ANNUAL BURDEN ESTIMATES

Instrument	Total number of respondents	Total number of responses per respondent	Average burden hours per response	Total burden hours	Annual burden hours
Sampling Decisions, Assurances, and Fieldwork Preparation Plan	52	1	106	5,512	1,837
Record Review Worksheet	52	276	6.33	90,848	30,283
State Improper Payments Report	52	1	639	33,228	11,076
Corrective Action Plan	5	2 [a]	156	1,560	520
Estimated Total Annual Burden Hours					43,716

[a] The total number of responses per respondent ranges from one to three, depending on how long it takes respondents to reduce the Improper Payment Rate to below the threshold. Respondents submit a *Corrective Action Plan* that covers a 1-year period; at the end of each year, if respondents have not reduced the Improper Payment Rate to below the threshold, they submit a new *Corrective Action Plan* for the following year. An average of two responses per respondent is used to calculate annual burden estimates.

Comments: The Department specifically requests comments on (a) whether the proposed collection of information is necessary for the proper performance of the functions of the agency, including whether the information shall have practical utility; (b) the accuracy of the agency's estimate of the burden of the proposed collection of information; (c) the quality, utility, and clarity of the information to be collected; and (d) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques or other forms of information technology. Consideration will be given to comments and suggestions submitted within 60 days of this publication.

Authority: 45 CFR part 98, subpart K.

Mary B. Jones,

ACF/OPRE Certifying Officer.

[FR Doc. 2021–07425 Filed 4–9–21; 8:45 am]

BILLING CODE 4184–43–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 hosted via a live virtual webcast on Thursday, May 20, 2021, 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, 2022. In addition to being publicly viewable at *http://www.regulations.gov,* comments received by June 21, 2021, 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, 2022. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of December 1, 2022. 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 comments will be made public, you are solely responsible for ensuring that your comments do 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, 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: Lisa Kable, Center for Veterinary Medicine, Food and Drug Administration, 240–402–6888, *lisa.kable@fda.hhs.gov.*

SUPPLEMENTARY INFORMATION:

I. Introduction

The authority for AGDUFA expires September 30, 2023. Without new legislation, FDA will no longer have the authority to collect user fees to 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. 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 third authorization (AGDUFA III). FDA has published a number of reports that provide useful background on AGDUFA I, AGDUFA II, and AGDUFA III. 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 18, 2021, 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 *cvmagdufa@fda.hhs.gov.* 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 contacted 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 7, 2021.

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 11, 2021. Selected presenters planning to use an electronic slide deck must submit an electronic copy of their presentation to Lisa Kable (see **FOR FURTHER INFORMATION CONTACT**) with the subject line ''AGDUFA Public Meeting Presentation'' on or before May 17, 2021. If presenters choose not to use a slide deck, they are requested to submit 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.

Dated: April 5, 2021.

Lauren K. Roth,

Acting Principal Associate Commissioner for Policy.

[FR Doc. 2021–07375 Filed 4–9–21; 8:45 am]

BILLING CODE 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; Stakeholder Consultation Meetings on the Animal Generic Drug User Fee Act Reauthorization; Request for Notification of Stakeholder Intention To Participate

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice: Request for notification of participation.

SUMMARY: The Food and Drug Administration (FDA, the Agency, or we) is issuing this notice to request that public stakeholders notify FDA of their intent to participate in periodic consultation meetings on reauthorization of the Animal Generic Drug User Fee Act (AGDUFA). The statutory authority for AGDUFA expires September 30, 2023. The Federal Food,