



Fibromyalgia Public Meeting on Patient-Focused Drug Development



March 26, 2014

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 Bob Rappaport, MD <i>Director, Division of Anesthesia, Analgesia, and Addiction Products (DAAAP), CDER, FDA</i>
1:10 – 1:20 pm	Overview of FDA’s Patient-Focused Drug Development Initiative Patrick Frey, MPP <i>Director, Office of Program and Strategic Analysis, CDER, FDA</i>
1:20 – 1:30 pm	Background on Fibromyalgia and Therapeutic Options Elizabeth Kilgore, MD <i>Medical Officer, DAAAP, 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 – 3:00 pm	Large-Group Facilitated Discussion on Topic 1 Patients and patient representatives in the audience are invited to add to the dialogue.
3:00 – 3:15 pm	Break
3:15 – 3:45 pm	Panel #2 Comments on Topic 2 Topic 2: Patients’ perspectives on current approaches to treating fibromyalgia.
3:45 – 4:25 pm	Large-Group Facilitated Discussion on Topic 2
4:25 – 4:55 pm	Open Public Comment
4:55 – 5:00 pm	Closing Remarks Sharon Hertz, MD <i>Deputy Director, DAAAP, CDER, FDA</i>

Discussion Questions

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

- 1) 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 chronic pain, fatigue, difficulty concentrating, sleep disorders, etc.)
- 2) 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, household chores, etc.)
 - a) How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?
- 3) How have your condition and its symptoms changed over time?
 - a) Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?
- 4) What worries you most about your condition?

Topic 2: Patients' perspectives on current approaches to treating fibromyalgia

- 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 non-drug therapies such as exercise.)
 - 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 improve your ability to do specific activities that are important to you in your daily life?
 - b) 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) What specific things would you look for in an ideal treatment for your condition?