



4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2014-N-1069]

Agency Information Collection Activities; Proposed Collection; 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 or Agency) is announcing an opportunity for public comment on the proposed collection of certain information by the Agency. Under the Paperwork Reduction Act of 1995 (PRA), Federal Agencies are required to publish notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on the information collection requirements relating to the blood establishment registration and product listing requirements in the Agency's regulations and Form FDA 2830.

DATES: Submit electronic or written comments on the collection of information by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. Electronic comments must be submitted on or before [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. The <https://www.regulations.gov> electronic filing system will accept comments until midnight Eastern Time at the end of [INSERT DATE 60 DAYS AFTER DATE OF

PUBLICATION IN THE *FEDERAL REGISTER*]. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are postmarked or the delivery service acceptance receipt is on or before that date.

Electronic Submissions

Submit electronic comments in the following way:

- Federal eRulemaking Portal: <https://www.regulations.gov>. Follow the instructions for submitting comments. Comments submitted electronically, including attachments, to <https://www.regulations.gov> will be posted to the docket unchanged. Because your comment will be made public, you are solely responsible for ensuring that your comment does not include any confidential information that you or a third party may not wish to be posted, such as medical information, your or anyone else's Social Security number, or confidential business information, such as a manufacturing process. Please note that if you include your name, contact information, or other information that identifies you in the body of your comments, that information will be posted on <https://www.regulations.gov>.
- If you want to submit a comment with confidential information that you do not wish to be made available to the public, submit the comment as a written/paper submission and in the manner detailed (see "Written/Paper Submissions" and "Instructions").

Written/Paper Submissions

Submit written/paper submissions as follows:

- Mail/Hand delivery/Courier (for written/paper submissions): Dockets Management Staff (HFA-305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

- For written/paper comments submitted to the Dockets Management Staff, FDA will post your comment, as well as any attachments, except for information submitted, marked and identified, as confidential, if submitted as detailed in "Instructions."

Instructions: All submissions received must include the Docket No. FDA-2014-N-1069 for "Blood Establishment Registration and Product Listing, Form FDA 2830." Received comments, those filed in a timely manner (see ADDRESSES), will be placed in the docket and, except for those submitted as "Confidential Submissions," publicly viewable at <https://www.regulations.gov> or at the Dockets Management Staff between 9 a.m. and 4 p.m., Monday through Friday.

- Confidential Submissions--To submit a comment with confidential information that you do not wish to be made publicly available, submit your comments only as a written/paper submission. You should submit two copies total. One copy will include the information you claim to be confidential with a heading or cover note that states "THIS DOCUMENT CONTAINS CONFIDENTIAL INFORMATION." The Agency will review this copy, including the claimed confidential information, in its consideration of comments. The second copy, which will have the claimed confidential information redacted/blacked out, will be available for public viewing and posted on <https://www.regulations.gov>. Submit both copies to the Dockets Management Staff. If you do not wish your name and contact information to be made publicly available, you can provide this information on the cover sheet and not in the body of your comments and you must identify this information as "confidential." Any information marked as "confidential" will not be disclosed except in accordance with 21 CFR 10.20 and other applicable disclosure law. For more information about

FDA's posting of comments to public docket, see 80 FR 56469, September 18, 2015, or access the information at: <https://www.gpo.gov/fdsys/pkg/FR-2015-09-18/pdf/2015-23389.pdf>.

Docket: For access to the docket to read background documents or the electronic and written/paper comments received, go to <https://www.regulations.gov> and insert the docket number, found in brackets in the heading of this document, into the "Search" box and follow the prompts and/or go to the Dockets Management Staff, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852.

FOR FURTHER INFORMATION CONTACT: Ila S. Mizrachi, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 301-796-7726, PRASStaff@fda.hhs.gov.

SUPPLEMENTARY INFORMATION: Under the PRA (44 U.S.C. 3501-3520), Federal Agencies must obtain approval from the Office of Management and Budget (OMB) for each collection of information they conduct or sponsor. "Collection of information" is defined in 44 U.S.C. 3502(3) and 5 CFR 1320.3(c) and includes Agency requests or requirements that members of the public submit reports, keep records, or provide information to a third party. Section 3506(c)(2)(A) of the PRA (44 U.S.C. 3506(c)(2)(A)) requires Federal Agencies to provide a 60-day notice in the *Federal Register* concerning each proposed collection of information, including each proposed extension of an existing collection of information, before submitting the collection to OMB for approval. To comply with this requirement, FDA is publishing notice of the proposed collection of information set forth in this document.

With respect to the following collection of information, FDA invites comments on these topics: (1) whether the proposed collection of information is necessary for the proper

performance of FDA's functions, including whether the information will have practical utility; (2) the accuracy of FDA's estimate of the burden of the proposed collection of information, including the validity of the methodology and assumptions used; (3) ways to enhance the quality, utility, and clarity of the information to be collected; and (4) ways to minimize the burden of the collection of information on respondents, including through the use of automated collection techniques, when appropriate, and other forms of information technology.

Blood Establishment Registration and Product Listing, Form FDA 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, places of business, and all such establishments, among other information, and must submit a list of all drug and all device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution, among other information. In 21 CFR part 607, FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

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

Section 607.21 requires the owner or operator of an establishments entering into the manufacturing of blood products to register the establishment 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 October 1 and December 31 and update their blood product listing every June and December.

Section 607.22(a) requires, in part, that initial and subsequent registrations and product listings be submitted electronically through the Blood Establishment Registration and Product Listing system or any future superseding electronic system.

Section 607.22(b) requires, in part, that requests for a waiver of the requirements of § 607.22 be submitted in writing and include the specific reasons why electronic submission is not reasonable for the registrant.

Section 607.22(c) provides that if FDA grants the waiver request, FDA may limit its duration and will specify the terms of the waiver and provide information on how to submit establishment registration, drug listings, other information, and updates, as applicable (e.g., Form FDA 2830).

Section 607.25 sets forth the information required for establishment registration and blood product listing.

Section 607.26 requires, in part, that certain changes, such as ownership or location changes, be submitted to FDA electronically as an amendment to establishment registration within 5 calendar days of such changes using the FDA Blood Establishment Registration and Product Listing system, or any future superseding electronic system.

Section 607.30(a), in part, sets forth the information required from owners or operators of establishments when they update their blood product listing information in June and December of each year (at a minimum).

Section 607.31 requires that certain additional blood product listing information be provided upon request by FDA.

Section 607.40 requires, in part, that certain foreign blood product establishments comply with the establishment registration and blood product listing information requirements in part 607, subpart B (§§ 607.20 through 607.39, 607.40(a) and (b)), and provide the name and address of the establishment and the name of the individual responsible for submitting establishment registration and blood product listing information (§ 607.40(c)) as well as the name, address, and phone number of its U.S. agent (§ 607.40(d)).

This information assists FDA in its inspections of facilities, among other uses, and its collection is essential to the overall regulatory scheme designed to ensure the safety of the Nation's blood supply.

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

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

Table 1.--Estimated Annual Reporting Burden¹

21 CFR Section	Activity/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, and 607.40	Initial Registration	115	1	115	1	115
607.21, 607.22, 607.25, 607.26, 607.31, and 607.40	Annual Registration	2,612	1	2,612	0.5 (30 minutes)	1,306
607.21, 607.25, 607.30(a), 607.31, and 607.40	Product Listing Update	200	1	200	0.25 (15 minutes)	50
607.22(b)	Waiver Requests	25		25	1	25
Total						1,496

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

The burden for this information collection has changed since the last OMB approval. Because of a slight increase in the number of initial registrations and product listing updates FDA has received during the past 3 years, we have increased our reporting burden estimate.

Dated: December 20, 2017.

Leslie Kux,

Associate Commissioner for Policy.

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