



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; Extension of Comment Period

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of public meeting; request for comments; extension of comment period.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is extending the comment period for the notice announcing a public meeting and requesting comments that appeared in the *Federal Register* of September 30, 2022. In that notice, FDA announced a public meeting to discuss the proposed recommendations for the reauthorization of the Animal Generic Drug User Fee Act (AGDUFA IV) for fiscal years 2024 through 2028 and that the comment period would be open until November 9, 2022. FDA is taking this action due to a delay in the posting of the AGDUFA IV Performance Goals and Procedures Letter. This extension will provide the public 30 days to comment as required.

DATES: FDA is extending the comment period announced in the notice of public meeting and request for comments published September 30, 2022 (87 FR 59441). Either electronic or written comments on the notice must be submitted by November 14, 2022, to ensure that the Agency considers your comments regarding this public meeting and request for comments.

ADDRESSES: 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 November 14, 2022. 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-2011-N-0655 for "Animal Generic Drug User Fee Act." 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: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 7500 Standish Pl., Rockville, MD 20855, 240-402-6888, Lisa.Kable@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: In the *Federal Register* of September 30, 2022, FDA published a notice announcing a public meeting and requesting comments on the proposed recommendations for the reauthorization of the AGDUFA IV for fiscal years 2024 through 2028.

Interested persons were originally given until November 9, 2022, to comment on the public meeting and request for comments. Due to a delay in the posting of the AGDUFA IV Performance Goals and Procedures Letter to our website at <https://www.fda.gov/industry/animal-generic-drug-user-fee-act-agdufa/agdufa-meetings>, we are extending the comment period until November 14, 2022, to allow for a 30-day comment period.

Dated: October 14, 2022.

Lauren K. Roth,

Associate Commissioner for Policy.

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