



DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2016-N-1110]

Public Meeting on Patient-Focused Drug Development for Neuropathic Pain Associated with Peripheral Neuropathy

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing a public meeting and an opportunity for public comment on Patient-Focused Drug Development for neuropathic pain associated with peripheral neuropathies. Patient-Focused Drug Development is part of FDA's performance commitments made as part of the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patient perspectives on the impact of neuropathic pain associated with peripheral neuropathies, patient views on treatment approaches, and decision factors taken into account when selecting a treatment.

DATES: The public meeting will be held on June 10, 2016, from 10 a.m. to 4 p.m. Registration to attend the meeting must be received by June 3, 2016 (see SUPPLEMENTARY INFORMATION for instructions). Submit electronic or written comments to the public docket by August 10, 2016.

ADDRESSES: You may submit comments as follows:

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <http://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <http://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <http://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Division of Dockets Management (HFA-305), Food and Drug Administration, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Division of Dockets Management, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2016-N-1110 for "Public Meeting on Patient-Focused Drug Development for Neuropathic Pain Associated with Peripheral Neuropathy." Received comments will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <http://www.regulations.gov> or at the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <http://www.regulations.gov>. Submit both copies to the Division of Dockets Management. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: <http://www.fda.gov/regulatoryinformation/dockets/default.htm>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <http://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Division of Dockets Management, 5630 Fishers Lane, rm. 1061, Rockville, MD 20852.

FDA will post the agenda approximately 5 days before the meeting at:
<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm>.
FOR FURTHER INFORMATION CONTACT: Meghana Chalasani, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, rm. 1146, Silver Spring, MD 20993-0002, 240-402-6525, FAX: 301-847-8443, Meghana.Chalasani@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background on Patient-Focused Drug Development

FDA has selected neuropathic pain associated with peripheral neuropathy as the focus of a public meeting under Patient-Focused Drug Development, an initiative that involves obtaining a better understanding of patient perspectives on the severity of a disease and the available therapies for that condition. Patient-Focused Drug Development is being conducted to fulfill FDA performance commitments that are part of the reauthorization of the PDUFA under Title I of the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112-144). The full set of performance commitments is available at <http://www.fda.gov/downloads/forindustry/userfees/prescriptiondruguserfee/ucm270412.pdf>.

FDA committed to obtain the patient perspective on at least 20 disease areas during the course of PDUFA V. For each disease area, the Agency is conducting a public meeting to

discuss the disease and its impact on patients' daily lives, the types of treatment benefit that matter most to patients, and patients' perspectives on the adequacy of the available therapies. These meetings will include participation of FDA review divisions, the relevant patient communities, and other interested stakeholders.

On April 11, 2013, FDA published a notice in the Federal Register (78 FR 21613) announcing the disease areas for meetings in fiscal years (FYs) 2013-2015, the first 3 years of the 5-year PDUFA V time frame. The Agency used several criteria outlined in that notice to develop the list of disease areas. FDA obtained public comment on the Agency's proposed criteria and potential disease areas through a public docket and a public meeting that was convened on October 25, 2012. In selecting the set of disease areas, FDA carefully considered the public comments received and the perspectives of review divisions at FDA. FDA initiated a second public process for determining the disease areas for FY 2016-2017, and published a notice in the Federal Register on July 2, 2015 (80 FR 38216), announcing the selection of eight disease areas. More information, including the list of disease areas and a general schedule of meetings, is posted at

<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm326192.htm>.

