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 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