

2024–D–0706 for “New Dietary Ingredient Notification Master Files for Dietary Supplements.” 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, 240–402–7500.

- 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.” We will review this copy, including the claimed confidential information, in our 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.govinfo.gov/content/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, 240–402–7500.

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

Submit written requests for single copies of the draft guidance to the Office of Dietary Supplement Programs, Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740. 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 guidance.

FOR FURTHER INFORMATION CONTACT: Lisa Bieniek, Office of Dietary Supplement Programs (HFS–810), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2371; or Lauren Kleinman, Office of Regulations and Policy (HFS–024), Center for Food Safety and Applied Nutrition, Food and Drug Administration, 5001 Campus Dr., College Park, MD 20740, 240–402–2378.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a draft guidance for industry titled, “New Dietary Ingredient Notification Master Files for Dietary Supplements.” We are issuing the draft guidance consistent with our 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 alternate approach if it satisfies the requirements of the applicable statutes and regulations.

The draft guidance, when finalized, will provide recommendations to industry on Master Files for new dietary ingredient notifications (NDINs). For purposes of the guidance, a new dietary ingredient notification Master File (NDIN Master File or Master File) is a file containing identity, manufacturing, and/or safety information relating to a new dietary ingredient (NDI) that the Master File owner submits to FDA for use in evaluating a potential future NDIN by the Master File owner or by another person designated by the Master File owner (e.g., business partner, supplement manufacturer). An NDIN Master File contains information about an NDI, a dietary supplement containing an NDI, or both. The Master File owner may refer to the Master File in an NDIN or may grant written authorization to other parties to incorporate information from the Master File by reference in NDINs. A written authorization granting a right of reference to a Master File in an NDIN does not include the right to see or copy the Master File.

The recommendations in this draft guidance expand upon and replace the recommendations related to Master Files in FDA’s revised draft guidance, “Dietary Supplements: New Dietary Ingredient Notifications and Related Issues,” dated August 2016. The purpose of this draft guidance, when finalized, will be to help industry

comply more easily with the NDIN requirement in the Federal Food, Drug, and Cosmetic Act (FD&C Act) by providing recommendations for the submission and use of NDIN Master Files (see section 413(a)(2) of the FD&C Act (21 U.S.C. 350b(a)(2))). The draft guidance contains information on establishing an NDIN Master File, updating or closing an NDIN Master File, the use of data from an NDIN Master File by the Master File owner and other parties authorized by the Master File owner, and FDA’s role in reviewing and administering NDIN Master Files. Master Files benefit NDIN submitters with a right of reference by allowing them to refer to data already on file with FDA, instead of having to develop the data themselves and resubmit it in each NDIN for the same ingredient.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collection of information in 21 CFR 190.6 has been approved under OMB control number 0910–0330, and the collections of information in 21 CFR part 111 have been approved under OMB control number 0910–0606.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either <https://www.fda.gov/regulatory-information/search-fda-guidance-documents> or <https://www.regulations.gov>. Use the FDA website listed in the previous sentence to find the most current version of the guidance.

Dated: March 28, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–07095 Filed 4–3–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a

meeting of the National Advisory Council for Biomedical Imaging and Bioengineering.

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 Advisory Council for Biomedical Imaging and Bioengineering (NACBIB).

Date: May 15, 2024.

Open: 09:00 a.m. to 12:30 p.m.

Agenda: Report from the Institute Director, Council Members and other Institute Staff.

Place: John Edward Porter Neuroscience Research Center, Building 35A, Room 620/630, 35 Convent Drive, Bethesda, Maryland 20892 (In-person Meeting).

Closed: 1:30 p.m. to 4:00 p.m.

Agenda: To review and evaluate grant applications and/or proposals.

Place: John Edward Porter Neuroscience Research Center, Building 35A, Room 620/630, 35 Convent Drive, Bethesda, Maryland 20892 (In-person Meeting).

