United States Food and Drug Administration

Establishment Registration and Product Listing for
Manufacturers of Human Blood and Blood Products and Licensed Devices

OMB Control No. 0910-0052

SUPPORTING STATEMENT

Part A: Justification:

1. Circumstances Making the Collection of Information Necessary

This information collection helps support implementation of section 510 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360), as well as related Agency regulations in Title 21 of the Code of Federal Regulations (CFR) part 607 and forms. All owners or operators of establishments that manufacture human blood and blood products are required to register with the FDA, unless they are exempt under 21 CFR 607.65. A list of every blood product manufactured, prepared, or processed for commercial distribution must also be submitted, among other information. Establishments must register within 5 days after beginning operations or submission of a biologics license application and register annually between October 1 and December 31.

The regulations set forth procedures and requirements pertaining to establishment registration and product listing for manufactures of human blood and blood products and licensed devices, including initial registration and product listing, annual registration, product listing updates and waiver requests. Owners or operators of certain establishments that engage in the manufacture of blood products must register and submit a list of every blood product in commercial distribution (21 CFR 607.20(a)).

We therefore request extension of OMB approval for the information collection provisions found in the regulations at 21 CFR part 607 and the electronic Blood Establishment Registration and Product Listing system (BER) as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

The information collection is used by FDA, and other government agencies, to keep an accurate list of all foreign and domestic blood establishments and their products. Establishment registration and product listing information assists FDA in its inspections of facilities, among other uses, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply. The information is necessary especially in the event of a product recall.

Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, independent laboratories that engage in quality control and testing for registered blood product establishments, and

manufacturers of devices listed under section 351 of the Public Health Service Act.

3. Use of Improved Information Technology and Burden Reduction

Electronic submission of blood establishment and product listing information is required under 21 CFR 607.22, unless waived in certain circumstances. All owners or operators of establishments that manufacture human blood and blood products are required to register with the FDA, unless they are exempt under 21 CFR 607.65. A list of every blood product manufactured, prepared, or processed for commercial distribution must also be submitted, among other information. Establishments must register within 5 days after beginning operations or submission of a biologics license application and register annually between October 1 and December 31. We estimate that 99% the establishment registration and product listing information will be submitted electronically.

Initial and subsequent registrations and product listings must be submitted electronically through FDA's Center for Biologics Evaluation and Research (CBER) Blood Establishment Registration and Product Listing system through the FDA Industry Systems page available at https://www.accessdata.fda.gov/. More information about the eBER system is available at https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing. Online instructions are available at https://www.fda.gov/media/116432/download?attachment.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection. Although GMP or quality system (QS) regulations appear in several parts of Title 21 (Food and Drugs) of the CFR, this collection covers provisions associated with requirements for biologics regulated under 21 CFR part 607.

5. Impact on Small Businesses or Other Small Entities

Under the FD&C Act, any person owning or operating a blood establishment must register with the Secretary of Health and Human Services, however we do not believe the requirements impose undue burden on small entities. At the same time, we assist small businesses in complying with agency requirements through CBER's Office of Communication, Outreach and Development (OCOD) and through the scientific and administrative staffs within the agency. We also provide a Small Business Guide on our website at http://www.fda.gov/ForIndustry/SmallBusinessAssistance/default.htm.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory and regulatory requirements and reflects a regulatory scheme designed to ensure the safety of the nation's blood supply.

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

There are no special circumstances associated with 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 1320.8(d), FDA published a 60-day notice for public comment in the *Federal Register* of March 12, 2024 (89 FR 17856). No comments were received in response to the notice.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

In preparing this supporting statement, we consulted with our Privacy Office to ensure appropriate identification and handling of the information collected. Data will be kept private to the extent provided by law.

The Privacy Act of 1974

This ICR collects personally identifiable information (PII). PII 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 is contact information submitted with a written request for an exception or alternative to labeling requirements that might include name, address, telephone number, email address and fax number. FDA 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 Act do not apply. Specifically, the contractor or FDA does not use name or any other personal identifier to retrieve records from the information collected. Through appropriate webpage design, FDA limited submission fields and minimized the PII collected to protect the privacy of the individuals.

Freedom of Information Act

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 collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

Table 1.--Estimated Annual Reporting Burden

21 CFR Part 607; IC Activity	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response (in hours)	Total Hours
607.20(a), 607.21, 607.22, 607.25, 607.40; initial registration	176	1	176	1	176
607.21, 607.22, 607.25, 607.26, 607.31, 607.40; annual registration	2,545	1	2,545	0.5 (30 min.)	1,273
607.21, 607.25, 607.30(a), 607.31, 607.40; product listing update	42	1	42	0.25 (15 min.)	10
607.22(b); waiver request	1	1	1	1	1
TOTAL					1,460

12b. Annualized Cost Burden Estimate

We estimate an annualized cost to respondents of $224,584. This cost is based on a pay rate of $54/hour for a medical technologist, $72/hour for a supervisor, and $117/hour for a medical director, who may be responsible for registering an establishment, recording and listing blood products, and has the training and skills to handle various reporting requirements. The average salary based on these estimates is $81. The salary estimates include benefits but no overhead costs.

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	176	$81	$14,256
Annual Registration	2,545	$81	$206,145
Product Listing Update	42	$81	$3,402
Waiver Requests	1	$81	$81
Total			$223,884

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

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

14. Annualized Cost to the Federal Government

The estimated annualized cost to the Federal Government is $126,949. We calculated this cost assuming one full time employee allocation with an annual salary of $126,949. This figure reflects pay for a Consumer Safety Officer (GS-13/5) to review and process registration forms, input data, and maintain the database. Salary estimate includes benefits but no overhead costs.

15. Explanation for Program Changes or Adjustments

The information collection reflects agency adjustments. Based on our evaluation of Fiscal Year 2022 data from CBER's Blood Establishment Registration and Product Listing system, we have adjusted the currently approved burden estimate we attribute to establishment registration and product listing to reflect a decrease in product listing updates and an increase in the number of initial registrations. Our estimated burden for the information collection reflects an overall decrease of 36 hours.

16. Plans for Tabulation and Publication and Project Time Schedule

This information collected will not be published or tabulated.

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

FDA will display the OMB expiration date as required by 5 CFR 1320.8.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.