FOOD AND DRUG ADMINISTRATION (FDA)

Center for Drug Evaluation and Research (CDER)

Development of Safe and Effective Drug Therapies for Chronic Fatigue Syndrome (CFS) and Myalgic Encephalomyelitis (ME)

Bethesda Marriott
5151 Pooks Hill Rd., Bethesda, MD 20814
April 25 and 26, 2013

DRAFT AGENDA

April 25, 2013: Patient Focused Drug Development Workshop

1:00 p.m. Welcome
1:10 p.m. Background and goals of meeting
1:20 p.m. Overview of FDA's Patient-Focused Drug Development initiative
1:30 p.m. Overview of discussion format

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

Panel 1 Questions:

1. What are the most significant symptoms that you experience resulting from your condition? (Examples may include prolonged exhaustion, confusion, muscle pain, heat or cold intolerance, etc.)
2. What are the most negative impacts on your daily life that result from your condition and its symptoms? (Examples may include difficulty with specific activities, sleeping through the night, etc.)
    a. How does the condition affect your daily life on the best days and worst days?
    b. What changes have you had to make in your life because of your condition?

2:50 p.m. Break

Panel 2: Patient perspective on treating CFS and ME

Panel 2 Questions:

1. What treatments are you currently using to help treat your condition or its symptoms? (Consider prescription medicines, over-the-counter products and non-drug therapies such as activity limitations).
    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 have these treatments improved your daily life (for example, improving your ability to do specific activities)?
    b. How well have these treatments worked for you as your condition has changed over time?
    c. What are the most significant downsides of these treatments (for example, specific side effects)?

4:15 p.m. Open public comment period
4:45 p.m. Closing remarks
5:00 p.m. Adjourn

April 26, 2013: Scientific Drug Development Workshop

Panel 1: Regulatory and Drug Development Innovation for CFS and ME

8:30 am Panel Presentations

- Topics: background, drug innovation, repurposing drugs, regulatory pathways to expediting drug treatments

10:00 am Audience Question and Answer Period

10:20 am Break

Panel 2: Key Symptoms of CFS and ME (Patient and Clinician Panel)

10:30 am Panel Discussion

- Topics: symptoms, outcome measures, disease heterogeneity

11:15 am Audience Question and Answer Period

11:30 am Lunch

Panel 3: CFS and ME Clinical Trial Endpoints and Design

12:30 pm Panel Presentations

- Topics: clinical trial design, exercise challenge, outcome measures

2:30 pm Audience Question and Answer Period

3:00 pm Break

Panel 4: Summary and Scientific Gaps

3:15 pm Panel Discussion

- Topics: key messages, scientific gaps, possible next steps

4:45 pm Audience Question and Answer Period

5:00 pm Closing Remarks

Scientific Drug Development Workshop Confirmed Speakers, Panelists, and Moderators
April 26, 2013

Lucinda Bateman, MD
Lisa Corbin, MD
Lily Chu, MD, MHSH (patient)
Jordan Dimitrakoff, MD, PhD
Nancy Klimas, MD
Dennis Mangan, PhD
Robert Miller (patient)
José Montoya, MD
Bernard Munos, PhD
Peter Rowe, MD
Christopher Snell, PhD
Jennie Spotila, JD (patient)
Elizabeth Unger, MD, PhD
Suzanne Vernon, PhD
Christine Williams, MEd (patient)

Note: Final agenda including titles of talks will be posted approximately 1 week prior to the meeting. This agenda has been released for informational purposes only.