Human Drug Compounding
Under Sections 503A and 503B (21 U.S.C. 353a and 353b)
of the Federal Food, Drug, and Cosmetic Act

OMB Control No. 0910-0800 – Extension

SUPPORTING STATEMENT - **Part A: Justification**

1. Circumstances Making the Collection of Information Necessary

This information collection helps support Food and Drug Administration ("FDA, the agency, us or we") implementation of sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 353a and 353b); *Pharmacy Compounding and Outsourcing Facilities*. Compounding is generally a practice in which a licensed pharmacist, a licensed physician, or, in the case of an outsourcing facility, a person under the supervision of a licensed pharmacist, combines, mixes, or alters ingredients of a drug to create a medication tailored to the needs of an individual patient. Although compounded drugs can serve an important medical need for certain patients, they also present risk. Our compounding program aims to protect patients from unsafe, ineffective, and poor quality compounded drugs, while preserving access to lawfully-marketed compounded drugs for patients who have a medical need for them. Respondents to the information collection are those engaged in the practice of pharmacy compounding and registered outsourcing facilities.

The information collection is intended to account for burden attributable to recommendations in the guidance document entitled, "*Adverse Event Reporting for Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*," (October 2015). The guidance document is intended for firms that have registered with the Food and Drug Administration (FDA) under section 503B of the Federal Food, Drug, and Cosmetic Act (FD&C Act) as human drug compounding outsourcing facilities (outsourcing facilities). Under section 503B(b)(5) of the FD&C Act, an outsourcing facility must submit adverse event reports to FDA "*in accordance with the content and format requirements established through guidance or regulation under section 310.305 of title 21, Code of Federal Regulations (or any successor regulations).*" The guidance document explains that, under 21 CFR 310.305(c)(1), manufacturers, packers, and distributors of marketed prescription drug products that are not the subject of an approved new drug or abbreviated new drug application submit to FDA adverse event reports within 15 calendar days of receiving the information and must submit follow-up reports within 15 calendar days of receipt of new information about the adverse event, or as requested by FDA. Also, under §310.305(f), entities must maintain for 10 years the records of all adverse events required to be reported under § 310.305.

The guidance document also explains that, in accordance with regulatory requirements, adverse event reports must be submitted in an electronic format that FDA can process, review, and archive (collection of information is submitted via Form FDA 3500A (MedWatch), approved

under OMB control number 0910-0291). A copy of the current labeling of the compounded drug product must be provided in the report.

The information collection also accounts for activities pertaining to certain registration and reporting activities by outsourcing facilities of drugs, as established in sections 503B(b)(1) through 503B(b)(3) of the FD&C Act (previously approved in OMB control no. 0910-0827). To help respondents understand statutory requirements, how we interpret them, and the associated information collection, we developed the procedural guidance document entitled, "*Electronic Drug Product Reporting for Human Drug Compounding Outsourcing Facilities Under Section 503B of the Federal Food, Drug, and Cosmetic Act*" (December 2016), available on our website at https://www.fda.gov/media/90173/download. The guidance is intended for entities that compound human drugs and elect to register as outsourcing facilities under section 503B of the FD&C Act. Once an entity has elected to register as an outsourcing facility, it must submit reports identifying the drugs compounded by the outsourcing facility. The guidance describes who must report, the format of the report, the content to include in each report, when to report, how outsourcing facilities may submit reports to FDA, and the consequences of outsourcing facilities' failure to submit reports.

Finally, the information collection accounts for activities associated with States entering into memoranda of understanding with the Secretary, as described in section 503A(b)(3) of the FD&C Act, and activities pertaining to adverse experience reporting discussed in section 503B(b)(5) of the FD&C Act.

We are therefore requesting OMB extend its approval of the information collection elements discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The recordkeeping and reporting associated with adverse events enables us to monitor the safety of compounded drug products. Compounded drug products present a greater risk to patients than approved drug products because they do not undergo premarket review for safety, effectiveness, or quality.

3. Use of Improved Information Technology and Burden Reduction

Statutory requirements in section 503B(b)(4) require electronic registration and reporting. FDA regulations at 21 CFR 310.305 also prescribe electronic format requirements for the submission of information. The information is submitted via the agency's Electronic Submission Gateway. Compounded product information must also be submitted using the Structured Product Labeling (SPL) format and in accordance with section IV of the FDA guidance entitled "*Providing Regulatory Submissions in Electronic Format--Drug Establishment Registration and Drug Listing*" (available at https://www.fda.gov/RegulatoryInformation/Guidances/default.htm).

