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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