

**ADDRESSES:** Interested parties may participate in the dialogue through the online platform by reviewing the information and participation dates posted at [www.cao.gov](http://www.cao.gov).

**FOR FURTHER INFORMATION CONTACT:** Christopher Zeleznik at [dataactpmo@hhs.gov](mailto:dataactpmo@hhs.gov) or 202-205-3514 or Emily Gartland at [IAEO Outreach@gsa.gov](mailto:IAEO Outreach@gsa.gov) or 703-605-2532.

**SUPPLEMENTARY INFORMATION:**

This notice announces a dialogue to explore opportunities to streamline processes and reduce or eliminate burden in federal procurement and grants processes. This dialogue furthers the goals of the President's Management Agenda, which lays the foundation for creating a 21st century government that delivers better results to the American people, and addresses requirements in the Digital Accountability and Transparency Act of 2014 (Public Law 113-101) to gain a better understanding of the costs of compliance with Federal contracting and grants awards as well as recommendations to standardize data, eliminate unnecessary duplication, and reduce compliance costs.

During last year's Open Dialogue on Federal Procurement, published in the **Federal Register** at 79 FR 22682, on April 23, 2014, many commenters pointed to the potential reduction of redundant reporting and related processes as one way to improve the efficiency and effectiveness of the government's acquisition practices. This feedback is helping to support ongoing efforts to modernize the IT infrastructure supporting Federal procurement data collection and display, which will include development of a single Web site for Federal contractors to use for federal contract reporting requirements.

Management of federal contract and grant business arrangements requires multiple layers of reporting across multiple agencies. In some cases, lack of standardization results in slight (or significant) variations in reports that create additional administrative and burdensome requirements for awardees that could be readily rectified. This dialogue is intended to continue the conversation begun last year in the context of federal procurement and expand it to cover federal grants by identifying opportunities for reducing burden, discussing ideas for standardizing processes and forms, and identifying recommended actions to reduce costs and eliminate duplication for awardees. The open dialogue focuses on three topics (campaigns). Each campaign focuses on a unique aspect of the Federal contracting and grants

process for which we welcome your insight, ideas, and feedback.

- Campaign 1—Reporting compliance requirements shared by prime and sub-awardees of Federal procurements and grants.
- Campaign 2—Procurement practices, processes, and reporting.
- Campaign 3—Grants practices and processes.

*Note—We are looking for ideas to reduce your burden through data standards and changes to reporting procedures. We are interested in hearing about proposed changes that can be accomplished through executive (regulatory, administrative, or management) action, as well as potential legislative proposals where requirements are based in statute.*

To facilitate a national dialogue, an online platform will be launched in May 2015 so that interested parties may submit ideas, comment on others, respond to questions posed by moderators, and vote to indicate which ideas they think are most promising and impactful. Information on the platform, and the dates for participating in the dialogue, will be posted at [www.cao.gov](http://www.cao.gov). A separate notice will be posted to address additional dialogue topics on federal procurement for conversation later in the spring and summer.

Dated: March 27, 2015.

**William Clark,**

*Director, Office of Government-wide Acquisition Policy, Office of Acquisition Policy, Office of Government-wide Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2015-D-0838]

#### **Procedures for Meetings of the Medical Devices Advisory Committee; Draft Guidance for Industry and Food and Drug Administration Staff; Availability**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA) is announcing the availability of the draft guidance entitled "Procedures for Meetings of the Medical Devices Advisory Committee." The Center for Devices and Radiological Health (CDRH) is issuing this guidance to provide additional information regarding the processes for meetings of the Medical Devices Advisory

Committee panels other than the Dispute Resolution Panel (DRP). This guidance describes the general circumstances in which CDRH consults with a panel, the process for exchange of information between CDRH, the members of the panel, industry, and the public, and the conduct of panel meetings. This guidance supplements existing FDA Agency-wide guidance on the conduct of Advisory Committee meetings. This draft guidance is not final nor is it in effect at this time.

**DATES:** Although you can comment on any guidance at any time (see 21 CFR 10.115(g)(5)), to ensure that the Agency considers your comment of this draft guidance before it begins work on the final version of the guidance, submit either electronic or written comments on the draft guidance by June 1, 2015.

**ADDRESSES:** An electronic copy of the guidance document is available for download from the Internet. See the **SUPPLEMENTARY INFORMATION** section for information on electronic access to the guidance. Submit written requests for a single hard copy of the draft guidance document entitled "Procedures for Meetings of the Medical Devices Advisory Committee" to the Office of the Center Director, Guidance and Policy Development, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5431, Silver Spring, MD 20993-0002. Send one self-addressed adhesive label to assist that office in processing your request.

Submit electronic comments on the draft guidance to <http://www.regulations.gov>. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852. Identify comments with the docket number found in brackets in the heading of this document.

**FOR FURTHER INFORMATION CONTACT:** James Swink, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 1609, Silver Spring, MD 20993-0002, 301-796-6313.

