Authority: 42 U.S.C. 1315.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2019–09756 Filed 5–10–19; 8:45 am]

BILLING CODE 4184–41–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2019–N–1875]

Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; 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 ''Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.'' The purpose of the public meeting is to meet performance commitments included in the Prescription Drug User Fee Act (PDUFA) VI, Biosimilar User Fee Act (BsUFA) II, and Generic Drug User Fee Amendments (GDUFA) II. The public meeting will include presentations from FDA on the 5-year plans for the PDUFA VI, BsUFA II, and GDUFA II; the Agency's progress in implementing resource capacity planning and modernized time reporting; and the results of the fiscal year (FY) 2018 evaluation of PDUFA, BsUFA, and GDUFA resource management. The Agency will also address the impact of the modernized fee structure changes on the PDUFA and BsUFA programs and report on the contribution of the BsUFA spending trigger to the BsUFA program.

DATES: The public meeting will be held on June 7, 2019, from 9 a.m. to 12 p.m. Submit either electronic or written comments on this public meeting by July 8, 2019. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held at FDA's White Oak Campus, 10903 New Hampshire Ave., Bldg. 31 Conference Center, the Great Room (Rm. 1503), Silver Spring, MD 20993. Entrance for the public meeting participants (non-FDA employees) is through Building 1 where routine security check procedures will be performed. For parking and security information, please refer to *https://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 July 8, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 8, 2019. 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–2019–N–1875 for ''Financial Transparency and Efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments; 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.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: Graham Thompson, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New

Hampshire Ave., Bldg. 51, Rm. 1146, Silver Spring, MD 20993–0002, 301–796–5003, Fax: 301–847–8443, *Graham.Thompson@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

This public meeting is intended to satisfy FDA's commitment to host an annual public meeting in the third quarter of each fiscal year beginning in FY 2019 (II.B.3 of PDUFA VI (p. 38), IV.B.3 of BsUFA II (p. 28), and VI.B.4 of GDUFA II (p.22)). These user fee programs were reauthorized as part of the Food and Drug Administration Reauthorization Act of 2017, signed by the President on August 18, 2017. The complete set of performance goals for each program are available at:

- *PDUFA VI program: https://www.fda.gov/downloads/ForIndustry/UserFees/PrescriptionDrugUserFee/UCM511438.pdf*
- *BsUFA II program: https://www.fda.gov/downloads/forindustry/userfees/biosimilaruserfeeactbsufa/ucm521121.pdf*
- *GDUFA II program: https://www.fda.gov/downloads/forindustry/userfees/genericdruguserfees/ucm525234.pdf*

Each of these user fee programs included a set of commitments related to financial management. These included commitments to publish a 5-year financial plan that should be updated annually, develop resource capacity planning capability and modernize time reporting practices, and have a third-party evaluation of resource management practices for these user fee programs. In addition, each user fee program includes a commitment to host a public meeting in the third quarter of each fiscal year, beginning in FY 2019, to discuss specific topics.

II. Topics for Discussion at the Public Meeting

This public meeting will provide FDA the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VI, BsUFA II, and GDUFA II. FDA will present the 5-year financial plans for each of these programs and discuss the vision for the resource capacity planning capability, as well as update participants on the progress towards implementing resource capacity planning and modernizing its time reporting approach. FDA will also address the impact of the fee structure changes on PDUFA VI and BsUFA II, as well as the contribution of the BsUFA spending trigger to the BsUFA program. Finally, the meeting will include a presentation from representatives of the MITRE Corporation or Grant Thornton on their evaluation of PDUFA, BsUFA, and GDUFA resource management during FY 2018 and FDA's response to this evaluation.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://fdafinancemeeting.eventbrite.com.* 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 webcast. Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Registration is free and based on space availability, with priority given to early registrants. Persons interested in attending this public meeting must register by June 3, 2019, at 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. Registrants will receive confirmation once they have been accepted. If time and space permit, onsite registration on the day of the public meeting will be provided beginning at 8 a.m. We will let registrants know if registration closes before the day of the public meeting.

If you need special accommodations due to a disability, please contact Graham Thompson no later than June 3, 2019, 11:59 p.m. Eastern Time.

Streaming Webcast of the Public Meeting: This public meeting will also be webcast. Please register for the webcast by visiting *https://fdafinancemeeting.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**).

Dated: May 7, 2019.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

[FR Doc. 2019–09803 Filed 5–10–19; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2017–E–6549]

Determination of Regulatory Review Period for Purposes of Patent Extension; GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS

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 the GORE VIABAHN VBX BALLOON EXPANDABLE ENDOPROSTHESIS and is publishing this notice of that determination as required by law. FDA has made the determination because of the submission of an application to the Director of the U.S. Patent and Trademark Office (USPTO), Department of Commerce, for the extension of a patent which claims that medical device.

DATES: Anyone with knowledge that any of the dates as published (see the **SUPPLEMENTARY INFORMATION** section) are incorrect may submit either electronic or written comments and ask for a redetermination by July 12, 2019. 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 November 12, 2019. 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 July 12, 2019. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 12, 2019. 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,