April 25, 2013: Patient-Focused Drug Development Meeting

1:00 pm Welcome— RADM Sandra Kweder, M.D., Deputy Director, Office of New Drugs, Center for Drug Evaluation and Research (CDER), FDA

1:10 pm Overview of FDA’s Patient-Focused Drug Development Initiative – Theresa Mullin, Ph.D., Director, Office of Planning and Informatics, CDER, FDA

1:20 pm Overview of Discussion Format – Sara Eggers, Ph.D., Office of Planning and Analysis, Office of Planning and Informatics, CDER, FDA

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

Moderators: Sara Eggers and Theresa Toigo, R.Ph., M.B.A., Associate Director for Drug Safety Operations, CDER, FDA

1:30 pm Panel Comments
   • A panel of patients and patient representatives will provide comments to start the discussion on Topic 1.

2:00 pm Large-group Facilitated Discussion
   • Patients and patient representatives in the audience are invited to add to the dialogue on Topic 1.

2:40 pm Break

Discussion Topic 2: Patient perspective on treating CFS and ME

Moderators: Sara Eggers and Theresa Toigo

2:50 pm Panel Comments
   • A panel of patients and patient representatives will provide comments to start the discussion on Topic 2.

3:20 pm Large-group Facilitated Discussion
   • Patients and patient representatives in the audience are invited to add to the dialogue on Topic 1.

4:00 pm Open Public Comment Period
4:45 pm  Closing Remarks — Theresa Mullin, Ph.D.

5:00 pm  Adjourn