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) 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 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: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, 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--21 CFR 361.1

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. This information collection request supports those regulations. 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. 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.

Section 361.1(c)(2) requires that each RDRC will select a chairman, who will sign all applications, minutes, and reports of the committee. Each committee will meet at least once each quarter in which research activity has been authorized or conducted. Minutes will be kept and will include the numerical results of votes on protocols involving use in human subjects. Under § 361.1(c)(3), each RDRC will submit an annual report to FDA. The annual report will include the names and qualifications of the members of and of any consultants used by the RDRC, using Form FDA 2914 entitled “Radioactive Drug Research Committee Report on Research Use of

Radioactive Drugs Membership Summary." The annual report will also include a summary of each study conducted during the preceding year, using Form FDA 2915 entitled "Radioactive Drug Research Committee Report on Research Use of Radioactive Drugs Study Summary."

Under § 361.1(d)(5), each investigator will 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, based on a pregnancy test, be confirmed as not pregnant.

Under § 361.1(d)(8), the investigator will immediately report to the RDRC all adverse effects associated with use of the drug, and the committee will 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 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, 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. The burden estimates are based on our experience with these reporting and recordkeeping requirements and the number of submissions we received under the regulations over the past 3 years.

In the *Federal Register* of January 21, 2020 (85 FR 3390), we published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

FDA estimates the burden of this collection of information as follows:

Table 1.--Estimated Annual Reporting Burden[1,2]

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)[3]	62	1	62	1	62
§ 361.1(c)(3) reports (Form FDA 2915: Study Summary)[4]	40	10	434	3.5	1,519
§ 361.1(d)(8) adverse events	10	1	10	.5 (30 minutes)	5
Total			506		1,586

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.
[3] https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM094979.pdf
[4] https://www.fda.gov/downloads/AboutFDA/ReportsManualsForms/Forms/UCM074720.pdf

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

21 CFR Section	No. of Recordkeepers	No. of Records 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 minutes)	326
Total			682		2,806

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] Numbers may not sum due to rounding.

We have adjusted our estimate for the information collection to reflect an annual decrease of 525 hours and 147 responses since last OMB review. This adjustment corresponds to fewer submissions we have received under the information collection over the last few years.

Dated: June 24, 2020.

Lowell J. Schiller,

Principal Associate Commissioner for Policy.

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