Procedure: Interested persons may present data, information, or views, orally or in writing, on issues pending before the committee. All electronic and written submissions submitted to the Docket (see **ADDRESSES**) on or before May 5, 2023, will be provided to the committee. Comments received after May 5, 2023, and by May 11, 2023, will be taken into consideration by FDA. Oral presentations from the public will be scheduled between approximately 12:30 p.m. and 1:30 p.m. Eastern Time on May 12, 2023. Those individuals interested in making formal oral presentations should notify the contact person and submit a brief statement of the general nature of the evidence or arguments they wish to present; the names, phone numbers, and email addresses of proposed participants; and an indication of the approximate time requested to make their presentation on or before 12 p.m. Eastern Time on April 26, 2023. Time allotted for each presentation may be limited. If the number of registrants requesting to speak is greater than can be reasonably accommodated during the scheduled open public hearing session, FDA may conduct a lottery to determine the speakers for the scheduled open public hearing session. The contact person will notify interested persons regarding their request to speak by 6 p.m. Eastern Time on April 28, 2023.

For press inquiries, please contact the Office of Media Affairs at *fdaoma@fda.hhs.gov* or 301–796–4540.

FDA welcomes the attendance of the public at its advisory committee meetings and will make every effort to accommodate persons with disabilities. If you require accommodations due to a disability, please contact Marie DeGregorio at *ctgtac@fda.hhs.gov* (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days in advance of the meeting.

FDA is committed to the orderly conduct of its advisory committee meetings. Please visit our website at *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm111462.htm* for procedures on public conduct during advisory committee meetings.

Notice of this meeting is given under the Federal Advisory Committee Act (5 U.S.C. app. 2).

Dated: April 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07518 Filed 4–10–23; 8:45 am]

BILLING CODE 4164–01–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 topic to be discussed is the financial transparency and efficiency of the Prescription Drug User Fee Act, Biosimilar User Fee Act, and Generic Drug User Fee Amendments.

DATES: The public meeting will be held on June 8, 2023, from 9:30 a.m. to 10:30 a.m. via ZoomGov. Either electronic or written comments on this public meeting must be submitted by July 8, 2023. See the **SUPPLEMENTARY INFORMATION** section for registration date and information.

ADDRESSES: The public meeting will be held virtually due to extenuating circumstances.

You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of July 8, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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, 240–402–7500.

- 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, 240–402–7500.

FOR FURTHER INFORMATION CONTACT: Monica Ellerbe, Office of Finance, Budget, Acquisitions, and Planning, Food and Drug Administration, Rm. 72044, Beltsville, MD 20705, 301–796–5276, *OFBAPBusinessManagementServices@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Background

The meeting will include presentations from FDA on: (1) the 5-year plan for the Prescription Drug User Fee Act (PDUFA) VII, Biosimilar User Fee Act (BsUFA) III, and Generic Drug User Fee Amendments (GDUFA) III; and (2) the Agency's progress in implementing resource capacity planning and modernized time reporting. This meeting is intended to satisfy FDA's commitment to host an annual public meeting in the third quarter of each fiscal year and can be found in the Commitment Letters listed below (sections II.B.2 of PDUFA VII (p. 58), III.B.2 of BsUFA III (p. 33), and VIII.D.3 of GDUFA III (p.40–41)).

PDUFA VII, BsUFA III, and GDUFA III were reauthorized as part of the FDA User Fee Reauthorization Act of 2022, which was signed by the President on September 30, 2022. The complete set of performance goals for each program are available at:

- *PDUFA VII: https://www.fda.gov/media/151712/download*
- *BsUFA III: https://www.fda.gov/media/152279/download*
- *GDUFA III: https://www.fda.gov/media/153631/download*

Each of these user fee programs' Commitment Letters included a set of commitments related to financial management. These included commitments to publish a 5-year financial plan and update that plan annually, continue activities to mature FDA's resource capacity planning capability, and modernize time reporting practices. In addition, each user fee program includes a commitment to host a public meeting in the third quarter of each fiscal year to discuss specific topics.

II. Topics for Discussion at the Public Meeting

This meeting will provide FDA with the opportunity to update interested public stakeholders on topics related to the financial management of PDUFA VII, BsUFA III, and GDUFA III. These topics include the 5-year financial plans for each of these programs and FDA's progress toward implementing resource capacity planning and modernizing its time reporting approach.

III. Participating in the Public Meeting

Registration: To register for the public meeting, please visit the following website: *https://fda.zoomgov.com/webinar/register/WN_K0tpd9eXTvCyfQ_1iJrgXg.* Please provide complete contact information for each attendee, including name, title, affiliation, address, email, and telephone.

Persons interested in attending this public meeting must register by June 5, 2023, at 11:59 p.m. Eastern Time. If registration closes before the day of the public meeting, the Webinar Registration website will be updated.

If you need special accommodations due to a disability, please indicate this during registration or contact Monica Ellerbe at *OFBAPBusinessManagementServices@fda.hhs.gov* no later than June 5, 2023.

Streaming Webcast of the Public Meeting: This public meeting will be webcast. To register for the public meeting and obtain the webcast information, please visit the following website: *https://fda.zoomgov.com/webinar/register/WN_K0tpd9eXTvCyfQ_1iJrgXg.*

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 also be viewed at the Dockets Management Staff (see **ADDRESSES**).

Dated: April 5, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–07506 Filed 4–10–23; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–0378]

Vaccines and Related Biological Products Advisory Committee; Notice of Meeting; Establishment of a Public Docket; Request for Comments

AGENCY: Food and Drug Administration, HHS.

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

SUMMARY: The Food and Drug Administration (FDA) announces a forthcoming public advisory committee meeting of the Vaccines and Related Biological Products Advisory Committee (VRBPAC). The general function of the committee is to provide advice and recommendations to FDA on regulatory issues. The committee will discuss the biologics license application (BLA) 125768 from Pfizer, Inc. for ABRYSVO (Respiratory Syncytial Virus Vaccine) with the requested indication for the prevention of lower respiratory tract disease and severe lower respiratory tract disease caused by respiratory syncytial virus (RSV) in infants from birth through 6 months of age by active immunization of pregnant individuals. The meeting will be open to the public. FDA is establishing a docket for public comment on this document.

DATES: The meeting will be held virtually on May 18, 2023, from 8:30 a.m. to 5:30 p.m. Eastern Time.

ADDRESSES: Please note that due to the impact of COVID–19, all meeting participants will be joining this advisory committee meeting via an online teleconferencing platform. Answers to commonly asked questions about FDA advisory committee meetings, including information regarding special accommodations due to a disability, may be accessed at: *https://www.fda.gov/AdvisoryCommittees/AboutAdvisoryCommittees/ucm408555.htm.* The online web conference meeting will be available at the following link at: *https://youtube.com/live/NXVMILYvocM?feature=share.*

FDA is establishing a docket for public comment on this meeting. The docket number is FDA–2023–N–0378. Please note that late, untimely filed comments will not be considered. The docket will close on May 17, 2023. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end