

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

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

Voting and Nonvoting Consumer Representative Members on Public Advisory Committees and Panels; Notice of Public Meeting

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting.

The Food and Drug Administration (FDA) is announcing a public meeting for individuals and groups interested in nominating voting and nonvoting consumer representatives to FDA advisory committees and panels. This public meeting also is for individuals interested in serving as voting and nonvoting representatives of FDA advisory committees and panels. The purpose of the public meeting is to inform individuals and groups with consumer interests on how to participate in the nomination and selection process for members representing consumer interests on advisory committees, provide information on the structure and function of advisory committees seeking individuals to serve as consumer representatives, and update individuals and consumer groups and individuals on current committee vacancies.

Date and Time: The public meeting will be held on April 30, 2010, from 8:15 a.m. to approximately 4:30 p.m.

Location: The public meeting will be held at the Food and Drug Administration, Center for Drug Evaluation and Research Advisory Committee Conference Room, rm. 1066, 5630 Fishers Lane, Rockville, MD. Please use the lower entrance, which faces Parklawn Drive. Visitor badges will be held at the guard station at the entrance to the building. Participants will need a picture identification to pick up their badge. Public parking is not available at the 5630 Fishers Lane location. A public parking lot is available on Fishers Lane across from the Parklawn Building at 5600 Fishers Lane, and additional public parking is available at the Twinbrook Metro Station located several blocks west of the meeting location.

Contact Person: Doreen Brandes, Office of the Commissioner (HF-4), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-827-8858, FAX: 301-827-1041, or e-mail: Doreen.Brandes@fda.hhs.gov. After April 15, 2010, the contact person's location and contact

information will change. All correspondence should be mailed to Doreen Brandes, Office of the Commissioner, 10903 New Hampshire Ave., Bldg. 32, rm. 5103, Silver Spring, MD 20993-0002, 301-796-8858, FAX: 301-847-8640, or e-mail: Doreen.Brandes@fda.hhs.gov.

Registration: Register by e-mail or fax to the contact person no later than April 23, 2010. Provide complete information for each attendee, including name, title, organization's name, address, e-mail, and telephone and fax numbers

If you need special accommodations due to a disability, please contact Doreen Brandes (see *Contact Person*) at least 7 days in advance.

SUPPLEMENTARY INFORMATION:

I. Criteria for Members

FDA believes that persons nominated for membership as a consumer representative on the committee/panels should meet the following criteria: (1) Demonstrate ties to consumer and community-based organizations, (2) be able to analyze technical data, (3) understand research design, (4) be able to discuss benefits and risks, and (5) be able to evaluate the safety and efficacy of products under review. The consumer representative represents the consumer perspective on issues and actions before the advisory committee; serves as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitates dialogue with the advisory committees on scientific issues that affect consumers.

II. Nomination Procedures

When individuals are nominated to serve as consumer representatives on FDA advisory committee and panels, all nominations should include a cover letter, a curriculum vita or resume (that includes the nominee's office address, telephone number, and e-mail address), and a list of consumer or community-based organizations for which the candidate can demonstrate active participation. Nominations will specify the advisory committee(s) or panel(s) for which the nominee is recommended. Any interested person or organization may nominate one or more qualified persons for membership as consumer representatives on the advisory committee/panels. Self-nominations are also accepted. Potential candidates will be required to provide detailed information concerning such matters as financial holdings, employment, and research grants and/or contracts to permit evaluation of possible sources of a conflict of interest. The nomination should specify the committees/panels of

interest. The term of office is up to 4 years, depending on the appointment date.

Additional background information regarding the topics for the public meeting will be available 5 days before the meeting and may be found at: <http://www.fda.gov/AdvisoryCommittees/default.htm> (look for link to Advisory Committee Public Meeting for Consumer Representatives.)

Dated: March 24, 2010.

Jill Hartzler Warner,

Acting Associate Commissioner for Special Medical Programs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meeting.

The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: Center for Scientific Review Special Emphasis Panel; Member Conflict: BSCH.

Date: April 1, 2010.

Time: 3 p.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: National Institutes of Health, 6701 Rockledge Drive, Bethesda, MD 20892 (Telephone Conference Call).

Contact Person: Jose H. Guerrier, PhD, Scientific Review Officer, Center for Scientific Review, National Institutes of Health, 6701 Rockledge Drive, Room 5218, MSC 7852, Bethesda, MD 20892, 301-435-1137, guerriej@csr.nih.gov.

This notice is being published less than 15 days prior to the meeting due to the timing limitations imposed by the review and funding cycle.

(Catalogue of Federal Domestic Assistance Program Nos. 93.306, Comparative Medicine; 93.333, Clinical Research, 93.306, 93.333, 93.337, 93.393-93.396, 93.837-93.844, 93.846-93.878, 93.892, 93.893, National Institutes of Health, HHS)