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

OMB Control No. 0910-0052

SUPPORTING STATEMENT

Justification

1. Circumstances Making the Collection of Information Necessary

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 the Federal Register of August 31, 2016 (81 FR 60170), the Food and Drug Administration issued a final rule amending its regulations at 21 CFR part 607. The final rule entitled, "*Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs That Are Regulated Under a Biologics License Application, and Animal Drugs,*" revises 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.

Under § 607.22(a),blood establishments must submit initial and subsequent registration and product listing electronically through the *Blood Establishment Registration and Product Listing* system, or any future superseding electronic system. Under § 607.22(b), both domestic and foreign establishments may request a waiver from the requirement to submit electronically. If the waiver is granted, respondents may use Form FDA 2830, "*Blood Establishment Registration and Product Listing*."

Under § 607.25(b)(1), blood establishments are required to list blood products by the established and proprietary name. Previously, manufacturers of plasma derivatives and bulk product substances registered and listed under both parts 607 and 207. The final rule revises this requirement by requiring persons who engage solely in the production of plasma derivatives, bulk product substances, and recombinant version of plasma derivatives or animal derived plasma derivatives to register and list only under part 207, however reduction in burden is expected to be minimal (approximately 20 establishments).

Under § 607.40, foreign establishments must include information for the United States agent as part of its initial and updated registration. The final rule requires submission of minimal additional information (i.e., email address) for the United States agent. The final rule requires the foreign establishment to report to FDA changes in the United States agent's name, address, telephone number, and email address within 30 calendar days of the change. The final rule lengthens from 10 business days to 30 calendar days the time period for reporting changes in the United States agent's information to FDA.

Accordingly, we are requesting approval of the revised information collection provisions found in 21 CFR part 607, as well as Form FDA 2830, "*Blood Establishment Registration and Product Listing*."

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 supports the agency's public health protection responsivities by enabling the monitoring and inspection of manufacturers of life-saving biological products, including blood products, and ensuring the safety of the nation's blood supply.

3. Use of Improved Information Technology and Burden Reduction

The Center for Biologics Evaluation and Research (CBER) utilizes the Electronic Blood Establishment Registration and Product Listing System for the blood establishment registration and product listing process. The agency continually monitors and accepts feedback on its systems and plans for improvements 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

The information collection requirements apply to all businesses alike. FDA provides assistance for small businesses through guidance available at: http://www.fda.gov/ForIndustry/SmallBusinessAssistance/SmallBusinessRepresentatives/guidance CBER's Office of Communication, Outreach, and Development, Division of Manufacturer's Assistance and Training, also provides assistance to small businesses subject to FDA's regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

The information collection schedule is consistent with statutory requirements.

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 the Federal Register of August 29, 2006 (71 FR 51276) FDA published a proposed rule entitled, "*Requirements for Foreign and Domestic Establishment Registration and Listing for Human Drugs, Including Drugs that are Regulated Under a Biologics License Application, and Animal Drugs,*" including a PRA analysis and invited public comment. While several comments were received, none addressed the four information collection topics solicited in the proposal. Substantive comments are addressed in the agency's final rule that published August 31, 2016 (81 FR 60170) at *Section III* and may be found under Docket No. FDA–2005–N–0464 (formerly Docket No. 2005N–0403). FDA finalized the rule in the Federal Register of August 31, 2016 (81 FR 60170) and again invited public comment. None were received regarding the information collection.

9. Explanation of any Payment or Gift to Respondents

No payment or gift was 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

The estimated annual burden for this information collection is 1,401 hours.

TABLE 1 – Estimated Annual Reporting Burden

Activity; 21 CFR Sections	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Initial Establishment Registration and Product Listing; 607.22(a), 607.25(a) and (b)(3)	68	1	68	1	68

Activity; 21 CFR Sections	No. of Respondents	No. of Responses Per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
Annual Review and Update of Establishment Registration and Blood Product Listing; 607.22(a), 607.25(a) and (b)(3)	2,615	1	2,615	0.5	1,308
Waiver requests; 607.22(b))	25	1	25	1	25
TOTAL					1,401

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

Respondents to this 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.

FDA estimates the burden of this collection of information based upon information obtained from CBER's database. The average burden per response is based on our experience with the blood establishment registration and product listing requirements including initial registration, re-registration, and product listing updates.

The blood establishments for the most part are familiar with the regulations and registration requirements to fill out this form for the first time. Approximately 68 new Form FDA 2830s are received annually. The blood establishments need only refer to their files or written instructions for a small portion of the information required.

Under § 607.22(b), both domestic and foreign establishments may request a waiver from the requirement that information must be provided to FDA in electronic format. We expect few waiver requests because only a computer, Internet access, and an email address are needed to register and list electronically. We estimate that approximately 25 manufacturers will request a waiver annually and that each request will take approximately 1 hour to prepare and submit to us.

12b. Annualized Cost Burden Estimate

The estimated annualized cost to the respondents is $170,604. This cost is based on a pay rate of $42/hour for a medical technologist, $56/hour for a supervisor, and $91/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 $63. The salary estimates include benefits but no overhead costs.

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	68	$63	$4,284
Updates	2,615	$63	$164,745
Waiver Requests	25	$63	$1,575
Total			$170,604

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

There are no capital costs or operating and maintenance costs associated with this collection of information.

14. Annualized Cost to Federal Government

The estimated annualized cost to the Federal Government is $140,828. This cost is based on 1½ Technical Information Specialists (GS-11/5) that review and process the registration forms, input the data, and maintain the database. These salary estimates include benefits but no overhead costs.

Activity	Number of FTEs	Average Annual Salary	Total Cost
Registration Form Review/Process	1.5	$93,885	$140,828
Total			$140,828

15. Explanation for Program Changes or Adjustments

The information collection is being revised by rulemaking (see Q8 for public notice and comment discussion). IC 2, "*Annual review and update*" consolidates two previously itemized ICs (*re-registration* and *product listing update*) but reflects no change in burden. While we expect slightly fewer respondents to the collection as a result of the requirement that certain manufacturers of plasma derivatives and bulk product substances must register only under 21 part 207, we have added minor additional data elements. These are discussed under Qs 1 and 12 of this supporting statement and in *Section III* of the final rule (81 FR at 60170). IC 3 reflects burden under § 607.22(b) – *waiver requests*, but shows an overall reduction to the collection by **141** responses and **17** hours that results from consolidating reporting elements under IC 2.

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 expiration date is appropriate.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.