United States Food and Drug Administration

Radioactive Drug Research Committees

OMB Control No. 0910-0053

SUPPORTING STATEMENT

Part A – Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection request supports the implementation of statutory and regulatory requirements and associated Agency forms. Sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 321, 355, and 371) establish provisions under which FDA (Agency or we) issues regulations governing the use of radioactive drugs for basic scientific research.  Specifically, § 361.1 (21 CFR 361.1) sets forth regulations about establishing and composing radioactive drug research committees (RDRCs) and their role in approving and monitoring basic research studies using radiopharmaceuticals, including reporting, recordkeeping and labeling requirements. 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 radioactive 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 regulations and include studies of metabolism, human physiology, pathophysiology, or biochemistry.

FDA developed the guidance document entitled, “*Radioactive Drug Research Committee: Human Research Without an Investigational New Drug Application”* (August 2010), available at <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/radioactive-drug-research-committee-human-research-without-investigational-new-drug-application>, which provides information to help determine whether research studies may be conducted under an FDA-approved RDRC, or whether research studies must be conducted under an investigational new drug application (IND). It also offers answers to frequently asked questions on conducting research with radioactive drugs and provides information on the membership, functions, and reporting requirements of an RDRC approved by FDA. All Agency guidance documents are issued consistent with our good guidance practice regulations at 21 CFR 10.115.

Respondents to this information collection are the chairperson or chairpersons of each individual RDRC, investigators, and participants in the studies. These respondents are subject to the human subject protection provisions of both the Federal Food, Drug, and Cosmetic Act and the Public Health Service Act, with implementing regulations at 21 CFR parts 50 and 56. The information collection for 21 CFR parts 50 and 56 is currently approved under OMB control number 0910-0130.

To assist respondents with the applicable reporting requirements we developed Form FDA 2914 entitled, “Report on Research Use of Radioactive Drugs: Membership Summary,” and available at <https://www.fda.gov/media/73820/download>; and Form FDA 2915, entitled, “Report on Research Use of Radioactive Drugs: Study Summary,” and available at <https://www.fda.gov/media/71805/download>.

Types of research studies not permitted under the regulations 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 IND under 21 CFR part 312, and the associated information collections, are covered in OMB control number 0910-0014.

We, therefore, request extension of OMB approval for the information collection associated with RDRCs found in 21 CFR 361.1, along with Forms FDA 2914 and 2915, as discussed in this supporting statement.

1. Purpose and Use of the Information Collection

The primary purpose of this collection of information is to determine whether the research studies are being conducted in accordance with applicable statutes and 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.

The RDRC is responsible for the review of basic science research protocols using radioactive drugs in humans that are subject to § 361.1. RDRC approval of a research study is based on assurance that the following requirements of § 361.1(d)(1)–(9) are met:

* Appropriate limit on the radiation dose
* Appropriate limit on the pharmacologic dose
* Qualified study investigators
* Medical facility properly licensed to possess and handle radioactive materials
* Appropriate selection and consent of research subjects
* Appropriate quality of radioactive drug administered
* Sound research protocol design
* Reporting of adverse events by the investigator to the RDRC
* Approval by an appropriate institutional review board

In addition, FDA uses the information to ensure adherence to applicable administrative functions of the RDRC, as required under § 361.1.

1. Use of Improved Information Technology and Burden Reduction

We encourage the electronic submission of Forms FDA 2914 and 2915 when feasible, as well as the other reporting submissions in these regulations. FDA has outlined instructions for submitting these form on its website (<https://www.fda.gov/drugs/science-and-research-drugs/radioactive-drug-research-committee-rdrc-program>). Respondents may submit RDRC submissions electronically through the CDER NextGen portal, or by emailing the required information to the RDRC Team at RDRC@cder.fda.gov; or by mailing the required information to the RDRC Team at the address found on our website. Based on historical experience, we estimate nearly 100% of respondents will utilize electronic means to provide the information. FDA has also issued guidance documents on regulatory submissions to FDA in electronic format, available at [https://www.fda.gov/RegulatoryInf](http://www.fda.gov/RegulatoryInformation/Guidances/default.htm)orma[tion/Guidances/default.htm](http://www.fda.gov/RegulatoryInformation/Guidances/default.htm).

1. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. The U.S. Nuclear Regulatory Commission and some state and Federal agencies (e.g., 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.

1. 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 provide general assistance to the research community.

1. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements. Composition of committee membership is reported to FDA on Form FDA 2914 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 RDRC. 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 FDA on Form FDA 2915 in the annual report. Less frequent reporting could result in safety risks to human subjects because of a delay in the detection of studies that are inappropriate under § 361.1.

