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: Patrick Clouser, Office of the Commissioner, Food and Drug Administration, 240–402–5276.

SUPPLEMENTARY INFORMATION:

I. Background

The Drug Price Competition and Patent Term Restoration Act of 1984 (Pub. L. 98–417) and the Generic Animal Drug and Patent Term Restoration Act (Pub. L. 100–670) generally provide that a patent may be extended for a period of up to 5 years so long as the patented item (human drug or biological product, animal drug product, medical device, food additive, or color additive) was subject to regulatory review by FDA before the item was marketed. Under these acts, a product's regulatory review period forms the basis for determining the amount of extension an applicant may receive.

A regulatory review period consists of two periods of time: a testing phase and an approval phase. For human drug products, the testing phase begins when the exemption to permit the clinical investigations of the drug becomes effective and runs until the approval phase begins. The approval phase starts with the initial submission of an application to market the human drug product and continues until FDA grants permission to market the drug product. Although only a portion of a regulatory review period may count toward the actual amount of extension that the Director of USPTO may award (for example, half the testing phase must be subtracted as well as any time that may have occurred before the patent was issued), FDA's determination of the length of a regulatory review period for a human drug product will include all of the testing phase and approval phase as specified in 35 U.S.C. 156(g)(1)(B).

FDA has approved for marketing the human drug product, BIZENGRI (zenocutuzumab-zbco). BIZENGRI is indicated for the treatment of adults with advanced unresectable or metastatic non-small cell lung cancer (NSCLC) harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). BIZENGRI is indicated for the treatment of adults with advanced unresectable or metastatic pancreatic adenocarcinoma harboring a neuregulin 1 (NRG1) gene fusion with disease progression on or after prior systemic therapy. This indication is approved under accelerated approval based on overall response rate and duration of response. Continued approval for this indication may be contingent upon verification and description of clinical benefit in a confirmatory trial(s). Subsequent to this approval, the USPTO received a patent term restoration application for BIZENGRI (U.S. Patent Nos. 9,248,181; 10,329,596; 11,279,770; 11,780,925; and 12,139,548) from Merus N.V. and the USPTO requested FDA's assistance in determining the patent's eligibility for patent term restoration. In a letter dated 10/8/2025, FDA advised the USPTO that this human drug product had undergone a regulatory review period and that the approval of BIZENGRI represented the first permitted commercial marketing or use of the product. Thereafter, the USPTO requested that FDA determine the product's regulatory review period.

II. Determination of Regulatory Review Period

FDA has determined that the applicable regulatory review period for BIZENGRI is 2,909 days. Of this time, 2,634 days occurred during the testing phase of the regulatory review period, while 275 days occurred during the approval phase. These periods of time were derived from the following dates:

1. *The date an exemption under section 505(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 355(i)) became effective:* 12/16/2016. FDA has verified the applicant's claim that the date the investigational new drug application became effective was 12/16/2016.

2. *The date the application was initially submitted with respect to the human biological product under section 351 of the Public Health Service (PHS) Act:* 3/4/2024. FDA has verified the applicant's claim that the biological license application (BLA) for BIZENGRI (BLA 761352) was initially submitted on 3/4/2024.

3. *The date the application was approved:* 12/4/2024. FDA has verified the applicant's claim that BLA 761352 was approved on 12/4/2024.

This determination of the regulatory review period establishes the maximum potential length of a patent extension. However, the USPTO applies several statutory limitations in its calculations of the actual period for patent extension. In its application for patent extension, this applicant seeks 1,594 days, 1,133 days, 633 days, 23 days, or 23 days, respectively, of patent term extension.

III. Petitions

Anyone with knowledge that any of the dates as published are incorrect may submit either electronic or written comments and, under 21 CFR 60.24, ask for a redetermination (see **DATES**). Furthermore, as specified in § 60.30 (21 CFR 60.30), any interested person may petition FDA for a determination regarding whether the applicant for extension acted with due diligence during the regulatory review period. To meet its burden, the petition must comply with all the requirements of § 60.30, including but not limited to: must be timely (see **DATES**), must be filed in accordance with § 10.20, must contain sufficient facts to merit an FDA investigation, and must certify that a true and complete copy of the petition has been served upon the patent applicant. (See H. Rept. 857, part 1, 98th Cong., 2d sess., pp. 41–42, 1984.) Petitions should be in the format specified in 21 CFR 10.30.

Submit petitions electronically to *https://www.regulations.gov* at Docket No. FDA–2013–S–0610. Submit written petitions (two copies are required) to the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16713 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

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) 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 16, 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 0910–0014. 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:

Investigational New Drug Application Requirements—21 CFR Part 312

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 (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. Other updates include the addition of fields necessary for ensuring compliance with enhancing security for human biospecimens. 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.* For information regarding updated FDA forms, including Forms FDA 1571 and 1572 visit *https://www.fda.gov/about-fda/forms/new-and-updated-fda-forms.*

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.*

In the **Federal Register** of March 13, 2026 (91 FR 12422) we published a 60-day notice requesting public comment on the proposed collection of information. Three comments were received all offering general support for the information collection. Two comments pertained to FDA rulemaking (RIN 0910–AH07, Docket No. FDA–2019–N–2650) proposing to amend regulations on investigational new drug applications (INDs) to exempt from the IND requirements certain clinical investigations of lawfully marketed foods for human consumption (including both conventional foods and dietary supplements) and cosmetics when the product is to be studied to evaluate its use as a drug. While the comments fall beyond the scope of the information collection topics solicited in our 60-day notice in accordance with 5 CFR 1320.8(d)(1), we have added the comments to the respective rulemaking docket for Agency consideration.

