



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2018-N-1621]

Patient-Focused Drug Development on Chronic Pain; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is announcing a public meeting and an opportunity for public comment on “Patient-Focused Drug Development for Chronic Pain.” The public meeting will provide patients (including adult and pediatric patients) with an opportunity to present to FDA their perspectives on the impacts of chronic pain, views on treatment approaches for chronic pain, and challenges or barriers to accessing treatments. FDA is particularly interested in hearing from patients who experience chronic pain that is managed with analgesic medications such as opioids, acetaminophen, nonsteroidal anti-inflammatory drugs (NSAIDs), antidepressants; other medications; and non-pharmacologic interventions or therapies.

DATES: The public meeting will be held on July 9, 2018, from 10 a.m. to 4 p.m. Submit either electronic or written comments on this public workshop by September 10, 2018. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: The public meeting will be held at FDA’s White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD

20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to <https://www.fda.gov/AboutFDA/WorkingatFDA/BuildingsandFacilities/WhiteOakCampusInformation/ucm241740.htm>.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before September 10, 2018. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of September 10, 2018. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://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 <https://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): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, 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-2018-N-1621 for “Patient-Focused Drug Development on Chronic Pain; Public Meeting; Request for Comments.” Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as “Confidential Submissions,” publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff 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 <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. 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: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://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 Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

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

This meeting will provide FDA the opportunity to better understand patients' perspectives on the impacts of chronic pain, patient views on treatment approaches for chronic pain, and challenges or barriers to accessing treatments. Chronic pain is defined as either pain that persists for more than 3 months or pain that lasts more than 1 month beyond the normal healing time. Chronic pain is diverse and can include primary pain, cancer pain, postsurgical and posttraumatic pain, neuropathic pain, headache and orofacial pain, visceral pain, and musculoskeletal pain. There are a number of therapeutic approaches for the treatment of chronic pain, including prescription and non-prescription medications, invasive and non-invasive medical devices, and behavioral and physical therapies. FDA is particularly interested in patients' (including adult and pediatric patients) perspectives on types of chronic pain that are managed with analgesic medications such as opioids, acetaminophen, NSAIDs, antidepressants; other medications; and non-pharmacologic interventions or therapies.

At the meeting, patients and patient representatives will provide patient perspectives on the symptoms and daily impacts of chronic pain and on treatment approaches for chronic pain. The questions that will be asked of patients and patient representatives at the meeting are listed in the following section and 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 representative participants. In addition to input generated through this public meeting, FDA is interested in receiving patient and patient representative input addressing these questions through written comments, which can be submitted to the public docket (see ADDRESSES). When submitting comments, if you are

commenting on behalf of a patient, please indicate that you are doing so and answer the following questions as much as possible from the patient's perspective.

FDA will post the agenda and other meeting materials approximately 5 days before the meeting at: <https://www.fda.gov/Drugs/NewsEvents/ucm603093.htm>.

II. Topics for Discussion at the Public Meeting

Topic 1: Symptoms and Daily Impacts of Chronic Pain That Matter Most to Patients

1. How would you describe your chronic pain? (Characteristics could include location, radiation, intensity, duration, constancy or intermittency, triggers etc.)
2. What are the most significant symptoms that you experience resulting from your condition? (Examples may include restricted range of motion, muscle spasms, changes in sensation, etc.)
3. 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 chronic pain? (Examples of activities may include work or school activities, sleeping through the night, daily hygiene, participation in sports or social activities, intimacy with a spouse or partner, etc.)
4. How has your chronic pain changed over time? (Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities.)

Topic 2: Patients' Perspectives on Current Approaches to Treatment of Chronic Pain

1. What are you currently doing to help treat your chronic pain? (Examples may include prescription medicines, over-the-counter products, and non-drug therapies.)
 - a. How has your treatment regimen changed over time, and why? (Examples may include change in your condition, change in dose, or treatment side effects.)

- b. What factors do you take into account when making decisions about selecting a course of treatment?
2. How well does your current treatment regimen manage your chronic pain?
(Considerations include severity and frequency of your chronic pain and the effects of chronic pain on your daily activities.)
3. What are the most significant downsides to your current treatments, and how do they affect your daily life?
4. What challenges or barriers to accessing or using medical treatments for chronic pain have you or do you encounter?
5. What specific things would you look for in an ideal treatment for your chronic pain?

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit <https://chronicpain-pfdd.eventbrite.com>. Please register by July 2, 2018. Persons without access to the internet can call 240-402-6525 to register. 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.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by July 2, 2018. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 9 a.m. If you need special accommodations because of a

disability, please contact Meghana Chalasani (see FOR FURTHER INFORMATION CONTACT) no later than July 2, 2018.

Panelist Selection: Patients or patient representatives 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 or patient representatives also will be asked to send PatientFocused@fda.hhs.gov a brief summary of responses to the topic questions by June 25, 2018. 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.

Open Public Comment: There will be time allotted during the meeting for open public comment. Signup for this session will be on a first-come, first-serve basis on the day of the workshop. Individuals and organizations with common interests are urged to consolidate or coordinate and request time for a joint presentation. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the webcast by visiting <https://chronicpain-pfdd.eventbrite.com>.

If you have never attended a Connect Pro event before, test your connection at https://collaboration.fda.gov/common/help/en/support/meeting_test.htm. To get a quick overview of the Connect Pro program, visit https://www.adobe.com/go/connectpro_overview. FDA has verified the website addresses in this document, as of the date this document publishes in the *Federal Register*, but websites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public meeting is available, it will be accessible at <https://www.regulations.gov>. It may be viewed at the Dockets Management Staff (see ADDRESSES). A link to the transcript will also be available on the internet at <https://www.fda.gov/Drugs/NewsEvents/ucm603093.htm>.

Dated: May 10, 2018.

Leslie Kux,

Associate Commissioner for Policy.

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