TABLE 3—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]—Continued

Activity; 21 CFR section	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Total	.....	.....	.....	.....	23,100

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

Upon evaluation of the information collection, we have made no adjustment to our currently approved burden estimate of 615,380 hours annually, based on 12 tracking orders. We attribute the attendant burden to the following activities:

Under § 821.25(a) (21 CFR 821.25(a)), device manufacturers subject to FDA tracking orders must adopt a tracking method that can provide certain device, patient, and distributor information to FDA within 3 to 10 working days. Assuming one occurrence per year, we estimate it would take a firm 20 hours to provide FDA with location data for all tracked devices and 56 hours to identify all patients and/or multiple distributors possessing tracked devices.

Under § 821.25(d) manufacturers must notify FDA of distributor noncompliance with reporting requirements. Based on the number of audits manufacturers conduct annually, we estimate no more than one notice will be received in any year, and that it would take 1 hour per incident.

Under § 821.30(c)(2) (21 CFR 821.30(c)(2)), multiple distributors must provide data on current users of tracked devices, current device locations, and other information, upon request from a manufacturer or FDA. Assuming one multiple distributor receives one request in a year from either a manufacturer or FDA, and that lists may be generated electronically, we estimate a burden of 1 hour to comply.

Under § 821.30(d) distributors must verify data or make required records available for auditing, if a manufacturer provides a written request. We assume 5 percent of tracked devices distributed for estimating burden. Each audited database entry prompts one distributor audit response. Because lists may be generated electronically, we estimate a burden of 1 hour to comply.

Dated: August 3, 2023.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2023–16933 Filed 8–7–23; 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; 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 September 7, 2023.

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"	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.

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.

[FR Doc. 2023–16923 Filed 8–7–23; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–2851]

Agency Information Collection Activities; Proposed Collection; Comment Request; Time and Extent Applications for Nonprescription Drug Products

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA or Agency) 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, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on time and extent applications for nonprescription drug products.

DATES: Either electronic or written comments on the collection of information must be submitted by October 10, 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 October 10, 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–2023–N–2851 for ''Time and Extent Applications for Nonprescription Drug Products.'' Received comments, those