responses should include a discussion of how the information or data can be applied specifically to tobacco products or to lung injuries associated with the use of vaping products.

For this RFI, FDA is requesting: (1) Unpublished data or information (summarized); (2) unpublished or prepublication copies of manuscripts, conference presentations, and/or posters; (3) dissertations and/or theses; and (4) white papers or other unpublished reports. FDA is requesting data and information from all interested parties, including, but not limited to, academic and government researchers, industry, and any other sources.

Specifically, FDA is requesting unpublished data or information on the following:

- Specific chemicals, compounds, ingredients or combinations of ingredients that when inhaled or aerosolized, may be associated with the symptoms observed in ''e-cigarette, or vaping, product use-associated lung injury'' (EVALI) patients; *e.g.,* cough, chest pain, shortness of breath, abdominal pain, nausea, vomiting, diarrhea, fever, chills; [3]
- nature of pulmonary pathological changes associated with inhaling the specific chemicals, compounds, ingredients, or combinations of ingredients that elicit the symptoms observed in EVALI;
- methods or sources for obtaining chemicals, compounds, ingredients, or combinations of ingredients, other than those intended by the manufacturer, that are added to vaping products;
- in what ways and how frequently consumers add chemicals, compounds, ingredients or combinations of ingredients, other than those intended by the manufacturer, to vaping products and how these changes affect the health impacts, frequency, and patterns of consumer use of the products;
- methods for identifying and detecting materials added or modifications to vaping products after the manufacturing process and not intended by the manufacturer; and
- methods of changing the manufacturing process or product design features for vaping products that will reduce or prevent consumers from modifying products after the manufacturing process.

Data may come from studies outside of the United States; however, FDA prefers that reports be submitted in English.

[3] For more information concerning the symptoms observed in EVALI patients, please see *https://www.cdc.gov/tobacco/basic_information/e-cigarettes/severe-lung-disease/need-to-know/index.html#symptoms.*

When submitting information, please include details about how the data were collected, including the sample composition, year(s) of data collection, and a detailed summary of the methods and measures used. For data summaries, please include both point estimates and measures of variance, as well as effect sizes (if available).

Please also note that when submitting information and data to the docket, certain compressed file formats (*e.g.,* zip files) are not allowed. Acceptable file formats include: .doc, .docx, .pdf, .ppt, .pptx, .rtf, .txt, .xls, .xlsx, .xlsm, .xlsb, and .wpd.

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03160 Filed 2–14–20; 8:45 am]

BILLING CODE 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: The Food and Drug Administration (FDA, the Agency, or we) is announcing the following public meeting entitled ''Patient-Focused Drug Development for Stimulant Use Disorder.'' 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 March 10, 2020, from 12:30 p.m. to 5 p.m. Submit either electronic or written comments on this public meeting by May 11, 2020. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the Silver Spring Civic Building, 1 Veterans Pl., Silver Spring, MD 20910. The building is located at Veterans Plaza in downtown Silver Spring and is accessible via the Silver Spring Metro Station on the Red Line. Paid public parking is also available at the Town Square Garage (Garage 61), 801 Ellsworth Dr., Silver Spring, MD 20910, and the Wayne-Ellsworth Garage (Garage 60), 921 Wayne Ave., Silver Spring, MD 20910. For more information regarding parking, Metro access, and the meeting location, please refer to *https://www.montgomerycountymd.gov/cupf/info-reservation/SSCB.html.*

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 May 11, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 11, 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.

• 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.

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

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. 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.

3. What are the biggest factors that you consider when making decisions about seeking out or engaging in treatment for stimulant use disorder?

4. What specific things would you look for in an ideal treatment for stimulant use disorder?

5. 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?

III. Participating in the Public Meeting

Registration: To register for the public meeting, visit *https://stimulantusedisorder-pfdd.eventbrite.com/.* Contact information provided during registration will remain confidential and only be used to send meeting updates to participants.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by March 3, 2020, 11:59 p.m. Eastern Time. Early registration is recommended because seating is limited; therefore, FDA may limit the number of participants from each organization. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 11:30 a.m.

If you need special accommodations due to a disability, please contact Lyna Merzoug (**SEE FURTHER INFORMATION CONTACT**) no later than March 3, 2020.

Panelist Selection: Stakeholders, particularly people suffering from stimulant use disorder, 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 stakeholders also will be asked to send *PatientFocused@fda.hhs.gov* a brief summary of responses to the discussion questions listed above by February 26, 2020. Panelists will be notified of their selection approximately 7 days before the public meeting. We will try to accommodate all 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.

Persons attending FDA's meetings are advised that FDA is not responsible for providing access to electrical outlets.

Streaming Webcast of the public meeting: FDA will also stream a live audio recording of this public meeting with the presentation slides. The audio recording and presentation slides, along with a meeting transcript and summary report, will also be made publicly available after the meeting. Because of the sensitive nature of the meeting topic, and the importance of gathering candid, meaningful input from individuals who have come forward to speak about living with stimulant use disorder, no other audio recording, video recording, and/or photography will be allowed at this Patient-Focused Drug Development meeting. FDA is asking for your cooperation and strongly requests that you respect the privacy of all attendees. You will be asked to indicate in your registration whether you plan to attend in person or via the webcast. To register for the webcast, please visit *https://stimulantusedisorder-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/industry/prescription-drug-user-fee-amendments/fda-led-patient-focused-drug-development-pfdd-public-meetings.*

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03159 Filed 2–14–20; 8:45 a.m.]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2017–E–5899 and FDA–2017–E–5911]

Determination of Regulatory Review Period for Purposes of Patent Extension; INTRAROSA

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or the Agency) has determined the regulatory review period for INTRAROSA and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of applications to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that human drug product.

DATES: Anyone with knowledge that any of the dates as published (see **SUPPLEMENTARY INFORMATION**) are incorrect may submit either electronic or written comments and ask for a redetermination by April 20, 2020. Furthermore, any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period by August 17, 2020. See ''Petitions'' in the **SUPPLEMENTARY INFORMATION** section for more information.

ADDRESSES: 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 April 20, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of April 20, 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: