UNITED STATES FOOD & DRUG ADMINISTRATION

Investigational New Drug Applications;
Exemptions for Clinical Investigations to Evaluate a Drug Use of a Product Lawfully Marketed as a Conventional Food, Dietary Supplement, or Cosmetic

Agency Rulemaking: **RIN 0910-AH07**

OMB Control No. - NEW

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

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA, us or we) rulemaking **RIN 0910-AH07**. We are taking this action to exempt 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, from the IND requirements. As communicated in our rulemaking, under the proposal, clinical studies to evaluate a drug use of such products would not have to be conducted under an IND when, among other things, the study is not intended to support a drug development plan or a labeling change that would cause the lawfully marketed product to become an unlawfully marketed drug, and the study does not present a potential for significant risk to the health, safety, or welfare of subjects. Though exempt from the IND requirements, such investigations would still be subject to other regulations designed to protect the rights and safety of subjects, including requirements for informed consent and review by institutional review boards (IRBs). By exempting from the IND requirements certain clinical investigations of products lawfully marketed as a food or cosmetic, the proposed provisions are intended to reduce the regulatory burden of conducting such studies while retaining protections for human subjects.

Specifically the rule revises 21 CFR part 312.2 - *Applicability*:

- Under the self-determined exemption, if a clinical investigation to evaluate a drug use of a product lawfully marketed in the United States as a food or cosmetic meets the criteria, the study would be exempt from the IND regulations.

- Under the "*FDA-determined exemption*," the sponsor of a clinical investigation could request FDA to exempt the investigation from the IND requirements if the investigation meets the self-determined exemption criteria. Upon receiving such a request for exemption from the IND requirements, FDA would evaluate any risks to subjects and would grant an exemption if we found that the investigation did not present a potential for significant risk (or decrease the acceptability of the risks) to the health, safety, or welfare of subjects.

- The proposal also would authorize FDA to exempt a study from the IND requirements

on our own initiative if we determined, upon review of an IND for the study, that the study met the decision criteria for an FDA-determined exemption.

- The proposal also provides for FDA revocation of the exemption as set forth in the revised regulation.

We therefore request approval for the information collection modifications in 21 CFR 312 resulting from the rulemaking and discussed in this supporting statement.

2. Purpose and Use of the Information Collection

Adopting these proposed IND exemptions would reduce the burden of conducting certain clinical investigations evaluating drug uses of products lawfully marketed as foods or cosmetics, as well as the Agency's burden of reviewing such studies, without eliminating requirements that help ensure the safety of subjects and the quality of data submitted in support of drug product approval.

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 75536) 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[1]

21 CFR Part	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
312.2(b)(5); Written request for exemption	28	1	28	24	672

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

12b. Annualized Cost Burden Estimate

Costs to respondents are discussed in our Preliminary Regulatory Impact Analysis (PRIA) submitted with this supporting statement.

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 $1,000,000 for costs of rulemaking.

15. Explanation for Program Changes or Adjustments

The proposed rulemaking would add 672 hours and 28 responses to FDA's active 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.