Blood Establishment Registration and Product Listing, Form FDA 2830

0910-0052

SUPPORTING STATEMENT

JUSTIFICATION

1. Circumstances Making the Collection of Information Necessary

The Food and Drug Administration (FDA) is requesting an extension of OMB Control No. 0910-0052 and OMB approval of the following information collection requirements in 21 CFR Part 607 and Form FDA 2830 (Tab A) for Blood Establishment Registration and Product Listing:

21 CFR 607.20(a)	Reporting	Requires owners or operators of certain establishments that engage in the manufacture of blood products to register and submit a list of every blood product in commercial distribution.
21 CFR 607.21	Reporting	Requires the owners or operators of establishments entering into the manufacturing of blood products to register within 5 days after beginning such operation and to submit a list of every blood product in commercial distribution at the time. If the owner or operator of the establishment has not previously entered into such operation for which a license is required, registration must follow within 5 days after the submission of a biologics license application. In addition, establishments are required to register annually between November 15 and December 31 and update their blood product listing every June and December of each year.
21 CFR 607.22	Reporting	Requires the use of Form FDA 2830 for initial registration, for annual registration, and blood product listing.
21 CFR 607.25	Reporting	Indicates information required for establishment registration and blood product listing.
21 CFR 607.26	Reporting	Requires certain changes to be submitted on Form FDA 2830 as amendments to the establishment registration within 5 days of such changes.
21 CFR 607.30(a)	Reporting	Indicates the information required for owners or operators of establishments to update their blood product listing information every June and December, or at the discretion of the registrant at the time a change occurs.
21 CFR 607.31	Reporting	Requires that additional blood product listing

		information, be provided upon FDA request.
21 CFR 607.40	Reporting	Requires certain foreign blood product establishments to register and submit the blood product listing information and to provide the name and address of the individual responsible for submitting the blood product listing information as well as the name, address, and phone number of the U.S. agent.

Under section 510 of the Federal Food, Drug, and Cosmetic 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 must register with the Secretary of Health and Human Services, on or before December 31 of each year, his or her name, place of business, and all such establishments and must submit, among other information, a listing of all drug or device products manufactured, prepared, propagated, compounded or processed by him or her for commercial distribution.

All establishments engaged in the manufacture, preparation, propagation, or processing of human blood and blood products are subject to the requirements of section 510 of the Act. The regulations of establishment registration and product listing for blood establishments are found in 21 CFR Part 607. These establishments are required to submit the information on Form FDA 2830.

After the initial registration and listing of human blood and blood products, re-registration by the establishment is required annually between November 15 and December 31 of each year. FDA sends an annual pre-printed Form FDA 2830 to each registrant by November 15 of each year to each previously registered establishment.

2. Purpose and Use of the Information Collection

The information obtained from the registration of blood establishments and listing of blood products on Form FDA 2830 is used by FDA, and other government agencies, to keep an accurate, up to date list of all blood establishments and their different products, not only located in this country, but also those in foreign countries. FDA uses this list for inspectional purposes as required by the Act. In addition, the data is used by industry, consumers, private institutions, etc., to keep up with the names and locations of blood establishments and their various blood products. Data from this file is used for many purposes and is essential for the sending out of letters by FDA and other government agencies regarding emerging health problems as they relate to the blood product industry. In addition, FDA uses the information on the different types of listed products for both regulatory and research purposes.

Through registration information on domestic and foreign blood establishments, regulatory agencies are able to determine the sources of specific products; this information is essential to the overall regulatory scheme designed to ensure the safety of the nation’s blood supply.

3. Use of Improved Technology and Burden Reduction

The collection of information does currently involve the use of an automated, electronic technological collection technique. The Center for Biologics Evaluation and Research (CBER) currently has a program that offers electronic registration. Most establishments (over 85%) now register electronically. CBER is minimizing the burden on the blood industry by sending out blood establishment registration forms asking for the information required by the regulations. All of the required information is pre-printed on the form so that the annual registrants need only record changes that have occurred.

4. Efforts to Identify Duplication and Use of Similar Information

FDA is the only agency that requests this information. There is no similar kind of information available from any other source.

5. Impact on Small Businesses or Other Small Entities

FDA believes that the regulations should apply equally to all enterprises. While FDA does not believe it can apply different standards with respect to statutory requirements, FDA does provide special help to small businesses. CBER's Office of Communication, Training, and Manufacturers Assistance provides guidance to small businesses concerning regulatory requirements.

6. Consequences of Collecting the Information Less Frequently

Among other uses, this information assists FDA in the inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the nation's blood supply. In addition, it is very important for FDA to know about the existence of all current blood establishments in order to transmit health related information to all these blood establishments. Less frequent collection would increase the likelihood that the information possessed by FDA would be incorrect or obsolete, and hinder the conduct of regulatory actions.

There are no technical or legal obstacles to reducing the burden.

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), a 60-day notice for public comment (73 FR 46909) was published on August 12, 2008, in the ***Federal Register***. No comments were received from the public.

9. Explanation of any Payment or Gift to Respondents

FDA has not provided and has no intention to provide any payments or gifts 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 the agency'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. Such information is deleted from any information released by FDA under FOIA and 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

The estimated annual burden for this information collection is 1,467 hours.

Estimated Annual Reporting Burden						
21 CFR Section	**Form FDA 2830**	**No. of Respondents**	**Annual Frequency per Response**	**Total Annual Responses**	**Hours per Response**	**Total Hours**
607.20(a), 607.21, 607.22, 607.25, 607.40	Initial Registration	111	1	111	1	111
607.21, 607.22, 607.25, 607.26, 607.31, 607.40	Re-Registration	2,621	1	2,621	0.5	1,311
607,21, 607.25, 607.30, 607.31, 607.40	Product Listing Update	180	1	180	0.25	45

Total						1,467

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 the Center for Biologics Evaluation and Research's database, and FDA's experience with the blood establishment registration and product listing requirements.

The time needed for industry to complete the Form FDA 2830 is estimated to be 1 hour for new firms. 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 111 new Form FDA 2830's are received annually. With annual re-registration of blood establishments, the time needed for industry to complete the Form FDA 2830 is estimated to be ½ hour. The blood establishments need only to refer to their files or written instructions for a small portion of the information required. Approximately 2,621 Form FDA 2830's are received annually for re-registration. Approximately 180 Form FDA 2830's are received annually for the product listing update with an estimated average of 15 minutes to complete the form.

Cost to Respondents

The estimated annualized cost to the respondents is $79,218. This cost is based on a pay rate of $36/hour for a medical technologist, $48/hour for a supervisor, and $79/hour for a Medical Director, who may be responsible for registering an establishment, recording and listing blood products, and have the training and skills to handle various reporting requirements. The average salary of the three is $54. The salary estimates include benefits but no overhead costs.

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	111	$54	$5,994
Re-Registration	1,311	$54	$70,794
Product Listing Update	45	$54	$2,430
Total			$79,218

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

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

14. Annualized Cost to Federal Government

The estimated annualized cost to the Federal Government is $96,260. This cost is based on 1½ Technical Information Specialists (GS-8/5) 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	$64,173	$96,260
Total			$96,260

15. Explanation for Program Changes or Adjustments

The estimated total annual burden for this information collection requirement was 1,533 hours in 2005. The current decrease to 1,467 hours (-66 hours) is mostly attributed to a decrease in the number of blood product establishments (foreign and domestic) under re-registration.

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

FDA is not seeking approval to exempt display of the expiration date for OMB approval.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

Not Applicable