

PUBLIC COMMENT SUBMISSION GUIDE

Docket Number FDA-2012-N-0967

Drafted for Narcolepsy Community

By Julie Flygare, JD 10/22/12

IMPORTANT: PRIVACY NOTICE & ANONYMOUS COMMENTS

All the information you provide in your comment AND in attached letter may be publicly disclosed in a rulemaking docket or on the Internet.

However, FDA allows you to comment **anonymously**. To do so, fill in the name fields as “Anonymous” or simply leave the name fields blank. Do not list your name anywhere in your comment or attached letter.

HOW TO SUBMIT PUBLIC COMMENT:

- Customize Sample Letter (below) and Save to Desktop with title like “*My FDA Letter*”
- Go to <http://regulations.gov>
- Search for: FDA-2012-N-0967
- *Comment Now!*

Prescription Drug User Fee Act Patient-Focused Drug
Development Meeting

Comment Now!

1. ENTER INFORMATION

- Organization Name (Required): NARCOLEPSY NETWORK
- Submitter’s Representative (Optional): Leave Blank
- Category (Required): INDIVIDUAL CONSUMER

2. TYPE COMMENT

Comment field limited to 2,000 characters. I suggest writing a short comment and submitting letter as an attachment.

Short comment example: I urge FDA to select “narcolepsy” as one of the twenty disease areas chosen for Patient-Focused Drug Development Program. Please see attached letter. Thank you.

3. UPLOAD FILE(S) (Optional)

Choose File...

Choose your personalized saved letter *"My FDA Letter"*

4. SUBMIT COMMENT

Preview Comment

Submit

✓ **Your comment was submitted successfully!**

Thank you for making a difference for narcolepsy!

Questions? Concerns?

Contact Julie Flygare at julieflygare@gmail.com.

SAMPLE NARCOLEPSY PATIENT LETTER TO FDA

[DATE]

Food and Drug Administration
Division of Dockets Management (HFA-305)
5630 Fishers Lane, Room 1061
Rockville, MD 20852

RE: Docket Number FDA-2012-N-0967

I would like to express my thanks to the Food and Drug Administration (FDA) for nominating “narcolepsy” as a disease area considered for the new patient-focused drug development initiative. I urge FDA to please select “narcolepsy” as one of the twenty disease areas chosen for this important effort.

Narcolepsy is a neurological autoimmune chronic sleep disorder affecting 1 in every 2,000 people in America. The disorder’s affect upon quality-of-life is comparable to epilepsy and Parkinson’s disease. Narcolepsy is a complex disorder. Not all patients experience all the major symptoms to the same degree.

As an orphan disease, there is no known cure for narcolepsy and better solutions are needed as soon as possible. Even with the best treatments available, narcolepsy severely inhibits critical cognitive functions and compromises education, employment, and personal lives. As a lifelong disorder, narcolepsy subpopulations requiring special consideration include children, elderly patients and pregnant women.

Providing FDA with a more comprehensive understanding of the narcolepsy patient experience should go a long way to more accurately informing regulatory decision-making and, ultimately, facilitating the approval of effective treatments.

[In a few sentences, explain that impact narcolepsy has on your life.

Suggested Topics:

- **Diagnosis: major event leading to diagnosis OR long time undiagnosed and/or misdiagnosed.**
- **Affects on your ability to work, go to school, raise a family, etc.**
- **Difficulty with treatment options and side effects.]**

In closing, I once again ask FDA to please select “narcolepsy” for the new patient-focused drug development initiative. Thank you for your time.

Sincerely,

[Name]

[Address] OR [Anonymous: do not list name/address to comment anonymously]