4164-01-P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA-2024-N-0783]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices

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: Submit written comments (including recommendations) 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 submitted to https://www.reginfo.gov/public/do/PRAMain. Find this particular information collection by selecting "Currently under Review--Open for Public Comments" or by using the search function. The OMB control number for this information collection is 0910-0052. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Rachel Showalter, Office of Operations, Food and Drug Administration, Three White Flint North, 10A-12M, 11601 Landsdown St., North Bethesda, MD 20852, 240-994-7399, PRAStaff@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.

Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices

OMB Control Number 0910-0052--Extension

This information collection helps support implementation of section 510 of the Federal Food Drug and Cosmetic Act (21 U.S.C. 360), as well as related Agency regulations in part 607 (21 CFR part 607) and forms. All owners or operators of establishments that manufacture human blood and blood products are required to register with FDA, unless they are exempt under § 607.65. A list of every blood product manufactured, prepared, or processed for commercial distribution must also be submitted, among other information. Establishments must register within 5 days after beginning operations or submission of a biologics license application and register annually between October 1 and December 31.

The regulations set forth procedures and requirements pertaining to establishment registration and product listing for manufactures of human blood and blood products and licensed devices, including initial registration and product listing, annual registration, product listing updates and waiver requests. Owners or operators of certain establishments that engage in the manufacture of blood products must register and submit a list of every blood product in commercial distribution (§ 607.20(a)). Initial and subsequent registrations and product listings must be submitted electronically through FDA's Center for Biologics Evaluation and Research (CBER) Blood Establishment Registration and Product Listing system through the FDA Industry Systems page available at https://www.access.fda.gov. More information about the electronic blood establishment registration (eBER) system is available at: https://www.fda.gov/vaccines-blood-biologics/biologics-establishment-registration/blood-establishment-registration-and-product-listing. Online instructions are available at: https://www.fda.gov/media/116432/download?attachment. The Form FDA 2830 previously associated with this information collection is no longer in use.

FDA may grant a request for waiver of this requirement prior to the date on which the information is due (§ 607.22(a)). Waiver requests must be submitted in writing and must include, among other information, the specific reasons why electronic registration is not reasonable for the registrant.

Establishment registration and product listing 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.

Description of Respondents: Respondents to this collection of information are human blood and plasma donor centers, blood banks, certain transfusion services, other blood product manufacturers, independent laboratories that engage in quality control and testing for registered blood product establishments and manufacturers of devices licensed under section 351 of the Public Health Service Act.

In the *Federal Register* of March 12, 2024 (89 FR 17856), 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 Burden[1]

21 CFR Section; Activity	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 and submission of product listing	176	1	176	1	176
607.21, 607.22, 607.25, 607.26, 607.31, 607.40; Annual registration	2,545	1	2,545	0.5 (30 minutes)	1,273
607.21, 607.25, 607.30(a), 607.31, 607.40; Product listing update	42	1	42	0.25 (15 minutes)	10
607.22(b); Written waiver request	1	1	1	1	1
Total					1,460

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

Based on our evaluation of calendar year 2022 data from CBER's Blood Establishment Registration and Product Listing system, we have adjusted the currently approved burden

estimate we attribute to establishment registration and product listing to reflect a decrease in product listing updates and an increase in the number of initial registrations. Our estimated burden for the information collection reflects an overall decrease of 36 hours.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

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