

OMB INFORMATION COLLECTION
SUPPORTING STATEMENT
0910-0052

Blood Establishment Registration and Product Listing Form - FDA 2830

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 607 (Attachment A) and Form FDA 2830 (Attachment B) for Blood Establishment Registration and Product Listing:

21 CFR 607.20(a)	Reporting	Requires a list of every blood product in commercial distribution.
21 CFR 607.21	Reporting	Requires initial and annual registration, and semi-annual product listing update.
21 CFR 607.22	Reporting	Requires the use of Form FDA 2830 to register establishment and list blood products.
21 CFR 607.25	Reporting	Indicates information required for establishment registration and blood product listing.
21 CFR 607.26	Reporting	Requires an amendment to establishment registration for certain changes.
21 CFR 607.30	Reporting	Requires semi-annual update of blood product listing information, as needed.
21 CFR 607.31	Reporting	Requires additional blood product listing information as needed.

Under the provisions of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360) (Attachment C), Section 510(b) states: "On or before December 31 of each year every person who owns or operates any establishment in any State engaged in the manufacture, preparation, propagation, compounding, or processing of a drug or drugs or a device or devices shall register with the Secretary (of DHHS) his name, places of business, and all such establishments."

Section 510(j)(1) further states: "Every person who registers with the Secretary under subsection (b)... shall, at the time of registration under any such subsection, file with the Secretary a list of all drugs... which are being manufactured, prepared, propagated, compounded, or processed by him for commercial distribution..."

Section 201(g)(1) defines the term "drug": "The term "drug" means (A) articles recognized in the official United States Pharmacopoeia, official Homeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals;... and (D) articles intended for use as a component of any articles specified in clause (A), (B), or (C)." Blood and blood components or derivatives, as used in the treatment and prevention of disease in man, are covered by this Act. Therefore, all establishments engaged in the manufacture, preparation, propagation, or processing of

human blood and blood products are subject to the requirements of Section 510 as cited above. The regulations for establishment registration and product listing for blood establishments are found in 21 CFR Part 607.

The first registration and listing of human blood and blood product establishments were required to be submitted to FDA in November 1975. After the initial registration and listing of human blood and blood products, re-registration is required annually between November 15 and December 31 of each year. FDA sends the annual request for re-registration, with a pre-printed Form FDA 2830, to each registrant by November 15.

2. Purpose and Use of the Information

The information obtained from the registration and listing of blood establishments on Form FDA 2830 is used by FDA and other government agencies to keep an accurate, up to date list of all blood establishments located in this country. FDA uses this list for inspectional purposes as required by the FD&C Act. In addition, the data is used by industry, consumers, private institutions etc., to keep up with names and locations of blood establishments. Data from this file is used for many purposes and is essential for sending out letters by this agency and other government agencies regarding emerging health problems as they relate to the blood product industry. In addition, FDA uses information on the different types of listed products for regulatory and research purposes.

Registration information on domestic and foreign blood establishments enable regulatory agencies to determine the source of specific products, particularly products that were impure, or products whose safety or efficacy had not been established.

3. Use of Information Technology and Burden Reduction

The collection of information does not currently involve the use of automated, electronic, mechanical, or other technological collection techniques. The Center for Biologics Evaluation and Research (CBER) is minimizing the burden on the blood industry by sending out blood establishment registration forms asking for information required by the regulations. All of the required information is pre-printed on the form; annual registrants need only record changes.

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

Most biological manufacturers fit the definition of small businesses. Collecting only necessary information has minimized the data required. In order to provide assistance and guidance in filing, general instructions are attached to the form.

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

If collection of this data were less frequent, FDA would not benefit from research data regarding human blood and blood products. It is also very important to know all current blood establishments in order to transmit health related information to blood banks. In addition, 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 is no special circumstances for the collection of the information requirements.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside Agency

On September 3, 1999, the 60-day notice was published (64 FR 48408) (Attachment D). No comments were received from the public.

