

UNITED STATES FOOD & DRUG ADMINISTRATION

Investigational New Drug Applications:
Annual Reporting
Agency Rulemaking: **RIN 0910-AH37**

OMB Control No. - NEW

SUPPORTING STATEMENT – **Part A: Justification:**

1. Circumstances Making the Collection of Information Necessary

In the Federal Register of October 11, 1995 (60 FR 53078), we published a notice entitled, “*International Harmonization, Policy on Standards*” that described FDA’s policy for working with other countries to achieve greater harmonization of regulatory requirements and guidelines. It also described FDA’s views on international harmonization and collaboration as a way to enhance regulatory effectiveness by providing more consumer protection without added expenditure of government resources. Harmonization and collaboration can also increase worldwide consumer access to safe, effective, and high-quality products. This information collection supports Food and Drug Administration (FDA, us or we) rulemaking **RIN 0910-AH37** we are proposing to replace the current annual reporting requirement for investigational new drug applications (INDs) with the annual FDA development safety update report (FDA DSUR). The proposed annual FDA DSUR is intended to be consistent with the format and content of the DSUR that is supported by the International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use (ICH), described in FDA’s ICH guidance for industry entitled “E2F Development Safety Update Report” (E2F DSUR) (August 2011). The proposed annual FDA DSUR regulation, if finalized, would require an annual report that is more comprehensive and informative than the IND annual report currently required under FDA regulations. Specifically the rule revises 21 CFR part 312.33 – *Annual Reports*.

We therefore request approval for the information collection modifications in 21 CFR 312.33 resulting from the rulemaking and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

We believe the proposed annual FDA DSUR will provide greater utility over the current IND annual report by enabling us to identify and review new safety signal information; by creating a more efficient reporting process for certain sponsors by supporting a more comprehensive format for submission to FDA and multiple regulatory authorities worldwide; and by allowing regulatory authorities worldwide to have access to the same data within the same timeframes more efficiently. Furthermore, we believe implementing reporting requirements similar to those used internationally could help sponsors who need to satisfy annual reporting requirements in different countries and regions and would help prevent sponsors from sending duplicative information in different formats to different regulatory authorities. A similar annual reporting

requirement would also help provide authorities in different countries with a common description of the evolving safety profile of a drug, and thus, could help ensure greater consistency and predictability in regulatory actions. We expect that the proposed annual FDA DSUR would help harmonize FDA's requirements for IND annual reporting with the E2F DSUR.

Description of Respondents: Respondents to the information collection are individuals and organizations who plan to conduct or sponsor a clinical investigation evaluating a drug use of a product lawfully marketed in the United States as a conventional food, dietary supplement, or cosmetic for human use.

3. Use of Improved Information Technology and Burden Reduction

We utilize the “*Electronic Submission Gateway*” (ESG) to receive most submissions. We encourage respondents to prepare submissions in an “*Electronic Common Technical Document*” (eCTD) format, a standardized format for applications, amendments, supplements, and reports to FDA's Center for Biologics Evaluation and Research (CBER) and Center for Drug Evaluation and Research (CDER). In this way, reviewers can easily find and access requisite information, whether part of an original submission or an amendment. We continue to develop and provide resources for submitting information to FDA using the ESG, including the fact sheet available at <https://www.fda.gov/media/98901/download>.

Additionally, we utilize administrative cover sheets pursuant to 21 CFR 312.23, which sets forth format and content requirements, to facilitate the processing of submissions. Cover sheets are included within the “*Administrative Module*” of the eCTD. We also provide resource information regarding eCTD technical specifications and submission requirements. We estimate 76% of IND submissions will be completed electronically. We are unaware of any legal or technological obstacles to reducing burden.

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

The information collection poses no undue impact on small entities. We have conducted a preliminary regulatory impact analysis in support of the proposed rulemaking.

6. Consequences of Collecting the Information Less Frequently

The information collection is consistent with statutory and regulatory requirements.

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

There are no special circumstances for this collection of information.

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

In accordance with 5 CFR 1320.11, we published a proposed rule in the Federal Register of December 9, 2022 (87 FR 75551) that included an analysis under the PRA and solicited public comment on the proposed information collection.

9. Explanation of Any Payment or Gift to Respondents

This information collection does not provide any payments or gifts to respondents.

10. Assurance of Confidentiality Provided to Respondents

Consistent with 5 CFR 1320.5(d)(2)(vii), data will be kept private to the extent allowed by law:

The Privacy Act of 1974

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although this ICR collects personally identifiable information (PII), it 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 submitted via Form FDA 1571 (Investigational New Drug Application (IND)) is name, address, telephone number, fax number, and email address. The PII submitted via Form FDA 1572 (Statement of Investigator) is name, address, and education. The PII submitted via Form FDA 3926 (Individual Patient Expanded Access Investigational New Drug Application (IND)) is patient's initials, brief medical history, physician's name, physician's IND number, address, email address, telephone number, and fax number.

The PII submitted via Form FDA 3674 (Certification of Compliance) is name, address, country, telephone number, and fax number. Sometimes investigators include Form FDA 3455 (Disclosure: Financial Interests and Arrangements of Clinical Investigators). The PII submitted via Form FDA 3455 is name, title, and financial information. We have determined that the PII collected is not subject to the Privacy Act of 1974 and the particular notice and other requirements of the Privacy Act do not apply. Specifically, FDA does not use names or any other personal identifiers to routinely retrieve records from the information collected. FDA minimizes the PII collected to protect the privacy of the individuals.

The Freedom of Information Act (FOIA)

Under the Freedom of Information Act (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

This information collection does not include questions that are of a personally sensitive nature.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden for Human Drugs Regulated by CDER¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 312.33	2,877	3.38	9,736	396	3,855,456

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

Table 2.--Estimated Annual Reporting Burden for Human Drugs Regulated by CBER¹

21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
§ 312.33 – annual reports	745	2.49	1,856	396	734,976

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

Note: The Total Annual Responses may not sum up as a result of rounding.

12b. Annualized Cost Burden Estimate

Costs of implementation are discussed in our analysis of impacts statement submitted with this ICR.

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

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

14. Annualized Cost to the Federal Government

We assume costs to the Federal government will be reflected in additional review hours, albeit offset by industry user fees. We estimate \$1,000,000 for costs of rulemaking.

15. Explanation for Program Changes or Adjustments

The proposed rulemaking would add 11,592 responses and 4,595,190 hours annually to FDA's active information collection inventory.

16. Plans for Tabulation and Publication and Project Time Schedule

The information from this collection will not be published or tabulated.

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

Displaying the OMB approval date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.