Submit written requests for single copies of the Engineering Research Center for Structured Organic Particulate Systems (C-SOPS) document to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 2201, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the C-SOPS document.

FOR FURTHER INFORMATION CONTACT: Sau (Larry) Lee, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 22, Rm. 2128, Silver Spring, MD 20993–0002, 301–796–2905, *Sau.Lee@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

During a May 7, 2015, workshop on the Future of Pharmaceutical Manufacturing, FDA agreed that interested parties could submit for Agency consideration draft guidance or other materials discussing the science, technology, and best practices related to continuous manufacturing. On June 13, 2016, C-SOPS submitted to FDA an industry-coordinated best practices document on continuous manufacturing. FDA is interested in public comments about the science, technology, and practices discussed in the C-SOPS document and is opening this docket for that purpose. In addition, FDA is seeking comments on other recommendations regarding continuous manufacturing that have already been published, including ''Regulatory and Quality Considerations for Continuous Manufacturing: May 20–21, 2014, Continuous Manufacturing Symposium.'' FDA invites comment on control strategy, facility, and process validation considerations for continuous manufacturing of solid oral dosage forms. This request is not limited to comments on the proposal described in the C-SOPS submission.

II. Electronic Access

Persons with access to the Internet may obtain the C-SOPS document at *https://www.regulations.gov.*

Dated: June 15, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13195 Filed 6–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3067]

Patient-Focused Drug Development for Alopecia Areata; 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 Alopecia Areata.'' Patient-Focused Drug Development is part of FDA's performance commitments under the fifth authorization of the Prescription Drug User Fee Act (PDUFA V). The public meeting is intended to allow FDA to obtain patients' perspectives on the impact of alopecia areata, including on daily life. FDA is also seeking patients' views on treatment approaches and decision factors taken into account when selecting a treatment.

DATES: The public meeting will be held on September 11, 2017, from 1 p.m. to 5 p.m. Submit either electronic or written comments on this public meeting by November 13, 2017. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at the FDA White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993–0002. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For more information on parking and security procedures, please refer to *http://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 November 13, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of November 13, 2017. 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–2017–N–3067 for ''Patient-Focused Drug Development for Alopecia Areata.'' 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.

FDA will post the agenda approximately 5 days before the meeting at: *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm554443.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 alopecia areata as the focus of a public meeting under the Patient-Focused Drug Development initiative. This initiative involves obtaining a better understanding of patients' 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 PDUFA reauthorization 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 on the FDA Web site 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 benefits 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 timeframe. 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 *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm347317.htm.*

II. Purpose and Scope of the Meeting

As part of Patient-Focused Drug Development, FDA will obtain patient and patient stakeholder input on the symptoms of alopecia areata that matter most to patients and on current approaches to treating alopecia areata. Alopecia areata is an autoimmune disease that causes hair loss. The hair loss usually occurs on the scalp but can also affect the beard, eyebrows, and other areas of the body. While there is currently no cure, there are available treatments, such as corticosteroids or non-drug therapies, which may help hair regrowth. FDA is interested in the perspectives of patients with alopecia areata on: (1) The impact of their condition, (2) treatment approaches, and (3) decision factors taken into account when selecting a treatment.

The questions that will be asked of patients and patient stakeholders at the meeting are listed in this 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 stakeholder participants. In addition to input generated through this public meeting, FDA is interested in receiving patient input addressing these questions through electronic or written comments, which can be submitted to the Dockets Management Staff (see **ADDRESSES**).

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

1. Of all the symptoms or disease manifestations that you experience because of your condition, which one to three symptoms or manifestations have the most significant impact on your life? Examples may include location or type of hair loss (*i.e.* loss of hair on scalp, loss of eyebrows, loss of all hair on body patchy hair loss), nail changes, hair quality upon regrowth.

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 condition? Examples of activities may include daily hygiene, engagement in personal relationships, participation in sports or social activities, completion of school or work activities, etc.

3. How do your symptoms and their negative impacts affect your daily life on the best days? On the worst days?

4. How has your condition changed over time?

- Would you define your condition today as being well-managed?

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 condition or its symptoms? Examples may include prescription medicines, over-the-counter products, and non-drug therapies such as diet modification.

- How has your treatment regimen changed over time, and why?

2. How well does your current treatment regimen control your condition?

- How well have these treatments worked for you as your condition has changed over time?

