled ''Compliance Policy Guide Sec. 540.750 Use of *The Seafood List* to Determine Acceptable Seafood Names.'' The draft CPG, if finalized, will update the previously issued ''CPG Sec. 540.750—Common or Usual Names for Seafood in Interstate Commerce.'' The draft CPG is intended to provide guidance for FDA staff regarding use of *The Seafood List* to determine whether a seafood name is acceptable. The draft CPG explains when we may consider a seafood product to be misbranded under section 403 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 343). The draft CPG also contains information that may be useful to the regulated industry and to the public.

We are issuing this draft CPG consistent with our good guidance practices regulation (21 CFR 10.115). The draft CPG, when finalized, will represent our current thinking on acceptable names for seafood in interstate commerce. It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternate approach if it satisfies the requirements of the applicable statutes and regulations.

II. Electronic Access

Persons with access to the Internet may obtain the draft CPG from FDA's Office of Regulatory Affairs CPG history page at *http://www.fda.gov/ICECI/ComplianceManuals/CompliancePolicyGuidanceManual/default.htm* or *http://www.regulations.gov.* Use the FDA Web site listed in the previous sentence to find the most current version of the guidance.

Dated: November 15, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016–27843 Filed 11–17–16; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Notice of Joint Meeting by the Urology Interagency Coordinating Committee and the Diabetes Mellitus Interagency Coordinating Committee Meeting

SUMMARY: The Diabetes Mellitus Interagency Coordinating Committee (DMICC) and the Urology Interagency Coordinating Committee (UICC) will hold a joint meeting on December 16, 2016. The subject of the meeting will be ''The Urologic Complications of Diabetes.'' The meeting is open to the public.

DATES: The meeting will be held on December 16, 2016; from 9:00 a.m. to 12:00 p.m. Individuals wanting to present oral comments must notify the contact person at least 10 days before the meeting date.

ADDRESSES: The meeting will be held in the Democracy 2 Building at 6707 Democracy Blvd., Bethesda, MD, in Conference Room 7050.

FOR FURTHER INFORMATION CONTACT: For further information concerning this meeting, see the DMICC Web site, *www.diabetescommittee.gov,* or contact Dr. B. Tibor Roberts, Executive Secretary of the Diabetes Mellitus Interagency Coordinating Committee, National Institute of Diabetes and Digestive and Kidney Diseases, 31 Center Drive, Building 31A, Room 9A19, MSC 2560, Bethesda, MD 20892–2560, telephone: 301–496–6623; FAX: 301–480–6741; email: *dmicc@mail.nih.gov.*

SUPPLEMENTARY INFORMATION: The DMICC and the UICC, both chaired by the National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) comprising members of the Department of Health and Human Services and other federal agencies that support diabetes-related or urologic-related activities respectively, facilitate cooperation, communication, and collaboration on diabetes among government entities. The Committees' meetings, held several times a year, provide an opportunity for their members to learn about and discuss current and relevant future programs in their member organizations and to identify opportunities for collaboration. The December 16, 2016 joint meeting will focus on The Urologic Complications of Diabetes.

Any member of the public interested in presenting oral comments to the Committees should notify the contact person listed on this notice at least 10 days in advance of the meeting. Interested individuals and representatives or organizations should submit a letter of intent, a brief description of the organization represented, and a written copy of their oral presentation in advance of the meeting. Only one representative of an organization will be allowed to present; oral comments and presentations will be limited to a maximum of 5 minutes. Printed and electronic copies are requested for the record. In addition, any interested person may file written comments with the Committees by forwarding their statement to the contact person listed on this notice. The statement should include the name, address, telephone number and when applicable, the business or professional affiliation of the interested person. Because of time constraints for the meeting, oral comments will be allowed on a first-come, first-serve basis.

Members of the public who would like to receive email notification about