U.S. FOOD & DRUG ADMINISTRATION

ANNUAL SUMMARY REPORTING REQUIREMENTS
UNDER THE RIGHT TO TRY ACT: 21 CFR PART 300, SUBPART D

OMB Control No. 0910-0893 – NEW
RIN: 0910-AI36

SUPPORTING STATEMENT **Part A – Justification:**

1. Circumstances Making the Collection of Information Necessary

This information collection supports Food and Drug Administration (FDA) rulemaking pertaining to the submission to FDA of an annual summary of investigational drugs supplied under the Trickett Wendler, Frank Mongiello, Jordan McLinn, and Matthew Bellina Right to Try Act of 2017 (Right to Try Act). The rulemaking amends regulations in 21 CFR part 300 to add subpart D (21 CFR 300, subpart D), which sets forth requirements that include a submission schedule for reporting information to FDA, as well as prescribes specific content elements that must be included in the report. Authority for the requirements are found in section 561B (21 U.S.C. 360bbb-0), of the Federal Food, Drug, and Cosmetic Act. Specifically, 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:

(1) for which a Phase 1 clinical trial has been completed (section 561B(a)(2)(A));
(2) that has not been approved or licensed for any use by FDA (section 561B(a)(2)(B));
(3) for which an application has been filed with 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 FDA (section 561B(a)(2)(C)); and
(4) whose active development or production is ongoing, and that has not been discontinued by the manufacturer or placed on clinical hold by FDA (section 561B(a)(2)D)).

We therefore request OMB approval for the information collection provisions established under section 561B of the FD&C Act and implemented in 21 CFR part 300, subpart D.

2. Purpose and Use of the Information Collection

The information collection is intended to help support an established alternative option for patients who meet certain criteria to request access to certain unapproved drug products and for sponsors and manufacturers who agree to provide those certain unapproved drug products, other than through FDA's expanded access program. (Information collection associated with FDA's Expanded Patient Access Program is approved under OMB Control No. 0910-0814.)

3. Use of Improved Information Technology and Burden Reduction

Because associated regulations require the electronic submission of information, we expect that 100% of respondents will use electronic means to satisfy the reporting requirements. The information is submitted to an FDA-designated point of contact, consistent with 21 CFR 300.200. We are currently in the process of developing an electronic form to submit the information and will submit request for OMB review and approval accordingly.

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

We do not believe the information collection imposes undue impact on small businesses. We provide a detailed analysis of impacts in our rulemaking.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with current statutory and final regulatory requirements.

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

No special circumstances are associated with this collection of information.

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

As required by section 3506(c)(2)(B) of the Paperwork Reduction Act of 1995 (PRA), we published a proposed rule in the Federal Register of July 24, 2020 (85 FR 44803) inviting public comment, including comment on the proposed collection of information. The comments and FDA's response are discussed in the preamble of the final rule.

9. Explanation of Any Payment or Gift to Respondents

Respondents will not receive any payments or gifts as a result of this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted our Privacy Office to ensure appropriate identification and handling of information collected. Although the 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). While FDA is currently developing an electronic form to assist respondents with the submission of information, we do not expect reports before March 31, 2023.

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

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

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

21 CFR 300.200	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
Preparation and submission of annual summary report	6	1	6	2.5	15

Consistent with estimates found in section II.F of our Final Regulatory Impact Analysis (FRIA), we estimate that 6 sponsors and manufacturers will prepare and submit 6 annual summaries and assume that it takes 2.5 hours to prepare and submit each, which results in a total of 15 hours annually.

12b. Annualized Cost Burden Estimate

As discussed in Section VI. of our FRIA, we estimate costs as the time sponsors and manufacturers expend preparing and submitting to FDA annual summaries based on eligible patients' requests for investigational new treatments. Assuming a fully-loaded industry wage rate of approximately $197.56 per hour, we estimate these costs as approximately $2,963.40.

Table 2. – Estimated Annual Cost Burden

Type of Labor Category	Total Burden Hours	Hourly Wage Rate	Total Costs
Medical and health services managers in the pharmaceutical and medicine manufacturing labor costs	15	$197.56	$2,963.40

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

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

14. Annualized Cost to the Federal Government

Estimating the allocation of 1 full-time employee (FTE) to review annual summaries submitted to FDA and to coordinate their posting on our website, we calculate an annualized cost of $3,450. This assumes a wage rate for an FTE whose salary is commensurate with a GS-15 ($172,500) employee in the Washington DC-Metropolitan area, using wage and salary data from www.opm.gov. This also assumes the expenditure of 40 hours of labor costs per year.

15. Explanation for Program Changes or Adjustments

This is a new information collection.

16. Plans for Tabulation and Publication and Project Time Schedule

Consistent with the regulation, annual summaries will be posted to FDA's website at www.fda.gov.

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

No exceptions to the certification are associated with this information collection.