animal drug application for which payment is made. The form, when completed electronically, will result in the generation of a unique payment identification number used by FDA to track the payment. FDA's Center for Veterinary Medicine and FDA's Office of Management will use the information collected to initiate the administrative screening of new animal drug applications and supplements to determine whether the payment has been received.

Description of Respondents: Respondents to this collection of information are new animal drug applicants.

In the **Federal Register** of October 21, 2016 (81 FR 72810), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments. FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act section/ description	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
740(a)(1); Animal Drug User Fee cover sheet.	FDA 3546	21	1	21	1	21

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

The estimates in table 1 are based on our experience with new animal drug applications and supplemental animal drug applications and the average number of Animal Drug User Fee cover sheets submitted during fiscal years 2013–2015. We estimate 21 respondents will each submit a cover sheet (Form FDA 3546) for a total of 21 responses. We calculate a reporting burden of 1 hour per response, for a total of 21 hours. The burden hours are increased. The overall increase in burden hours (by 4 hours) is due to the normal variation in the number of Animal Drug User Fee cover sheets submitted to FDA.

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–14997 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2007–N–0037]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Animal Drug User Fee Act Waivers and Reductions

AGENCY: Food and Drug Administration, 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: Fax written comments on the collection of information by August 17, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 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, 10A63, 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.

Animal Drug User Fees and Fee Waivers and Reductions OMB Control Number 0910–0540—Extension

Enacted on November 18, 2003, the Animal Drug User Fee Act (Pub. L. 108–130) amended the Federal Food, Drug, and Cosmetic Act (the 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. Thus, to implement this statutory provision of ADUFA, FDA developed a guidance entitled ''Guidance for Industry: Animal Drug User Fees and Fee Waivers and Reductions.'' This document provides guidance on the types of fees FDA is authorized to collect under ADUFA, and how to request waivers and reductions from FDA's animal drug user fees. Further, this guidance also describes the types of fees and fee waivers and reductions; 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.

Respondents to this collection of information are new animal drug sponsors. Requests for waivers or reductions may be submitted by a person paying any of the animal drug user fees assessed, including application fees, product fees, establishment fees, or sponsor fees.

In the **Federal Register** of October 17, 2016 (81 FR 71506), FDA published a 60-day notice requesting public comment on the proposed collection of information. FDA received no comments.

FDA estimates the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

FD&C act section/activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
740(d)(1)(A); significant barrier to innovation	55	1 time for each application.	55	2	110
740(d)(1)(B); fees exceed cost	8	3.75	30	.5 (30 minutes)	15
740(d)(1)(C); free choice feeds	5	1 time for each application.	5	2	10
740(d)(1)(D); minor use or minor species	69	1 time for each application.	69	2	138
740(d)(1)(E); small business	1	1 time for each application.	1	2	2
Request for reconsideration of a decision	1	1 time for each application.	1	2	2
Request for review (user fee appeal officer)	0	1 time for each application.	0	0	0
Total					277

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

Based on FDA's database system, from fiscal year (FY) 2014 to 2016 there were an estimated 177 sponsors subject to ADUFA. However, not all sponsors will have any submissions in a given year and some may have multiple submissions. The total number of waiver requests is based on the average number of submission types received by FDA in FY 2014 to 2016. The burden has not changed since the last OMB approval.

Dated: July 12, 2017.

Anna K. Abram,

Deputy Commissioner for Policy, Planning, Legislation, and Analysis.

[FR Doc. 2017–14998 Filed 7–17–17; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2010–N–0583]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Radioactive Drug Research Committees

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: Fax written comments on the collection of information by August 17, 2017.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202–395–7285, or emailed to *oira_submission@omb.eop.gov.* All comments should be identified with the OMB control number 0910–0053. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonnalynn Capezutto, Office of Operations, Food and Drug Administration, Three White Flint North, 10A63, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–3794, *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.

Radioactive Drug Research Committees

OMB Control Number 0910–0053—Extension

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA has the authority to issue regulations governing the use of radioactive drugs for basic scientific research. Section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees (RDRCs) and their role in approving and monitoring basic research studies utilizing radiopharmaceuticals. No basic research study involving any administration of a radioactive drug to research subjects is permitted without the authorization of an FDA-approved RDRC (§ 361.1(d)(7)). The type of research that may be undertaken with a radiopharmaceutical drug must be intended to obtain basic information and not to carry out a clinical trial for safety or efficacy. The types of basic research permitted are specified in the regulation, and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

Section 361.1(c)(2) requires that each RDRC shall select a chairman, who shall sign all applications, minutes, and reports of the committee. Each committee shall meet at least once each quarter in which research activity has been authorized or conducted. Minutes shall be kept and shall include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC shall submit an annual report to FDA. The annual report shall include the names and qualifications of the members of, and of any consultants used by, the RDRC, using Form FDA 2914, and a summary of each study conducted during the preceding year, using Form FDA 2915.

Under § 361.1(d)(5), each investigator shall obtain the proper consent required under the regulations. Each female research subject of childbearing potential must state in writing that she is not pregnant, or on the basis of a pregnancy test be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator shall immediately report to the RDRC all adverse effects associated with use of the drug, and the committee shall then report to FDA all adverse reactions probably attributed to the use of the radioactive drug.

Section 361.1(f) sets forth labeling requirements for radioactive drugs.