

collections of information are subject to review by the Office of Management and Budget under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 314 have been approved under OMB control number 0910–0001. The collections of information in 21 CFR parts 210 and 211 pertaining to current good manufacturing practice has been approved under OMB control number 0910–0139. The collections of information in 21 CFR part 11 for electronic records and electronic signatures have been approved under OMB control number 0910–0303. The collections of information pertaining to the submissions of GDUFA III commitment letter, meetings related to generic drug development, and the Generic Drug User Fee Program have been approved under OMB control number 0910–0727.

### III. Electronic Access

Persons with access to the internet may obtain the draft guidance at <https://www.fda.gov/drugs/guidance-compliance-regulatory-information/guidances-drugs>, <https://www.fda.gov/regulatory-information/search-fda-guidance-documents>, or <https://www.regulations.gov>.

Dated: August 30, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA–2023–N–3575]

#### Reauthorization of the Over-the-Counter Monograph Drug User Fee Program; 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, Agency, or we) is announcing a public meeting to discuss proposed recommendations for the reauthorization of the Over-the-Counter (OTC) Monograph Drug User Fee Program (OMUFA) for fiscal years (FYs) 2026 through 2030. OMUFA authorizes FDA to assess and collect user fees to support OTC monograph drug activities. The current legislative authority for OMUFA expires September 30, 2025. At that time, new legislation will be

required to reauthorize the OMUFA program for future fiscal years. The Federal Food, Drug, and Cosmetic Act (FD&C Act) directs that FDA consult with the public as part of the OMUFA reauthorization process. FDA invites public comment as the Agency begins the process to reauthorize the program for FYs 2026 through 2030.

**DATES:** The public meeting will be held on September 28, 2023, from 9 a.m. to 5 p.m. Registration to attend the meeting should be received by September 27, 2023. Either electronic or written comments on this public meeting must be submitted by October 27, 2023. 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, 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/about-fda/visitor-information>. Any changes to the public meeting location and remote information, as appropriate, will be posted to <https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa> in advance of the meeting.

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 October 27, 2023. 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–2023–N–3575 for “Reauthorization of the Over-the-Counter Monograph Drug User Fee Program; 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. Transcripts of the meeting will be available on the FDA website at: <https://www.fda.gov/industry/fda-user-fee-programs/over-counter-monograph-drug-user-fee-program-omufa> after the meeting.

**FOR FURTHER INFORMATION CONTACT:**

Grace Carmouze-Cunningham, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6170, Silver Spring, MD 20993-0002, 301-796-4223, [Grace.Carmouze@fda.hhs.gov](mailto:Grace.Carmouze@fda.hhs.gov).

**I. Background**

FDA is announcing a public meeting to begin the process for developing reauthorization recommendations for the OMUFA program under section 744M of the FD&C Act (21 U.S.C. 379j-72). This legislation authorizes FDA to assess and collect OMUFA user fees to support OTC monograph drug activities, including in various components in FDA including the Center for Drug Evaluation and Research, the Office of the Commissioner, and the Office of Regulatory Affairs. The current authorization of the program (OMUFA I) expires in September 2025. New legislation is required to reauthorize the OMUFA program for future fiscal years, to help fund OTC monograph drug activities. Section 744N(d) of the FD&C Act requires that FDA consult with the public on the development of proposed reauthorization recommendations. This notice, the public meeting, the 30-day comment period after the meeting, and the posting of the comments on the FDA website will help satisfy these requirements. The purpose of the meeting is to hear stakeholder views on OMUFA as we develop recommendations for elements to

propose, update, or possibly discontinue in the program. FDA is interested in responses to the following questions and welcomes any other pertinent information stakeholders would like to share:

- What current elements of OMUFA should be modified to ensure the continued efficiency and effectiveness of FDA’s OTC monograph drug activities?
- What new elements should FDA consider recommending be added to the program to enhance the efficiency and effectiveness of the Agency’s OTC monograph drug activities?

