TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity/21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours [2]
Television receiver critical component warning—1020.10(c)(4)	1	1	1	1	1
Cold cathode tubes—1020.20(c)(4)	1	1	1	1	1
Information on diagnostic x-ray systems—1020.30(g)	6	1	6	55	330
Statement of maximum line current of x-ray systems—1020.30(g)(2)	6	1	6	10	60
Diagnostic x-ray system safety and technical information—1020.30(h)(1) through (4)	6	1	6	200	1,200
Fluoroscopic x-ray system safety and technical information—1020.30(h)(5) and (6) and 1020.32(a)(1), (g), and (j)(4)	5	1	5	25	125
CT equipment—1020.33(c), (d), (g)(4), and (j)	5	1	5	150	750
Cabinet x-ray systems information—1020.40(c)(9)(i) and (ii)	6	1	6	40	240
Microwave oven radiation safety instructions—1030.10(c)(4)	1	1	1	20	20
Microwave oven safety information and instructions—1030.10(c)(5)(i) through (iv)	1	1	1	20	20
Microwave oven warning labels—1030.10(c)(6)(iii)	1	1	1	1	1
Laser products information—1040.10(h)(1)(i) through (vi)	3	1	3	20	60
Laser product service information—1040.10(h)(2)(i) and (ii)	3	1	3	20	60
Medical laser product instructions—1040.11(a)(2)	2	1	2	10	20
Sunlamp products instructions—1040.20	1	1	1	10	10
Mercury vapor lamp labeling—1040.30(c)(1)(ii)	1	1	1	1	1
Mercury vapor lamp permanently affixed labels—1040.30(c)(2)	1	1	1	1	1
Ultrasonic therapy products—1050.10(d)(1) through (d), (f)(1), and (f)(2)(iii)	1	1	1	56	56
Total					3,058

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Total hours have been rounded.

Based on a review of the information collection, we have made no adjustments to our burden estimate.

Dated: January 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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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: Submit either electronic or written comments on the collection of information by March 23, 2020.

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 March 23, 2020. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of March 23, 2020. 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 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 ''Agency Information Collection Activities; Proposed Collection; Comment Request; 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.

- 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.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

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 document 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.

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.	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.	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
Waiver 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: January 14, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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