

Dated: December 16, 2011.

Leslie Kux,

Acting Assistant Commissioner for Policy.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0508]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Blood Establishment Registration and Product Listing, Food and Drug Administration Form 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 January 23, 2012.

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) 395-7285, or emailed 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: Ila S. Mizrachi, Office of Information Management, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-7726, *Ila.Mizrachi@fda.hhs.gov*.

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, FDA Form 2830—21 CFR Part 607 (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, owners or operators of all establishments so engaged must register annually between November 15 and December 31 and must update their blood product listing information every June and December. Section 607.22 requires the use of FDA Form 2830 (Blood Establishment Registration and Product Listing) for initial registration, subsequent annual registration, and for blood product listing information. Section 607.25 sets forth 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 an amendment to establishment registration within 5 days of such changes. Section 607.30(a), in brief, 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 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 comply with the establishment registration and blood product listing information requirements discussed earlier in this document 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 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. FDA Form 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.

In the **Federal Register** of August 8, 2011 (76 FR 48167), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN¹

21 CFR Section	FDA Form 2830	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
607.20(a), 607.21, 607.22, 607.25, and 607.40.	Initial registration	49	1	49	1	49
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40.	Re-registration	2,589	1	2,589	0.5 (30 min.)	1,295

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN ¹—Continued

21 CFR Section	FDA Form 2830	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
607.21, 607.25, 607.30(a), 607.31, and 607.40.	Product listing update	180	1	180	0.25 (15 min.)	45
Total	1,389

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

Dated: December 19, 2011.
Leslie Kux,
Acting Assistant Commissioner for Policy.
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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2011-N-0511]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and “Lookback”

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 January 23, 2012.

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) 395-7285, or emailed to *oira_submission@omb.eop.gov*. All comments should be identified with the OMB control number 0910-0116. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Food and Drug Administration, 1350 Piccard Dr., PI50-400B, Rockville, MD 20850, (301) 796-7726, *Ila.Mizrachi@fda.hhs.gov*.

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.

Current Good Manufacturing Practices and Related Regulations for Blood and Blood Components; and Requirements for Donor Testing, Donor Notification, and “Lookback”—(OMB Control Number 0910-0116)—Extension

All blood and blood components introduced or delivered for introduction into interstate commerce are subject to section 351(a) of the Public Health Service Act (PHS Act) (42 U.S.C. 262). Section 351(a) of the PHS Act requires that manufacturers of biological products, which include blood and blood components intended for further manufacture into injectable products, have a license, issued upon a demonstration that the product is safe, pure, and potent and that the manufacturing establishment meets all applicable standards, including those prescribed in the FDA regulations designed to ensure the continued safety, purity, and potency of the product. In addition, under section 361 of the PHS Act (42 U.S.C. 264), by delegation from the Secretary of Health and Human Services, FDA may make and enforce regulations necessary to prevent the introduction, transmission, or spread of communicable diseases from foreign countries into the States or possessions, or from one State or possession into any other State or possession.

Section 351(j) of the PHS Act states that the Federal Food, Drug, and Cosmetic Act also applies to biological products. Blood and blood components for transfusion or for further manufacture into injectable products are drugs, as that term is defined in section 201(g)(1) of the Federal Food, Drug, and Cosmetics Act (21 U.S.C. 321(g)(1)). Because blood and blood components are drugs under the Federal Food, Drug, and Cosmetics Act, blood and plasma establishments must comply with the substantive provisions and related regulatory scheme of the act. For example, under section 501 of the

Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(a)), drugs are deemed “adulterated” if the methods used in their manufacturing, processing, packing, or holding do not conform to current good manufacturing practice (CGMP) and related regulations.

The CGMP regulations in part 606 (21 CFR part 606)) and related regulations implement FDA’s statutory authority to ensure the safety, purity, and potency of blood and blood components. The public health objective in testing human blood donors for evidence of infection due to communicable disease agents and in notifying donors is to prevent the transmission of communicable disease. For example, the “lookback” requirements are intended to help ensure the continued safety of the blood supply by providing necessary information to users of blood and blood components and appropriate notification of recipients of transfusion who are at increased risk for transmitting human immunodeficiency virus (HIV) or hepatitis C virus (HCV) infection.

The information collection requirements in the CGMP, donor testing, donor notification, and “lookback” regulations provide FDA with the necessary information to perform its duty to ensure the safety, purity, and potency of blood and blood components. These requirements establish accountability and traceability in the processing and handling of blood and blood components and enable FDA to perform meaningful inspections.

The recordkeeping requirements serve preventive and remedial purposes. The disclosure requirements identify the various blood and blood components and important properties of the product, demonstrate that the CGMP requirements have been met, and facilitate the tracing of a product back to its original source. The reporting requirements inform FDA of certain information that may require immediate corrective action.

Under the reporting requirements, § 606.170(b), in brief, requires that facilities notify FDA’s Center for Biologics Evaluation and Research