



**Functional Gastrointestinal Disorders
Public Meeting on
Patient-Focused Drug Development
May 11, 2015**



| | |
|-----------------|--|
| 12:00 – 1:00 pm | Registration |
| 1:00 – 1:05 pm | Welcome Sara Eggers, PhD <i>Office of Strategic Programs (OSP), Center for Drug Evaluation and Research (CDER), FDA</i> |
| 1:05 – 1:10 pm | Opening Remarks Donna Griebel, MD <i>Director, Division of Gastro-enterology and Inborn Error Products (DGIEP), CDER, FDA</i> |
| 1:10 – 1:20 pm | Overview of FDA’s Patient-Focused Drug Development Initiative Theresa Mullin, PhD <i>Director, OSP, CDER, FDA</i> |
| 1:20 – 1:30 pm | Background on Disease Area and Treatment Laurie Muldowney, MD <i>Medical Officer, DGIEP, CDER, FDA</i> |
| 1:30 – 1:40 pm | Overview of Discussion Format Sara Eggers, PhD <i>OSP, CDER, FDA</i> |
| 1:40 – 2:10 pm | Panel #1 Comments on Topic 1 Topic 1: Disease symptoms and daily impacts that matter most to patients. A panel of patients and patient representatives will provide comments to start the discussion. |
| 2:10 – 2:45 pm | Large-Group Facilitated Discussion on Topic 1 Patients and patient representatives in the audience are invited to add to the dialogue. |
| 2:45 – 2:55 pm | Break |
| 2:55 – 3:25 pm | Panel #2 Comments on Topic 2 Topic 2: Patient perspectives on current approaches to treating functional GI disorders. A panel of patients and patient representatives will provide comments to start the discussion. |
| 3:25 – 4:25 pm | Large-Group Facilitated Discussion on Topic 2 Patients and patient representatives in the audience are invited to add to the dialogue. |
| 4:25 – 4:55 pm | Open Public Comment |
| 4:55 – 5:00 pm | Closing Remarks Andrew Mulberg, MD, FAAP <i>Deputy Director, DGIEP, CDER, FDA</i> |

Discussion Questions

Topic 1: Disease symptoms and daily impacts that matter most to patients

- 1) Have you received a diagnosis of a functional GI disorder from a healthcare provider? If so, please state the condition.
- 2) Of all the symptoms that you experience because of your condition, which 1-3 symptoms have the most significant impact on your life? (Examples may include pain, bloating, constipation, vomiting)
- 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)
 - a) How do your symptoms and their negative impacts affect your daily life on the **best days**? On the **worst days**?
- 4) How has your condition and its symptoms **changed over time**?
 - a) Do your symptoms come and go or are they ongoing? If so, do you know of anything that worsens your symptoms?
- 5) What **worries you most** about your condition?

Topic 2: Patients' perspectives on current approaches to treating functional GI disorders

- 1) **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.)
 - a) What specific symptoms do your treatments address?
 - b) How has your treatment regimen changed over time, and why?
- 2) **How well** does your current treatment regimen treat the most significant symptoms of your disease?
 - a) How well do these treatments stop or slow the progression of your condition?
 - b) How well do these therapies improve your ability to do specific activities that are important to you in your daily life?
 - c) How well have these treatments worked for you as your condition has changed over time?
- 3) 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.)
- 4) Assuming there is no complete cure for your condition, what specific things would you look for in an **ideal treatment** for your condition?

Docket Information

We encourage you to submit your written comments to the docket by July 13, 2015:

<http://www.regulations.gov/#/documentDetail;D=FDA-2015-N-0244-0001> or go to www.regulations.gov and search for: **Functional Gastrointestinal Disorders patient-focused drug development.**