

dietary supplement product is subject to the notification requirement, so we continue to provide clarifications on when premarket notifications are required.¹ A transparent, common understanding of the requirements surrounding dietary ingredient status and notification, with predictable expectations regarding compliance and consequences for non-compliance, will help our regulatory processes operate effectively. Public discussion of these issues will further our efforts to strengthen regulation of dietary supplements through modernization and reform and help us better protect the public health.

II. Topics for Discussion at the Public Meeting

FDA will host a one-day public meeting to provide interested parties an opportunity to discuss various issues related to responsible innovation in dietary supplements, including the following topics:

(1) The scope of the phrase “dietary substance for use by man to supplement the diet by increasing the total dietary intake,” as used in DSHEA (section 201(ff)(1)(E) of the FD&C Act);

(2) Understanding exceptions to the requirement for premarket notification, and evaluating whether and how growth in the marketplace since 1994 has altered the impact of those provisions;

(3) Potential commercial or marketing advantages to incentivize responsible innovation; and

(4) Promoting overall compliance with the premarket notification requirement through enforcement.

The issues discussed at the public meeting, including the above topics, and any comments submitted to the docket by July 15, 2019, will help us evaluate how to proceed with our efforts to modernize and reform FDA’s oversight of dietary supplements.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm>. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability. Persons interested in

attending this public meeting should register by May 6, 2019, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting. Please visit the website at <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm> for this information as well as the final meeting agenda.

If you need special accommodations due to a disability, please contact Juanita Yates (see **FOR FURTHER INFORMATION CONTACT**) no later than May 1, 2019.

Requests for Oral Comments: During online registration you may indicate if you wish to present during a public comment session and which topic(s) you wish to address. We are seeking a broad representation of ideas and issues presented at the meeting. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their remarks and to request time for a joint comment. After registration closes, we will determine the amount of time allotted to each participant and the approximate time each oral comment is to begin and will select and notify participants by May 10, 2019. All requests to make oral comments must be received by the close of registration on May 1, 2019. No commercial or promotional material will be permitted to be presented or distributed at the public meeting.

Those without internet or email access can register and/or request to participate by contacting Juanita Yates by the above dates (see **FOR FURTHER INFORMATION CONTACT**).

Streaming Webcast of the public meeting: This public meeting will also be webcast. Please visit the following website to register: <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm>.

FDA has verified the website addresses in this document, as of the date this document publishes in the **Federal Register**, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It also may be viewed at the Dockets

Management Staff (see **ADDRESSES**). A link to the transcript will also be available on the internet at <https://www.fda.gov/Food/NewsEvents/WorkshopsMeetingsConferences/ucm632939.htm>.

Dated: April 4, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019-07168 Filed 4-10-19; 8:45 am]

BILLING CODE 4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Cancer Institute; Amended Notice of Meeting

Notice is hereby given of a change in the meeting of the National Cancer Institute Council of Research Advocates, April 11, 2019, 9:30 a.m. to 4:00 p.m., National Institutes of Health, Building 31, Room 10A28, 31 Center Drive, Bethesda, MD 20892 which was published in the **Federal Register** on February 15, 2019, 84 FR 4487.

This meeting notice is amended to change the meeting date, start time, and location. The meeting will now be held on May 20, 2019 at 9:00 a.m. at the National Institutes of Health, Building 40, Room 1201/1203, 40 Convent Drive, Bethesda, MD 20892. This meeting is open to the public.

Dated: April 8, 2019.

Melanie J. Pantoja,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-07181 Filed 4-10-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Biomedical Imaging and Bioengineering; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Institute of Biomedical Imaging and Bioengineering Special Emphasis Panel.

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,

¹ See, e.g., Draft Guidance for Industry: Dietary Supplements: New Dietary Ingredient Notifications and Related Issues (August 2016), available at <https://www.fda.gov/food/guidanceregulation/guidancedocumentsregulatoryinformation/dietary-supplements/ucm257563.htm>. This draft guidance, when finalized, will represent FDA’s current thinking on this topic.

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 Biomedical Imaging and Bioengineering Special Emphasis Panel; Brain Initiative RFAs (EB-17-003; EB-17-004) Review SEP.

Date: May 3, 2019.

Time: 8:00 a.m. to 5:30 p.m.

Agenda: To review and evaluate grant applications.

Place: The William F. Bolger Center, 9600 Newbridge Drive, Potomac, MD 20854.

