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, Agency, 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: Submit written comments (including recommendations) on the collection of information by [INSERT DATE 30 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review - Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0053. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, 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

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 issues regulations governing the use of radioactive drugs for basic scientific research. Specifically, § 361.1 (21 CFR 361.1) sets forth specific 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 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.

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

We also 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.

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.

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 or chairpersons of each individual RDRC, investigators, and participants in the studies.

In the *Federal Register* of March 16, 2023 (88 FR 16272), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

Table 1.--Estimated Annual Reporting Burden[1]

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

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

Table 2.--Estimated Annual Recordkeeping Burden[1]

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

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

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 0.75 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 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)).

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.

Dated: August 7, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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