UNITED STATES FOOD & DRUG ADMINISTRATION

Establishment Registration and Product Listing for Manufacturers of
Human Blood and Blood Products and Licensed Devices
21 CFR Part 607

OMB Control No. 0910-0052

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) regulations. Under section 510 of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or a device, as well as licensed biological products used in the manufacture of a licensed device, must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, places of business, and all such establishments, among other information and must submit, a listing of all drug and device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution, among other information. In 21 CFR part 607, FDA has issued regulations implementing these requirements.

The regulations set forth procedures and requirements pertaining to establishment registration and product listing for manufacturers of human blood and blood products and licensed devices, including initial registration, annual registration, product listing updates, and waiver requests. Owners or operators of certain establishments that engage in the manufacture of blood products shall register and submit a list of every blood product in commercial distribution (21 CFR 607.20(a)). 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, or any future superseding electronic system, unless FDA has granted a request for waiver of this requirement prior to the date on which the information is due (21 CFR 607.22(a)). Waiver requests must be submitted in writing and must include, among other information, the specific reasons why electronic submission is not reasonable for the registrant (21 CFR 607.22(b)).

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.

We therefore request extension of OMB approval for the information collection provisions found in the regulations at 21 CFR part 607; the electronic Blood Establishment Registration and Product Listing system (BER); and associated collection instruments, 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.

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. Blood establishments that must register and list electronically under 21 CFR part 607 should use the electronic Blood Establishment Registration (BER) system to meet the requirement for electronic submission of establishment registration and product listing. We estimate that nearly all of the establishment registration and product listing information will be submitted electronically in the next three years.

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 February 18, 2021 (86 FR 10085). 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 our Privacy Office to ensure appropriate identification and handling of information collected. Although personally identifiable information (PII) is collected, it pertains 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. Through appropriate guidance, we limit submission fields and minimized the PII collected to protect the privacy of the individuals.

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	152	1	152	1	152
607.21, 607.22, 607.25, 607.26, 607.31, 607.40; annual registration	2,557	1	2,557	0.5 (30 min.)	1,279
607.21, 607.25, 607.30(a), 607.31, 607.40; product listing update	256	1	256	0.25 (15 min.)	64
607.22(b); waiver request	1	1	1	1	1
TOTAL					1,496

12b. Annualized Cost Burden Estimate

We estimate an annualized cost to respondents of $216,518. This cost is based on a pay rate of $49/hour for a medical technologist, $65/hour for a supervisor, and $106/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 $73. The salary estimates include benefits but no overhead costs.

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	152	$73	$11,096
Annual Registration	2,557	$73	$186,661
Product Listing Update	256	$73	$18,688
Waiver Requests	1	$73	$73
Total			$216,518

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 $148,200. We calculated this cost assuming a 1½ full time employee allocation with an annual salary of $98,800 (1.5 x $98,800). This figure reflects pay for a Technical Information Specialist (GS-12/5) 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 2019 data from CBER's Blood Establishment Registration and Product Listing system, we have adjusted the currently approved burden estimate to reflect an increase in annual product listing updates by 14 responses annually.

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

Display of OMB Expiration Date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.