

We received this message from United States Food and Drug Administration regarding the Fibromyalgia Public Meeting on Patient-Focused Drug Development on Wednesday, March 26, 2014:

Dear fibromyalgia meeting attendees,

Thank you for attending the public meeting on fibromyalgia patient-focused drug development! FDA collected valuable information on fibromyalgia, the impact it has on patients' lives, and patients' perspectives on treatment options. We truly appreciate the courage, effort and time invested from everyone who was able to attend the meeting in person or on the web.

We know that not everyone who wanted to come to this meeting was able to attend. For anyone who missed the meeting or is interested in what was discussed, we have posted a full recording of the meeting on our website: <http://www.fda.gov/forindustry/userfees/prescriptiondruguserfee/ucm363203.htm>

In addition to the input we gathered at the March 26 meeting, we encourage fibromyalgia patients, caregivers, and other stakeholders to submit written comments to the online public docket. The comment period closes on May 26, 2014. Submit your comments through this website: <http://www.regulations.gov/#!documentDetail;D=FDA-2013-N-1041-0004> .

FDA is particularly interested in hearing patients' perspectives on the questions outlined in the Federal Register Notice that announced this meeting. These questions are pasted below for your reference, and the Federal Register Notice can be found here: <https://www.federalregister.gov/articles/2013/09/23/2013-23019/fibromyalgia-public-meeting-on-patient-focused-drug-development>

Again, thank you to everyone who attended the March 26 meeting. If you have any questions,

please email PatientFocused@fda.hhs.gov .

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.)

1. How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?

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

1. Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

2. 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.)

1. What specific symptoms do your treatments address?

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

3. How well does your current treatment regimen treat the most significant symptoms of your disease?

1. How well do these treatments improve your ability to do specific activities that are important to you in your daily life?

2. 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?