4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0655]

Animal Generic Drug User Fee Act; 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 virtual public meeting entitled “Animal Generic Drug User Fee Act." The purpose of the public meeting is to invite public comment on the Animal Generic Drug User Fee Act (AGDUFA) program and suggestions regarding the features FDA should consider for the next reauthorization of the AGDUFA program. The meeting will be open to the public.

DATES: The public meeting will be held virtually on May 27, 2026, from 11 a.m. to 1 p.m. Eastern Time. See the **SUPPLEMENTARY INFORMATION** section for registration dates and information. To permit the widest possible opportunity to obtain comments on all aspects of the public meeting, the docket will remain open for comment throughout the reauthorization process of AGDUFA, until December 1, 2027. In addition to being publicly viewable at http://www.regulations.gov, comments received by July 1, 2026, suggesting changes to the program, will also be published on https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings.

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 December 1, 2027. The https://www.regulations.gov electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 1, 2027. 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. 2011-N-0655 for "Animal Generic Drug User Fee Act." Received comments, those filed in a timely manner, 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. A transcript of the public meeting will be made available in the docket, as well as on the FDA website at: https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings.

FOR FURTHER INFORMATION CONTACT: Madeline Faunce, on detail to Office of Operations, Office of Finance, Budget, and Acquisitions, Food and Drug Administration, 301-796-3464, AGDUFAReauth@fda.hhs.gov.

SUPPLEMENTARY INFORMATION:

I. Introduction

The authority for AGDUFA expires September 30, 2028. Without new legislation, FDA will no longer have the authority to collect user fees to help fund the new animal generic drug review process for future fiscal years. Prior to beginning negotiations with the regulated industry on AGDUFA reauthorization, section 742(d)(2) of the Federal Food, Drug, and Cosmetic Act (the FD&C Act) (21 U.S.C. 379j-22(d)(2)) requires FDA to: (1) Publish a notice in the Federal Register requesting public input on the reauthorization; (2) hold a public meeting at which the public may present its views on the reauthorization, including specific suggestions for changes to the goals referred in section 742(a) of FD&C Act; (3) provide a period of 30 days after the public meeting to obtain written comments from the public suggesting changes; and (4) publish the comments on FDA's website. This notice, the public meeting, the comment period after the meeting, and the posting of the comments on the FDA website will satisfy these requirements. FDA is holding a public meeting to gather information on what FDA should consider including in the reauthorization of AGDUFA. FDA is interested in responses from the public on the following two general questions and welcomes other pertinent information that stakeholders would like to share:

1. What is your assessment of the overall performance of the AGDUFA program thus far?

2. What aspects of AGDUFA should be retained, changed, or discontinued to further strengthen and improve the program?

II. Background

FDA considers the timely review of generic new animal drug submissions to be central to the Agency's mission to protect and promote human and animal health. The AGDUFA program

began in FY 2009 and is currently in the fourth authorization (AGDUFA IV). FDA has published a number of reports that provide useful background on AGDUFA I, AGDUFA II, AGDUFA III, and AGDUFA IV. AGDUFA-related *Federal Register* notices, guidances, legislation, performance reports, and financial reports can be found at: https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa.

III. Participating in the Public Meeting.

Registration: Persons interested in attending this public meeting must register no later than midnight Eastern time on May 22, 2026, by emailing complete contact information for each attendee, including name, title, affiliation, address, email, telephone number, and if you need reasonable accommodations due to a disability (e.g., Closed Captioning) to AGDUFAReauth@fda.hhs.gov. Registration is free and early registration is recommended. Registrants will receive confirmation when their registration has been received and will be provided the webcast link.

Requests for Oral Presentations: During online registration you may indicate if you wish to make an oral presentation during the public meeting. To facilitate agenda development, registrants requesting to present will be asked to provide information regarding which topics they intend to address and the title of their presentation. We will do our best to accommodate requests to make an oral presentation. Individuals and organizations with common interests are urged to consolidate or coordinate their presentations, and request time for a joint presentation, or submit requests for designated representatives to participate. All requests to make oral presentations must be received by May 1, 2026.

We will determine the amount of time allotted to each presenter and the approximate time each oral presentation is to begin, and we will notify participants by May 8, 2026. Presenters planning to use an electronic slide deck must email an electronic copy of their presentation to Madeline Faunce at AGDUFAReauth@fda.hhs.gov (see **FOR FURTHER INFORMATION CONTACT**) with the subject line "AGDUFA Public Meeting Presentation" on or before May

15, 2026. If presenters choose not to use a slide deck, they are requested to email a single slide with their name, affiliation, title of their presentation, and contact information. No commercial or promotional material will be permitted to be presented at the public meeting.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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