

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6116 Executive Boulevard, 8041, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Bratin K. Saha, PhD, Scientific Review Officer, Program Coordination and Referral Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Boulevard, Room 8041, Bethesda, MD 20892. (301) 402-0371. sahab@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel. NCI Cancer Prevention Research II.

Date: October 30, 2009.

Time: 10 a.m. to 12 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6116 Executive Boulevard, Room # 210, Rockville, MD 20852. (Telephone Conference Call).

Contact Person: Irina Gordienko, PhD, Scientific Review Officer, Scientific Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, NIH, 6116 Executive Blvd., Rm. 7073, Bethesda, MD 20892. 301-594-1566. gordienkoiv@mail.nih.gov.

Name of Committee: National Cancer Institute Special Emphasis Panel. Community Clinical Oncology Programs.

Date: December 1-2, 2009.

Time: 7 p.m. to 4 p.m.

Agenda: To review and evaluate grant applications.

Place: Marriott Courtyard Gaithersburg Washingtonian Ctr, 204 Boardwalk Place, Gaithersburg, MD 20878.

Contact Person: Gerald G. Lovinger, PhD, Scientific Review Administrator, Special Review and Logistics Branch, Division of Extramural Activities, National Cancer Institute, 6116 Executive Blvd., Room 8101, Bethesda, MD 20892-8329. 301/496-7987. lovingeg@mail.nih.gov.

(Catalogue of Federal Domestic Assistance Program Nos. 93.392, Cancer Construction; 93.393, Cancer Cause and Prevention Research; 93.394, Cancer Detection and Diagnosis Research; 93.395, Cancer Treatment Research; 93.396, Cancer Biology Research; 93.397, Cancer Centers Support; 93.398, Cancer Research Manpower; 93.399, Cancer Control, National Institutes of Health, HHS)

Dated: September 21, 2009.

Jennifer Spaeth,

Director, Office of Federal Advisory Committee Policy.

[FR Doc. E9-23269 Filed 9-25-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Pulmonary-Allergy Drugs 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: Pulmonary-Allergy Drugs 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 18, 2009, from 8 a.m. to 5 p.m.

Location: Hilton Washington DC/Silver Spring, The Ballrooms, 8727 Colesville Rd., Silver Spring, MD. The hotel phone number is 301-589-5200.

Contact Person: Kristine T. Khuc, Center for Drug Evaluation and Research (HFD-21), Food and Drug Administration, 5600 Fishers Lane (for express delivery, 5630 Fishers Lane, rm. 1093), Rockville, MD 20857, 301-827-7001, FAX: 301-827-6776, e-mail: Kristine.Khuc@fda.hhs.gov, or FDA Advisory Committee Information Line, 1-800-741-8138 (301-443-0572 in the Washington, DC area), code 3014512545. 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 biologics license application (BLA) 103976, supplement 5149, for XOLAIR (omalizumab), manufactured by Genentech USA, Inc. and Novartis Pharmaceuticals Corp. The proposed indication for this product is to treat moderate to severe persistent asthma in patients between 6 and 11 years of age whose symptoms are inadequately controlled with inhaled steroid medications and have: (1) A positive reaction to skin testing with common substances that can cause allergies and asthma, such as pollen or (2) in vitro reactivity, which is measured with a blood test that confirms the presence of specific proteins consistent with allergies and asthma.

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 November 3, 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 October 26, 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 October 27, 2009.

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 Kristine T. Khuc 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, 2009.

David Horowitz,

Assistant Commissioner for Policy.

[FR Doc. E9-23292 Filed 9-25-09; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Pulmonary-Allergy Drugs Advisory Committee; Notice of Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.