UNITED STATES FOOD AND DRUG ADMINISTRATION

Investigational New Drug Regulations

OMB Control No. 0910-0014 – Revision

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

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 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 FDA with 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.

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:

- "*Establishment and Operation of Clinical Trial Data Monitoring Committees*" guidance (March 2006);
- "*Special Protocol Assessment*" guidance (April 2018).
- "*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. FDA prepares annual agendas, inviting public participation in the guidance development process, consistent with these provisions.

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 are therefore requesting OMB approval of the information collection provisions accordingly, and as discussed in this supporting statement.

2. Purpose and Use of the Information Collected

The information provides a means for sponsors of clinical trials involving human drugs and biological products to implement improved and more-efficient approaches to manage quality throughout all stages of the clinical trial process while continuing to ensure the protection of human subjects and the reliability of trial results.

3. Use of Improved Information Technology and Burden Reduction

We encourage electronic submission of the information required under parts 312, 314, and 601 and have developed several guidance documents describing the process for submitting information to us in electronic format. These guidance documents and others are available on our website at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm.

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. As part of the proposed pilot, FDA is exploring the use of a rolling submission platform that would allow FDA to review QRI recommendations regarding completed components of the IND submission on a rolling basis. Similar to the rolling review of an NDA or BLA under FDA's expedited review programs, this approach would facilitate FDA review of completed individual IND components prior to formal IND submission. Once the last component of the Phase 1 IND is submitted, the IND would be considered submitted such that the 30-day IND review clock starts. Since all the IND submission components would have been reviewed by FDA on a rolling basis, the sponsor may receive a safe to proceed notification before the 30-day IND review period ends. The rolling review could minimize the need for FDA to impose a clinical hold because it would provide an earlier opportunity for FDA to identify deficiencies, prior to the 30-day review period starting. Similarly, the rolling review could minimize the need for FDA to issue a clinical hold or information request. The pilot aims to test whether these processes may accelerate Phase 1 FIH study initiation.

Additionally, FDA intends to work with sponsors and QRIs to review and refine QRI performance objectives and key deliverables as part of the pilot, with the goal of gathering information that could inform a potential process for establishing a process for QRI certification by FDA. FDA will monitor and evaluate QRI performance through clearly defined metrics. FDA will implement a new technology platform to perform a rolling IND submission by submitting individual IND components and receiving FDA feedback in real time.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

Information collection recommendations found in the guidance apply to both small and large businesses. We routinely aid small businesses in complying with Agency requirements through its Regional Small Business Representatives and through the scientific and administrative staffs within the Agency. We have provided a Small Business Assistance on the Agency's website at https://www.fda.gov/industry/small-business-assistance.

6. Consequences of Collecting the Information Less Frequently

We believe the recommended reporting and recordkeeping schedules found in the guidance represent minimal burden on respondents. Less frequent collection might undermine important oversight regarding implementation of clinical trials.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

This information collection is consistent with the requirements of 5 CFR 1320.5.

8. Comments in Response to the *Federal Register* Notice and Efforts to Consult Outside the Agency

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.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is associated with the information collection.

10. Assurance of Respondent Privacy and Confidentiality

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. This ICR collects personally identifiable information (PII). PII is collected in the context of the subject individuals' professional capacity and the FDA-related work performed for their employer (e.g., point of contact at a regulated entity). The PII is collected using the Electronic Submission Gateway and includes a username and password. FDA determined that although PII is collected, the collection is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate form and webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under FOIA (5 U.S.C. 552), the public has broad access to government documents. However, FOIA provides certain exemptions from mandatory public disclosure of government records (5 U.S.C. 552(b)(1-9)). FDA will make the fullest possible disclosure of records to the public, consistent with the rights of individuals to privacy, the property rights of persons in trade and confidential commercial or financial information.

11. Justification for Sensitive Questions

There are no questions of a sensitive nature associated with the information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden for Biologics[1]

21 CFR Section; Activity	No. of Respondents	No. 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
§ 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	No. of Recordkeepers	No. 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	No. of Respondents	No. 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 Requests for Special Protocol Assessment Reports	106 113	1.78 1.03	189 116	8 15	1,510 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
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	2	1	2	48	96

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)					
§ 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	No. of Recordkeepers	No. 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.

12b. Annualized Cost Burden Estimate

Using a fully loaded wage rate of $156 per hour for regulatory personnel that would be engaged in the information collection and multiplying that by the total number of hours (138,744), we calculate the annual cost to respondents for the information collection as $21,644,064.

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no capital expenditures or start-up, operating, or maintenance costs associated with this information collection.

14. Annualized Cost to the Federal Government

We estimate no change in annual costs of administering the IND program.

15. Explanation for Program Changes or Adjustments

Although we have made no changes to the individual or cumulative burden estimates, we have revised **Form FDA 1571** (IND Application) as discussed in Q-1. Specifically, we have updated the form 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. We are also updating the form to include the addition of fields necessary for ensuring compliance with enhancing security for human biospecimens consistent with

Preventing Access to Americans' Bulk Sensitive Personal Data and United States Government-Related Data by Countries of Concern (E.O. 14117) (89 FR 15421).

We have also developed the form entitled, "*Expedited IND Pilot Program; Application for Pilot Participation – HHS Operation Trialblazer*," for limited-time use for those electing to submit the form. We announced a request for information and the establishment of public docket FDA-2026-N-4699 to begin evaluating targeting submission points for potential process improvements. We discuss this effort and provide more information including agency webinars at FDA Actions to Accelerate and Modernize Early and Late-Stage Clinical Development | FDA. We developed the form to facilitate participation in the pilot.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no publications or other schedules.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

We display the OMB expiration date as required by 5 CFR 1320.5.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification statement.