U.S. Food and Drug Administration
Blood Establishment Registration and Product Listing

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, the 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. Regulations at 21 CFR part 607 (21 CFR 607) set forth establishment registration and product listing requirements for manufacturers of products that meet the definition of a device under the Federal Food, Drug, and Cosmetic Act (FD&C Act) and that are licensed under section 351 of the Public Health Service Act.

In accordance with statutory requirements, registration information is submitted electronically and must be submitted annually as prescribed in the regulations through FDA's Blood Establishment Registration and Product Listing system. The regulations also provide for waivers. Requests for a waiver of the requirements from 21 CFR 607.22(a), *use of the electronic Blood Establishment Registration and Product Listing system,* can be made in writing stating the specific reasons why electronic submission is not reasonable for the registrant. Waivers may be approved by FDA with FDA specifying the terms and duration of the waiver.

We therefore request extension of OMB approval for the information collection provisions found under 21 CFR Part 607; the electronic Blood Establishment Registration and Product Listing system; and associated Form FDA 2830 entitled "*Blood Establishment Registration and Product Listing*," which we retain for use in cases where waivers have been granted.

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. The information collection enables FDA to fulfill its public health protection responsibilities by ensuring the safety of the nation's blood supply. The information is necessary as well in the event of a product recall.

3. Use of Improved Information Technology and Burden Reduction

Since last OMB review, rulemaking (RIN 0910-0049) revised the regulations to conform with section 510 of the FD&C act, as amended by the Food and Drug Administration Amendments Act, to require electronic submissions. We believe utilizing electronics means will improve

management of drug establishment registration and drug listing requirements, including biologics, and to make these processes more efficient and effective for both respondents and FDA. We remain open to technological advancements that would enhance or otherwise refine the current system and will employ such improvements as resources permit.

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 our Regional Small Business Representatives 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 agency 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 for 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 December 26, 2017 (82 FR 61013). No comments were received in response to the notice.

9. Explanation of any Payment or Gift to Respondents

No payment or gift is provided to respondents.

10. Assurance of Confidentiality Provided to Respondents

The confidentiality of information received by FDA is consistent with the Freedom of Information Act (FOIA) and FDA's published regulations of "Public Information" under 21 CFR Part 20, which prohibit FDA from releasing to the public the names of patients, individual

reporters, health care practitioners, hospitals, and any geographical identifiers. This information is for internal use and may be subject to, in whole or part, the FOIA and applicable FDA regulations.

11. Justification for Sensitive Questions

Questions of a sensitive nature are not applicable to this information collection.

12. Estimates of Annualized Burden Hours and Costs

12a. Annualized Hour Burden Estimate

We estimate the annual hourly burden for the information collection as follows:

TABLE 1 – Estimated Annual Reporting Burden

21 CFR Part 607 – Procedures for Domestic and Foreign Blood Establishments	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial establishment registration and product listing	115	1	115	1	115
Annual update of establishment registration and blood product listing	2,812	1	2,812	0.5 (between 15-30 mins.)	1,356
Waiver requests	25	1	25	1	25
TOTAL					1,496

[1] There are no capital or operating or maintenance costs associated with the information collection.

Respondents to the collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, and independent laboratories that engage in quality control and testing for registered blood product establishments. Our estimate of the information collection burden is based on agency data and our experience with the information collection. Based on our review, approximately 115 new establishments initially register and list their products and that it will take one hour to do so. We estimate there are approximately 2,612 respondents who will submit annual updates of establishment registration and 200 will submit product listings, and that this will require between 15 and 30 minutes. Finally, we estimate 25 waivers will be submitted, and that it takes one hour to do so.

12b. Annualized Cost Burden Estimate

We estimate an annualized cost to respondents of $194,952. This cost is based on a pay rate of $44/hour for a medical technologist, $59/hour for a supervisor, and $96/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 $66. The salary estimates include benefits but no overhead costs.

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	115	$66	$7,590
Annual Registration	2,612	$66	$172,392
Product Listing Update	200	$66	$13,320
Waiver Requests	25	$66	$1,650
Total			$194,952

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

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

14. Annualized Cost to Federal Government

The estimated annualized cost to the Federal Government is $142,500. We calculated this cost assuming a 1½ full time employee allocation with an annual salary of $95,000 (1.5 x $95,000). This figure reflects pay for a Technical Information Specialist (GS-11/5) 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. Due to an increase in the number blood establishment registrations submitted to FDA, we have increased our estimate of the number respondents to the collection. This results in an increase of 95 annual hours and 244 annual responses.

16. Plans for Tabulation and Publication and Project Time Schedule

There are no tabulated results to publish for this information collection.

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.