II. Public Meeting Information

A. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on the impacts of neuropathic pain associated with peripheral neuropathies. Peripheral neuropathy is a neurological disorder that develops as a result of damage to the peripheral nerves and is associated with both a physical and psychological burden. Nerve damage can be caused by diseases such as diabetes, physical injury, or exposure to drugs or toxins. The pain associated with neuropathies of sensory nerves may be characterized as a pins

and needles sensation, as sharp, jabbing, or burning, or as an exaggeratedly intense or distorted pain response to typically nonpainful touch. While there is currently no cure, treatments for the pain associated with peripheral neuropathy include prescription medications and other approaches such as transcutaneous electrical nerve stimulation, braces, and behavioral therapies. FDA is interested in the perspectives of patients with peripheral neuropathy on specifically: (1) The impact of neuropathic pain associated with peripheral neuropathy and (2) treatment approaches for the neuropathic pain associated with peripheral neuropathy.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this section, organized by topic. For each topic, a brief initial patient panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other patient and patient stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through written comments, which can be submitted to the public docket (see ADDRESSES).

Topic 1: Disease Symptoms and Daily Impacts that Matter Most to Patients

1. How would you describe your neuropathic pain associated with peripheral neuropathy?

What terms would you use to describe the most bothersome aspects of pain? (Examples may include stabbing sensations, electric shocks, burning or tingling, 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 neuropathic pain? (Examples of activities may include sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
3. How do your neuropathic pain and its negative impacts affect your daily life on the best days? On the worst days?

4. How has your neuropathic pain changed over time?
5. What worries you most about your condition?

Topic 2: Patients' Perspectives on Current Approaches to Treatment

1. What are you currently doing to help treat your neuropathic pain associated with peripheral neuropathy? (Examples may include prescription medicines, over-the-counter products, and other therapies including non-drug therapies). How has your treatment regimen changed over time, and why?
2. How well does your current treatment regimen control your neuropathic pain?
 - a. How well have these treatments worked for you as your condition has changed over time?
 - b. Would you define your condition today as being well managed?
3. What are the most significant downsides to your current treatments, and how do they affect your daily life? (Examples of downsides may include bothersome side effects, going to the hospital or clinic for treatment, time devoted to treatment, restrictions on driving, etc.)
4. Assuming there is no complete cure for your neuropathic pain, what specific things would you look for in an ideal treatment for your neuropathic pain? What would you consider to be a meaningful improvement in your condition (for example, specific symptom improvements or functional improvements) that a treatment could provide?
5. If you had the opportunity to consider participating in a clinical trial studying experimental treatments for neuropathic pain, what things would you consider when deciding whether or not to participate? (Examples may include how severe your neuropathic pain is, how well current treatments are working for you, your concern about risks, etc.)

B. Meeting Attendance and Participation

If you wish to attend this meeting, visit <https://peripheralneuropathypfdd.eventbrite.com>. Please register by June 3, 2016. If you are unable to attend the meeting in person, you can register to view a live Webcast of the meeting. You will be asked to indicate in your registration if you plan to attend in person or via the Webcast. Seating will be limited, so early registration is recommended. Registration is free and will be on a first-come, first-served basis. However, FDA may limit the number of participants from each organization based on space limitations. Registrants will receive confirmation once they have been accepted. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations because of a disability, please contact Meghana Chalasani (see FOR FURTHER INFORMATION CONTACT) at least 7 days before the meeting.

Patients who are interested in presenting comments as part of the initial panel discussions will be asked to indicate in their registration which topic(s) they wish to address. These patients also must send to PatientFocused@fda.hhs.gov a brief summary of responses to the topic questions by May 27, 2016. Panelists will be notified of their selection approximately 7 days before the public meeting. We 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.

Docket Comments: Regardless of whether you attend the public meeting, you can submit electronic or written responses to the questions pertaining to topics 1 and 2 to the public docket (see ADDRESSES) by August 10, 2016. Received comments may be seen in the Division of Dockets Management between 9 a.m. and 4 p.m., Monday through Friday, and will be posted to the docket at <http://www.regulations.gov>.

Transcripts: As soon as a transcript is available, FDA will post it at
<http://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm470608.htm>.

Dated: April 13, 2016.

Leslie Kux,

Associate Commissioner for Policy.

[FR Doc. 2016-08881 Filed: 4/15/2016 8:45 am; Publication Date: 4/18/2016]