supplemental biologics license application (sBLA) 103949/5153, PEGINTRON (peginterferon alfa-2b), Schering Corp., proposed indication for adjuvant treatment of melanoma. On March 13, 2008, the committee will discuss the cumulative data, including recent study results, on the risks of erythropoeisis-stimulating agents when administered to patients with cancer. Agents to be discussed include ARANESP (darbepoetin alfa), EPOGEN (epoetin alfa), PROCRIT (epoetin alfa, Amgen, Inc.), and MIRCERA (methoxy polyethylene glycol-epoetin beta, Hoffman-La Roche Inc.). This is a followup to the May 10, 2007, Oncologic Drugs Advisory Committee Meeting.

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and 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 February 27, 2008. Oral presentations from the public will be scheduled between approximately 10:30 a.m. to 11 a.m., and 3:30 p.m. to 4 p.m. on March 12, 2008, and between approximately 1 p.m. to 2 p.m. on March 13, 2008. 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 February 19, 2008. 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 February 20, 2008.

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 Nicole Vesely 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/oc/advisory/default.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: January 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–1295 Filed 1–24–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Pediatric 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: Pediatric Advisory Committee.

General Function of the Committee: To provide advice and recommendations to the agency on FDA's regulatory issues. The committee also advises and makes recommendations to the Secretary of Health and Human Services under 45 CFR 46.407 on research involving children as subjects that is conducted or supported by the Department of Health and Human Services, when that research is also regulated by FDA.

Date and Time: The meeting will be held on Tuesday, March 25, 2008, from 8 a.m. to 5 p.m.

Location: Hilton, Washington DC North/Gaithersburg, Grand Ballroom, 620 Perry Pkwy., Gaithersburg, MD.

Contact Person: Carlos Peña, Office of Science and Health Coordination, Office of the Commissioner (HF–33), Food and Drug Administration, 5600 Fishers Lane (for express delivery, rm. 14B–08), Rockville, MD 20857, 301–827–3340, e-mail: *carlos.peña@fda.hhs.gov*, or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area), code 8732310001. 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 March 25, 2008, the Pediatric Advisory Committee will hear and discuss reports by the agency, as mandated in section 17 of the Best Pharmaceuticals for Children Act, on adverse event reports for TOPROL XL (metoprolol), BREVIBLOC (esmolol HCl), LOTENSIN (benazepril), COREG (carvedilol), COLAZAL (balsalazide), ELOXATIN (oxaliplatin), CELEBREX (celecoxib), and SUPRANE (desflurane).

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/ohrms/dockets/ac/acmenu.htm*, click on the year 2008 and 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 March 3, 2008. Oral presentations from the public will be scheduled between approximately 1 p.m. and 2 p.m. on March 25, 2008. 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 February 22, 2008. 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 February 25, 2008.

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FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our Web site at *http://www.fda.gov/oc/advisory/default.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: January 17, 2008.

Randall W. Lutter,

Deputy Commissioner for Policy.

[FR Doc. E8–1296 Filed 1–24–08; 8:45 am]

BILLING CODE 4160–01–S

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

Request for Nominations for Voting Consumer Representative Members on Public Advisory Committees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting consumer representatives to serve on the Cellular, Tissue, and Gene Therapies Advisory Committee and the Allergenic Products Advisory Committee in the Center for Biologics Evaluation and Research (CBER). Nominations will be accepted for vacancies that will occur through August 31, 2008.

DATES: Nominations will be accepted for those voting consumer representative vacancies that will occur on or before August 31, 2008. Nominations submitted on or before April 1, 2008, will be given first consideration for membership on the Cellular, Tissue, and Gene Therapies Advisory Committee and the Allergenic Products Advisory Committee. Nominations received after April 1, 2008, will be considered for nomination to the committee should nominees still be needed.

ADDRESSES: All nominations for membership should be sent electronically to *CV@OC.FDA.GOV*, or by mail to Advisory Committee Oversight and Management Staff (HF–4), 5600 Fisher Lane, rm. 15A–12, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: Regarding all nomination questions for membership, the primary contact is Gail Dapolito, Center for Biologics Evaluation and Research, 301–827–0314, FAX: 301–827–0294, e-mail: *Gail.Dapolito@fda.hhs.gov*. Information about becoming a member on an FDA advisory committee can also be obtained by visiting FDA's Web site at *http://www.fda.gov/oc/advisory/default.htm*.

SUPPLEMENTARY INFORMATION: FDA is requesting nomination for voting consumer representative members on the following CBER committees:

I. Functions

A. Cellular, Tissue, and Gene Therapies Advisory Committee

The committee reviews and evaluates available data relating to the safety, effectiveness, and appropriate use of human cells, human tissues, gene transfer therapies, and xenotransplantation products which are intended for a broad spectrum of human diseases and in the reconstruction, repair, or replacement of tissues for various conditions. The committee also considers the quality and relevance of FDA's research program which provides scientific support for the regulation of these products, and makes appropriate recommendations to the Commissioner of Food and Drugs (the Commissioner).

B. Allergenic Products Advisory Committee

The committee reviews and evaluates available data concerning the safety, effectiveness, and adequacy of labeling of marketed and investigational allergenic biological products or materials that are administered to humans for the diagnosis, prevention, or treatment of allergies and allergic disease. The committee also makes appropriate recommendations to the Commissioner on its findings regarding the affirmation or revocation of biological product licenses, the safety, effectiveness, and labeling of the products, clinical and laboratory studies of such products, amendments or revisions to regulations governing the manufacture, testing, and licensing of allergenic biological products, and on the quality and relevance of FDA's research programs which provide the scientific support for regulating these agents.

II. Criteria for Members

Persons who are nominated for membership as consumer representatives on the committees must 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) discuss benefits and risks, and (5) evaluate the safety and efficacy of products under review. The consumer representative must be able to represent the consumer perspective on issues and actions before the advisory committee; serve as a liaison between the committee and interested consumers, associations, coalitions, and consumer organizations; and facilitate dialogue with the advisory committee on scientific issues that affect consumers.

III. Selection Procedures

The selection of members representing consumer interests is conducted through procedures that include the use of organizations representing the public interest and consumer advocacy groups. The organizations have the responsibility of recommending candidates of the agency's selection.

IV. Nomination Procedures

All nominations must include a cover letter, a curriculum vitae 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. Any interested person or organization may nominate one or more qualified persons for membership to represent consumer interests on one or more of the advisory committees. Self-nominations are also accepted. FDA will ask the potential candidates 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 committee(s) of interest. The term of office is up to 4 years, depending on the appointment date.

FDA has a special interest in ensuring that women, minority groups, and individuals with disabilities are adequately represented on its advisory committees and, therefore, encourages nominations of qualified candidates from these groups.