4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2015-N-0244]

Patient-Focused Drug Development for Functional Gastrointestinal Disorders; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for functional gastrointestinal (GI) disorders, including irritable bowel syndrome, gastroparesis, chronic persistent symptomatic gastroesophageal reflux despite standard therapeutic interventions, and chronic idiopathic constipation. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of functional GI disorders on daily life and patient views on treatment approaches.

DATES: The public meeting will be held on May 11, 2015, from 1 p.m. to 5 p.m. Registration to attend the meeting must be received by May 1, 2015 (see SUPPLEMENTARY INFORMATION for instructions). Submit electronic or written comments to the public docket by July 13, 2015.

ADDRESSES: The meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (rm. 1503), Silver Spring, MD

20993-0002. Participants must enter through Building 1 and undergo security screening. For more information on parking and security procedures, please refer to http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm.

Submit electronic comments to www.regulations.gov. Submit written comments to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 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/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm430885.htm.

FOR FURTHER INFORMATION CONTACT: Pegah Mariani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1146, Silver Spring, MD 20993-0002, 240-402-4513, FAX: 301-847-8443, Sayyedeh.Mariani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected functional GI disorders as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for that condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144). The full set of

performance commitments is available at http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf.

FDA committed to obtain the patient perspective on 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 communities, and other interested stakeholders.

On April 11, 2013, FDA published a document in the Federal Register (78 FR 21613) announcing the disease areas for meetings in fiscal years (FYs) 2013-2015, the first 3 years of the 5-year PDUFA V timeframe. The Agency used several criteria outlined in that document to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA has initiated a second public process for determining the disease areas for FY 2016-2017. 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

The purpose of this Patient-Focused Drug Development meeting is to obtain input on the symptoms and other impacts of functional GI disorders, such as irritable bowel syndrome, gastroparesis, chronic persistent symptomatic gastroesophageal reflux despite standard

therapeutic interventions, and chronic idiopathic constipation, that matter most to patients, as well as perspectives on current approaches to treating these conditions. Functional GI disorders are common disorders that are characterized by persistent and recurring GI symptoms and occur as a result of abnormal functioning of the GI tract. These disorders are not caused by structural abnormalities, thus routine medical tests may be normal, and diagnosis is based primarily on symptoms. Functional GI disorders can affect any part of the GI tract, including the esophagus, bile duct, and intestines. Treatment for functional GI disorders focuses on management of different symptoms over a period of time. Treatments may include dietary management as well as over-the-counter and prescription medications (e.g., antispasmodics, pro-motility agents, antidiarrheals, and antidepressants). In addition, psychological treatments, such as relaxation therapy or cognitive behavioral therapy, may help manage the symptoms of functional GI disorders.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see ADDRESSES).

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

- Have you received a diagnosis of a functional GI disorder from a health care provider? If so, please state the condition.

- Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include pain, bloating, constipation, vomiting)
- 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)
    - How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
- How has your condition and its symptoms changed over time?
    - Do your symptoms come and go or are they ongoing? If so, do you know of anything that worsens your symptoms?
- What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches to Treating Functional GI Disorders

- What are you currently doing to help treat your condition or its symptoms? (Examples may include prescription medicines, over-the-counter products, and other therapies including nondrug therapies such as diet modification.)
    - What specific symptoms do your treatments address?
    - How has your treatment regimen changed over time, and why?
- How well does your current treatment regimen treat the most significant symptoms of your disease?
    - How well do these treatments stop or slow the progression of your condition?
    - How well do these therapies improve your ability to do specific activities that are important to you in your daily life?

- How well have these treatments worked for you as your condition has changed over time?

- 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, going to the hospital for treatment, restrictions on driving, etc.)
- Assuming there is no complete cure for your condition, what specific things would you look for in an ideal treatment for your condition?

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit http://pfddfunctionalgidisorders.eventbrite.com. Please register by May 1, 2015. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if 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 meeting will be based on space availability. If you need special accommodations because of a disability, please contact Pegah Mariani (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 will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to PatientFocused@fda.hhs.gov a brief summary of responses to the topic questions by April 24, 2015. 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.

III. Comments

Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to Topics 1 and 2 to the public docket (see ADDRESSES) by July 13, 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.

IV. Transcripts

As soon as a transcript is available, FDA will post it at http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm430885.htm.

Dated: February 5, 2015.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2015-02804 Filed 02/10/2015 at 8:45 am; Publication Date: 02/11/2015]