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

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

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

In accordance with 5 CFR 1320.8(d), we published a 60-day notice for public comment in the *Federal Register* of March 16, 2023 (88 FR 16272). No comments were received.

1. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

1. Assurance of Respondent Privacy and Confidentiality

In preparing this Supporting Statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected.

This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals’ professional capacity and the FDA-related work they perform for their employer (e.g., point of contact at a regulated entity). The PII submitted via Form FDA 2914 (Radioactive Drug Research Committee-RDRC, Report on Research Use of Radioactive Drugs, Membership Summary) includes name, address, email address, telephone number, fax number, RDRC committee number, employment history, and educational history. The PII submitted via Form FDA 2915 (Radioactive Drug Research Committee-RDRC, Report on Research Use of Radioactive Drugs Study, Summary) includes name and RDRC committee number. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Under the Freedom of Information Act (FOIA) (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

Data is secured, with limited access to authorized FDA personnel only.

1. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

1. Estimates of Annualized Burden Hours and Costs

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

*12a. Annualized Hour Burden Estimate*

Table 1.--Estimated Annual Reporting Burden

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 21 CFR Section; FDA Form or Activity | No. of Respondents | No. 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) | 56 | 1 | 56 | 1 | 56 |
| § 361.1(c)(3) reports; Form FDA 2915 (Study Summary) | 37 | 10 | 370 | 3 | 1,110 |
| § 361.1(d)(8); adverse events | 10 | 1 | 10 | 0.5(30 mins) | 5 |
| Total | 1,171 |

Table 2.--Estimated Annual Recordkeeping Burden

|  |  |  |  |  |  |
| --- | --- | --- | --- | --- | --- |
| 21 CFR Section; and Activity | No. of Recordkeepers | No. of Records per Recordkeepers | Total Annual Records | Average Burden per Recordkeeping | Total Hours |
| § 361.1(c)(2); RDRC maintains meeting minutes involving use in human research subjects§ 361.1(d)(5); RDRC obtains consent of human research subjects | 56 | 10.61 | 594 | 4.239 | 2,518 |
| Total | 2,518 |

The burden attributed to recordkeeping activities is assumed to be distributed among the individual elements and averaged among respondents. In the burden estimate, we assume an average burden per record of 10 hours for the RDRC respondents to maintain meeting minutes and .75 hours (45 minutes) for a subset of the respondents (37 RDRCs) to obtain consent of human research subjects.

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)).

The burden hour total for this ICR is 3,689 hours (1,171 reporting hours + 2,518 recordkeeping hours).

*12b. Annualized Cost Burden Estimate*

There are labor costs resulting from this information. Based on an average industry wage rate of $76.12 per hour (averaged from wages for professional, scientific, technical, and clerical support, plus overhead and personnel benefits using data provided by the U.S. Bureau of Labor Statistics: May 2021 National Industry-Specific Occupational Employment and Wage Estimates, available at <https://www.bls.gov/oes/current/naics2_54.htm>), we estimate the total cost burden to respondents is $280,806.68 ((1,171 hours + 2,518 hours) x $76.12) per year.

1. 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.

1. Annualized Cost to the Federal Government

The estimate of the cost to the Federal Government is $114,550 per year.

This figure is based on past experience, a current reevaluation, 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 $33 per hour; and
4. Administrative and professional review time at $83 per hour.

|  |
| --- |
| Table 3.--Estimated Cost to the Federal Government |
| Item | Printing Cost | Clerical Time (hours) | Clerical Cost | Administrative and Professional Review Time (hours) | Administrative and Professional Review Cost | Total Cost (Clerical + Administrative/ Professional Review) |
| Letter | $0 | 20 | $660 | 320 | $26,560 | $27,220 |
| 2914 | $30 | -- | -- | 250 | $20,750 | $20,780 |
| 2915 | $150 | -- | -- | 800 | $66,400 | $66,550 |
| Total | $180 | 20 hours | $660 | 1,370 hours | $113,710 | **$114,550** |

1. Explanation for Program Changes or Adjustments

Our estimated burden for the information collection reflects an overall decrease of 703 hours and a corresponding decrease of 158 responses. We attribute this adjustment to a decrease in the average burden per response, from 3.5 hours to 3 hours per response, associated with the public reporting burden for Form FDA 2915. The decrease is based on our program experience and matches the burden hours reflected on the form. In addition, this adjustment is also attributable to the Agency receiving fewer submissions over the last few years.

1. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

1. Reason(s) Display of OMB Expiration Date Is Inappropriate

FDA will display the OMB expiration date as required by 5 CFR 1320.8.

1. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.