4164-01-P

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; Reporting Associated with Animal Drug and Animal Generic Drug User Fees

AGENCY: Food and Drug Administration, Health and Human Services (HHS).

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) 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 [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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.

Reporting Associated with Animal Drug and Animal Generic Drug User Fees--21 U.S.C. 379j-12 and 379j-21

OMB Control Numbers 0910-0540--Extension

This information collection supports FDA's animal drug and animal generic drug user fee programs. The Animal Drug User Fee Act of 2003 (ADUFA) (Pub. L. 108-130) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act) by adding section 740 of the FD&C Act (21 U.S.C 379j-12), which requires that FDA assess and collect user fees with respect to new animal drug applications for certain applications, products, establishments, and sponsors. It also requires the Agency to grant a waiver from, or a reduction of, those fees in certain circumstances. The Animal Generic Drug User Fee Act of 2008 (AGDUFA) (Pub. L. 110-316) added section 741 of the FD&C Act (21 U.S.C. 379j-21), which establishes three different kinds of user fees: (1) fees for certain types of abbreviated applications for generic new animal drugs; (2) annual fees for certain generic new animal drug products; and (3) annual fees for certain sponsors of abbreviated applications for generic new animal drugs and/or investigational submissions for generic new animal drugs (21 U.S.C. 379j-21(a)). On August 14, 2018, H.R. 5554, the Animal Drug and Animal Generic Drug User Fee Amendments of 2018, was signed into law to reauthorize the ADUFA and AGDUFA programs administered by FDA.

Sponsors of new animal drug applications prepare and submit user fee cover sheets. 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) to initiate the administrative screening of new animal drug applications and supplements. The information collection associated with the Animal Drug User Fee cover sheet currently is approved under OMB control number 0910-0539.

Sponsors of abbreviated new animal drug applications also prepare and submit user fee cover sheets. The Animal Generic Drug User Fee cover sheet (Form FDA 3728) similarly is 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. The information collection associated with the Animal Generic Drug User Fee cover sheet currently is approved under OMB control number 0910-0632.

FDA has also developed a guidance for industry (GFI) #170 entitled "Animal Drug User Fees and Fee Waivers and Reductions." This guidance provides guidance on the types of fees

FDA is authorized to collect under section 740 of the FD&C Act, and how to request waivers and 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; how to submit such a request; and FDA's process for reviewing requests. FDA uses the information submitted by respondents to determine whether to grant the requested fee waiver or reduction. The information collection associated with GFI #170 currently is approved under OMB control number 0910-0540.

The information collection provisions approved under OMB control numbers 0910-0539, 0910-0540, and 0910-0632 are similar in that they support FDA's animal drug and animal generic drug user fee programs. Thus, with this notice, FDA proposes to consolidate these collections of information into one OMB control number for government efficiency and to allow the public to look to one OMB control number for all reporting associated with FDA's animal drug and animal generic drug user fee programs. Because we are proposing to combine all reporting associated with FDA's animal drug user fees into one collection, we are consolidating the burden under OMB control number 0910-0540 and discontinuing OMB control numbers 0910-0539 and 0910-0632.

Description of Respondents: Respondents to this collection of information are new animal drug applicants and abbreviated new animal drug applicants. In addition, requests for waivers or reductions of user fees may be submitted by a person responsible for paying or potentially responsible for paying any of the animal drug user fees assessed, including application fees, product fees, establishment fees, or sponsor fees.

In the *Federal Register* of January 23, 2020 (85 FR 3929), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates 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	21	1	21	1	21
741; Animal Generic Drug User Fee Cover Sheet	FDA 3728	20	2	40	0.08 (5 minutes)	3
Waivers and Other Requests, by Type						
740(d)(1)(A); significant barrier to innovation	N/A	55	1	55	2	110
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	5	1	5	2	10
740(d)(1)(D); minor use or minor species	N/A	69	1	69	2	138
740(d)(1)(E); small business	N/A	1	1	1	2	2
Request for reconsideration of a decision	N/A	1	1	1	2	2
Request for review (user fee appeal officer)	N/A	1	1	1	2	2
Total						303

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

For the purpose of this consolidation, we rely on our previous estimates of the number of user fee cover sheet and waiver and other request submissions. We estimate 21 respondents will each submit 1 Animal Drug User Fee cover sheet (Form FDA 3546) for a total of 21 responses. We estimate 20 respondents will each submit 2 Animal Generic Drug User Fee cover sheets (Form FDA 3728) for a total of 40 responses. Our estimate of the number of waiver and other request submissions is detailed in table 1. These estimates are consistent with our previous estimates except for the row labeled, Request for review (user fee appeal officer), for which we

have increased the estimated number of respondents from zero to one and the average burden per response from 0 to 2 hours to correct the error in our previous submission. We base our estimates of the average burden per response on our experience with the submission of similar cover sheets and waiver and other requests.

The information collection reflects an increase in burden by an additional 26 hours and 62 responses due to the consolidation of the information collections covered by OMB control numbers 0910-0539, "Animal Drug User Fee Cover Sheet," and 0910-0632, "Animal Generic Drug User Fee Cover Sheet" and the correction of the error in our previous submission.

Dated: June 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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