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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 February meeting, the Advisory Council will hear presentations from the three subcommittees (Research, Clinical Care, and Long-Term Services and Supports), which will inform the 2014 recommendations. The Advisory Council will discuss the G8 Dementia Summit that was held on December 11, 2013.

DATES: The meeting will be held on February 3, 2013 from 9:30 a.m. to 4:30 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 on the agenda to hear public comments. In lieu of oral comments, formal written comments may be submitted for the record to Helen Lamont, Ph.D., OASPE, 200 Independence Avenue SW., Room 424E, Washington, DC 20201. Comments may also be sent to napa@hhs.gov. Those submitting written comments should identify themselves and any relevant organizational affiliations.

FOR FURTHER INFORMATION CONTACT: Helen Lamont, Ph.D. (202) 690-7996, helen.lamont@hhs.gov. Note: Seating may be limited. Those wishing to attend the meeting must send an email to napa@hhs.gov and put "February 3 meeting attendance" in the Subject line by Friday, January 24, 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 from the three subcommittees (Research, Clinical Care, and Long-Term Services and Supports), which will inform the 2014 recommendations. The Advisory Council will discuss the G8 Dementia Summit that was held on December 11, 2013.

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.

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: January 2, 2014.

Donald Moulds,

Acting Assistant Secretary for Planning and Evaluation.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-0001]

Microbiology Devices Panel of the Medical Devices Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

This notice announces a forthcoming meeting of a public advisory committee of the Food and Drug Administration (FDA). The meeting will be open to the public.

Name of Committee: Microbiology Devices Panel of the Medical Devices Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the Agency on FDA's regulatory issues.

Date and Time: The meeting will be held on March 12, 2014, from 8 a.m. to 6 p.m.

Location: College Park Holiday Inn, Ballroom, 10000 Baltimore Ave., College Park, MD 20740; 301-345-6700.

Contact Person: Shanika Craig, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, Shanika.Craig@fda.hhs.gov, 301-796-6639, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area). A notice in the **Federal Register** about last minute modifications that impact a previously announced advisory committee meeting cannot always be published quickly enough to provide timely notice. Therefore, you should always check the Agency's Web site at <http://www.fda.gov/AdvisoryCommittees/default.htm> and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: On March 12, 2014, the committee will discuss, make recommendations, and vote on a premarket approval application for a new indication for the cobas Human Papillomavirus (HPV) Test, sponsored by Roche Molecular Systems, Inc. The cobas HPV Test is a qualitative in vitro test for the detection of HPV that is currently approved for use in conjunction with cervical cytology. Roche is seeking a claim whereby the cobas HPV Test can be used as a first-line primary cervical screening test. The test utilizes amplification of target DNA by the polymerase chain reaction and nucleic acid hybridization for the detection of 14 high risk (HR) HPV types in a single analysis. The test specifically identifies types HPV 16 and HPV 18 while concurrently detecting the rest of the high risk types (31, 33, 35, 39, 45, 51, 52, 56, 58, 59, 66, and 68). Per the proposed indication, women who test negative for high risk HPV types by the cobas HPV Test would be followed up in accordance with the physician's assessment of screening and medical history, other risk factors, and professional guidelines. Women who test positive for HPV genotypes 16 and/or 18 by the cobas HPV Test would be referred to colposcopy. Women who test high risk HPV positive and 16/18 negative by the cobas HPV Test (12 other HR HPV positive) would be evaluated by cervical cytology to determine the need for referral to colposcopy.

FDA intends to make background material available to the public no later than 2 business days before the meeting. If FDA is unable to post the background

material on its Web site prior to the meeting, the background material will be made publicly available at the location of the advisory committee meeting, and the background material will be posted on FDA's Web site after the meeting. Background material is available at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee meeting link.

Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. Written submissions may be made to the contact person on or before March 3, 2014. On March 12, 2014, oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present, the names and addresses of proposed participants, and an indication of the approximate time requested to make their presentation on or before February 21, 2014. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by February 25, 2014.

Persons attending FDA's advisory committee meetings are advised that the Agency is not responsible for providing access to electrical outlets.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with physical disabilities or special needs. If you require special accommodations due to a disability, please contact James Clark, Committee Management Staff, james.clark@fda.hhs.gov, or 301-796-5293 at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at <http://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm> for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: January 14, 2014.

Jill Hartzler Warner,
Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2014-00939 Filed 1-17-14; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2013-N-0001]

Request for Notification From Industry Organizations Interested in Participating in the Selection Process for Nonvoting Industry Representatives and Request for Nominations for Nonvoting Industry Representatives on the Device Good Manufacturing Practice Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting that any industry organization interested in participating in the selection of a nonvoting industry representative to serve on the Device Good Manufacturing Practice Advisory Committee (DGMPAC) in the Center for Devices and Radiological Health notify FDA in writing. A nominee may either be self-nominated or nominated by an organization to serve as a nonvoting industry representative. Nominations will be accepted for the upcoming vacancy effective with this notice.

FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees, and therefore, encourages nominations of appropriately qualified candidates from these groups. Specifically, in this document, nominations for nonvoting representatives of industry interests are encouraged from device manufacturing industry.

DATES: Any industry organizations interested in participating in the selection of an appropriate nonvoting member to represent industry interests must send a letter stating that interest to the FDA by February 20, 2014, for the vacancy listed in this notice. Concurrently, nomination materials for prospective candidates should be sent to FDA by February 20, 2014.

ADDRESSES: All letters of interest and nominations should be submitted in writing to Margaret J. Ames (see **FOR FURTHER INFORMATION CONTACT**).

FOR FURTHER INFORMATION CONTACT:

Margaret J. Ames, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 5234, Silver Spring, MD 20993, 301-796-5960, email: margaret.ames@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Section 520 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360(j)), as amended, provides that the DGMPAC shall be composed of two representatives of interests of the device manufacturing industry. The Agency is requesting nominations for a nonvoting industry representative on the DGMPAC.

I. Function of DGMPAC

The DGMPAC reviews proposed regulations issuance regarding good manufacturing practices governing the methods used in, and the facilities and controls used for manufacture, packaging, storage, installation, and servicing of devices, and make recommendations regarding the feasibility and reasonableness of those proposed regulations. The DGMPAC also reviews and makes recommendations on proposed guidelines developed to assist the medical device industry in meeting the good manufacturing practice requirements, and provides advice with regard to any petition submitted by a manufacturer for an exemption or variance from good manufacturing practice regulations.

II. Qualifications

Persons nominated for the DGMPAC should possess appropriate qualifications to understand and contribute to the committee's work as described in the DGMPAC's function.

III. Selection Procedure

Any industry organization interested in participating in the selection of an appropriate nonvoting member to represent industry interests should send a letter stating that interest to the FDA contact (see **FOR FURTHER INFORMATION CONTACT**) within 30 days of publication of this document (see **DATES**). Within the subsequent 30 days, FDA will send a letter to each organization that has expressed an interest. Attached to the letter will be a complete list of all such organizations and a list of all nominees along with their current resumes. The letter will also state that it is the responsibility of the interested organizations to confer with one another and select a candidate to serve as the nonvoting member to represent industry interests for a particular committee within 60 days of receiving the FDA's