Advocacy works!

The ME/CFS Community received the letter below from a spokesperson at the Food & Drug Administration, agreeing to our request for a meeting to address streamlining drug and biomarker development for ME/CFS. A teleconference on this topic is planned for September 13, 2012.

Dear Colleagues:

The U.S. Food & Drug Administration (FDA) is pleased to invite you to a stakeholder teleconference between FDA and Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) patients and advocacy organizations on September 13, 2012. Dr. Janet Woodcock, Director of the Center of Drug Evaluation and Research, will lead the call. The purpose of the call is to discuss issues of mutual interest and concern including the lack of approved treatment options available for ME/CFS and how treatment development might be facilitated.

The teleconference is scheduled for Thursday, September 13, 2012 from 10:00 am - 11:30 am. Registration is required and must be received by September 7, 2012. Early registration is recommended because telephone lines will be limited to the first 50 groups and/or individuals who register. FDA may limit the number of participants from each organization, as well as the total number of participants, based on current space limitations.

If you would like to participate, please send your name, email address, telephone number and affiliation information to Randi Clark (randi.clark@fda.hhs.gov) by no later than September 7. Registrants will receive confirmation and additional information about the teleconference once registration has been received and accepted.

FDA looks forward to your participation.

This letter followed the announcement during a conference call on July 2:

Thank you for writing to Dr. Janet Woodcock, the Director of the Center for Drug Evaluation and Research (CDER) in the Food and Drug Administration (FDA), requesting a stakeholder meeting to discuss treatment options for Myalgic Encephalomyelitis/Chronic Fatigue Syndrome (ME/CFS) patients. Your e-mail was forwarded to the Division of Drug Information for a direct reply.

The Health and Human Services (HHS) and FDA share your concern about safe and effective treatments for CFS and are sympathetic to the sometimes desperate situation of patients with illnesses and conditions such as ME/CFS, for whom there are no available therapies. Based on the letters and e-mails received from ME/CFS advocates, both HHS and FDA have already taken a number of steps to address this request for a stakeholders meeting.

On June 13 and 14, 2012, HHS convened an open public meeting of the Chronic Fatigue Syndrome Advisory Committee (CFSAC) opened by Dr. Howard Koh, MD, MPH, Assistant Secretary for Health. As you may know, the CFSAC is comprised of 10 voting members with clinical or research expertise in CFS, a patient advocate member, and 7 Ex-Officio members from various HHS agencies, including a representative from FDA. During the meeting, the committee heard 3 hours of public testimony that included a presentation by a drug manufacturer. In addition, there were separate presentations by 5 different ME/CFS advocacy organizations: the CFIDS Association of America, Speak Up About ME, PANDORA, Phoenix Rising, and the New Jersey CFS Association.

Separately from the CFSAC, HHS convened the Ad Hoc Workgroup on CFS to develop a Department-wide strategy to address CFS and allow active collaboration among agencies. So far, the workgroup has held two meetings with high level leaders of the following agencies: National Institutes of Health (NIH), Centers for Disease Control (CDC), Agency for Healthcare Research and Quality (AHRQ), Substance Abuse and Mental Health Services Administration (SAMHSA), Center for Medicare and Medicaid Services (CMS), Food and Drug Administration (FDA), and Administration for Children and Families (ACF). A third meeting is being scheduled for later this summer, where an important agenda item will be a FDA-hosted multidisciplinary scientific workshop on drug and biomarker development for CFS.

FDA is reaching out to individual patient advocates in order to better ascertain achievable goals for a stakeholder's meeting. This outreach has included teleconferences with various leaders of the advocacy campaign, including a call by Dr. Janet Woodcock with the following advocates: Robert Miller, ME/CFS Patient/Advocate; Patricia LaRosa, RN, MSN, New Jersey Chronic Fatigue Syndrome Association; Mary Dimmock, ME/CFS Patient representative; Denise Lopez Majano, founder of Speak Up About ME; and Cort Johnson, founder of Phoenix Rising.

Based on these calls, FDA plans to host a cross-agency coordinated multidisciplinary scientific workshop to address drug and biomarker development issues in ME/CFS.

As plans for a multidisciplinary scientific workshop on drug development are underway, FDA is continuing calls to stakeholders to assist in the planning of such a workshop. Stakeholders wishing to provide input into the planning of the drug development workshop should contact David Banks, PhD, at FDA at the following e-mail address: oshi@fda.hhs.gov.

Finally, efforts are underway at FDA to improve the infrastructure for drug development in the field of ME/CFS. To overcome obstacles that may be introduced by a fragmented approach to the disease, FDA consolidated all ME/CFS drug applications in the Division of Pulmonary, Allergy, and Rheumatology Products as of January 16, 2011. This consolidation has allowed for development of expertise in ME/CFS among reviewers in the Division, which will facilitate uniform criteria for drug development.

Again, thank you for your request regarding a stakeholder meeting on ME/CFS treatments. As outlined above, please know that HHS and FDA are actively pursuing a ME/CFS strategy in order to address this important issue.

Sincerely,
Mary Kremzner, Pharm.D.
Director, Division of Drug Information

Read the Joint Request from the ME/CFS Community for Action