DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2020–N–0145]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug and Animal Generic Drug User Fee Submissions

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 11, 2023.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to *https://www.reginfo.gov/public/do/PRAMain.* Find this particular information collection by selecting ''Currently under Review—Open for Public Comments'' or by using the search function. The OMB control number for this information collection is 0910–0540. Also include the FDA docket number found in brackets in the heading of this document.

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: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Animal Drug and Animal Generic Drug User Fee Submissions

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 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 the Center for Veterinary Medicine (CVM) 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 CVM 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.

In the **Federal Register** of April 27, 2023 (88 FR 25658), we published a 60-day notice soliciting public comment on the proposed information collection. One general comment was received encouraging FDA in its mission to promote and protect animal health.

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.	Number of respondents	Number 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.	3546	15	1	15	1	15
741(a)(1); Animal Generic Drug User Fee cover sheet.	3728	22	2	44	0.08 (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: August 8, 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–1006]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Medical Devices; Reports of Corrections and Removals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Submit written comments (including recommendations) on the collection of information by September 11, 2023.

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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.*

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