The Office of Blood Research and Review (OBRR) works continuously to improve its blood product establishment registration system. OBRR consults with persons both inside and outside the agency to obtain their views on the availability of data, frequency of collection, the clarity of instructions, recordkeeping, disclosure, or reporting format and ongoing data elements to be recorded, disclosed or reported. Three of our contacts are:

Sue Preston, Alpha Therapeutic Corporation, 5555 Valley Boulevard, Los Angeles, CA 90032, (213)-225-2221.

Steve Kassapian, The American National Red Cross, 1616 North Fort Myer Drive, Arlington, VA, 22209, (703) 312-5609.

Kay Gregory, American Association of Blood Banks, 8101 Glenbrook Road, Bethesda, MD 20814-2749, (301) 907-6977.

9. Explanation of Any Payment or Gifts 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 Hour Burden Including Annualized Hourly Costs

The estimated annual burden for this information collection is 1,969 hours.

Estimated Annual Reporting Burden						
21 CFR Part	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	Initial Registration	300	1	300	1	300
607.21, 607.22, 607.25, 607.26, 607.31	Re-registration	3,300	1	3,300	0.5	1,650
607.21, 607.25, 607.30,	Product Listing Update	75	1	75	0.25	19
TOTAL		3,600		3,600		1,969

The burden is based on estimates by FDA's Division of Blood Applications from past experience and from discussion with the blood establishments registered and listing blood and blood products. The total estimated annual burden includes the time and resources which are necessary to produce and assemble all documentation required by 21 CFR 607 for all blood establishment registration and product listing under Form FDA 2830.

The time needed for industry to complete the Form FDA 2830 is estimated to be 1 hour for new firms. The blood banks for the most part are familiar with the regulations and registration requirements to fill out this form for the first time. Approximately 300 new Form FDA 2830s are received annually, therefore, the total burden is 300 hours. With annual re-registration of blood banks the time needed for industry to complete the Form FDA 2830 form is estimated to be 1/2 hour. The blood banks for the most part are familiar with the regulations and re-registration requirements and only need to refer to their files or written instructions for a small portion of the information required. Approximately 3,300 Form FDA 2830s are received annually, therefore, the total annual burden for this is 1,650 hours. Approximately 75 Form FDA 2830s are received annually for the product listing update, estimating an average of 15 minutes to complete the form, and thus resulting in a burden hours of 19.

Cost to Respondents

The estimated annualized cost to the respondents is \$49,225. This cost is based on a pay rate of \$25 per hour for a mid level professional who has the training and skills to handle the various reporting requirements. This salary estimate includes benefits but no overhead costs. The \$25.00 hourly rate is taken from the proposed rule for Foreign Establishment Registration and Listing.

Cost to Respondents			

Activity	Number of Hours	Cost per Hour	Total Cost
Initial Registration	300	\$25	\$7,500
Registration	1,650	\$25	\$41,250
Product Listing Update	19	\$25	\$475
TOTAL			\$49,225

13. Estimate of Other Total Annual Cost Burden to Respondents or Record-keepers

There are no capital and start-up, or operation, maintenance and purchase costs associated with the information collection.

14. Annualized Costs to the Federal Government

The estimated annual cost to the government is \$120,000.00 and is based on the following: OBRR indicates the current staffing assigned to review the blood product documents is 1 Technical Information Specialist on an annual basis. Estimated annual operating costs for these employees is approximately \$70,000.00. In addition, the Office is estimated to use approximately \$30,000.00 annually for computer support to input data into and maintain the database. FDA field support for blood product establishment registration and listing matters which includes instructing firms how to fill out forms, maintaining regulation compliance, following up on blood product establishments which fail to register is about \$20,000.00 per year.

15. Explanation of Program Changes or Adjustments

The estimated total annual burden for this information collection requirements was 1,800 hours in 1996. The current increase to 1,950 hours is a program adjustment, which reflects an increase in the number of blood product establishments reporting to the agency.

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

There are no exceptions to Item 19 of OMB Form 83-I.