

301-827-0314, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512391. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: In open session on November 18, 2009, the committee will discuss and make recommendations on the safety and effectiveness of a Pneumococcal 13-valent Conjugate Vaccine (Diphtheria CRM197 Protein), BLA 125324, and will hear an update on FDA's Influenza A (H1N1) 2009 monovalent vaccine activities; Postmarketing surveillance. On November 19, 2009, the committee will discuss and make recommendations on the safety and effectiveness of an Influenza Vaccine, Purified Recombinant Influenza Hemagglutinin, BLA STN125285.

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 link.

Procedure: On November 18, 2009, from 8 a.m. to approximately 5:45 p.m. and on November 19, 2009, from approximately 9 a.m. to approximately 3:15 p.m., the meeting is open to the public. 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 November 16, 2009. Oral presentations from the public will be scheduled between approximately 1:20 p.m. and 1:50 p.m. on November 18, 2009, and approximately 1:30 p.m. and 2 p.m. on November 19, 2009. Those desiring to make 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 November 9, 2009. 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 November 10, 2009.

Closed Committee Deliberations: On November 19, 2009, from 8 a.m. to approximately 9 a.m., the meeting will be closed to permit discussion and review of trade secret and/or confidential commercial information (5 U.S.C. 552b(c)(4)).

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 Christine Walsh or Denise Royster 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: October 9, 2009.

David Horowitz,

Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2009-N-0664]

The Neurological 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: Neurological 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 November 20, 2009, from 8 a.m. to 5 p.m.

Location: Holiday Inn, Ballroom, Two Montgomery Village Ave., Gaithersburg, MD.

Contact Person: Deborah Falls, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Silver Spring, MD 20993, 301-796-6459, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512513. Please call the Information Line for up-to-date information on this meeting. 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 and call the appropriate advisory committee hot line/phone line to learn about possible modifications before coming to the meeting.

Agenda: On November 20, 2009, the committee will discuss, make recommendations and vote on a premarket approval application for the Deep Brain Stimulation System for Epilepsy sponsored by Medtronic, Inc. This device is indicated as adjunctive therapy for reducing the frequency of seizures in individuals diagnosed with epilepsy. For this device, a patient's epilepsy should be characterized by partial-onset seizures (affecting only a part of the brain when they begin), with or without secondary generalization, that are refractory to antiepileptic medications. "Secondary generalization" is used to describe a partial-onset seizure that later spreads to the whole brain. "Refractory" to antiepileptic medications means that the patient's epilepsy does not respond to approved medications.

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 on the FDA Internet under the appropriate date at <http://www.fda.gov/AdvisoryCommittees/Calendar/default.htm>. Scroll down to the appropriate advisory committee 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 November 16, 2009. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. Those desiring to make 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 November 12, 2009. 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 November 13, 2009.

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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 AnnMarie Williams, 301-796-5966, 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: October 9, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-24893 Filed 10-15-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Agency for Healthcare Research and Quality

Meeting of the National Advisory Council for Healthcare Research and Quality

AGENCY: Agency for Healthcare Research and Quality (AHRQ), HHS.

ACTION: Notice of public meeting.

SUMMARY: In accordance with section 10(a) of the Federal Advisory Committee Act, 5 U.S.C. app. 2, this notice announces a meeting of the National Advisory Council for Healthcare Research and Quality.

DATES: The meeting will be held on Friday, November 13, 2009, from 9 a.m. to 3 p.m.

ADDRESSES: The meeting will be held at the Eisenberg Conference Center, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850.

FOR FURTHER INFORMATION CONTACT: Deborah Queenan, Coordinator of the Advisory Council, at the Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850, (301) 427-1330. For press-related information, please contact Karen Migdail at (301) 427-1855.

If sign language interpretation or other reasonable accommodation for a disability is needed, please contact the Food and Drug Administration (FDA) Office of Equal Employment Opportunity and Diversity Management on (301) 827-4840, no later than October 30, 2009. The agenda, roster, and minutes are available from Ms. Bonnie Campbell, Committee Management Officer, Agency for Healthcare Research and Quality, 540 Gaither Road, Rockville, Maryland 20850. Ms. Campbell's phone number is (301) 427-1554.

SUPPLEMENTARY INFORMATION:

I. Purpose

The National Advisory Council for Healthcare Research and Quality was established in accordance with Section 921 (now Section 931) of the Public Health Service Act 42 U.S.C. 299c. In accordance with its statutory mandate, the Council is to advise the Secretary of the Department of Health and Human Services and the Director, Agency for Healthcare Research and Quality (AHRQ), on matters related to actions of AHRQ to enhance the quality, improve the outcomes, and reduce the costs of health care services; improve access to such services through scientific

research; and promote improvements in clinical practice and in the organization, financing, and delivery of health care services. The Council is composed of members of the public, appointed by the Secretary, and Federal *ex-officio* members.

II. Agenda

On Friday, November 13, the Council meeting will convene at 9 a.m., with the call to order by the Council Chair and approval of previous Council summary notes. The AHRQ director will present her update on current research, programs, and initiatives. The agenda will include a report from the subcommittee of Child Health Insurance Program Reauthorization Act (CHIPRA) Quality Provisions, and discussion of the Patient Safety and Medical Liability Reform Demonstration Project.

The final agenda will be available on the AHRQ Web site at <http://www.ahrq.gov> no later than November 9, 2009.

Dated: October 7, 2009.

Carolyn M. Clancy,
Director.

[FR Doc. E9-24885 Filed 10-15-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Council on Graduate Medical Education; Notice of Meeting

In accordance with section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), notice is hereby given of the following meeting:

Name: Council on Graduate Medical Education (COGME).

Dates and Times: November 18, 2009, 8:30 a.m.-4:45 p.m.; November 19, 2009, 7:30 a.m.-4:15 p.m.

Place: Hilton Washington DC/Rockville Executive Meeting Center, Regency Ballroom, 1750 Rockville Pike, Rockville, MD 20854, Telephone: (301) 468-1100.

Status: The meeting will be open to the public.

Agenda: On the morning of November 18, following the welcoming remarks from the COGME Chair and the Executive Secretary of COGME, there will be a presentation on the AAMC and the Physician Workforce given by Darrell G. Kirch, M.D., followed by a panel presentation: "Does the Nation Have the Right Number and Mix of GME Slots," given by Edward Salsberg, M.P.A.; David Sundwall, M.D.; and Fitzhugh Mullan, M.D. The Vice Chair of COGME, Robert Phillips, Jr., M.D., M.S.P.H., will be the facilitator.

In the late morning there will be a presentation of Bureau of Health Professions