questions through written comments that can be submitted to the public docket (see **ADDRESSES**). When submitting comments, if you are commenting on behalf of a child, please indicate that and answer the following questions as much as possible from the patient's perspective.

Topic 1: Disease Symptoms and Daily Impacts That Matter Most to Patients

1. What *worries you most* about your condition?

2. Do you experience symptoms because of your condition? If so, of all the symptoms that you experience, which *one to three* symptoms have the most significant impact on your life? (Examples may include irregular heartbeat, shortness of breath, difficulty swallowing, stomach pain, or constipation.)

3. Are there *specific activities* that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, daily hygiene, driving, being a blood or organ donor, or for women in reproductive age concern about getting pregnant and transmitting the infection to your children, etc.)

4. How have your condition and its symptoms *changed over time*?

5. Do your symptoms come and go? If so, do you know of anything that makes your symptoms better or worse?

Topic 2: Patient Perspectives on Current Approaches To Treat Chagas Disease

1. *What are you currently doing* to help treat your condition? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies such as diet modification.)

a. What specific symptoms do your treatments address?

b. How has your treatment regimen changed over time, and why?

2. What are the most significant *downsides to your current treatments,* and how do they affect your daily life? (Examples of downsides may include bothersome side effects, length of treatment, number of pills to take daily, going to the hospital for frequent checkups or treatment, restrictions on driving, potential consequences to your health and your child's health during pregnancy, etc.)

3. What specific things would you look for in an *ideal treatment* for your condition?

In the afternoon, discussion will be related to scientific topics, with the goal of understanding issues that may affect the development of drugs for the treatment of Chagas disease and identifying topics for future discussion. Discussion topics for the afternoon will include designs and endpoints for clinical trials as well as appropriate trial populations.

B. Meeting Attendance and Participation

If you wish to attend the meeting, visit *http://chagasdiseasepatientfocused.eventbrite.com.* Please register for the meeting by April 20, 2015. If you are unable to attend the meeting in person, you can register to view a live Webcast. You will be asked to indicate in your registration whether you plan to attend in person or via the Webcast.

Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meetings will be based on space availability. If you need special accommodations because of a disability, please contact Pujita Vaidya (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions must indicate in their registration which topic(s) they wish to address. These patients also must send a brief summary of responses to the topic questions by April 10, 2015, to *PatientFocused@fda.hhs.gov.* Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

FDA will hold an open public comment period to give the public an opportunity to comment. Registration for open public comment will occur at the registration desk on the day of the meeting on a first-come, first-served basis.

III. Comments

Regardless of attendance at the Patient-Focused Drug Development meeting, you can submit electronic or written comments, including responses to the questions pertaining to Topics 1 and 2, to the public docket (see **ADDRESSES**) by June 29, 2015. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at *http://www.regulations.gov.*

III. Transcripts

As soon as a transcript is available, FDA will post it at *http://www.fda.gov/Drugs/NewsEvents/ucm420130.htm.*

Dated: December 3, 2014.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2014–28828 Filed 12–9–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–0001]

Oncologic 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: Oncologic 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 January 7, 2015, from 8 a.m. to 5 p.m.

Location: FDA White Oak Campus, 10903 New Hampshire Ave., Building 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Information regarding special accommodations due to a disability, visitor parking, and transportation may be accessed at: *http://www.fda.gov/AdvisoryCommittees/default.htm;* under the heading ''Resources for You,'' click on ''Public Meetings at the FDA White Oak Campus.'' Please note that visitors to the White Oak Campus must enter through Building 1.

Contact Person: Caleb Briggs, 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: *ODAC@fda.hhs.gov,* or FDA Advisory Committee Information Line, 1–800–741–8138 (301–443–0572 in the Washington, DC area). 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 at *http://www.fda.gov/AdvisoryCommittees/default.htm* and scroll down to the appropriate advisory committee meeting link, or call the advisory committee information line to learn about possible modifications before coming to the meeting.

Agenda: The committee will discuss biologics license application (BLA) 125553 for EP2006, a proposed biosimilar to Amgen Inc.'s NEUPOGEN (filgrastim), submitted by Sandoz, Inc. The proposed indications (uses) for this product are: (1) To decrease the incidence of infection, as manifested by febrile neutropenia, in patients with nonmyeloid malignancies receiving myelosuppressive anti-cancer drugs associated with a significant incidence of severe neutropenia with fever; (2) for reducing the time to neutrophil recovery and the duration of fever, following induction or consolidation chemotherapy treatment of adults with acute myeloid leukemia; (3) to reduce the duration of neutropenia and neutropenia-related clinical sequelae, *e.g.*, febrile neutropenia in patients with nonmyeloid malignancies undergoing myeloablative chemotherapy followed by marrow transplantation; (4) for the mobilization of hematopoietic progenitor cells into the peripheral blood for collection by leukapheresis; and (5) for chronic administration to reduce the incidence and duration of sequelae of neutropenia (*e.g.*, fever, infections, oropharyngeal ulcers) in symptomatic patients with congenital neutropenia, cyclic neutropenia, or idiopathic neutropenia.

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 meeting 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 December 22, 2014. Oral presentations from the public will be scheduled between approximately 2:15 p.m. to 3:15 p.m. Those individuals interested in making 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 December 12, 2014. 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 December 15, 2014.

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 Caleb Briggs 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: December 3, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–28847 Filed 12–8–14; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2014–N–2032]

Request for Nominations for Voting Members on the Food Advisory Committee

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is requesting nominations for voting members to serve on the Food Advisory Committee, Office of Regulations, Policy, and Social Sciences, Center for Food Safety and Applied Nutrition. FDA seeks to include the views of women and men, members of all racial and ethnic groups, and individuals with and without disabilities on its advisory committees and, therefore, encourages nominations of appropriately qualified candidates from these groups.

DATES: Nominations received on or before January 30, 2015, will be given first consideration for membership on the Food Advisory Committee. Nominations received after January 30, 2015, will be considered for nomination to the committee as later vacancies occur.

ADDRESSES: All nominations for membership should be submitted electronically by logging into the FDA Advisory Committee Membership Nomination Portal: *https://www.accessdata.fda.gov/scripts/FACTRSPortal/FACTRS/index.cfm,* by mail to Advisory Committee Oversight and Management Staff, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 32, Rm. 5103, Silver Spring, MD 20993–0002, or by FAX to 301–847–8640.

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/AdvisoryCommittees/default.htm.*

FOR FURTHER INFORMATION: *Regarding all nominations questions for membership, the primary contact is:* Karen Strambler, Office of Regulations, Policy, and Social Sciences, Center for Food Safety and Applied Nutrition, 5100 Paint Branch Pkwy., Rm. 1C–016, College Park, MD 20740, 240–402–2589, FAX: 301–436–2637, *FoodAdvisoryCommittee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION: FDA is requesting nominations for voting members on the Food Advisory Committee.

I. General Description of the Committee Duties

The Food Advisory Committee provides advice to the Commissioner of Food and Drugs and other appropriate officials on emerging food safety, food science, nutrition, and other food-related health issues that FDA considers of primary importance for its food and cosmetics programs. The Committee may be charged with reviewing and evaluating available data and making recommendations on matters such as those relating to: (1) Broad scientific and technical food- or cosmetic-related