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.

These requirements are not in the reporting burden estimate because they are information supplied by the Federal Government to the recipient for the purposes of disclosure to the public (5 CFR 1320.3(c)(2)).

Types of research studies not permitted under this regulation are also specified, and include those intended for immediate therapeutic, diagnostic, or similar purposes or to determine the safety or effectiveness of the drug in humans for such purposes (*i.e.,* to carry out a clinical trial for safety or efficacy). These studies require filing of an investigational new drug application under 21 CFR part 312, and the associated information collections are covered in OMB control number 0910–0014.

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with required regulations and that human subject safety is assured. If these studies were not reviewed, human subjects could be subjected to inappropriate radiation or pharmacologic risks. Respondents to this information collection are the chairperson(s) of each individual RDRC, investigators, and participants in the studies. The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements and the number of submissions received by FDA under the regulations over the past 3 years.

In the **Federal Register** of April 25, 2017 (82 FR 19052), we published a 60-day notice requesting public comment on the proposed extension of this collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR Section/Form FDA	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
361.1(c)(3) (Reports) and (c)(4) (Approval); Form FDA 2914 (Membership Summary)	69	1	69	1	69
361.1(c)(3) (Reports); Form FDA 2915 (Study Summary)	35	14	490	3.5	1,715
361.1(c)(8) (Adverse Events)	10	1	10	*0.5	5
Total			569		1,789

[1] There are no capital or operating and maintenance costs associated with the information collection.
* 30 minutes.

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
361.1(c)(2)	69	4	276	10	2,760
361.1(d)(5)	35	14	490	*0.75	368
Total			766		3,128

[1] There are no capital or operating and maintenance costs associated with the information collection.
* 45 minutes.

Dated: July 11, 2017.

Anna K. Abram,

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

[FR Doc. 2017–15000 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–2017–N–2428]

Agency Information Collection Activities; Proposed Collection; Comment Request; Animal Drug Adverse Event Reporting and Recordkeeping

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 existing reporting and recordkeeping requirements for animal drug adverse events and product/manufacturing defects.

DATES: Submit either electronic or written comments on the collection of information by September 18, 2017.

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 September 18, 2017. The *https://www.regulations.gov* electronic filing system will accept comments until midnight Eastern Time at the end of September 18, 2017. 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