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In the Federal Register of July 14, 2015 (80 FR 41046), FDA announced the availability of the draft guidance and interested persons were invited to comment by October 13, 2015.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.


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]
BILLING CODE 4164–01–P

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 Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed and postage-paid adhesive labels to assist that office in forwarding their statement 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 Drug Administration, 12420 Parklawn Dr., Rockville, MD 20857. Send two self-addressed and postage-paid adhesive labels to assist that office in forwarding their statement to the Division of Dockets Management, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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.

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.

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.