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.

Dated: December 4, 2014.

Jill Hartzler Warner,

Associate Commissioner for Special Medical Programs.

[FR Doc. 2014–28881 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–1998]

Patient-Focused Drug Development Public Meeting on Chagas Disease

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for Chagas disease. Patient-Focused Drug Development is part of FDA's performance commitments in the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The meeting is intended to allow FDA to obtain patients' perspectives on the impact that Chagas disease has on their daily lives, as well as their perspectives on the available therapies for Chagas disease. FDA is also interested in discussing issues related to scientific challenges in developing drugs to treat Chagas disease. In the afternoon, FDA will provide information for and gain perspective from patients and patient advocacy organizations, health care providers, academic experts, and industry on various aspects of clinical development of drug products intended to treat Chagas disease. The input from this public meeting will help in developing topics for further discussion.

DATES: The meeting will be held on April 28, 2015, from 9 a.m. to 5 p.m. Registration to attend the meeting must be received by April 20, 2015. See the **SUPPLEMENTARY INFORMATION** section for information on how to register for the meeting. Submit electronic or written comments by June 29, 2015.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, Sections B and C of the Great Room (Rm. 1503), Silver Spring, MD 20993. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please visit *http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.*

Submit electronic comments to *http://www.regulations.gov.* Submit written comments to the Division of Dockets Management (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Room 1061, Rockville, MD 20852. All comments should be identified with the docket number found in brackets in the heading of this document.

FDA will post the agenda approximately 5 days before the meeting at *http://www.fda.gov/Drugs/NewsEvents/ucm420130.htm.*

FOR FURTHER INFORMATION CONTACT: Pujita Vaidya, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1144, Silver Spring, MD 20993, 301–796–0684, FAX: 301–847–8443, *Pujita.Vaidya@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected Chagas disease as the focus of a meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patients' perspectives on the severity of the disease and the available therapies for the condition. Patient-Focused Drug Development is being conducted to fulfill FDA's performance commitments made as part of the authorization of PDUFA V under Title I of the Food and Drug Safety and Innovation Act (Public Law 112–144). The full set of performance commitments is available on the FDA Web site at *http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.*

FDA has committed to obtain the patient perspective in 20 disease areas during the course of PDUFA V. For each disease area, the Agency will conduct a public meeting to discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient community, and other interested stakeholders.

On April 11, 2013, FDA published a notice (78 FR 21613) in the **Federal Register** announcing the disease areas for meetings in fiscal years (FYs) 2013 through 2015, the first 3 years of the 5-year PDUFA V time frame. To develop the list of disease areas, the Agency used several criteria that were outlined in the April 11 notice. The Agency obtained public comment on these criteria and potential disease areas through a notice for public comment published in the **Federal Register** on September 24, 2012 (77 FR 58849), and through a public meeting held on October 25, 2012. In selecting the disease areas, FDA carefully considered the public comments received and the perspectives of its review divisions. On October 8, 2014, FDA published a notice in the **Federal Register** to initiate another public process to determine the disease areas for FYs 2016 through 2017 (79 FR 60857). More information, including the list of disease areas and a general schedule of meetings, is posted at *http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm.*

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on symptoms of Chagas disease (American trypanosomiasis) that matter most to patients and on current approaches to treating Chagas disease. When left untreated, acute Chagas disease may progress to chronic Chagas disease. There are currently no FDA-approved drug therapies to treat acute or chronic Chagas disease. FDA is committed to working with all stakeholders to develop safe and effective therapies for affected individuals.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section and organized by topic. For each topic, a brief patient panel discussion will begin the dialogue, followed by a facilitated discussion inviting comments from other patients and patient stakeholders. In addition to input received through this public meeting, FDA is interested in receiving patient input addressing these

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