FOOD AND DRUG ADMINISTRATION:
Radioactive Drug Research Committees

OMB Control No. 0910-0053

SUPPORTING STATEMENT

Terms of Clearance: None.

A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration ("FDA" or "we") regulations. Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371), FDA is authorized to issue regulations governing the use of radioactive drugs for basic scientific research. Accordingly, section 361.1 (21 CFR 361.1) sets forth specific regulations regarding the establishment and composition of Radioactive Drug Research Committees (RDRC) 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. Specific provisions of FDA regulations are discussed below.

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 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 FDA Form 2914, and a summary of each study conducted during the proceeding year, using FDA Form 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 (IND) under 21 CFR part 312, and the associated information collections are covered under OMB Control Number 0910-0014.

The purpose of the collection of information is to determine whether research studies involving radioactive drugs 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.

2. Purpose and Use of the Information Collection

Section 361.1, which governs the use of radioactive drugs for basic scientific research, sets forth regulations regarding the establishment and composition of 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. The types of research that may be undertaken with a radiopharmaceutical drug are specified in the regulation and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

3. Use of Improved Information Technology and Burden Reduction

FDA encourages the electronic submission of Forms FDA 2914 and 2915 when feasible, as well as the other reporting submissions in these regulations. FDA has issued guidance documents on regulatory submissions to FDA in electronic format:
http://www.fda.gov/Drugs/GuidanceComplianceRegulatoryInformation/Guidances/ucm064994.htm

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only Federal agency responsible for regulating the activities required by 21 CFR 361.1. The Nuclear Regulatory Commission (NRC), and some state and Federal agencies such as the Department of the Army also regulate the possession and use of radioactive materials and other radiation sources (x-ray) necessary to conduct some of these RDRC studies. However, their responsibility is primarily related to occupational radiation safety and not the human use of the radiolabeled drug, and is therefore not duplicative.

5. Impact on Small Businesses or Other Small Entities

Collection of this information does not involve small businesses. Most committees are affiliated with large institutions. However, FDA and the Center for Drug Evaluation and Research (CDER) provide general assistance to the research community.

6. Consequences of Collection the Information Less Frequently

The composition of committee membership is reported to the FDA on Form FDA 2914 (Membership Summary) yearly along with the annual report. Changes in membership may occur at any time during the year, and must be reported (also on Form FDA 2914) as soon as, or before vacancies occur on the Committee. Less frequent reporting could allow unqualified members to

serve on RDRCs for extended periods of time thereby placing the safety of human research subjects at risk as these RDRCs continue to evaluate and approve research protocols. Approved study protocols are reported to the FDA on Form FDA 2915 (Study Summary) in the annual report. Less frequent reporting could result in safety risks to human subjects due to a delay in the detection of studies that are inappropriate under 21 CFR 361.1.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection is consistent with the requirements of 5 CFR 1320.5.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

In accordance with 5 CFR 1320.8(d), FDA published a 60 day notice for public comment in the Federal Register of April 25, 2017 (82 FR 19052). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No payment or gift has been provided.

10. Assurance of Confidentiality Provided to Respondents

The contents of submitted Forms FDA 2914 (Membership Summary) and FDA 2915 (Study Summary) are available for public disclosure unless confidentiality is requested by the investigator and it is evident from the report(s) that the material contains trade secret or confidential commercial information as defined in 21 CFR 20.61. When confidentiality is requested and justified, the forms will be marked as not releasable and will be maintained in a manner similar to other confidential information. Data will be secured in a locked area with access limited to appropriate FDA personnel. Applicable confidentiality will be maintained as long as the data are maintained.

11. Justification for Sensitive Questions

No questions of a private or sensitive nature are asked.

12. Estimates of Annualized Burden Hours and Costs

12a. *Annualized Hour Burden Estimate*

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Section 361.1(c)(3) requires that each Radioactive Drug Research Committee 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 Radioactive Drug Research Committee, using FDA Form 2914, and a summary of each study conducted during the proceeding year, using FDA Form 2915.

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Section 361.1(d)(8) requires that the investigator immediately report to the Radioactive Drug Research Committee 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 (IND) under 21 CFR part 312, and the associated information collections are covered in OMB Control Number 0910-0014.

Respondents to this information collection are the chairperson(s) of each individual Radioactive Drug Research Committee, investigators, and participants in the studies.

The burden estimates are based on FDA's experience with these reporting and recordkeeping requirements over the past few years and the number of submissions received by FDA under the regulations. We therefore estimate the burden of the information collection as follows:

Table 1 – Estimated Annual Reporting Burden[1]

21 CFR Section (and applicable FDA Form)	Number of respondents	Number of responses per respondent	Total annual responses	Avg. burden per response	Total hours
361.1(c)(3) reports & (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(d)(8) – adverse events	10	1	10	.5	5
TOTAL			569		1,789

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

Table 2 – Estimated Annual Recordkeeping Burden[1]

21 CFR Section	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Avg. burden per recordkeeping	Total hours
361.1(c)(2); RDRC	69	4	276	10	2,760
361.1(d)(5); human research subjects	35	14	490	.75	368
TOTAL			766		3,128

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

12b. *Annualized Cost Burden Estimate*

Using an average salary of $75 per hour (clerical and professional salaries combined), the total estimated cost to the respondents is $364,350 ((1,740 hours + 3,118 hours) x $75).

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital expenditures, or start-up, operating or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

The estimate of the cost to the government is $117,230 per year. This figure is based on past experience, a current re-evaluation, and the cost of the following activities:

(1) Preparing letters to RDRCs;
(2) Printing Forms FDA 2914 and 2915;
(3) Clerical time for processing and mailing documents at $30 per hour; and
(4) Administrative and professional review time at $75 per hour.

Estimated Cost to the Federal Government						
Item	Printing	Clerical Time (hrs)	Clerical Cost	Prof. Time (hrs)	Prof. Cost	Total Cost
Letter	$0	20	$600	320	$ 24,000	$ 24,600
2914 2915	$30 $150	--	--	250 800	$ 18,750 $ 60,000	$ 18,780 $ 60,150
Total	$180	20 hrs	$600	1370 hrs	$102,750	$103,530

15. Explanation for Program Changes or Adjustments

The information collection reflects an agency adjustment of 170 fewer annual responses and a corresponding adjustment of 90 fewer annual burden hours.

16. Plans for Tabulation and Publication and Project Time Schedule

FDA does not intend to publish results of the information collection.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

Display of OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.