A third comment suggested FDA increase its estimate for effort attributable to reporting elements under 21 CFR parts 312.23 and 312.33, explaining that certain first time applicants may incur more burden that our figures suggest. We acknowledge that individual respondents may incur greater than or less than the estimate proffered, however, consistent with 5 CFR 1320.5(a)(1)(iv), figures are cumulative and averaged among respondents. The comment also recommended specific automated improvements that might facilitate the submission of IND applications. As announced in the **Federal Register** of June 24, 2026 (91 FR 37996; Docket No. 2026–N–4699), FDA is inviting comment on a proposed IND pilot program. At the conclusion of the pilot, we intend to identify potential refinements to the IND review process targeting those we can address with our limited resources.

FDA greatly appreciates the comments it received, however we have made no changes to our estimates, which are 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

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
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
§ 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
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

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
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 recordkeepers	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

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

21 CFR section; activity	Number of recordkeepers	Number of records per recordkeepers	Total annual records	Average burden per recordkeeping	Total hours
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.

While we have corrected an inadvertent calculation error pertaining to 21 CFR 300.200, we have otherwise retained the currently approved estimates attributable to IND requirements. We also note that reporting activities applicable to the ''Right to Try'' provisions began in 2020 and we continue to monitor the information collection activity.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–16715 Filed 8–14–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket Nos. FDA–2025–N–1560; FDA–2021–N–1351; FDA–2025–N–2549; FDA–2025–N–0426; FDA–2026–N–0746; FDA–2026–N–0497; FDA–2025–N–0953; FDA–2024–N–4467; FDA–2025–N–4942; FDA–2025–N–2195; FDA–2025–N–0354; FDA–2025–N–3215; FDA–2025–N–1108; FDA–2025–N–0419; FDA–2025–N–1210; FDA–2025–N–0414; FDA–2025–N–1115; FDA–2025–N–1109; FDA–2025–N–1330; FDA–2024–N–5943; FDA–2025–N–0351; FDA–2025–N–3656; FDA–2025–N–2220; FDA–2024–N–5890; FDA–2012–D–0429; FDA–2025–N–0348; FDA–2025–N–1812; FDA–2025–N–2548; FDA–2025–N–4348; FDA–2024–N–1055; FDA–2025–N–0615; FDA–2024–N–3762; FDA–2023–N–0894; FDA–2025–N–0308; FDA–2024–N–0668; FDA–2025–N–1732]

Agency Information Collection Activities; Announcement of Office of Management and Budget Approvals

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is publishing a list of information collections that have been approved by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995.

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SUPPLEMENTARY INFORMATION: The following is a list of FDA information collections recently approved by OMB under section 3507 of the Paperwork Reduction Act of 1995 (44 U.S.C. 3507). The OMB control number and expiration date of OMB approval for each information collection are shown in table 1. Copies of the supporting statements for the information collections are available on the internet at *https://www.reginfo.gov/public/do/PRAMain.* An Agency may not conduct or sponsor, and a person is not required to respond to, a collection of information unless it displays a currently valid OMB control number.

TABLE 1—LIST OF INFORMATION COLLECTIONS APPROVED BY OMB

Title of collection	OMB control number	Date approval expires
Electronic Products Requirements	0910–0025	5/31/2029
Registration of Producers of Drugs and Listing of Drugs in Commercial Distribution	0910–0045	5/31/2029
Investigational Device Exemptions	0910–0078	5/31/2029
Agreement for Shipments of Devices for Sterilization	0910–0131	6/30/2029
Current Good Manufacturing Practice (CGMP): Manufacturing, Processing, Packing, and Holding of Drugs; GMP for Finished Pharmaceuticals (Including API), and AMT Designation	0910–0139	7/31/2029
Patent Term Restoration, Due Diligence Petitions, Filing, Format, and Content of Petitions	0910–0233	7/31/2029
Export of Medical Devices; Foreign Letters of Approval	0910–0264	3/31/2029
Prescription Drug User Fee Program	0910–0297	1/31/2029
Mammography Standards Quality Act Requirements	0910–0309	5/31/2029
Medical Devices; Humanitarian Use Devices	0910–0332	6/30/2029
Substances Prohibited from Use in Animal Food or Feed; Animal Proteins Prohibited in Ruminant Feed	0910–0339	5/31/2029
Food Safety, Health, and Diet Survey	0910–0345	3/31/2029
510(k) Third-Party Review Program	0910–0375	6/30/2029
Medical Device Reporting	0910–0437	2/28/2029
Postmarket Surveillance of Medical Devices	0910–0449	6/30/2029