Unite Narcolepsy

Working together toward a brighter future

FREQUENTLY ASKED QUESTIONS

Why is FDA hosting the narcolepsy meeting?
The Food and Drug Administration (FDA) is hosting the Narcolepsy Meeting on Sept 24, 2013 as part of FDA's Patient Focused Drug Development Initiative (PFDDI). In April 2013, narcolepsy was selected as one of 20 conditions to be addressed in this five-year initiative. FDA aims to gain patients' perspectives on the impact of narcolepsy on daily life as well as the adequacy of available therapies.

What is FDA interested in learning about?
FDA would like to gain a better understanding of narcolepsy's impact on patients' daily lives, the types of treatment benefits that matter most to patients, and patients' perspectives on how well available therapies work for them. The key questions proposed by FDA are here [link to questions].

How will this initiative help patients?
The Food & Drug Administration (FDA) is the agency within the U.S. federal government that is responsible for regulating products that represent one-fourth of all consumer spending – products like human and veterinary drugs, medical devices (like pacemakers and knee implants), foods and cosmetics. FDA has a very important role in helping to speed innovations that make medicines more effective, safer, and more affordable and by helping the public get the accurate, science-based information they need to use medicines and foods to maintain and improve their health. Participating in the FDA initiative will ensure that narcolepsy patients' priorities and concerns are understood by FDA in its reviews of current and future treatments as they are studied and used by consumers.

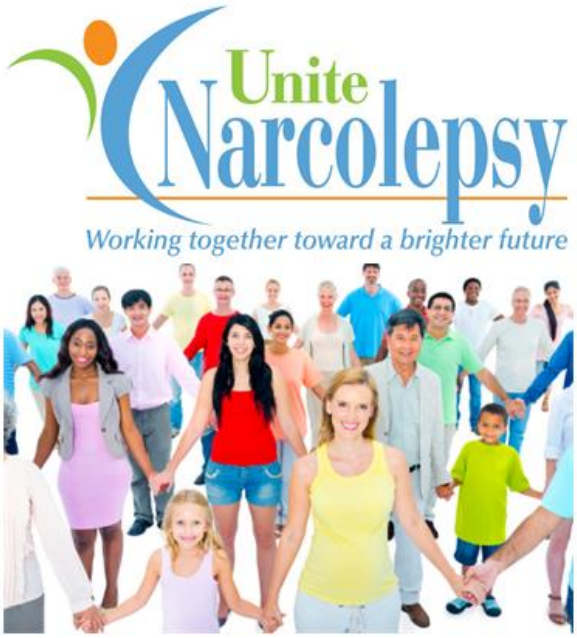
Strong participation will also serve as a signal to the greater health community that narcolepsy advocates are organized and ready to take action in shaping a brighter future for all those living with narcolepsy.

What is the time frame?
Prior to the meeting, patients are encouraged to take the survey and participate in the educational webinars being hosted by Unite Narcolepsy. On Sept. 24, patients can participate in the live meeting via webcast or in-person. After the meeting, the comment docket will remain open until November 25, 2013.

After the docket closes on Nov. 25, the FDA will produce a meeting report to be posted on FDA's website and circulated within the agency. The patients' perspective may also point to a need for new patient-focused outcome measures to be developed and qualified for use in drug development, to capture patient input more systematically, for example, in clinical trials.

What is Unite Narcolepsy?

Organizations and individuals across the narcolepsy community are joining efforts to make the most of this landmark opportunity. **Unite Narcolepsy** is an education and empowerment initiative created to help inform people affected by narcolepsy about the FDA's invitation and to prepare them to respond meaningfully to it. By encouraging and equipping broad participation, we aim to honor patients' experiences and use the power of their testimony to ensure that patient needs are at the center of research efforts and regulatory decisions about narcolepsy treatment.



Together we'll increase awareness and deepen understanding about what it's like to live with narcolepsy. Together we'll accelerate better care. Together we'll create a better future for all those affected by narcolepsy.

Is this initiative only about treatment options? What about the narcolepsy research funding, awareness, insurance and disability issues?

The narcolepsy community has many concerns beyond pharmaceutical treatments, including research funding, public awareness, insurance and disability issues. While this initiative cannot address all of these concerns, by coming together we are creating a strong coalition of narcolepsy advocates capable of collaborating with various stakeholders, organizations and government agencies in the future to pursue our other priorities and concerns.

Will the FDA be looking at vitamins and supplements in addition to pharmaceutical treatments?

For this initiative, the FDA is interested in learning about what works for patients – including prescription medications, over-the-counter drugs, alternative treatments and lifestyle habits. Although FDA regulates these products differently than medicine, if vitamins and supplements are part of your treatment regimen, be sure to include this information in your survey responses and comments to FDA.