Contact Person: Ruixia Zhou, Ph.D., Scientific Review Officer, National Institute of Biomedical Imaging and Bioengineering, National Institutes of Health, Two Democracy Boulevard, Suite 957, 6707 Democracy Blvd., Bethesda, MD 20892, 301-496-4773, zhour@mail.nih.gov.

Dated: April 5, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-07183 Filed 4-10-19; 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: Center for Scientific Review Special Emphasis Panel; AREA Applications in Oncological Sciences.

Date: May 22, 2019.

Time: 11:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892.

Contact Person: Svetlana Kotliarova, Ph.D., Scientific Review Officer, Center for

Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 6214, Bethesda, MD 20892, 301-594-7945, kotliars@mail.nih.gov.

Name of Committee: Infectious Diseases and Microbiology Integrated Review Group; Host Interactions with Bacterial Pathogens Study Section.

Date: June 5, 2019.

Time: 8:00 a.m. to 6:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Residence Inn Bethesda, 7335 Wisconsin Avenue, Bethesda, MD 20814.

Contact Person: Fouad A El-Zaatari, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 3186, MSC 7808, Bethesda, MD 20892, (301) 435-1149, elzaataf@csr.nih.gov.

Name of Committee: Musculoskeletal, Oral and Skin Sciences Integrated Review Group; Oral, Dental and Craniofacial Sciences Study Section.

Date: June 6-7, 2019.

Time: 8:00 a.m. to 2:00 p.m.

Agenda: To review and evaluate grant applications.

Place: Ritz-Carlton Hotel at Pentagon City, 1250 South Hayes Street, Arlington, VA 22202.

Contact Person: Yi-Hsin Liu, Ph.D., Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 4214, MSC 7814, Bethesda, MD 20892, 301-435-1781, liuyh@csr.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)

Dated: April 5, 2019.

Sylvia L. Neal,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-07180 Filed 4-10-19; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Eunice Kennedy Shriver National Institute of Child Health & Human Development; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended, notice is hereby given of a meeting of the National Advisory Board on Medical Rehabilitation Research.

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.

Name of Committee: National Advisory Board on Medical Rehabilitation Research.

Date: May 6-7, 2019.

Time: May 6, 2019, 9:00 a.m. to 5:00 p.m.

Agenda: NICHD Director's report; Strategy to update the NIH Rehabilitation Research Plan; Initial Planning for the Rehabilitation Research Conference; Complementary and Integrative Health Update; Centers for Medicare and Medicaid Services Research Policies and Efforts.

Place: NICHD Offices, 6710B Rockledge Drive, Rooms 1425/1427, Bethesda, MD 20892.

Time: May 7, 2019, 9:00 a.m. to 12:00 p.m.

Agenda: Concept Clearance; Use of Secondary Data for Rehabilitation Science; Scientific Presentation on Extending the Reach of Rehabilitation Using Technology.

Place: NICHD Offices, 6710B Rockledge Drive, Rooms 1425/1427, Bethesda, MD 20892.

Contact Person: Ralph M. Nitkin, Ph.D., Deputy Director, National Center for Medical Rehabilitation Research (NCMR), Eunice Kennedy Shriver National Institute of Child Health and Human Development, NIH, DHHS, 6710B Rockledge Drive, Room 2116, Bethesda, MD 20892-7002, (301) 402-4206, RN21e@nih.gov.

Individuals will also be able to view the meeting via NIH Videocast. Select the following link for Videocast the day of the meeting: <https://videocast.nih.gov/default.asp>.

Information is also available on the Institute's/Center's home page: <http://www.nichd.nih.gov/about/advisory/nabmrr/Pages/index.aspx> where the current roster and minutes from past meetings are posted. (Catalogue of Federal Domestic Assistance Program Nos. 93.864, Population Research; 93.865, Research for Mothers and Children; 93.929, Center for Medical Rehabilitation Research; 93.209, Contraception and Infertility Loan Repayment Program, National Institutes of Health, HHS)

Dated: April 8, 2019.

Ronald J. Livingston, Jr.,

Program Analyst, Office of Federal Advisory Committee Policy.

[FR Doc. 2019-07182 Filed 4-10-19; 8:45 am]

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DEPARTMENT OF HOMELAND SECURITY

Coast Guard

[Docket No. USCG-2018-1057]

RIN 1625-AA00

Extension of Comment Period for the Safety Zone; Gastineau Channel, Juneau, AK

AGENCY: Coast Guard, DHS.

ACTION: Extension of comment period.

SUMMARY: The United States Coast Guard is extending the comment period for the notice of proposed rulemaking