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What is the Patient-Focused Drug Development Initiative?

The Food and Drug Administration (FDA) is announcing a public meeting and an opportunity for public comment related to FDA's patient-focused drug development initiative. This initiative is being conducted to fulfill FDA performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). This effort provides for a more systematic approach under PDUFA V for obtaining patient perspective on the disease severity and the currently available treatments for a set of disease areas.

The public is invited to comment on this preliminary list through a public docket and at a public meeting where FDA will provide an overview of the patient-focused drug development initiative with discussion of the nominated disease areas.

Why is it so important?

FDA has published a preliminary list of nominated disease areas (available in its entirety at the Federal Register website) for its patient-focused drug development initiative and the criteria used for nomination. At this time, there are 39 diseases on this list, but only 20 will be ultimately selected. *Two of the diseases on this list are Chronic Fatigue Syndrome and Fibromyalgia.*

What needs to be done?

The FDA is seeking public comments on this preliminary list of diseases from patients. All that patients need to do is identify the disease which they consider to be the greatest priority for this initiative and provide reasons in support their recommendation.

When are patient comments/recommendations due?

Patients can submit either electronic or written comments by November 1, 2012. The public meeting will be held on October 25, 2012, from 9 a.m. to 12:30 p.m. Registration to attend the meeting must be received by October 18, 2012. To complete the process, patients should go to the link provided below.

Where can patients can get more information?

The entire FDA initiative is detailed at: [Prescription Drug User Fee Act Patient-Focused Drug Development; Public Meeting and Request for Comment.](#)