UNITED STATES FOOD & DRUG ADMINISTRATION

Right to Try Act of 2017:
Reporting Requirements

OMB Control No. 0910-NEW

SUPPORTING STATEMENT **Part A – Justification**:

1. Circumstances Making the Collection of Information Necessary

   This information collection supports proposed rulemaking intended to implement The Right to Try Act of 2017. The Right to Try Act amended Chapter V of the Federal Food Drug and Cosmetic Act (FD&C Act) by adding section 561B (21 U.S.C. 360bbb-0), which provides for the submission of an annual summary of the use of eligible investigational drug by sponsors or manufacturers (21 U.S.C. 360bbb-0a). The proposed rule would add subpart D to our regulations in 21 CFR part 300 pertaining to general drug provisions.

   Under Right to Try, patients may request and sponsors or manufacturers may elect to provide, access to certain unapproved, investigational drugs and biological products for patients diagnosed with life-threatening diseases or conditions who have exhausted approved treatment options and who are unable to participate in a clinical trial involving the investigational drug. This includes an investigational drug or biological product:

   - for which a Phase 1 clinical trial has been completed (section 561B(a)(2)(A));
   - that has not been approved or licensed for any use by the FDA (section 561B(a)(2)(B));
   - for which an application has been filed with the FDA or is under investigation in a clinical trial that is intended to form the primary basis of a claim of effectiveness in support of FDA approval or licensure and is the subject of an active investigational new drug application submitted to the FDA (section 561B(a)(2)(C)); and
   - whose active development or production is ongoing, and that has not been discontinued by the manufacturer or placed on clinical hold by the FDA (section 561B(a)(2)D)).

   We therefore request OMB approval for the information collection provisions set forth in our proposed rulemaking establishing reporting requirements under 21 CFR part 300, subpart D.

2. Purpose and Use of the Information Collection

   We are taking this action to provide a pathway for eligible patients to request access to investigational drugs under certain conditions, as governed by section 561B.

3. Use of Improved Information Technology and Burden Reduction

   Because associated regulations require the electronic submission of information, we expect 100% of respondents will utilize electronic means to satisfy the reporting requirements.

4. Efforts to Identify Duplication and Use of Similar Information

   We are unaware of duplicative information collection. The proposed rule would add new subpart D to 21 CFR part 300 to specify the deadline and content for submission of an annual summary of use under section 561B of the FD&C Act.

5. Impact on Small Businesses or Other Small Entities

   No small businesses will be impacted by the information collection.

6. Consequences of Collecting the Information Less Frequently

   The information collection schedule is consistent with current statutory and proposed 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

   As required by section 44. U.S.C. 3506(c)(2)(B), we invited public comment on the proposed collection of information in the *Federal Register* of July 24, 2020 (85 FR 44803).

9. Explanation of Any Payment or Gift to Respondents

   No remuneration is provided to respondents to the information collection.

10. Assurance of Confidentiality Provided to Respondents

    Although patient information is provided to determine criteria for eligibility, no personally identifiable information (PII) is used as a means of retrieval for the information collection, nor is this element included as part of respondent submissions. At the same time, we have consulted our Privacy Office and are conducting a comprehensive assessment under The Privacy Act of 1974.

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

The proposed rule would establish requirements for the deadline and content of an annual summary for sponsors and manufacturers who provide an eligible investigational drug for use by an eligible patient. We estimate that 6 sponsors and manufacturers would prepare and submit 1 annual summary and that it would take approximately 2.5 hours to prepare and submit each report. Our estimate is based on data and information discussed in Section VI. Preliminary Economic Analysis of Impacts of this document.

Table 1.--Estimated Annual Reporting Burden

21 CFR Citation; Type of Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
300.200; annual summaries from sponsors and manufacturers under the Right to Try Act	6	1	6	2.5 (150 minutes)	15

12b. Annualized Cost Burden Estimate

We calculate labor costs with the estimated 15 reporting hours described above. As discussed in Section VI. of our Preliminary Economic Analysis of Impacts, we estimate costs as the time sponsors and manufacturers would prepare and submit annual summaries based on eligible patients' requests for investigational new treatments. Assuming a fully-loaded industry wage rate of approximately $212.78 per hour, we estimate these costs as approximately $3,191.70

Table 2. – Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Medical and Health Services Managers in the Pharmaceutical and Medicine Manufacturing average wage grade for preparing and submitting this information collection	15	$212.78	$3,191.70

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

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

14. Annualized Cost to the Federal Government

Our estimated cost to the Federal Government reflects the allocation of 1 full-time employee who will review the annual summaries sent to FDA under 21 CFR 300, subpart D and assist the FDA web team with posting annual summaries on our website. Using a fully-loaded wage, meaning both salary and non-wage benefits, per employee for the Washington DC-Metropolitan area found at www.opm.gov, we calculate an annual cost of $284,299 for a GS-13-5.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

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

FDA will 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.