| Application No. | Drug name | Active ingredient(s) | Strength(s) | Dosage form/route | Applicant |
|---|---|---|---|---|---|
| NDA 019941 | EMLA | Lidocaine; Prilocaine | 2.5%; 2.5% | Cream; Topical | Teva Branded Pharmaceutical Products R & D Inc. |
| NDA 020105 | TRIOSTAT | Liothyronine Sodium | EQ 0.01 mg Base/mL | Injectable; Injection | Par Sterile Products, LLC. |
| NDA 020125 | ACCURETIC | Hydrochlorothiazide; Quinapril Hydrochloride. | 12.5 mg, EQ 10 mg Base; 12.5 mg, EQ 20 mg Base; 25 mg, EQ 20 mg Base. | Tablet; Oral | Pfizer Pharmaceuticals Ltd. |
| NDA 020406 | PREVACID | Lansoprazole | 15 mg | Capsule, Delayed Release Pellets; Oral. | Takeda Pharmaceuticals USA, Inc. |
| NDA 020666 | ALBENZA | Albendazole | 200 mg | Tablet; Oral | Impax Laboratories Inc. |
| NDA 020723 | ALDARA | Imiquimod | 5% | Cream; Topical | Bausch Health US LLC. |
| NDA 020972 | SUSTIVA | Efavirenz | 50 mg; 200 mg | Capsule; Oral | Bristol Myers Squibb Co. |
| NDA 021009 | ALOCRIL | Nedocromil Sodium | 2% | Solution/Drops; Ophthalmic. | Allergan Inc. |
| NDA 021526 | RANEXA | Ranolazine | 500 mg; 1 g | Tablet, Extended Release; Oral. | Menarini International Operations Luxembourg SA. |
| NDA 021565 | ELESTAT | Epinastine Hydrochloride | 0.05% | Solution/Drops; Ophthalmic. | Allergan Inc. |
| NDA 021775 | ENTEREG | Alvimopan | 12 mg | Capsule; Oral | Cubist Pharmaceuticals, Inc. |
| NDA 021790 | DACOGEN | Decitabine | 50 mg/Vial | Injectable; Intravenous | Otsuka Pharmaceutical Co., Ltd. |
| NDA 050095 | CAPASTAT SULFATE | Capreomycin Sulfate | EQ 1 g Base/Vial | Injectable; Injection | Epic Pharma, LLC. |
| NDA 050795 | DORYX | Doxycycline Hyclate | EQ 50 mg Base; EQ 100 mg Base; EQ 120 mg Base. | Tablet, Delayed Release; Oral. | Mayne Pharma International Pty Ltd. |
| NDA 050801 | EVOCLIN | Clindamycin Phosphate | 1% | Aerosol, Foam; Topical | Mylan Pharmaceuticals Inc. |
| NDA 200179 | STAXYN | Vardenafil Hydrochloride | 10 mg | Tablet, Orally Disintegrating; Oral. | Bayer Healthcare Pharmaceuticals Inc. |
| NDA 202515 | MORPHINE SULFATE | Morphine Sulfate | 15 mg/mL | Injectable; Injection | Hospira, A Pfizer Company. |
| NDA 203667 | MINASTRIN 24 FE | Ethinyl Estradiol; Norethindrone Acetate. | 0.02mg, 1mg | Tablet; Oral | Allergan Pharmaceuticals International, Ltd. |
| NDA 210854 | XOFLUZA | Baloxavir Marboxil | 20 mg | Tablet; Oral | Genentech, Inc. |

FDA has reviewed its records and, under § 314.161, has determined that the drug products listed were not withdrawn from sale for reasons of safety or effectiveness. Accordingly, the Agency will continue to list the drug products in the ''Discontinued Drug Product List'' section of the Orange Book. The ''Discontinued Drug Product List'' identifies, among other items, drug products that have been discontinued from marketing for reasons other than safety or effectiveness.

Approved ANDAs that refer to the drug products listed are unaffected by the discontinued marketing of the products subject to these applications. Additional ANDAs that refer to these products may also be approved by the Agency if they comply with relevant legal and regulatory requirements. If FDA determines that labeling for these drug products should be revised to meet current standards, the Agency will advise ANDA applicants to submit such labeling.

Dated: April 4, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–07494 Filed 4–8–24; 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 or the Agency) 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 6, 2024, from 9:30 a.m. to 10:40 a.m. via ZoomGov. Either electronic or written comments on this public meeting must be submitted by July 6, 2024. 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 6, 2024. 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:** Kichelle Joseph, Office of Finance, Budget, Acquisitions, and Planning, Food and Drug Administration, 4041 Powder Mill Rd., Rm. 72064, Beltsville, MD 20705, 301–796–7251, *OFBAPBusinessManagementServices@fda.hhs.gov.*

**SUPPLEMENTARY INFORMATION:**

## I. Background

The meeting will include presentations from FDA on 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 the Agency's progress in implementing resource capacity planning as part of fee setting 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 represent the reauthorization of these user fee programs for FYs 2023–2027 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 as part of fee setting and modernized time reporting.

## 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_RyzDcgPYQ8uJT9TWfgyPOw.* Please provide complete contact information for each attendee, including name, title, affiliation, and email.

Persons interested in attending this public meeting must register by June 3, 2024, 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 Kichelle Joseph at *OFBAPBusinessManagementServices@fda.hhs.gov* no later than June 3, 2024.

*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_RyzDcgPYQ8uJT9TWfgyPOw.*

*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 4, 2024.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2024–07493 Filed 4–8–24; 8:45 am]

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