limited; therefore, FDA may limit the number of participants from each organization. Registrants will receive confirmation when they have been accepted. If time and space permit, onsite registration on the day of the public meeting/public workshop will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public workshop.

If you need special accommodations due to a disability, please contact Susan Monahan, Center for Devices and Radiological Health, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 66, Rm. 4321, Silver Spring, MD 20993–0002, 301–796–5661, email: *susan.monahan@fda.hhs.gov* no later than August 30, 2017.

Requests for Oral Presentations: During online registration you may indicate if you wish to present during the public comment session, and which topic you wish to present. We will do our best to accommodate requests to make public comments. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation. Following the close of registration, we will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and will select and begin notifying participants by September 5, 2017. All requests to make oral presentations must be received by the close of registration on September 1, 2017. If selected for presentation, any presentation materials must be emailed to Natasha Townsend (see **FOR FURTHER INFORMATION CONTACT**) no later than September 8, 2017, 5 p.m. No commercial or promotional material will be permitted to be presented or distributed at the public workshop.

Streaming Webcast of the Public Workshop: This public workshop will also be Webcast. Persons interested in viewing the Webcast must register online by September 8, 2017, 4 p.m. The Webcast link will be available on the registration Web page after September 8, 2017. Organizations are requested to register all participants, but to view using one connection per location.

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: *http://www.adobe.com/go/connectpro_overview.* FDA has verified the Web site addresses in this document, as of the date this document publishes in the **Federal Register**, but Web sites are subject to change over time.

Transcripts: Please be advised that as soon as a transcript of the public workshop 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 approximately 45 days after the public workshop on the Internet at *http://www.fda.gov/MedicalDevices/NewsEvents/WorkshopsConferences/default.htm.* (Select this public workshop from the posted events list).

Dated: June 23, 2017.

Anna K. Abram,

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

[FR Doc. 2017–13611 Filed 6–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–N–3199]

Program for Enhanced Review Transparency and Communication for Original 351(k) Biologics License Applications in Biosimilar User Fee Act II

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice; establishment of docket; request for comments.

SUMMARY: The Food and Drug Administration (FDA) is announcing an opportunity for public comment on the statement of work for an assessment of the Program for Enhanced Review Transparency and Communication for original biologics license applications (BLAs) (351(k)s) submitted under the Public Health Service Act (hereafter referred to as 351(k) applications) (hereafter referred to as the Program). The Program is part of the FDA performance commitments under the proposed reauthorization of the Biosimilar User Fee Act (BsUFA), which, if enacted into law, will allow FDA to collect user fees for the review of 351(k) applications for fiscal years (FYs) 2018–2022. As part of the FDA performance commitments described in this document, the Program will be evaluated by an independent contractor in an interim and final assessment.

DATES: FDA is providing a period of 30 days for public comment on the statement of work before beginning the assessment. The statement of work can be accessed at *https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM559341.pdf.* Public comments will be accepted through July 31, 2017. See **ADDRESSES** section below for information about submitting comments to the public docket.

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 July 31, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of July 31, 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–3199 for ''Program for Enhanced Review Transparency and Communication for Original 351(k) Biologics License Applications in BsUFA II.'' 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: Azada Hafiz, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 1148, Silver Spring, MD 20993, 240–402–6073, Fax: 301–847–8443, *Azada.Hafiz@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The timely review of 351(k) applications is central to FDA's mission to protect and promote the public health. The BsUFA was first enacted by Congress in 2012 and authorizes FDA to collect user fees for 351(k) applications. FDA dedicates BsUFA user fees to the efficient review of 351(k) applications and to facilitate the development of safe and effective biosimilar biological products for the American public. FDA dedicates the additional fee resources to hire reviewers and support staff and upgrade its information technology systems. With the availability of these additional fee resources, FDA was able to agree to certain review performance goals, including a complete review of 351(k) applications and taking regulatory action within specified timeframes. The current authorization of the program (BsUFA I) expires in September 2017.

As directed by statute, FDA prepared recommendations for the reauthorization of BsUFA for a new 5-year period by conducting negotiations with the regulated industry and holding regular consultations with public stakeholders including patient advocates, consumer advocates, and healthcare professionals. Following these discussions, related public meetings, and Agency requests for public comment, FDA transmitted proposed recommendations for BsUFA II for fiscal years 2018–2022. FDA's BsUFA II recommendations include an FDA commitment to implement a new review program for 351(k) applications to promote the efficiency and effectiveness of the first-cycle review process and minimize the number of review cycles necessary for approval of these complex applications. The Program is described in detail in section I.B of the document entitled ''Biosimilar Biological Product Reauthorization Performance Goals and Procedures Fiscal Years 2018 Through 2022'' available at *https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf.*

II. BsUFA II Program for Enhanced Review Transparency and Communication for Original 351(k) BLAs

FDA recognizes that increasing communication between the Agency and applicants during FDA's review has the potential to increase efficiency in the review process. To enhance review transparency and improve communication between the FDA review team and the applicant, FDA has proposed for BsUFA II a new review model (the Program), for the review of all 351(k) applications. The Program will allow for additional communication between FDA review teams and the applicants of biosimilar biological products in the form of a Biological Product Development Type 4 (pre-351(k) BLA) meetings, mid-cycle communications, and late-cycle meetings. To accommodate this increased interaction during regulatory review and to address the need for additional time to review these complex applications, FDA's review clock will begin after the 60-day administrative filing review period for applications reviewed under the Program.

The goal of the Program is to improve the efficiency and effectiveness of the first-cycle review process by increasing communications during application review. This will provide sponsors with the opportunity to clarify previous submissions and provide additional data and analyses that are readily available, potentially avoiding the need for an additional review cycle when concerns can be promptly resolved without compromising FDA's standards for approval.

Dated: June 23, 2017.

Anna K. Abram,

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

[FR Doc. 2017–13609 Filed 6–28–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

National Institutes of Health

Center for Scientific Review; Notice of Closed Meetings

Pursuant to section 10(d) of the Federal Advisory Committee Act, as amended (5 U.S.C. App.), notice is hereby given of the following meetings.

The meetings 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: Center for Scientific Review Special Emphasis Panel; PAR16–274: