DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–1736]

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 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 information collection associated with investigational new drugs and investigational new drug applications.

DATES: Either electronic or written comments on the collection of information must be submitted by May 12, 2026.

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 May 12, 2026. 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–2026–N–1736 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: Anne Taylor, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 240–402–5683, *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—21 CFR Part 312

OMB Control Number 0910–0014—Extension

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 (see § 312.145 (21 CFR 312.145)) to assist persons in complying with the applicable requirements. The information collection applies to all clinical investigations subject to section 505 of the FD&C Act and include the following types of INDs:

- An Investigator IND is submitted by a physician who both initiates and investigates, and under whose immediate direction the investigational drug is administered or dispensed. A physician might submit a research IND to propose studying an unapproved drug or an approved product for a new indication or in a new patient population.
- Emergency Use IND allows FDA to authorize use of an experimental drug in an emergency situation that does not allow time for submission of an IND in accordance with § 312.23 or § 312.20 (21 CFR 312.23 or 312.20). It is also used for patients who do not meet the criteria of an existing study protocol or if an approved study protocol does not exist.
- Treatment IND is submitted for experimental drugs showing promise in clinical testing for serious or immediately life-threatening conditions while the final clinical work is conducted and FDA's review takes place.

There are two IND categories: commercial and research (non-commercial).

General IND requirements include submitting an initial application as well as amendments to that application; submitting reports on significant revisions of clinical investigation plans; submitting information to the clinical trials data bank (*https://clinicaltrials.gov*) established by the National Institutes of Health/National Library of Medicine, including expanded information on certain clinical trials and information on the results of these clinical trials; and reporting information on a drug's safety or effectiveness. In addition, sponsors are required to provide to FDA an annual summary of the previous year's clinical experience. The regulations also include recordkeeping requirements regarding the disposition of drugs, records regarding individual case histories, and certain other documentation verifying clinical investigators' fulfillment of responsibilities.

Form FDA 1571 entitled ''Investigational New Drug Application (IND)'' and Form FDA 1572 entitled ''Statement of Investigator,'' were developed to assist respondents with the information collection and provide for uniform reporting of required data elements. The information is required to be submitted electronically. Individuals who are interested in receiving printed forms may send an email request to the FDA Forms Manager at *formsmanager@OC.FDA.GOV.* Fees may apply. Sponsors (including sponsor-investigators) interested in filing or updating a research IND may use a new web-based interface developed for use by mobile device or desktop to help in completing Form FDA 1571. The web-based interface also allows respondents to electronically submit completed Form FDA 1571 and associated files. Form FDA 1571 was recently updated to include the new tracking information for real world evidence and real-world data (RWE/RWD). The new RWE/RWD fields will capture submissions with RWE/RWD based on the requirements set forth in the PDUFA VII commitment letter and the resulting *Advancing Real World Evidence Program,* so that FDA can track and report on its performance related to these commitments. In addition, collection of this data will support the consistent integration of real-world evidence data into the regulatory review and approval process for new drugs and biologics. For more information regarding Forms FDA 1571 and 1572 visit *https://www.fda.gov/news-events/expanded-access/how-complete-form-fda-1571-and-form-fda-1572.*

Human drug, biological product, and device product submissions must be accompanied by Form FDA 3674, as discussed in the guidance document entitled ''Form FDA 3674—Certifications To Accompany Drug, Biological Product, and Device Applications/Submissions'' (updated November 2017), available from our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/form-fda-3674-certifications-accompany-drug-biological-product-and-device-applicationssubmissions.* The guidance document provides procedural instruction on completing and submitting required information to FDA. As communicated in the instructions, the certification must accompany the application or submission and be included at the time of submission to FDA.

Regulations in part 312, subpart B, specify content and format requirements for applications, amendments, annual reporting, and withdrawals, including content and format requirements for protocol and information amendments. The regulations also explain phases of an investigation and set forth principles of IND submissions. To date we have developed and issued the following guidance documents to assist respondents:

- ''*Establishment and Operation of Clinical Trial Data Monitoring Committees*'' guidance (March 2006); and
- ''*Special Protocol Assessment*'' guidance (April 2018).

All Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* that utilizes topic specific search terms.

Regulations in part 312, subpart C, describe administrative actions pertaining to respondents' requests for and responses to clinical holds, terminations, and inactive IND status determinations, as well as various types of meetings (for example, End-of-Phase 2 and Pre-new drug application (NDA) meetings).

Regulations in part 312, subpart D, set forth sponsor and investigator responsibilities, including general responsibilities; transfer of obligations to a contract research organization; recordkeeping and record retention controls; reporting responsibilities; and responsibility for disposition of unused supply of investigational drug. The regulations also provide for investigator controls including review of ongoing investigations; compliance with requirements regarding the protection of human subjects and institutional review board assurance; and disqualification of clinical investigators.

Regulations in part 312, subpart E, sets forth requirements applicable to drugs intended to treat life-threatening and severely debilitating illnesses. The

regulations establish procedures to reflect that physicians and patients accept greater risk or side effects from products that treat life-threatening and severely debilitating illnesses than they would accept from products that treat less serious illnesses. The procedures also reflect the recognition that the benefits of the drug need to be evaluated in light of the severity of the disease being treated.

Regulations in part 312, subpart F, include provisions pertaining to import and export requirements; foreign clinical studies not conducted under an IND; the disclosure of data and information in an IND; and the issuance of guidance documents. To date we have developed and issued the following guidance documents to assist respondents:

- ''*Oversight of Clinical Investigations*'' guidance (August 2013);
- ''*Pharmacogenomic Data Submissions*'' guidance (March 2005);
- ''*Adaptive Designs for Clinical Trials of Drugs and Biologics*'' guidance (December 2019); and
- ''*E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1)*'' guidance (March 2018).

All Agency guidance documents are issued in accordance with our Good Guidance Practice regulations in 21 CFR 10.115, which provide for public comment at any time. We maintain a searchable guidance database on our website at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents* that utilizes topic specific search terms.

Regulations in part 312, subpart G, provide for drugs for investigational use in laboratory research animals or in vitro tests.

Finally, 21 CFR 300.200 requires the submission of an annual report by sponsors and manufacturers who provide an ''*eligible investigational drug*'' under the Right to Try Act. The regulation also establishes content and format elements and requires that information be submitted to FDA no later than March 31 of each year, including data for the preceding calendar year. Respondents use Form FDA 5023 entitled ''*Right to Try Reporting Requirement: Annual Summary*,'' currently available for download from our website at *https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try-annual-reporting-summary.* As required by the applicable statute, section 561B of the FD&C Act (21 U.S.C. 360bbb–0a), the information is submitted to an FDA-designated point of contact, and in accordance with instructions to be posted at: *https://www.fda.gov/patients/learn-about-expanded-access-and-other-treatment-options/right-try.*

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart A—General Provisions: §§ 312.1 through 312.10					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	454	1.528	694	24	16,656
§ 312.8; requests to charge for an investigational drug	14	1.64	23	48	1,104
§ 312.10; waiver requests	5	1	5	24	120
Subtotal Subpart A Center for Biologics Evaluation and Research (CBER)			722		17,880
Subpart B—Investigational New Drug Application (IND): §§ 312.20 through 312.38 (Including Forms FDA 1571, 1572, and 3674)					
§ 312.23(a) through (f); IND content and format	2,075	3.382	7,018	300	2,105,400
§ 312.30(a) through (e); protocol amendments	1,781	4.6692	8,316	284	2,361,744
§ 312.31(b); information amendments	169	2.48	419	100	41,900
§ 312.32(c) and (d); IND safety reports	224	10.59	2,372	32	75,904
§ 312.33(a) through (f); IND annual reports	971	2.2739	2,208	360	794,880
§ 312.38(b) and (c); notifications of withdrawal of an IND	712	3.057	2,177	28	60,956
Subtotal Subpart B CBER			22,510		5,440,784
Subpart C—Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modification	154	1.65	254	284	72,136
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	86	1.22	105	16	1,680
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	48	1.48	71	12	852
§ 312.47; meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	157	1.80	283	160	45,280
Subtotal Subpart C CBER			713		119,948
Subpart D—Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.53(c); investigator reports submitted to the sponsor, including Form FDA 1572, curriculum vitae, clinical protocol, and financial disclosure	1,068	5.23	5,586	80	446,880
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	4	4.25	17	48	816
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	1	1	1	48	48
§ 312.55(a); number of investigator brochures submitted by the sponsor to each investigator	473	2.224	1,052	48	50,496
§ 312.55(b); number of sponsor reports to investigators on new observations, especially adverse reactions and safe use	243	4.95	1,203	48	57,744
§ 312.56(b), (c), and (d); review of ongoing investigations and associated notifications; sponsor notifications	915	2.948	2,698	80	215,840
§ 312.58; inspection of records and reports by FDA	7	1	7	8	56
§ 312.64; number of investigator reports to the sponsor, including progress reports, safety reports, final reports, and financial disclosure reports	2,728	3.816	10,411	24	249,864

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN FOR BIOLOGICS [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
§ 312.70; disqualification of a clinical investigator by FDA	5	1	5	40	200
Subtotal Subpart D CBER			20,980		1,021,944
Subpart F—Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); number of written certifications and written statements submitted to FDA relating to the export of an investigational drug	18	1	18	75	1,350
§ 312.120(b); number of submissions to FDA of "supporting information" related to the use of foreign clinical studies not conducted under an IND	280	9.82	2,750	32	88,000
§ 312.120(c); number of waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	7	2.29	16	24	384
§ 312.130; number of requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	350	1.342	470	8	3,760
Subtotal Subpart F CBER			3,254		93,494
Total			48,179		6,694,050

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

TABLE 2—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR BIOLOGICS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart D—Responsibilities of Sponsors and Investigators: §§ 312.50 through 312.70					
§ 312.52(a); sponsor records for the transfer of obligations to a contract research organization.	94	2.26	212	2	424
§ 312.57; sponsor recordkeeping showing the receipt, shipment, or other disposition of the investigational drug, and any financial interest.	335	2.70	904	100	90,400
§ 312.62(a); investigator recordkeeping of the disposition of drugs	453	1	453	40	18,120
§ 312.62(b); investigator recordkeeping of case histories of individuals	453	1	453	40	18,120
Subtotal Subpart D CBER			2,022		127,064
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	111	1.40	155	0.5 (30 minutes)	78
§ 312.160(c) shipper records of alternative disposition of unused drugs	111	1.40	155	0.5 (30 minutes)	78
Subtotal Subpart G CBER			310		156
Total			2,332		127,220

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

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart A—General Provisions					
§ 312.2(e); requests for FDA advice on the applicability of part 312 to a planned clinical investigation	419	1	419	24	10,056
§ 312.8; requests to charge for an investigational drug	25	1.28	32	48	1,536
§ 312.10; requests to waive a requirement in part 312	68	1.5	102	24	2,448
Subtotal Subpart A Center for Drug Evaluation and Research (CDER)			553		14,040
Subpart B—Investigational New Drug Application (IND)					
§ 312.23(a) through (f); IND content and format (including Forms FDA 1571 and 3674)	4,886	1.4662	7,164	300	2,149,200
§ 312.30(a) through (e); protocol amendments	11,847	3.2367	38,346	284.25	10,899,850
§ 312.31(b); information amendments	8,094	3.30899	26,783	100	2,678,300
§ 312.32(c) and (d); IND safety reports	892	15.848	14,137	32	452,384
§ 312.33(a) through (f); IND annual reports	3,777	2.9097	10,990	360	3,956,400
§ 312.38(b) and (c); notifications of withdrawal of an IND	1,549	1.834	2,841	28	79,548
§ 312.145; Guidance Documents:					
Establishment and Operation of Clinical Trial Data Monitoring Committees (2006)	37	32.027	1,185	1.515	1,795
Special Protocol Assessment (2018)—Notification for Carcinogenicity Protocols	106	1.78	189	8	1,510
Requests for Special Protocol Assessment Reports	113	1.03	116	15	1,740
Subtotal Subpart B CDER			101,751		20,220,727

TABLE 3—ESTIMATED ANNUAL REPORTING BURDEN FOR HUMAN DRUGS [1]—Continued

21 CFR section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Subpart C—Administrative Actions: §§ 312.40 through 312.48					
§ 312.42; clinical holds and requests for modifications	181	1.28	232	284	65,888
§ 312.44(c) and (d); sponsor responses to FDA when IND is terminated	1	1	1	16	16
§ 312.45(a) and (b); sponsor requests for or responses to an inactive status determination of an IND by FDA	213	1.72	367	12	4,404
§ 312.47; meetings, including ''End-of-Phase 2'' meetings and ''Pre-NDA'' meetings	174	2.885	502	160	80,320
Subtotal Subpart C CDER			1,102		150,628
Subpart D—Responsibilities of Sponsors and Investigators					
§ 312.54(a); sponsor submissions to FDA concerning investigations involving an exception from informed consent under § 50.24	7	1.14	8	48	384
§ 312.54(b); sponsor notifications to FDA and others concerning an institutional review board determination that it cannot approve research because it does not meet the criteria in the exception from informed consent in § 50.24(a)	2	1	2	48	96
§ 312.56; review of ongoing investigations and associated notifications	4,570	5.4689	24,993	80	1,999,440
§ 312.58; inspection of records and reports by FDA	73	1	73	8	584
§ 312.70; disqualification of a clinical investigator by FDA.	5	1	5	40	200
Subtotal Subpart D CDER			25,081		2,000,704
Subpart F—Miscellaneous: §§ 312.110 through 312.145					
§ 312.110(b)(4) and (b)(5); written certifications and written statements submitted to FDA relating to the export of an investigational drug	8	22.375	179	75	13,425
§ 312.120(b); submissions to FDA of ''supporting information'' related to the use of foreign clinical studies not conducted under an IND	1,964	7.352	14,440	32	462,080
§ 312.120(c); waiver requests submitted to FDA related to the use of foreign clinical studies not conducted under an IND	68	1.5	102	24	2,448
§ 312.130; requests for disclosable information in an IND and for investigations involving an exception from informed consent under § 50.24	3	1	3	8	24
§ 312.145; Guidance Documents:					
Oversight of Clinical Investigations (2013)	88	1.5	132	4	528
Pharmacogenomic Data Submissions (2005)	1	1	1	50	50
Adaptive Designs for Clinical Trials of Drugs and Biologics (2019)	55	4.727	260	50	13,000
E6(R2) Good Clinical Practice: Integrated Addendum to ICH E6(R1) (2018)	1,880	4.916	9,242	15.012	138,744
Subtotal Subpart F CDER			24,359		630,299
§ 300.200; Right to try reporting requirements; submission of annual summary report using Form FDA 5023	10	1	10	2.5	25
Total			152,856		23,016,423

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

TABLE 4—ESTIMATED ANNUAL RECORDKEEPING BURDEN FOR HUMAN DRUGS [1]

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeeper	Total annual records	Average burden per recordkeeping	Total hours
Subpart D—Responsibilities of Sponsors and Investigators					
§ 312.52(a); transfer of obligations to a contract research organization	466	3.107	1,448	300	434,400
§ 312.57; records showing the receipt, shipment, or other disposition of the investigational drug and any financial interests.	13,000	1	13,000	100	1,300,000
§ 312.62(a); records on disposition of drugs	13,000	1	13,000	40	520,000
§ 312.62(b); records on case histories of individuals	2,192	6.587	14,439	40	577,560
Subtotal Subpart D CDER			41,887		2,831,960
Subpart G—Drugs for Investigational Use in Laboratory Research Animals or In Vitro Tests					
§ 312.160(a)(3); records pertaining to the shipment of drugs for investigational use in laboratory research animals or in vitro tests.	547	1.43	782	0.50 (30 minutes)	391
§ 312.160(c); shipper records of alternative disposition of unused drugs	547	1.43	782	0.50 (30 minutes)	391
Subtotal			1,564		782
Total			43,451		2,832,742

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

Based on a review of the information collection since our last request for OMB approval, we have retained the annual burden estimates for the majority of these activities. However, our estimated burden for the information

collection reflects an overall increase of 22 hours. We attribute the increase to the correction of an inadvertent error in the reported hours for 21 CFR 300.200, which requires the submission of an annual report on Form FDA 5023 by sponsors and manufacturers who provide an ''*eligible investigational drug*'' under the Right to Try Act.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–04938 Filed 3–12–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–4942]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Mammography Standards Quality Act Requirements

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 April 13, 2026.

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 0910–0309.

FOR FURTHER INFORMATION CONTACT: Amber Barrett, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Mammography Quality Standards Act Requirements—21 CFR Part 900

OMB Control Number 0910–0309—Extension

The Mammography Quality Standards Act (Pub. L. 102–539) requires the establishment of a Federal certification and inspection program for mammography facilities; standards for accreditation and certification bodies for mammography facilities; and standards for mammography equipment, personnel, and practices, including quality assurance. Implementing regulations are found in part 900 (21 CFR part 900). The regulations are intended to assure safe, reliable, and accurate mammography on a nationwide level. Under the regulations, as a first step in becoming certified, mammography facilities must become accredited by an FDA-approved accreditation body (AB). This requires undergoing a review of their clinical images and providing the AB with information showing that they meet the equipment, personnel, quality assurance, and quality control standards, and have a medical reporting and recordkeeping program, a medical outcomes audit program, and a consumer complaint mechanism. On the basis of this accreditation, facilities are then certified by FDA or an FDA-approved State certification agency and must prominently display their certificate. These actions are taken to ensure safe, accurate, and reliable mammography on a nationwide basis.

FDA meets with its National Mammography Quality Assurance Advisory Committee (NMQAAC) for the purposes of advising FDA's mammography program on advances in mammography technology and procedures and on appropriate quality standards for mammography facilities. NMQAAC is made up of representatives of the mammography community, consumer and industry groups, and government. The meetings are open to the public and time is allotted for public statements on issues of concern in the mammography field. The chairperson may also call upon attendees to contribute to the committee discussions.

FDA also regularly meets or holds teleconferences with its approved accreditation bodies and State certification agencies to discuss issues of mutual concern. We also engage with the Conference of State Radiation Program Directors (CRCPD), a professional organization of State agencies concerned with radiation protection. The CRCPD has established a standing Mammography Committee, which meets with FDA mammography staff at least once a year.

Finally, in recent years, FDA mammography staff have met several times with representatives of manufacturers working on the new applications of digital technology in mammography to resolve problems preventing the making of that technology generally available. FDA mammography staff have also worked with representatives of the manufacturers to develop quality assurance manuals for full field digital mammography units.

In the **Federal Register** of December 9, 2025 (90 FR 57070), FDA 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

Activity/21 CFR section/FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
PART 900, MAMMOGRAPHY					
Subpart A, Accreditation					
Notification of intent to become an AB—900.3(b)(1)	0.33	1	0.33	1	1
Application for approval as an AB; full [2]—900.3(b)(3)	0.33	1	0.33	320	106
Application for approval as an AB; limited [3]—900.3(b)(3)	5	1	5	30	150
AB renewal of approval—900.3(c)	1	1	1	15	15
AB application deficiencies—900.3(d)(2)	0.1	1	0.1	30	3
AB resubmission of denied applications—900.3(d)(5)	0.1	1	0.1	30	3
Letter of intent to relinquish accreditation authority—900.3(e)	0.1	1	0.1	1	1
Summary report describing all facility assessments—900.4(f)	338	1	338	7	2,366