3. What are the most significant downsides to your current treatments,

and how do they affect your daily life? Examples of downsides may include going to the clinic for treatment, time devoted to treatment, side effects of treatment, route of administration, etc.

4. What specific things would you look for in an ideal treatment for your condition?

• What would you consider to be a meaningful improvement in your condition that a treatment could provide?

5. What factors do you take into account when making decisions about selecting a course of treatment?

III. Meeting Attendance and Participation

If you wish to attend this meeting, visit *https://alopeciaareata.eventbrite.com.* Persons interested in attending this public meeting must register by August 28, 2017. 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. 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. Onsite registration on the day of the meeting will be based on space availability. If you need special accommodations due to a disability, please contact Meghana Chalasani (see **FOR FURTHER INFORMATION CONTACT**) no later than September 1, 2017.

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 August 21, 2017. 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.

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 at *https://www.fda.gov/ForIndustry/UserFees/PrescriptionDrugUserFee/ucm554443.htm.*

Dated: June 20, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–13194 Filed 6–22–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Health Resources and Services Administration

Agency Information Collection Activities: Proposed Collection: Public Comment Request Information Collection Request Title: Federal Tort Claims Act (FTCA) Program Deeming Applications for Free Clinics, OMB No. 0915–0293—Extension

AGENCY: Health Resources and Services Administration (HRSA), Department of Health and Human Services.

ACTION: Notice.

SUMMARY: In compliance with the requirement for opportunity for public comment on proposed data collection projects of the Paperwork Reduction Act of 1995, the Health Resources and Services Administration (HRSA) announces plans to submit an Information Collection Request (ICR), described below, to the Office of Management and Budget (OMB). Prior to submitting the ICR to OMB, HRSA seeks comments from the public regarding the burden estimate, below, or any other aspect of the ICR.

DATES: Comments on this Information Collection Request must be received no later than August 22, 2017.

ADDRESSES: Submit your comments to *paperwork@hrsa.gov* or mail the HRSA Information Collection Clearance Officer, Room 14N39, 5600 Fishers Lane, Rockville, MD 20857.

FOR FURTHER INFORMATION CONTACT: To request more information on the proposed project or to obtain a copy of the data collection plans and draft instruments, email *paperwork@hrsa.gov* or call the HRSA Information Collection Clearance Officer at (301) 443–1984.

SUPPLEMENTARY INFORMATION: When submitting comments or requesting information, please include the information request collection title for reference, in compliance with Section 3506(c)(2)(A) of the Paperwork Reduction Act of 1995.

Information Collection Request Title: Federal Tort Claims Act (FTCA) Program Deeming Applications for Free Clinics, OMB No. 0915–0293—Extension.

Abstract: Section 224(o) of the Public Health Service (PHS) Act (42 U.S.C. 233(o)), as amended, authorizes the ''deeming'' of certain individuals as PHS employees for the purposes of receiving Federal Tort Claims Act (FTCA) coverage. Section 224(o) relates to employees, officers, and contractors at qualifying free clinics. The Free Clinics FTCA Program is administered by HRSA's Bureau of Primary Health Care (BPHC). Sponsoring free clinics are required by law to submit deeming applications in the specified form and manner on behalf of named individuals for review and approval, resulting in a ''deeming determination'' that includes associated FTCA coverage for these individuals.

Need and Proposed Use of the Information: Deeming applications must address certain specified criteria required by law for deeming determinations to be issued, and FTCA application forms are critical to BPHC's deeming determination process. These forms provide BPHC with the information necessary to evaluate an application and determine whether an individual meets the requirements for deemed PHS employee status for the purposes of FTCA coverage. FTCA application forms for free clinics do not require any changes with this extension other than to update the applicable dates.

Likely Respondents: Respondents include free clinics seeking deemed PHS employee status on behalf of their sponsored individuals for purposes of FTCA coverage.

Burden Statement: Burden in this context means the time expended by persons to generate, maintain, retain, disclose, or provide the information requested. This includes the time needed to review instructions; to develop, acquire, install, and utilize technology and systems for the purpose of collecting, validating and verifying information, processing and maintaining information, and disclosing and providing information; to train personnel and to be able to respond to a collection of information; to search data sources; to complete and review the collection of information; and to transmit or otherwise disclose the information. The total annual burden hours estimated for this Information Collection Request are summarized in the table below.