**II. What is OMUFA? What does it do?**

The following information is provided to help potential meeting participants better understand the history of OMUFA and its status. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act (CARES Act) available at <https://www.congress.gov/116/bills/hr748/BILLS-116hr748enr.pdf> was signed into law. Division A of the CARES Act included an important legislative initiative, detailed in subtitle F of title III, that reformed and modernized the way certain nonprescription, OTC drugs are regulated in the United States. These drugs, known as OTC monograph drugs, may be marketed without an approved drug application under section 505 of the FD&C Act (21 U.S.C. 355) if they meet the requirements of section 505G of the FD&C Act, as well as other applicable requirements. Accompanying this OTC monograph reform legislation were provisions added by the CARES Act to the FD&C Act authorizing FDA to assess and collect user fees dedicated to OTC monograph drug activities.

This user fee program with respect to OTC monograph drugs, which we refer to as OMUFA, is modeled after the successful Prescription Drug User Fee Act (PDUFA). For OMUFA purposes, industry-paid fees help support FDA’s OTC monograph drug activities, and in the OMUFA I commitment letter negotiated with industry, FDA agreed to adhere to certain performance goals, including to review certain submissions within specific time frames. As with PDUFA, FDA anticipates that continuing this user fee program will provide additional resources to help the Agency conduct these important regulatory activities in a timely manner and ultimately help provide the public with access to innovative OTC monograph drugs.

OMUFA is authorized under sections 744L and 744M of the FD&C Act, as added by the CARES Act, under which FDA will assess and collect fees from

submitters of OTC Monograph Order Requests (OMORs), other than OMORs for certain safety changes, as well as from qualifying manufacturers of OTC monograph drugs, to help fund the Agency’s OTC monograph drug activities.

OMUFA is intended to provide for additional funding so that FDA can hire staff, improve systems, and establish and better manage the Agency’s OTC monograph drug activities, including to make important safety-related monograph changes and to facilitate timely availability of safe, effective, high-quality, and innovative OTC monograph drugs to the public. As part of FDA’s negotiated agreement with industry during each reauthorization, as reflected in the accompanying OMUFA commitment letter, the Agency agrees to certain performance and procedural goals and other commitments that apply to aspects of the Agency’s OTC monograph drug activities. These goals apply, for example, to the review of OMORs, including safety-related OMORs.

A list of the deliverables developed to meet OMUFA I commitments is available on the FDA web page at: <https://www.fda.gov/media/146283/download>.

**III. Public Meeting Information**

*A. Purpose and Scope of the Meeting*

In general, the meeting format will include presentations by FDA and a series of panels representing different stakeholder groups. FDA policy issues unrelated to the OMUFA user fee program are beyond the scope of these reauthorization recommendation discussions. Accordingly, the presentations should focus on elements of the OMUFA user fee program, including possible process enhancements, and not address other FDA matters. Please consider the following questions for this meeting:

- What new elements should FDA consider recommending be added to the program to enhance the efficiency and effectiveness of the Agency’s OTC monograph drug activities?
- What current elements of OMUFA should be modified to ensure the continued efficiency and effectiveness of the Agency’s OTC monograph drug activities?

*B. Participating in the Public Meeting*

*Registration:* Persons interested in attending this public meeting should register online by 11:59 p.m. Eastern Time on September 27, 2023, at [https://OMUFA\\_Reauthorization.eventbrite.com](https://OMUFA_Reauthorization.eventbrite.com). 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. Early registration is recommended because seating is 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 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 Grace Carmouze-Cunningham (see **FOR FURTHER INFORMATION CONTACT**) at least 7 days before the meeting.

**Streaming Webcast of the Public Meeting:** This public meeting will also be webcast. You will be asked to indicate in your registration if you plan to attend in person or via the webcast.

**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 on the internet at <https://www.fda.gov/industry/fda-user-fee-programs/prescription-drug-user-fee-amendments>.

Dated: August 29, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

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**DEPARTMENT OF HEALTH AND HUMAN SERVICES**

**Food and Drug Administration**

[Docket No. FDA–2023–N–3549]

**Merck Sharp & Dohme LLC, et al.;  
Withdrawal of Approval of 35 New  
Drug Applications**

**AGENCY:** Food and Drug Administration, HHS.

**ACTION:** Notice.

**SUMMARY:** The Food and Drug Administration (FDA or Agency) is withdrawing approval of 35 new drug

applications (NDAs) from multiple applicants. The applicants notified the Agency in writing that the drug products were no longer marketed and requested that the approval of the applications be withdrawn.

