

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 16, 2010, the committee will meet in open session to review and discuss the pathway to licensure for protective antigen-based anthrax vaccines for a post-exposure prophylaxis indication using the animal rule. On November 17, 2010, the committee will meet in open session to review and discuss the effectiveness of vaccinating males and females with Gardasil manufactured by Merck & Co. for the prevention of anal dysplasia and anal cancer.

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 16, 2010, from 9 a.m. until approximately 11:45 a.m. and from 2 p.m. until approximately 4 p.m. and on November 17, 2010, 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 10, 2010. Oral presentations from the public will be scheduled between approximately 2:15 p.m. and 2:45 p.m. on November 16, 2010, and between approximately 11:45 a.m. and 12:15 p.m. on November 17, 2010. 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 2, 2010. 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 3, 2010.

Closed Committee Deliberations: On November 16, 2010, between 12 p.m. and approximately 2 p.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)). The committee will hear firms discuss protocols they propose to use for the pathway to licensure for protective antigen-based anthrax vaccines for a post-exposure prophylaxis indication using the animal rule.

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 Donald W. Jehn 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: September 23, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

[FR Doc. 2010-24253 Filed 9-27-10; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2010-N-0001]

Joint Meeting of the Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management 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 Committees: Anesthetic and Life Support Drugs Advisory Committee and the Drug Safety and Risk Management Advisory Committee.

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

Date and Time: The meeting will be held on October 21, 2010, from 8:30 a.m. to 4:30 p.m. and on October 22, 2010, from 8:30 a.m. to 4 p.m.

Location: Hilton Washington DC North/Gaithersburg, The Ballrooms, 620 Perry Pkwy., Gaithersburg, MD. The hotel telephone number is 301-977-8900.

Contact Person: Kalyani Bhatt, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 31, rm. 2417, Silver Spring, MD 20993-0002, 301-796-9001, FAX: 301-847-8533, email: kalyani.bhatt@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), codes 3014512529 and 3014512535. 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: The committee will discuss considerations for the design of postmarketing studies for new drug applications (NDAs) 22-272, OxyContin (oxycodone hydrochloride controlled-release) Tablets, manufactured by Purdue Pharma, Inc., and NDA 22-321, EMBEDA (morphine sulfate extended-release with a sequestered naltrexone hydrochloride inner core) Capsules, manufactured by Alpharma Pharmaceuticals, LLC and King Pharmaceuticals Research & Development, Inc., approved for the management of moderate to severe pain when a continuous, around-the-clock opioid analgesic is needed for an extended period of time. The postmarketing studies are intended to be epidemiological or observational studies that will assess the known serious risks of these products and whether product-specific properties which are intended to discourage misuse and abuse actually result in a decrease in the risks of misuse and abuse, and their

consequences: Addiction, overdose, and death.

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: 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 October 14, 2010. Oral presentations from the public will be scheduled between approximately 10:45 a.m. and 11:45 a.m. on October 22, 2010. 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 October 6, 2010. 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 October 7, 2010.

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 Kalyani Bhatt 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: September 22, 2010.

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

[FR Doc. 2010-24251 Filed 9-27-10; 8:45 am]

BILLING CODE 4160-01-S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Institute of Mental Health; Notice of Meeting

Pursuant to section 10(a) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of a meeting of the Subcommittee for Planning the Annual Strategic Plan Updating Process of the Interagency Autism Coordinating Committee (IACC).

The purpose of the Subcommittee meeting is to plan the process for updating the IACC Strategic Plan for Autism Spectrum Disorder Research. The meeting will be open to the public and will also be accessible by webinar and conference call.

Name of Committee: Interagency Autism Coordinating Committee (IACC).

Type of meeting: Subcommittee for Planning the Annual Strategic Plan Updating Process.

Date: October 6, 2010.

Time: 9 a.m. to 12 p.m. Eastern Time.

Agenda: To discuss plans for updating the IACC Strategic Plan for ASD Research.

Place: The National Institute of Mental Health, Neuroscience Center, 6001 Executive Boulevard, Conference Room 8120, Rockville, MD 20852.

Webinar Access: <https://www2.gotomeeting.com/register/927802003>.

Registration: http://www.acclaroresearch.com/oarc/10-06-10_IACC. Pre-registration is recommended to expedite check-in. Seating in the meeting room is limited to room capacity and on a first come, first served basis.

Conference Call: Dial: 888-848-6715, Access code: 5341736.

Contact Person: Ms. Lina Perez, Office of Autism Research Coordination, Office of the Director, National Institute of Mental Health, NIH, 6001 Executive Boulevard, NSC, Room 8200, Bethesda, MD 20892-9669, Phone: (301) 443-6040, E-mail: IACCPublicInquiries@mail.nih.gov.

Please Note: The meeting will be open to the public and accessible via webinar and conference call. Members of the public who participate using the conference call phone number will be able to listen to the meeting but will not be heard. If you experience any technical problems with the conference call, please-mail IACCTechSupport@acclaroresearch.com.

If you experience any technical problems with the web presentation tool, please contact GoToWebinar at (800) 263-6317. To access the web presentation tool on the Internet the following computer capabilities are required: (A) Internet Explorer 5.0 or later, Netscape Navigator 6.0 or later or Mozilla Firefox 1.0 or later; (B) Windows® 2000, XP Home, XP Pro, 2003 Server or Vista; (C) Stable 56k, cable modem, ISDN, DSL or better Internet connection; (D) Minimum of Pentium 400 with 256 MB of RAM (Recommended); (E) Java Virtual Machine enabled (Recommended).

Individuals who participate in person or by using these electronic services and who need special assistance, such as captioning of the conference call or other reasonable accommodations, should submit a request to the Contact Person listed on this notice at least 7 days prior to the meeting.

This notice is being published less than 15 days prior to the meeting due to the urgent need for the Subcommittee to discuss the upcoming update of the IACC Strategic Plan prior to the IACC meeting scheduled for October 22, 2010.

Schedule is subject to change.

Information about the IACC is available on the Web site: <http://www.iacc.hhs.gov>.

Dated: September 22, 2010.

Jennifer S. Spaeth,
Director, Office of Federal Advisory Committee Policy.

[FR Doc. 2010-24280 Filed 9-27-10; 8:45 am]

BILLING CODE 4140-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Centers for Disease Control and Prevention

Disease, Disability, and Injury Prevention and Control Special Emphasis Panel (SEP): Member Conflict Review, Program Announcement (PA) 07-318, Initial Review

In accordance with Section 10(a)(2) of the Federal Advisory Committee Act (Pub. L. 92-463), the Centers for Disease Control and Prevention (CDC) announces the aforementioned meeting:

TIME AND DATE: 1 p.m.–3 p.m., November 15, 2010 (Closed).

Place: National Institute for Occupational Safety and Health (NIOSH), CDC, 1095 Willowdale Road, Morgantown, West Virginia 26506, telephone: (304)285-6143.

Status: The meeting will be closed to the public in accordance with provisions set forth in Section 552b(c) (4) and (6), Title 5 U.S.C., and the Determination of the Director, Management Analysis and Services Office, CDC, pursuant to Public Law 92-463.