

dietary supplement product is subject to the notification requirement, so we continue to provide clarifications on when premarket notifications are required.<sup>1</sup> 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.

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## 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.

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## 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,

<sup>1</sup> 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.