4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2020-N-0145]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Associated with Animal Drug and Animal Generic Drug User Fees

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection provisions of FDA's animal drug and animal generic drug user fee programs.

DATES: Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2020-N-0145 for "Reporting Associated With Animal Drug and Animal Generic Drug User Fees." 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: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, PRAStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Animal Drug and Animal Generic Drug User Fee Programs

OMB Control Number 0910-0540--Extension

This information collection helps support implementation of the Animal Drug User Fee Act of 2003 (ADUFA) (Pub. L. 108-130) and Animal Generic Drug User Fee Act of 2008 (AGDUFA) (Pub. L. 110-316), established in sections 740 and 741 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C 379j-12 and 21 U.S.C. 379j-21), respectively. Under ADUFA, FDA assesses and collects user fees for certain new animal drug applications and supplements, products, establishments, and sponsors of new animal drug applications and/or

investigational new animal drug file submissions. The ADUFA program is currently reauthorized through September 30, 2023, and FDA efforts to engage interested stakeholders in the 2023 reauthorization is ongoing. More information regarding the ADUFA program can be found at https://www.fda.gov/industry/fda-user-fee-programs/animal-drug-user-fee-act-adufa, including current user fee rates applicable to animal drug submissions. Under AGDUFA, FDA assesses and collects user fees for certain abbreviated (generic) new animal drug applications and supplements, products, and sponsors of generic new animal drug applications and/or generic investigational new animal drug file submissions. The AGDUFA program is currently reauthorized through September 30, 2023, and FDA efforts to engage interested stakeholders in the 2023 reauthorization is ongoing. More information regarding the AGDUFA program can be found at https://www.fda.gov/industry/fda-user-fee-programs/animal-generic-drug-user-fee-act-agdufa, including current user fee rates applicable to generic animal drug submissions.

These user fee program resources support FDA's responsibilities to ensure that new animal drugs are safe and effective for animals, as well as ensuring the safety of food from treated animals.

Sponsors of new animal drug applications complete a user fee cover sheet and submit it through CVM's eSubmitter. The Animal Drug User Fee cover sheet (Form FDA 3546) is designed to collect the minimum necessary information to determine whether a fee is required for the review of an application or supplement or whether an application fee waiver was granted, to determine the amount of the fee required, and to ensure that each animal drug user fee payment is appropriately linked to the animal drug application for which payment is made. The form, when completed electronically, results in the generation of a unique payment identification number used by FDA to track the payment. The information collected is used by FDA's Center for Veterinary Medicine (CVM, the Center) to initiate the administrative screening of new animal drug applications and supplements.

Similarly, sponsors of abbreviated new animal drug applications also complete a user fee cover sheet and submit it through CVM's eSubmitter. The AGDUFA cover sheet (Form FDA 3728) is also designed to collect the minimum necessary information to determine whether a fee is required for review of an application, to determine the amount of the fee required, and to ensure that each animal generic drug user fee payment is appropriately linked to the abbreviated new animal drug application for which payment is made. The form, when completed electronically, results in the generation of a unique payment identification number used by FDA to track the payment. The information collected is used by CVM to initiate the administrative screening of abbreviated new animal drug applications.

Both sections 740 and 741 of the FD&C Act provide for waivers, reductions, and exemptions of fees. To assist respondents with submitting requests for waivers or reductions of ADUFA user fees, we developed guidance for industry (GFI) #170 entitled "Animal Drug User Fees and Fee Waivers and Reductions" (April 2023), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-170-animal-drug-user-fees-and-fee-waivers-and-reductions. This document discusses the types of fees FDA is authorized to collect under section 740 of the FD&C Act, and how to request waivers or reductions from these fees. Further, this guidance also describes what information FDA recommends be submitted in support of a request for a fee waiver or reduction, a request for reconsideration of denial of a fee waiver or reduction request, or an appeal of the denial decision in accordance with 21 CFR 10.75; how to submit such a request or appeal; and FDA's process for reviewing such requests or appeals.

Similarly, we developed guidance for industry (GFI) #199 entitled "Animal Generic Drug User Fees and Fee Waivers and Reductions" (May 2009), available at https://www.fda.gov/regulatory-information/search-fda-guidance-documents/cvm-gfi-199-animal-generic-drug-user-fees-and-fee-waivers-and-reductions. This document discusses the types of fees FDA is authorized to collect under section 741(a)(1) of the FD&C Act, and how to

request waivers or reductions from these fees. Further, this guidance also describes what information FDA recommends be submitted in support of a request for a fee waiver or reduction, a request for reconsideration of denial of a fee waiver or reduction request, or an appeal of the denial decision in accordance with 21 CFR 10.75; how to submit such a request or appeal; and FDA's process for reviewing such requests or appeals.

We use the information submitted by respondents to determine whether requests for waiver or reduction of user fees, reconsideration requests, or appeals may be granted.

We estimate the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1]

FD&C Act Section; Activity	FDA Form No.	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
User fee cover sheets, by type						
740(a)(1); Animal Drug User Fee cover sheet	FDA 3546	15	1	15	1	15
741(a)(1); Animal Generic Drug User Fee cover sheet	FDA 3728	22	2	44	.08 (5 minutes)	3.5
Waiver and other requests, by type						
740(d)(1)(A); significant barrier to innovation	N/A	65	1	65	2	130
740(d)(1)(B); fees exceed cost	N/A	8	3.75	30	0.5 (30 minutes)	15
740(d)(1)(C); free choice feeds	N/A	4	1	4	2	8
740(d)(1)(D); minor use or minor species	N/A	73	1	73	2	146
740(d)(1)(E); small business	N/A	1	1	1	2	2
741(d)(1); minor use or minor species	N/A	2	1	2	2	4
Request for reconsideration of a decision	N/A	1	1	1	2	2
21 CFR 10.75; Appeal of a decision	N/A	1	1	1	2	2
Total						327.5

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.

Our estimated burden for the information collection reflects an overall increase. We attribute this adjustment to an increase in the number of submissions we have received since our last evaluation. The total number of annual responses is based on the average number of submissions received by FDA in fiscal years 2019 to 2021. The estimated time we attribute to the

hours per response is based on our experience with the various submissions and reflects the average burden we attribute to all respondents.

Dated: April 24, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023-08946 Filed: 4/26/2023 8:45 am; Publication Date: 4/27/2023]