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:

• *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 Nos. FDA–2017–E–5899 and FDA–2017–E–5911 for ''Determination of Regulatory Review Period for Purposes of Patent Extension; INTRAROSA.'' 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 § 10.20 (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: Beverly Friedman, Office of Regulatory Policy, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6250, Silver Spring, MD 20993, 301–796–3600.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: A testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, INTRAROSA (prasterone), indicated for the treatment of moderate to severe dyspareunia, a symptom of vulvar and vaginal atrophy, due to menopause. Subsequent to this approval, the USPTO received patent term restoration applications for INTRAROSA (U.S. Patent Nos. 8,629,129 and 8,957,054) from Endorecherche, Inc., and the USPTO requested FDA's assistance in determining the patents' eligibility for patent term restoration. In a letter dated February 20, 2018, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of INTRAROSA represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for INTRAROSA is 3,381 days. Of this time, 2,983 days occurred during the testing phase of the regulatory review period, while 398 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* August 17, 2007. FDA has verified the applicant's claim that the date the investigational new drug application became effective was August 17, 2007.

2. *The date the application was initially submitted with respect to the human drug product under section 505 of the FD&C Act:* October 16, 2015. FDA has verified the applicant's claim that the new drug application (NDA) for INTRAROSA (NDA 208470) was initially submitted on October 16, 2015.

3. *The date the application was approved:* November 16, 2016. FDA has verified the applicant's claim that NDA 208470 was approved on November 16, 2016.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its applications for patent extension, this applicant seeks 717 days or 518 days of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: Must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Dated: February 12, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2020–03115 Filed 2–14–20; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

[Document Identifier: OS–4040–0019]

Agency Information Collection Request; 30-Day Public Comment Request

AGENCY: Office of the Secretary, HHS.

ACTION: Notice.

SUMMARY: In compliance with the requirement of the Paperwork Reduction Act of 1995, the Office of the Secretary (OS), Department of Health and Human Services, is publishing the following summary of a proposed collection for public comment.

DATES: Comments on the ICR must be received on or before March 19, 2020.

ADDRESSES: Submit your comments to *OIRA_submission@omb.eop.gov* or via facsimile to (202) 395–5806.

FOR FURTHER INFORMATION CONTACT: Ed Calimag, *ed.calimag@hhs.gov* or (202) 690–7569. When submitting comments or requesting information, please include the document identifier 4040–0019–30D and project title for reference.

SUPPLEMENTARY INFORMATION: Interested persons are invited to send comments regarding this burden estimate or any other aspect of this collection of information, including any of the following subjects: (1) The necessity and utility of the proposed information collection for the proper performance of the agency's functions; (2) the accuracy of the estimated burden; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) the use of automated collection techniques or other forms of information technology to minimize the information collection burden.

Title of the Collections: Project Abstract Summary.

Type of Collection: Revision.

OMB No.: 4040–0019.

Abstract: Project Abstract Summary form provides the Federal grant-making agencies an alternative to the Standard Form 424 data set and form. Project Abstract Summary programs are not required to collect all the data that is required on the SF–424 core data set and form. *Grants.gov* seeks revision without renewal and designation as a Common Form due to updates to the IC. The IC was modified to remove data elements. The IC was renewed with an expiration date of 02/28/2022 and does not require an extension.

ESTIMATED ANNUALIZED BURDEN TABLE

Forms	Number of respondents	Number of responses per respondent	Average burden hours per response	Total burden hours
Project Abstract Summary	3,467	1	1	3,467
Total	3,467			3,467

Sherrette A. Funn,

Paperwork Reduction Act Reports Clearance Officer, Office of the Secretary.

[FR Doc. 2020–03128 Filed 2–14–20; 8:45 am]

BILLING CODE 4151–AE–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

National Heart, Lung, and Blood Institute; Notice of Closed Meeting

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended, notice is hereby given of the following meeting. The meeting will be closed to the public in accordance with the provisions set forth in sections 552b(c)(4) and 552b(c)(6), Title 5 U.S.C., as amended. The grant applications and the discussions could disclose confidential trade secrets or commercial property such as patentable material, and personal information concerning individuals associated with the grant applications, the disclosure of which would constitute a clearly unwarranted invasion of personal privacy.

Name of Committee: National Heart, Lung, and Blood Institute Special Emphasis Panel; Blood Brain Barrier.

Date: March 19, 2020.

Time: 8:00 a.m. to 4:30 p.m.

Agenda: To review and evaluate grant applications.

Place: Bethesda North Marriott Hotel & Conference Center, Montgomery County Conference Center Facility, 5701 Marinelli Road, North Bethesda, MD 20852.

Contact Person: Michael P. Reilly, Ph.D., Scientific Review Officer, Office of Scientific Review, National Heart, Lung, and Blood Institute, National Institutes of Health, 6701 Rockledge Drive, Room 7200, Bethesda, MD 20892, 301–827–7975, *reillymp@nhlbi.nih.gov.*

(Catalogue of Federal Domestic Assistance Program Nos. 93.233, National Center for Sleep Disorders Research; 93.837, Heart and Vascular Diseases Research; 93.838, Lung Diseases Research; 93.839, Blood Diseases