

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2008-N-0439]

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Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Blood Establishment Registration and Product Listing, Form FDA 2830

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA) is announcing that a proposed collection of information has been submitted to the Office of Management and Budget (OMB) for review and clearance under the Paperwork Reduction Act of 1995.

DATES: Fax written comments on the collection of information by *[insert date 30 days after date of publication in the Federal Register]*.

ADDRESSES: To ensure that comments on the information collection are received, OMB recommends that written comments be faxed to the Office of Information and Regulatory Affairs, OMB, Attn: FDA Desk Officer, FAX: 202-395-6974, or e-mailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0052. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Jonna Capezuto, Office of Information Management (HFA-710), Food and Drug Administration, 5600 Fishers Lane, Rockville, MD 20857, 301-796-3794.

SUPPLEMENTARY INFORMATION: In compliance with 44 U.S.C. 3507, FDA has submitted the following proposed collection of information to OMB for review and clearance.

Blood Establishment Registration and Product Listing, Form FDA 2830—(OMB Control Number 0910–0052)—Extension

Under section 510 of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 360), any person owning or operating an establishment that manufactures, prepares, propagates, compounds, or processes a drug or 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. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

Section 607.20(a), in brief, requires owners or operators of certain establishments that engage in the manufacture of blood products to register and to submit a list of every blood product in commercial distribution. Section 607.21, in brief, 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. Section 607.22

requires the use of Form FDA 2830, Blood Establishment Registration and Product Listing, for initial registration, for annual registration, and for blood product listing. Section 607.25 indicates the information required for establishment registration and blood product listing. Section 607.26, in brief, requires certain changes to be submitted on FDA Form 2830 as amendments to the establishment registration within 5 days of such changes. Section 607.30(a), in brief, 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 the change occurs. Section 607.31 requires that additional blood product listing information be provided upon FDA request. Section 607.40, in brief, requires certain foreign blood product establishments to register and submit the blood product listing information, and to provide the name and address of the establishment and the name of the individual responsible for submitting blood product listing information as well as the name, address, and phone number of its U.S. agent.

Among other uses, this information assists FDA in its inspections of facilities, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the nation's blood supply. Form FDA 2830 is used to collect this information.

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 FDA's Center for Biologics Evaluation and

Research's database and FDA 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 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 0.5 hours. 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 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 0.25 hours to complete the form.

In the **Federal Register** of August 12, 2008 (73 FR 46909), FDA published a 60-day notice requesting public comment on the information collection provisions. No comments were received.

FDA estimates the burden of this collection of information as follows:

TABLE 1.—ESTIMATED ANNUAL REPORTING BURDEN¹

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, and 607.40	Initial Registration	111	1	111	1	111
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40	Re-registration	2,621	1	2,621	0.5	1,311
607.21, 607.25, 607.30(a), 607.31, and 607.40	Product Listing Update	180	1	180	0.25	45
Total						1,467

¹ There are no capital costs or operating and maintenance costs associated with this collection of information.

Dated: 12/10/08
December 10, 2008.

Jeffrey Shuren

Jeffrey Shuren,
Associate Commissioner for Policy and Planning.

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Dawn P. Hawkins