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 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, owners or operators of all establishments so engaged 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, subsequent annual registration, and for blood product listing information.
21 CFR 607.25	Reporting	Sets forth the 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 an amendment to the establishment registration within 5 days of such changes.
21 CFR 607.30(a)	Reporting	Sets forth the information required from owners or operators of establishments when updating 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 comply with establishment registration and blood product listing information requirements and to provide the name and address of the establishment and the name of the individual responsible for submitting establishment registration and 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, unless exempt under 21 CFR 607.65. 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.

This collection of information is not related to the American Recovery and Reinvestment Act of 2009 (ARRA)

2. Purpose and Use of the Information Collection

The information obtained from the registration of blood establishments and the 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.

The information obtained through the registration and product listing of domestic and foreign blood establishments assists FDA in its inspections of facilities. This information is essential to the overall regulatory scheme designed to ensure 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. Most establishments (over 94%) now register electronically. CBER also minimizes the burden on the blood industry by sending out blood establishment registration forms asking for the information required by the regulations by both mail and e-mail. 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 requires this information. There is no similar information available from any other source.

5. Impact on Small Businesses or Other Small Entities

Although FDA must apply the statutory and regulatory requirements to all enterprises, FDA does provide special help to small businesses. CBER's Office of Communication, Outreach, and Development, Division of Manufacturer's Assistance and Training, provides assistance to small businesses concerning FDA's 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), FDA published a 60-day notice for public comment in the Federal Register of August 8, 2011 (76 FR 48167). No comments were received from the public.

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.

12a. Annualized Hour Burden Estimate

The estimated annual burden for this information collection is 1,389 hours.

Estimated Annual Reporting Burden						
21 CFR Section	Form FDA 2830	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Average Burden per Response	Total Hours
607.20(a), 607.21, 607.22, 607.25, 607.40	Initial Registration	49	1	49	1	49
607.21, 607.22, 607.25, 607.26,	Re-Registration	2,589	1	2,589	0.50 (30 min.)	1,295

607.31, 607.40						
607.21, 607.25, 607.30(a), 607.31, 607.40	Product Listing Update	180	1	180	0.25 (15 min.)	45
Total						1,389

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, 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 49 new Form FDA 2830s 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 2,589 Form FDA 2830s are received annually for re-registration. Approximately 180 Form FDA 2830s are received annually for the product listing update with an estimated average of 15 minutes to complete the form.

12b. Annualized Cost Burden Estimate

The estimated annualized cost to the respondents is $83,280. This cost is based on a pay rate of $40/hour for a medical technologist, $53/hour for a supervisor, and $87/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 of the three is $60. The salary estimates include benefits but no overhead costs.

Cost to Respondents			
Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	49	$60	$2,940
Re-Registration	1,294	$60	$77,640
Product Listing Update	45	$60	$2,700

Total			$83,280

13. Estimates of Other Total Annual Costs Burden to Respondents and/or Recordkeepers/Capital Costs

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 $105,885. 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	$70,590	$105,885
Total			$105,885

15. Explanation for Program Changes or Adjustments

The estimated total annual burden for this information collection requirement was 1,467 hours in 2008. The current decrease to 1,389 hours (-78 hours) is mostly attributed to a decrease in the number of initial registrations of blood product establishments (foreign and domestic).

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

N/A