Can parents of children with narcolepsy participate?

Yes, parents, spouses, and caregivers can get involved today through the survey, webinars and docket comments. On Sept. 24, 2013 you are encouraged to participate in the FDA meeting via webcast and in-person attendance. Your perspective on your loved one's experience is invaluable to help FDA better understand narcolepsy.

Can people with narcolepsy outside of the United States participate?

Yes, patients outside of the United States may participate in the survey, webinars, webcast and docket comments.

Will Idiopathic Hypersomnia be addressed?

People with Idiopathic Hypersomnia (IH) are encouraged to participate in the survey and webinars with the understanding that the FDA workshop will focus on narcolepsy as it is currently defined in the medical and scientific literature.

I cannot attend in person. How can I participate?
You can make a meaningful impact from home. Consider participating in the survey (at https://www.surveymonkey.com/s/unitenarcolepsy), educational webinars, comment docket and the live webcast on September 24th.

I want to help but don't have much time. What can I do quickly?
The survey is designed to take 15-25 minutes. Also, consider making comments on the FDA docket anytime between now and Nov. 25, 2013. You don't have to answer all the FDA's questions – do as much as you can and let your voice be heard!

Can I remain anonymous while participating?
Yes, we understand that privacy is extremely important to some patients. The survey is completely anonymous and confidential. Participants' privacy and identities will be protected during all our webinar programs. In addition, you can participate in the webcast and submit docket comments providing your initials when prompted to provide your name.

What are the "patient panels" at the workshop? Who will participate on them?
There will be two panels of patients and stakeholders (caregivers, family members, etc.) – topic 1 is focused on narcolepsy's impact on daily life and topic 2 is focused on narcolepsy treatment. Five individuals will be selected for each panel, so 10 people total will participate in the panels.

Individuals interested in presenting comments as part of the panel discussions are asked to send a brief summary of responses to the topic questions [link] to PatientFocused@fda.hhs.gov. Panelists will be notified of their selection soon after the close of registration on September 13, 2013.

If not selected for a panel, will I still be able to speak in-person at the meeting?
FDA will try to accommodate all patients and patient stakeholders who wish to speak, either through the panel discussion or audience participation; however, the duration of comments may be limited by time constraints.

In addition, FDA representatives will pose questions to the live and webcast audience, inviting both groups to provide answer by voting anonymously. The polling results will be tallied immediately and displayed live at the meeting.

Any tips for speaking in public?
Unite Narcolepsy will provide effective communication tips in an educational webinar scheduled for Sept. 11 at 2:00 PM (Eastern). Registration info for that webinar is coming soon. All narcolepsy advocates are encouraged to participate!

Are there scholarships available to attend the FDA meeting?
There are no scholarships opportunities to attend this meeting in person. However, you can make a meaningful impact from home. Please take the survey today, participate in the upcoming webinars, attend the meeting via webcast and submit docket comments.

Is there public transportation to the meeting?
The meeting will be located at the FDA White Oak Campus (10903 New Hampshire Ave., Building 31 Conference Center, Section A of the Great Room (Rm. 1503), Silver Spring, MD 20993).

Silver Spring Metro Station, on the Red Line, is the closest metro stop. The Silver Spring Metro Station is approximately 4 miles, a 20-minute cab ride, from the White Oak Campus. Ride-On Bus route 22 operates between the Silver Spring Metro Station and White Oak Campus. Additionally, C8 Metro Bus operates between College Park and White Flint and makes a stop at the FDA White Oak Campus. For more information and bus schedules, visit: http://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241743.htm.

What happens after the meeting?

After the Sept 24 meeting, FDA's comment docket will remain open for two months, until Nov. 25 to continue collecting written comments from patients and patient stakeholders. After Nov. 25, 2013, FDA will produce a meeting report, capturing the input obtained at the meeting and in written responses to the key questions about symptoms and treatment. The patients' perspective may also point to a need for new patient-focused outcome measures to be developed and qualified for use in drug development, to capture patient input more systematically, for example, in clinical trials.

How can I keep in touch with information about Unite Narcolepsy and the FDA's initiative?

Learn more during our first webinar on August 29 at 2:00 p.m. (Eastern) time: http://bit.ly/Aug29-webinar It's free and you can participate from home, office or mobile. You can follow us on Facebook (www.Facebook.com/UniteNarcolepsy) and Twitter (@UniteNarcolepsy). We will launch a new website with many more resources in the coming days, so look out for more information.

MORE INFORMATION COMING SOON!