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. We note, however, three other currently approved information collections that account for burden attributable to statutory requirements in sections 503A and 503B:

- OMB control number 0910-0776, established in 2014 to account for burden that may be attributable to FDA guidance discussing applicable fees;

- OMB control number 0910-0858, Human Drug Compounding, Repackaging, and Related Activities Regarding Sections 503A and 503B of the Federal Food, Drug, and Cosmetic Act, established in 2018 to account for burden that may be attributable to FDA guidance discussing various respective compounding activities; and

- OMB control number 0910-0883, Obtaining Information to Understand and Challenges and Opportunities Encountered by Compounding Outsourcing Facilities, established in 2020 to account for burden attributable to FDA efforts undertaken to help inform us how best to utilize our limited resources toward ensuring the safety of human drug compounding.

5. Impact on Small Businesses or Other Small Entities

We do not believe the information collection poses undue burden on small entities.

6. Consequences of Collecting the Information Less Frequently

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

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

There are no special circumstances relating to this information collection.

8. Comments in Response to the Federal Register Notice

In the *Federal Register* of November 24, 2025 (90 FR 52965), we published a 60-day notice soliciting comment on the proposed collection of information. Five comments were posted to the docket (FDA-2025-N-4348), which we subsequently evaluated and discuss in our 30-day notice announcing submission to OMB. All commenters appear to recognize the practical utility of the collection activities in supporting FDA's public health protection goals, but asked for increased transparency regarding specific elements. We expressed appreciation for this feedback and reminded interested readers that FDA published its 60-day notice in compliance with requirements of the PRA, as administered by OMB, and uses the notice as way to help us

with the ongoing evaluation of its existing collection inventory. Toward that end, we updated the explanatory text that accompanied our burden figures, but made no adjustments to our estimated annualized burden.

9. Explanation of Any Payment or Gift to Respondents

No remuneration is associated with the information collection.

10. Assurance of Confidentiality Provided to Respondents

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). The PII submitted via Adverse Events Reports is name, phone number, email address, address, and date of birth. Outsourcing Facility Product Reports are submitted through the Safety Reporting Portal (SRP) and Electronic Submission Gateway (ESG) which collects account setup information such as email, password, and User ID. No PII is submitted in the Outsourcing Facility Product Reports. We have 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 Privacy Act do not apply. Specifically, FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate web page guidance, 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 Hour Burden and Costs

12a. Annualized Hour Burden Estimate

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

Information Collection Activities	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Avg. Burden per Response	Total Hours
503B AERs	55	1	55	1.10	61
503B Recordkeeping AERs	55	1	55	16	880
503A Reporting	45	~ 197	8,879	0.87	7,968
503A Recordkeeping	45	2	90	1	90
503A Disclosure (MOU)	1	1	1	1	1
Outsourcing facility reporting under 503B(b)	75	~108	8,111	0.2	214
Total			0		0

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

While we have retained our currently approved burden estimates, we have corrected an inadvertent omission from our 60-day notice in row 6 of Table 1 reflecting the number of estimated responses and average burden per response.

12b. Annualized Cost Burden Estimate

To calculate respondent costs, we assume a mean hourly wage for general occupations of $76.47, as reported by the U.S. Department of Labor, Bureau of Labor Statistics, Occupational Employment and Wage Statistics for Management Occupations (SOC 11-0000), May 2021. We multiply this figure by the total hours for the activities reflected above to calculate an estimated $ 704,594.58 in annual costs to respondents.

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

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

14. Annualized Cost to the Federal Government

FDA allocates approximately 0.5 full-time employee (FTE) ($160,526.50; each FTE equals $321,053) annually to receive, review, acknowledge, and confirm outsourcing facility product reporting submissions; and to respond to inquiries regarding outsourcing facility product reporting, including interpretation of section 503B product reporting provisions. We estimate 3 FTEs ($963,159) will be allocated to review and evaluate reports of complaints and compounded human drug products distributed interstate. Together, with the cost of approximately 1 FTE ($321,053) to monitor adverse event reports submitted by outsourcing

facilities, we estimate a total cost to the Federal government of $1,444,738.50 annually.

15. Explanation for Program Changes or Adjustments

While we have retained our currently approved burden estimates, we have corrected an inadvertent omission from our 60-day notice in row 6 of Table 1 reflecting the number of estimated responses and average burden per response.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no plans for tabulation and publication and project time scheduling.

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

The OMB expiration date will be displayed as required.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification in 5 CFR 1320.9.