**DATES:** Approval is withdrawn as of October 5, 2023.

**FOR FURTHER INFORMATION CONTACT:** Kimberly Lehrfeld, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Ave., Bldg. 51, Rm. 6226, Silver Spring, MD 20993–0002, 301–796–3137, [Kimberly.Lehrfeld@fda.hhs.gov](mailto:Kimberly.Lehrfeld@fda.hhs.gov).

**SUPPLEMENTARY INFORMATION:** The applicants listed in the table have informed FDA that these drug products are no longer marketed and have requested that FDA withdraw approval of the applications under the process in § 314.150(c) (21 CFR 314.150(c)). The applicants have also, by their requests, waived their opportunity for a hearing. Withdrawal of approval of an application or abbreviated application under § 314.150(c) is without prejudice to refiling.

| Application No.  | Drug   | Applicant  |
|------------------|--|--|
| NDA 001546 ..... | Guanidine (guanidine hydrochloride (HCl)) Tablets, 125 milligrams (mg).  | Merck Sharp & Dohme LLC, 126 East Lincoln Ave., P.O. Box 2000, Rahway, NJ 07065.                   |
| NDA 010841 ..... | Peganone (ethotoin) Tablets, 250 mg and 500 mg .....   | Recordati Rare Diseases Inc., 100 Corporate Dr., Lebanon, NJ 08833.                                |
| NDA 016801 ..... | Xylocaine Preservative Free (lidocaine HCl) Injection, 1%, 2%, 4%, 10%, and 20%.   | Fresenius Kabi USA, LLC, 3 Corporate Dr., Lake Zurich, IL 60047.                                   |
| NDA 016822 ..... | FreAmine 8.5% (amino acids) Injection, 8.5 grams (g)/100 milliliters (mL).<br>FreAmine HBC 6.9% (amino acids) Injection, 6.9 g/100 mL.<br>FreAmine II 8.5% (amino acids) Injection, 8.5 g/100 mL.<br>FreAmine III 10% (amino acids) Injection, 10 g/100 mL.<br>FreAmine III 8.5% (amino acids) Injection, 8.5 g/100 mL.<br>FreAmine III 8.5% with electrolytes (amino acids, magnesium acetate, phosphoric acid, potassium acetate, potassium chloride, sodium acetate) Injection, 8.5%; 110mg/100mL; 230mg/100mL; 10mg/100mL; 440mg/100mL; 690mg/100mL.<br>FreAmine III 3% with electrolytes (amino acids, magnesium acetate, phosphoric acid, potassium chloride, sodium acetate, sodium chloride) Injection, 3%; 54mg/100mL; 40mg/100mL; 150mg/100mL; 200mg/100mL; 120mg/100mL. | B. Braun Medical Inc., 901 Marcon Blvd., Allentown, PA 18109.                                      |
| NDA 017407 ..... | Catapres (clonidine HCl) Tablets, 0.1 mg, 0.2 mg, and 0.3 mg.  | Boehringer Ingelheim Pharmaceuticals, Inc., 900 Ridgebury Rd., P.O. Box 368, Ridgefield, CT 06877. |
| NDA 017425 ..... | Proglycem (diazoxide) Capsules, 50 mg and 100 mg .....   | Teva Branded Pharmaceutical Products R&D, Inc., 145 Brandywine Pkwy., West Chester, PA 19380.      |
| NDA 017534 ..... | Fiorinal (aspirin, butalbital, caffeine) Capsules, 325 mg/50 mg/40 mg.<br>Fiorinal (aspirin, butalbital, caffeine) Tablets, 325 mg/50 mg/40 mg.  | AbbVie Inc., 1 North Waukegan Rd., North Chicago, IL 60064.  |
| NDA 018582 ..... | Procalamine (amino acids, calcium acetate, glycerin, magnesium acetate, phosphoric acid, potassium chloride, sodium acetate, sodium chloride) Injection, 3%; 26mg/100mL; 3g/100mL; 54mg/100mL; 41mg/100mL; 150mg/100mL; 200mg/100mL; 120mg/100mL.  | B. Braun Medical Inc.  |
| NDA 018676 ..... | HepatAmine 8% (amino acids) Injection, 8g/100mL .....  | Do.  |
| NDA 018878 ..... | Indocin (indomethacin sodium) Injection, equivalent to (EQ) 1 mg base/vial.  | Recordati Rare Diseases Inc.   |