4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0259]

Patient-Focused Drug Development for Stimulant Use Disorder; Public Meeting; Request for Comments

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments.

SUMMARY: In the *Federal Register* notice published on March 19, 2020, the Food and Drug Administration (FDA, the Agency, or we) announced the cancellation of the meeting entitled "Patient-Focused Drug Development for Stimulant Use Disorder" originally scheduled to occur on March 10, 2020, as announced in the *Federal Register* on February 18, 2020. FDA is announcing a new date for the meeting, to occur in a virtual format. The purpose of the public meeting is to allow FDA to obtain stakeholder perspectives on the impact of stimulant use disorder and views on treatment approaches for stimulant use disorder.

DATES: The public meeting will be held on October 6, 2020, from 12:30 p.m. Eastern Time to 5 p.m. Eastern Time. Submit either electronic or written comments on this public meeting by December 7, 2020. See the SUPPLEMENTARY INFORMATION section for registration date and information.

ADDRESSES: Please note that due to the impact of the COVID-19 pandemic, all meeting participants will be joining this public meeting via an online conferencing platform.

The docket number to accept comments is FDA-2020-N-0259. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or

before December 7, 2020. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 7, 2020. 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-2020-N-0259 for "Patient-Focused Drug Development for Stimulant Use Disorder; 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, 240-402-7500.

- 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.govinfo.gov/content/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, 240-402-7500.

FOR FURTHER INFORMATION CONTACT: Lyna Merzoug, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6308, Silver Spring, MD 20993-0002, 301-796-6001, PatientFocused@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Background

On March 19, 2020, FDA announced in the *Federal Register* (85 FR 15789) the cancellation of the meeting entitled "Patient-Focused Drug Development for Stimulant Use Disorder" originally scheduled to occur on March 10, 2020, as announced in the *Federal Register* on February 18, 2020 (85 FR 8877). The meeting has been rescheduled in a virtual format.

This meeting will provide FDA the opportunity to obtain input from individuals with stimulant use disorder and other related stakeholders on the impact of stimulant use disorder and views on treatment goals and approaches. FDA is interested in stakeholders' perspectives on:

(1) the health effects and daily impacts of their condition; (2) the impact (if any) of opioid and polysubstance use on their condition; (3) treatment goals; and (4) decision factors considered when seeking out or selecting a treatment.

Stimulant use disorder describes a range of problems associated with the use of illicit stimulant drugs, including methamphetamine and cocaine, and prescription stimulants (e.g., ADDERALL, RITALIN), but not including caffeine or nicotine. A diagnosis of stimulant use disorder is made when a clinician identifies a pattern of use of amphetamine-type substance, cocaine, or other stimulant that leads to clinically significant impairment or distress, including an inability to reduce or control consumption, cravings to use a stimulant, continued use of a stimulant despite it causing negative consequences, and the need to use increased amounts of a stimulant to achieve the desired effect. There are no FDA-approved medications for stimulant use disorder.

The questions that will be asked of individuals with stimulant use disorder and other stakeholders at the meeting are listed in the following section and organized by topic. For each topic, a brief initial panel discussion will begin the dialogue. This will be followed by a facilitated discussion inviting comments from other audience participants. In addition to input generated through this public meeting, FDA is interested in receiving stakeholder input addressing these questions through written comments, which can be submitted to the public docket (see ADDRESSES). As noted above, when submitting comments, 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." When submitting comments, if you are commenting on behalf of a stimulant user, please indicate that you are doing so and answer the following questions as

much as possible from the stimulant user's perspective, but please refrain from providing information that would identify third parties, including minor children.

FDA will post the agenda and other meeting materials approximately 5 days before the meeting at https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-stimulant-use-disorder-03102020-03102020.

II. Discussion Questions at the Public Meeting

A. Topic 1: Health Effects and Daily Impacts

1. How would you describe your experience with stimulant use disorder?
    a. Which stimulant(s) did you start using first?
    b. What stimulant(s) are you using now?
    c. Did you use any other illicit or prescription drugs before you started using the stimulant that you are currently using?
    d. How are you using stimulants? How has your stimulant(s) use changed over time? Are you using more frequently or at higher doses?
    e. Do you use stimulants in combination with other drug(s)? If so, what other drugs do you use and why?
    f. Have you used a stimulant(s) as treatment for opioid withdrawal and/or overdose?
2. Of all the ways that stimulant use disorder impacts your health and well-being, which effects have the most significant impact on your daily life and the daily life of your family and/or friends? Examples may include physical and mental effects of using stimulants (effects on your body and thinking), effects of stimulant withdrawal, effects of cravings, impacts on your ability to function in personal or professional life, or emotional or social effects.
    a. What drives your use of stimulants?

b. Are there certain activities that you can only do if you take a stimulant? If so, what are those activities?

c. 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 stimulant use? Examples of activities may include daily hygiene; meeting school, work, or family responsibilities; participation in social activities.

d. How does your stimulant use affect daily life on your best days? On your worst days?

3. What worries you most about your condition?

B. Topic 2: Current Approaches to Management

1. Have you considered seeking treatment? Why or why not?
2. If you are using more than one substance, would stimulant use be the primary or secondary reason to consider treatment?

   a. If not stimulants, what substance would be the primary reason you would seek treatment?

3. What are you currently doing to help manage your stimulant use?

   a. How well have these management approaches worked for you?

   b. How well have they helped address the effects of stimulant use that are most troubling to you?

   c. What are the biggest problems you have faced in using these approaches? Examples may include bothersome side effects, challenges or barriers to access, concern about stigma.

4. What are the biggest factors that you consider when making decisions about seeking out or engaging in treatment for stimulant use disorder?
5. What specific things would you look for in an ideal treatment for stimulant use disorder?

6. If you had the opportunity to participate in a clinical study to test an experimental treatment for stimulant use disorder, what factors would you consider when deciding whether you would participate?

C. Topic 3: Impact of COVID-19

1. Has the COVID-19 pandemic impacted your substance use or your desire to seek treatment? If yes, please describe how.

III. Participating in the Public Meeting

Registration: Persons interested in attending this public meeting via webcast must register online at https://pfdd-stimulantusedisorder.eventbrite.com. Contact information provided during registration will remain confidential and will only be used to send meeting updates to participants.

Registration for this virtual event is free, although there may be limited space for attendance based on bandwidth availability. Webcast information will be provided upon completion of registration. Closed captioning will be provided. Please check the meeting website for the latest information: https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-stimulant-use-disorder-03102020-03102020.

Streaming Webcast of the Public Meeting: This public meeting will be streamed via webcast only. The recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting. To register for the webcast, please visit https://pfdd-stimulantusedisorder.eventbrite.com. The webcast can be accessed via http://fda.yorkcast.com/webcast/Play/89f7acb8d56e4de8827d1ade8efa42661d. Simply click on the link and hit the "play" button and it will start. The webcast link will be activated 30 minutes prior to the start of the meeting.

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 meeting website at https://www.fda.gov/drugs/news-events-human-drugs/public-meeting-patient-focused-drug-development-stimulant-use-disorder-03102020-03102020.

Dated: September 24, 2020.

Lauren K. Roth,

Associate Commissioner for Policy.

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