

How can you help: **Please submit your comments to the FDA.**

For ME/CFS, this is an excellent opportunity to help the FDA better understand how ME/CFS affects the patients. Your support is essential to ensure that ME/CFS is one of the 20 selected diseases. A sample letter has been provided in case you want to pull from it to develop your own. As you write your own letter, make points that reflect how ME/CFS meets the criteria below.

**Please send your comments in by November 1, 2012**, to ensure that the FDA understands why ME/CFS should be selected as one of the 20 diseases. You can submit your letter electronically or mail it.

- Comments should be submitted electronically at <http://www.regulations.gov/#!docketDetail;D=FDA-2012-N-0967> Select 'Individual Consumer' for the 'Category' and 'None' for 'Organization' if no other choice is appropriate.
- Written comments can be submitted to the Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Further information on the patient focused drug development initiative and the list of 39 diseases initially nominated can be found here:  
<https://www.federalregister.gov/articles/2012/09/24/2012-23454/prescription-drug-user-fee-act-patient-focused-drug-development-public-meeting-and-request-for>

## **Sample Letter – limited to 2000 characters**

To: FDA Patient Focused Drug Development Initiative  
From:

I am writing to request that chronic fatigue syndrome (also called myalgic encephalomyelitis or ME/CFS) be included as one of the 20 diseases in the patient focused drug development initiative.

ME/CFS is a complex, neuroimmune disease that affects one million Americans. It affects people of all ages, races and income levels. Patients can be sick for decades, with 25% house,

bed or wheelchair bound, struggling to take care of themselves, let alone take care of their families or work. According to the CDC, ME/CFS can be as debilitating as Multiple Sclerosis (MS), end-stage renal disease, chronic obstructive pulmonary disease (COPD) and similar chronic conditions. One study suggests patients can die prematurely from cancer, heart disease and suicide.

What is tragic is that almost thirty years after the outbreaks that brought ME/CFS to national attention, there have been almost no clinical trials for drugs to treat ME/CFS and there are still NO approved treatments and NO biomarkers or outcome measures have been agreed upon.

By ensuring a thorough understanding of the severity of ME/CFS from a patient perspective, especially given the lack of any viable treatments to change the course of the disease, the patient focused drug development initiative could make a tremendous difference in the lives of one million Americans.

Sincerely yours,

## **FDA Disease Area Selection Criteria and How ME/CFS Meets These Criteria**

The listing that follows is intended to help you as you are writing your letter by providing additional information about how ME/CFS meets the FDA criteria for selection of disease areas. Try to include points in your letter that hit on these key criteria.

FDA Criteria, and

- How ME/CFS meets that criteria

Disease areas that are chronic, symptomatic, or affect functioning and activities of daily living

- Chronic, sick for decades, low percentage of patients improve
- 25% bedbound or homebound, unable to work. Patients who do work may work part time

and/or are underemployed. Relapsing course means little predictability. Impact of disease on patient's life is so great that suicide risk increased

Disease areas that reflect a range of severity

- Wide range of severity – some patients work a 40 hour week and compensate by sleeping weekends but many patients can not work at all. The most serious patients are unable to do little more than the most basic activities of personal care

Disease areas for which aspects of the disease are not formally captured in clinical trials

- There is only one drug in clinical trials and its been there since 1997
- There are a few INDs but most are focused on nutraceuticals. There have been studies into psychological treatments

Disease areas that have a severe impact on identifiable subpopulations (such as children or the elderly)

- Severe impact on children because they are unable to attend school or graduate. Even if they get better, they have missed on significant life lessons

Disease areas that represent a broad range in terms of size of the affected population

- Estimated that 1 million are affected – women and men, all economic levels, all ethnic groups

Disease areas for which there are currently no therapies or very few therapies, or the available therapies do not directly affect how a patient feels, functions, or survives

- No approved therapies, only limited symptom relief

Stigma and confusion about nature of disease

- Significant confusion on the nature of the disease and whether it's the same as depression or just 'all in the patient's head' has both
  - Misunderstanding and misperceptions about the burden of disease from a patient perspective. – its not “just tired”
  - No agreement on objective measures of patient function although 2 day CPET is a good measure.
  - Few validated subjective measures of patient function
  - Limited R&D investment