**SUPPLEMENTARY INFORMATION:**

#### **I. Background**

CDRH is issuing this draft guidance to provide additional information regarding the processes for meetings of the Medical Devices Advisory Committee panels other than the DRP. The term "panel," as used in this guidance, refers to the panels established under the Medical Devices Advisory Committee charter excluding the DRP. This guidance describes the

general circumstances in which CDRH consults with a panel of the Medical Devices Advisory Committee, the process for exchange of information between CDRH, the members of the panel, industry, and the public, and the conduct of panel meetings. The Medical Devices Advisory Committee includes 17 panels other than the DRP (Ref. 1). The panels, according to their specialty area and authorization, advise the Commissioner of Food and Drugs in discharging responsibilities as they relate to assuring the safety and effectiveness of medical devices, and as required, any other product for which FDA has regulatory responsibility.

This draft guidance is intended to provide more comprehensive information for industry and for CDRH staff on the processes associated with a panel meeting held for any of the reasons identified in the guidance. Once final, this guidance will replace the "Guidance on Amended Procedures for Advisory Panel Meetings" (Ref. 2) and the guidance document entitled "Panel Review of Premarket Approval Applications #P91-2 blue book memo" (Ref. 3). This guidance supplements existing FDA Agency-wide guidance on the conduct of Advisory Committee meetings.

## II. Significance of Guidance

This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the panel meeting process for medical devices. It does not create or confer any rights for or on any person and does not operate to bind FDA or the public. An alternative approach may be used if such approach satisfies the requirements of the applicable statute and regulations.

## III. Electronic Access

Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet. A search capability for all CDRH 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 "Procedures for Meetings of the Medical Devices Advisory Committee" may send an email request to [CDRH-Guidance@fda.hhs.gov](mailto:CDRH-Guidance@fda.hhs.gov) to receive an electronic copy of the document. Please use the document number 413 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 have been approved under OMB control number 0910-0120; the collections of information in 21 CFR part 860 have been approved under OMB control number 0910-0138; the collections of information in 21 CFR part 814 have been approved under OMB control number 0910-0231; and the collections of information in 21 CFR part 814, subpart H have been approved under OMB control number 0910-0332.

## V. Comments

Interested persons may submit either electronic comments regarding this document to <http://www.regulations.gov> or written comments to the Division of Dockets Management (see **ADDRESSES**). It is only necessary to send one set of comments. Identify comments with the docket number found in brackets in the heading of this document. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

## VI. References

The following references have been placed on display in the Division of Dockets Management (see **ADDRESSES**), and may be seen by interested persons between 9 a.m. and 4 p.m., Monday through Friday, and are available electronically at <http://www.regulations.gov>. (FDA has verified the Web site addresses, but we are not responsible for any subsequent changes to the Web sites after this document publishes in the **Federal Register**.)

1. CDRH's Medical Devices Advisory Committee, available at <http://www.fda.gov/AdvisoryCommittees/CommitteesMeetingMaterials/MedicalDevices/MedicalDevicesAdvisoryCommittee/default.htm>.

2. "Guidance for Industry and FDA Staff: Guidance on Amended Procedures for Advisory Panel Meetings," July 2000, available at <http://www.fda.gov/downloads/MedicalDevices/DeviceRegulationandGuidance/GuidanceDocuments/ucm073726.pdf>.

3. "Panel Review of Premarket Approval Applications #P91-2 (blue book memo)," May 1991, available at <http://www.fda.gov/MedicalDevices/>

[DeviceRegulationandGuidance/GuidanceDocuments/ucm081363.htm](http://www.fda.gov/DeviceRegulationandGuidance/GuidanceDocuments/ucm081363.htm).

Dated: March 26, 2015.

**Leslie Kux,**

*Associate Commissioner for Policy.*

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**BILLING CODE 4164-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Advisory Council on Alzheimer's Research, Care, and Services; Meeting

**AGENCY:** Assistant Secretary for Planning and Evaluation, HHS.

**ACTION:** Notice of meeting.

**SUMMARY:** This notice announces the public meeting of the Advisory Council on Alzheimer's Research, Care, and Services (Advisory Council). The Advisory Council on Alzheimer's Research, Care, and Services provides advice on how to prevent or reduce the burden of Alzheimer's disease and related dementias on people with the disease and their caregivers. During the April meeting, the Advisory Council will build on the goals of White House Conference on Aging (WHCOA) through a half-day session with dementia-focused panels on each WHCOA topic area: Healthy aging, long-term services and supports, retirement security, and elder justice. Following this session, the Advisory Council will also hold a brief discussion on the 2015 Update to the National Plan to Address Alzheimer's, as well as a discussion of international events on dementia.

**DATES:** The meeting will be held on April 28th, 2015 from 9:00 a.m. to 5:00 p.m. EDT.

**ADDRESSES:** The meeting will be held in Room 800 in the Hubert H. Humphrey Building, 200 Independence Avenue SW., Washington, DC 20201.

Comments: Time is allocated in the afternoon on the agenda to hear public comments. The time for oral comments will be limited to two (2) minutes per individual. In lieu of oral comments, formal written comments may be submitted for the record to Rohini Khillan, OASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. Comments may also be sent to [napa@hhs.gov](mailto:napa@hhs.gov). Those submitting written comments should identify themselves and any relevant organizational affiliations.

**FOR FURTHER INFORMATION CONTACT:** Rohini Khillan (202) 690-5932, [rohini.khillan@hhs.gov](mailto:rohini.khillan@hhs.gov). Note: Seating may be limited. Those wishing to attend the meeting must send an email to