Contact Person: David T. George, Ph.D., Associate Director for Research Administration, Office of Research Administration, National Institute of Biomedical Imaging and Bioengineering, 6707 Democracy Boulevard, Bethesda, MD 20892, georged@mail.nih.gov.

The meeting will be open to the public, with attendance limited to space available. Individuals who plan to attend and need special assistance, such as sign language interpretation or other reasonable accommodations, should notify the Contact Person listed below in advance of the meeting. In person attendees should register at (<https://www.nibib.nih.gov/about-nibib/advisory-council>) in advance of the meeting so that the meeting organizers can plan accordingly.

The meeting will be videocast and can be accessed from the NIH Videocasting website at (<https://videocast.nih.gov/watch=54286>).

Any interested person may file written comments with the committee by forwarding the 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.

Information is also available on the Institute's/Center's home page: <https://www.nibib.nih.gov/about-nibib/advisory-council> where an agenda and any additional information for the meeting will be posted when available.

Dated: March 29, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-07112 Filed 4-3-24; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Diabetes and Digestive and Kidney Diseases; Notice of Meeting

Pursuant to section 1009 of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Diabetes and Digestive and Kidney Diseases Advisory Council.

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 Diabetes and Digestive and Kidney Diseases Special Emphasis Panel; RFA-DK-22-028 Pilot and Feasibility Trials on the Integration of Social and Medical Care for T1D.

Date: June 7, 2024.

Time: 12:00 p.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, NIDDK, Democracy II, Suite 7000A, 6707 Democracy Boulevard, Bethesda, MD 20892 (Virtual Meeting).

Contact Person: Cheryl Nordstrom, Ph.D., Scientific Review Officer, Review Branch, DEA, NIDDK, National Institutes of Health, Room 7013, 6707 Democracy Blvd., Bethesda, MD 20892-2542, 301-402-6711, cheryl.nordstrom@nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.847, Diabetes, Endocrinology and Metabolic Research; 93.848, Digestive Diseases and Nutrition Research; 93.849, Kidney Diseases, Urology and Hematology Research, National Institutes of Health, HHS)

Dated: April 1, 2024.

Miguelina Perez,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2024-07156 Filed 4-3-24; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2024-0232]

National Maritime Security Advisory Committee; May 2024 Virtual Meeting

AGENCY: U.S. Coast Guard, Department of Homeland Security.

ACTION: Notice of open Federal advisory committee meeting.

SUMMARY: The National Maritime Security Advisory Committee (Committee) will conduct a virtual meeting to discuss a new Committee task to provide Comment on the U.S. Coast Guard's Notice of Proposed Rulemaking on Cybersecurity in the Marine Transportation System. The virtual meeting will be open to the public.

DATES:

Meeting: The Committee will meet virtually on Friday, May 10, 2024, from 1 p.m. until 3 p.m. Eastern Daylight Time (EDT). Please note that this meeting may close early if the Committee has completed its business.

Comments and supporting documentation: To ensure your comments are received by Committee members before the meeting, submit your written comments no later than May 9, 2024.

ADDRESSES: The meeting will be held virtually. To join the virtual meeting or to request special accommodations, contact the individual listed in the **FOR FURTHER INFORMATION CONTACT** section no later than 1 p.m. EDT on May 9, 2024, to obtain the needed information. The number of virtual lines are limited and will be available on a first-come, first-served basis.

Pre-registration information: Pre-registration is required for attending virtual meeting. You must request attendance by contacting the individual listed in the **FOR FURTHER INFORMATION CONTACT** section of this notice. You will receive a response with attendance instructions.

The National Maritime Security Advisory Committee is committed to ensuring all participants have equal access regardless of disability status. If you require reasonable accommodations due to a disability to fully participate, please email Mr. Ryan Owens at ryan.f.owens.uscg.mil or call (202) 302-6565 as soon as possible.

Instructions: You are free to submit comments at any time, including orally at the meetings as time permits, but if you want Committee members to review