## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

**[Docket No. FDA–2020–N–2231]**

### 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, Agency, or we) 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 July 12, 2021.

**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:** 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, *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—21 CFR Part 607

*OMB Control Number 0910–0052—Extension*

This information collection supports Agency regulations. 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 listing of all drug and device products manufactured, prepared, propagated, compounded, or processed by him or her for commercial distribution, among other information. In part 607 (21 CFR part 607), FDA has issued regulations implementing these requirements for manufacturers of human blood and blood products.

The regulations set forth procedures and requirements pertaining to establishment registration and product listing for manufacturers of human blood and blood products and licensed devices, including initial registration, annual registration, product listing updates, and waiver requests. Owners or operators of certain establishments that engage in the manufacture of blood products shall 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, or any future superseding electronic system, unless FDA has granted 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 submission is not reasonable for the registrant (§ 607.22(b)). 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 (42 U.S.C. 262).

In the **Federal Register** of February 18, 2021 (86 FR 10085), FDA published a 60-day notice requesting public comment on the proposed collection of information. No comments were received.

We estimate the burden of the information collection as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

| 21 CFR section; activity | Number of respondents | Number of responses per respondent | Total annual responses | Average burden per response (in hours) | Total hours |
|---|---|---|---|---|---|
| 607.20(a), 607.21, 607.22, 607.25, 607.40; Initial registration | 152 | 1 | 152 | 1 | 152 |
| 607.21, 607.22, 607.25, 607.26, 607.31, 607.40; Annual registration | 2,557 | 1 | 2,557 | 0.5 (30 minutes) | 1,279 |
| 607.21, 607.25, 607.30(a), 607.31, 607.40; Product listing update | 256 | 1 | 256 | 0.25 (15 minutes) | 64 |
| 607.22(b); Waiver request | 1 | 1 | 1 | 1 | 1 |
| Total | | | | | 1,496 |

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

Based on our evaluation of Fiscal Year 2019 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 slight increase in submissions; however, the overall burden has not changed.

Dated: June 3, 2021.

**Lauren K. Roth,**

*Acting Principal Associate Commissioner for Policy.*

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