UNITED STATES FOOD AND DRUG ADMINISTRATION

Radioactive Drug Research Committees

OMB Control No. 0910-0053 – Extension

SUPPORTING STATEMENT:

Part A – Justification

1. Circumstances Making the Collection of Information Necessary

Under sections 201, 505, and 701 of the Federal Food, Drug, and Cosmetic Act (FFDCA; 21 U.S.C. 321, 355, and 371), the Food and Drug Administration (FDA, the agency, us or we) has authority to issue regulations governing the use of radioactive drugs for basic scientific research. Accordingly we have issued regulations at 21 CFR 361.1. Section 361.1 (21 CFR 361.1) sets forth specific provisions governing the establishment and composition of Radioactive Drug Research Committees (RDRCs) and their role in approving and monitoring basic research studies using 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 regulations and include studies of metabolism, human physiology, pathophysiology, or biochemistry. This information collection supports implementation of statutory and regulatory requirements applicable to RDRCs and associated research.

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 www.fda.downloads/AboutFDA/Reports/ManualsForms/Forms/UCM094979.pdf; and Form FDA 2915, entitled, "*REPORT ON RESEARCH USE OF RADIOACTIVE DRUGS: Study Summary*," and available at www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074720.pdf.

Respondents to the information collection are also subject to the human subject protection provisions of both the FFDCA and the Public Health Service Act, with implementing regulations at 21 CFR parts 50 and 56 (information collection for 21 CFR parts 50 and 56 is currently approved under OMB control no. 0910-0130). Under § 361.1(d)(5), each investigator shall obtain the proper consent as required by all human subject protection regulations. Also, under § 361.1(d)(8), an 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. Finally, the provisions set forth labeling requirements for radioactive drugs. Because the labeling information is supplied by the Federal government to the recipient for the purposes of disclosure to the public as defined under 5 CFR 1320.3(c)(2), we estimate no attendant burden for such labeling.

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 investigational new drug application under 21 CFR part 312 (information collection for INDs is approved under OMB control no. 0910-0014).

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

2. Purpose and Use of the Information Collection

We use the information collection to ensure compliance with applicable statutes and regulations. 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 (IRB)

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

3. 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. We have issued guidance documents on regulatory submissions to FDA in electronic format: https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information. 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 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 (*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 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), we published a 60-day notice for public comment in the *Federal Register* of January 21, 2020 (85 FR 3390). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is provided to respondents.

10. Assurance of Respondent Privacy and Confidentiality

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate handling of information collected. We have determined that although PII is collected, the Privacy Act of 1974 does not apply. The PII collected includes the names of the chairperson(s) of each individual radioactive drug research committees (RDRCs), investigators, and participants in the studies. PII is submitted via Forms FDA 2914 and 2915, however we do not use this data or any other personal identifier to routinely retrieve

records from the information collected. We also have minimized the PII to be collected to protect the privacy of the individuals.

The contents of submitted Forms FDA 2914 and 2915 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 is secured, with limited access to authorized FDA personnel only.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate:

Table 1.--Estimated Annual Reporting Burden

21 CFR Section and Applicable Form	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)	62	1	62	1	62
§ 361.1(c)(3) reports (Form FDA 2915: Study Summary)	40	10	434	3.5 hrs.	1,519
§ 361.1(d)(8) adverse events	10	1	10	.5 (30 mins)	5
Total			506		1,586

Table 2.--Estimated Annual Recordkeeping Burden

21 CFR Section	No. of Recordkeepers	No. of Record per Recordkeepers	Total Annual Records	Average Burden per Recordkeeping	Total Hours
§ 361.1(c)(2) RDRC	62	4	248	10	2,480
§ 361.1(d)(5) human research subjects	40	10	434	.75 (45 mins)	326
Total			682		2,806

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 $329,400 ((1,586 hours + 2,806 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 Federal 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 (hours)	Clerical Cost	Prof. Time (hours)	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

We have adjusted our estimate to reflect a decrease of 525 hours and 147 responses to correspond with a decrease in submissions that we have observed since last review of the information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications or other schedules.

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

We will display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.