



FDA's Questions to Narcolepsy Community

FDA is interested in receiving patient input addressing these questions through the public docket:

<http://www.regulations.gov/-!submitComment;D=FDA-2013-N-0815-0001>.

Step-by-step instructions for submitting your answers follow the questions (reprinted from FDA).

Topic 1: Disease symptoms and daily impacts that matter most to patients

1. Of all the symptoms that you experience because of your condition, which one to three symptoms have the most significant impact on your life? (Examples may include excessive daytime sleepiness, cataplexy, etc.)

2. Are there specific activities that are important to you but that you cannot do at all or as fully as you would like because of your condition? (Examples of activities may include sleeping through the night, work and school performance, etc.)

3. How have your symptoms changed over time?
 - 3.1 Do your symptoms come and go? If so, do you know of anything that makes your symptoms better? Worse?

Topic 2: Patients' perspectives on current approaches to treating narcolepsy

1. What are you currently doing to help treat your condition or its symptoms? (Examples may include FDA-approved medicines, over-the-counter products, and other therapies including non-drug therapies such as lifestyle modifications.)



1.1 What specific symptoms do your therapies address?

1.2 How has your treatment regimen changed over time, and why?

2. How well does your current treatment regimen treat the most significant symptoms of your disease?

2.1 How well do these therapies improve your ability to do specific activities that are important to you in your daily life?

2.2 How well have these therapies worked for you as your condition has changed over time?

3. What are the most significant downsides to your current therapies, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, inconvenient dosing schedules, access issues, etc.)

4. Assuming there is no complete cure for your condition, what specific things would you look for in an ideal therapy for your condition?



Directions for submitting comments to FDA Docket

1. Review the FDA Questions above and type your answers in a separate Word document. Remember that you don't have to answer all the questions if you don't want to. You also don't have to use complete sentences or full paragraphs. (Consider sharing your answers with a loved one to make sure your writing conveys your authentic experience accurately and concisely.) Save your answers as a separate Word .doc on your computer. Use the "Word Count" function on the "Review" tab of Word to count the characters. You can also submit your answers by video. Use a cell phone or webcam to record a video and save it as a .wmv file or upload to a video sharing site (such as YouTube). You can send the file or a link to it to FDA just as you would a document (see below).
2. When ready to submit comments to FDA, go to: <http://www.regulations.gov/-/submitComment;D=FDA-2013-N-0815-0001>.
3. **Comment Box** - This box is limited to 5000 characters. If your answers are less than 5000 characters, copy and paste answers into the docket window. If your answers total more than 5000 characters, write "Please see attached comments" and attach your comments by uploading your saved Word .doc file or a PDF document.
4. Enter **First** and **Last Name** - If you choose to use your name, it may be included in a public docket and on the Internet. If you'd like to remain anonymous, fill in the name fields as "Anonymous" and be sure not to list your name anywhere in your comment or attached letter.
5. Check or uncheck "**I want to provide my contact information**" - this is up to you.
6. If you are submitting comments for yourself, uncheck "**I am submitting on behalf of a third party.**" If you are submitting comments on behalf of another person, leave this box checked.
7. **Category** (Required): Choose INDIVIDUAL CONSUMER
8. Continue to **Preview Page**: Preview your submission and check "I read and understand the statement above."
9. Submit Comments.

***Thank you for helping to build
a brighter future for narcolepsy!***