4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1721]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Investigational New Drug Application Requirements

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 0910-0014. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-5733, 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.

Investigational New Drug Application Requirements

OMB Control Number 0910-0014--Revision

This information collection supports implementation of provisions of section 505 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355) and of the licensing provisions of the Public Health Service Act (42 U.S.C. 201 et seq.) that govern investigational new drugs and investigational new drug applications (INDs). Implementing regulations are found in part 312 (21 CFR part 312) and provide for the issuance of guidance documents under 21 CFR 10.115 to assist persons in complying with the applicable requirements (see § 312.145). The information collection applies to all clinical investigations subject to section 505 of the FD&C Act.

For efficiency of Agency operations, we are revising the information collection to include burden that may be associated with recommendations found in the guidance document entitled "E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (March 2018)," currently approved in OMB control number 0910-0843. The guidance document is intended to facilitate implementation of improved and efficient approaches to clinical trial design, including conduct, oversight, recording, and reporting. The recommendations in the guidance help us ensure that sponsors of clinical trials are adhering to requirements prescribed in FDA regulations regarding new drug applications (NDA) (part 312), INDs (21 CFR part 314), and biological licensing applications (BLA) (21 CFR part 601). The guidance document is available for download from our website at https://www.fda.gov/media/93884/download.

In the *Federal Register* of April 11, 2023 (88 FR 21682), 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 Recordkeeping[1]

§ 312.145: Guidance Documents; Recommendations in ICH E6(R2) "Good Clinical Practice"	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours

Section 5.0.7. Risk Reporting--Describing the Quality Management Approach Implemented in a Clinical Trial and Summarizing Important Deviations From the Predefined Quality Tolerance Limits and Remedial Actions Taken in the Clinical Study Report	1,880	3.9	7,362	3	22,082
Section 5 Quality Management (including sections 5.0.1 to 5.0.7)--Developing a Quality Management System	1,880	1	1,880	60	112,800
Total			9,242		134,882

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

Respondents to the collection of information are sponsors of clinical trials of human drugs. Based on IND and NDA submission data, including submissions to both FDA's Center for Drug Evaluation and Research and the Center for Biologics Evaluation and Research, we estimate there are 1,880 respondents to the information collection. We assume the risk reporting recommendations and associated records discussed in section 5 of the guidance document requires 3 hours to complete, as reflected in table 1, row 1. In table 1, row 2, we account for burden associated with the development of a quality management system and associated recordkeeping also discussed in section 5 of the guidance document. We assume it will take respondents 60 hours to develop and implement each quality management system, as recommended. These estimates are based on our past experiences with INDs, BLAs, and NDAs submitted to FDA.

Since our last evaluation of the information collection burden we attribute to recommendations applicable to activities discussed in the guidance document, we have made no adjustments to our estimate.

Dated: August 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

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