Respondents to this collection of information will include members of the general public, healthcare professionals, the industry, and other stakeholders who are related to a product under FDA's jurisdiction. Inclusion and exclusion criteria will vary depending on the research topic.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| Activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response | Total hours |
|---|---|---|---|---|---|
| Focus group interviews | 12,000 | 1 | 12,000 | 1.75 | 21,000 |

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

The estimated burden for the information collection reflects an overall increase of 5,600 hours and a corresponding increase of 3,200 responses. We increased the number of consolidating the burden from ICR 0910–0677, ''Focus Groups About Drug Products as Used by the Food and Drug Administration.''

Dated: April 5, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–07515 Filed 4–10–23; 8:45 am]

**BILLING CODE 4164–01–P**

## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2014–N–1721]**

### Agency Information Collection Activities; Proposed Collection; 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 an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the **Federal Register** concerning each proposed collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection associated with the guidance ''E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1).''

**DATES:** Either electronic or written comments on the collection of information must be submitted by June 12, 2023.

**ADDRESSES:** You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of June 12, 2023. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received on or before that date.

*Electronic Submissions*

Submit electronic comments in the following way:

- *Federal eRulemaking Portal: https://www.regulations.gov.* Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to *https://www.regulations.gov* will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on *https://www.regulations.gov.*
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see ''Written/Paper Submissions'' and ''Instructions'').

*Written/Paper Submissions*

Submit written/paper submissions as follows:

- *Mail/Hand Delivery/Courier (for written/paper submissions):* Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.
- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in ''Instructions.''

*Instructions:* All submissions received must include the Docket No. FDA–2014–N–1721 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Investigational New Drug Application Requirements.'' Received comments, those filed in a timely manner (see **ADDRESSES**), will be placed in the docket and, except for those submitted as ''Confidential Submissions,'' publicly viewable at *https://www.regulations.gov* or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday, 240–402–7500.

- Confidential Submissions—To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states ''THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION.'' The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on *https://www.regulations.gov.* Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as ''confidential.'' Any information marked as ''confidential'' will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about FDA's posting of comments to public dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/pkg/FR-2015-09-18/pdf/2015-23389.pdf.*

*Docket:* For access to the docket to read background documents or the electronic and written/paper comments received, go to *https://www.regulations.gov* and insert the docket number, found in brackets in the heading of this document, into the ''Search'' box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500.

**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:** Under the PRA (44 U.S.C. 3501–3521), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. ''Collection of information'' is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the **Federal Register** concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

## 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 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.*

FDA estimates the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING [1]

| § 312.145: Guidance Documents; Recommendations in ICH E6(R2) ''Good Clinical Practice'' | Number of respondents | Number 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.

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 (sponsors of clinical trials of human drugs) 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.

Since last OMB approval of the information collection, we have made no adjustments to burden we attribute to recommendations that may be applicable to activities discussed in the guidance document.

Dated: April 5, 2023.

**Lauren K. Roth,**

*Associate Commissioner for Policy.*

[FR Doc. 2023–07529 Filed 4–10–23; 8:45 am]

**BILLING CODE 4164–01–P**