

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This draft guidance is intended to provide more comprehensive information for industry and for CDRH staff on the processes associated with a panel meeting held for any of the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This draft guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The draft guidance, when finalized, will represent the Agency's current thinking on the panel meeting process for medical devices.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Persons interested in obtaining a copy of the draft guidance may do so by downloading an electronic copy from the Internet.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.*

[FR Doc. 2015-07438 Filed 3-31-15; 8:45 am]

**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

[napa@hhs.gov](mailto:napa@hhs.gov) and put "April 28 Meeting Attendance" in the Subject line by Friday, April 17, so that their names may be put on a list of expected attendees and forwarded to the security officers at the Department of Health and Human Services. Any interested member of the public who is a non-U.S. citizen should include this information at the time of registration to ensure that the appropriate security procedure to gain entry to the building is carried out. Although the meeting is open to the public, procedures governing security and the entrance to Federal buildings may change without notice. If you wish to make a public comment, you must note that within your email.

**SUPPLEMENTARY INFORMATION:** Notice of these meetings is given under the Federal Advisory Committee Act (5 U.S.C. App. 2, section 10(a)(1) and (a)(2)). Topics of the Meeting: The Advisory Council will hear presentations on the basics of long-term care, including presentations on programs, settings, and payers. The Council will use a portion of the meeting to review the work it has accomplished thus far towards the 2025 goals, and then discuss the process for developing recommendations for the 2015 update to the National Plan. The Council will also hear presentations from the three subcommittees (Research, Clinical Care, Long-Term Services and Supports, and Ethics).

**Procedure and Agenda:** This meeting is open to the public. Please allow 30 minutes to go through security and walk to the meeting room. The meeting will also be webcast at [www.hhs.gov/live](http://www.hhs.gov/live).

**Authority:** 42 U.S.C. 11225; Section 2(e)(3) of the National Alzheimer's Project Act. The panel is governed by provisions of Public Law 92-463, as amended (5 U.S.C. Appendix 2), which sets forth standards for the formation and use of advisory committees.

Dated: March 25, 2015.

**Richard G. Frank,**

*Assistant Secretary for Planning and Evaluation.*

[FR Doc. 2015-07374 Filed 3-31-15; 8:45 am]

**BILLING CODE 4150-05-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### Office of Dietary Supplements VDSP Commutability Study 2

**SUMMARY:** NIH Office of Dietary Supplements (ODS) and the National Institute of Standards and Technology (NIST), in collaboration with the College of American Pathologists (CAP) and

Vitamin D External Quality Assessment Scheme (DEQAS), announce that as part of the Vitamin D Standardization Program (VDSP), they are recruiting laboratories to participate in a study of the commutability of pooled serum samples used in assays to measure total 25-hydroxyvitamin D [25(OH)D].

**DATES:** The expected start date for the study is June 2015.

**ADDRESSES:** For more information about the study and to let us know if you are interested in participating, please contact us at: [vdsp@mail.nih.gov](mailto:vdsp@mail.nih.gov).

**FOR FURTHER INFORMATION CONTACT:** Drs. Johanna Camara, NIST, and Christopher Sempos, ODS, Director and Co-Director, respectively, for the VDSP Commutability Study 2. Email: [VDSP@mail.nih.gov](mailto:VDSP@mail.nih.gov).

**SUPPLEMENTARY INFORMATION:** The objective of the study is to promote the standardized measurement of total 25(OH)D by evaluating the commutability of NIST Standard Reference Materials® (SRM) used as "trueness" controls and the materials used in the major Performance Testing/ External Quality (PT/EQA) programs administered by CAP and DEQAS. *Who Can Participate:* (1) All commercial manufacturers of 25(OH)D assays (requests from manufacturers with assays in development will be considered); (2) Clinical and research laboratories using a commercial assay platform; (3) Laboratories for national/subnational nutrition surveys; and (4) Laboratories using in-house developed assays.

For details about the study design and time lines, see the recently published paper in the February 2015 edition of Clinical Laboratory News, (<https://www.aacc.org/publications/cln/articles/2015/february/vitamin-d-commutability-study>).

Dated: March 24, 2015.

**Lawrence A. Tabak,**

*Deputy Director, National Institutes of Health.*

[FR Doc. 2015-07326 Filed 3-31-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

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 on Aging Special Emphasis Panel; Fibroblast Growth Factor And Aging.

*Date:* May 1, 2015.

*Time:* 1:00 p.m. to 5:00 p.m.

*Agenda:* To review and evaluate grant applications.

*Place:* National Institute on Aging, Gateway Building, Suite 2C212, 7201 Wisconsin Avenue, Bethesda, MD 20892, (Telephone Conference Call).

*Contact Person:* Alicja L. Markowska, Ph.D., DSC., Scientific Review Branch, National Institute On Aging, 7201 Wisconsin Avenue, Suite 2c212, Bethesda, MD 20892, 301-496-9666, [markowska@nia.nih.gov](mailto:markowska@nia.nih.gov).

(Catalogue of Federal Domestic Assistance Program Nos. 93.866, Aging Research, National Institutes of Health, HHS)

Dated: March 26, 2015.

**Melanie J. Gray,**

*Program Analyst, Office of Federal Advisory Committee Policy.*

[FR Doc. 2015-07338 Filed 3-31-15; 8:45 am]

**BILLING CODE 4140-01-P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### National Institutes of Health

#### National Institute on Aging; Notice of Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Board of Scientific Counselors, NIA.

The meeting will be open to the public as indicated below, 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.

The meeting will be closed to the public as indicated below in accordance with the provisions set forth in section 552b(c)(6), Title 5 U.S.C., as amended for the review, discussion, and evaluation of individual intramural programs and projects conducted by the NATIONAL INSTITUTE ON AGING, including consideration of personnel qualifications and performance, and the