TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Agency guidance recommendations; information collection	Form FDA No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Consultation Procedures: Foods Derived From New Plant Varieties						
Initial consultation	None	30	2	60	4	240
Final consultation	3,665	12	1	12	150	1,800
Early Food Safety Evaluation of New Non-Pesticidal Proteins Produced by New Plant Varieties Intended for Food Use						
Six data components	3,666	6	1	6	20	120
Total				78		2,160

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

Based on a review of the information collection since our last request for OMB approval, we have made minor adjustments to update our burden estimate to reflect recent annual response rates (increased initial consultations under the New Plant Variety consultation procedures) and to clarify the total number of responses under the Early Food Safety Evaluation (NPC) procedures.

Dated: March 7, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05219 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–0783]

Agency Information Collection Activities; Proposed Collection; 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 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 in the Agency's regulations relating to establishment registration and product listing for manufacturers of human blood and blood products and licensed devices.

DATES: Either electronic or written comments on the collection of information must be submitted by May 13, 2024.

ADDRESSES: You may submit comments as follows. Please note that late, untimely filed comments will not be considered. The *https://www.regulations.gov* electronic filing system will accept comments until 11:59 p.m. Eastern Time at the end of May 13, 2024. Comments received by mail/hand delivery/courier (for written/paper submissions) will be considered timely if they are received 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–2024–N–0783 for ''Establishment Registration and Product Listing for Manufacturers of Human Blood and Blood Products and Licensed Devices.'' 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, 240–402–7500.

- 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 dockets, see 80 FR 56469, September 18, 2015, or access the information at: *https://www.govinfo.gov/content/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, 240–402–7500.

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: Under the PRA (44 U.S.C. 3501–3521), 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.

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 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 21 CFR part 607 and forms. All owners or operators of establishments that manufacture human blood and blood products are required to register with the FDA, unless they are exempt under 21 CFR 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 (21 CFR 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 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 (21 CFR 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.

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	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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]—Continued

21 CFR Section; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
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: March 6, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–05215 Filed 3–11–24; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2023–N–3847]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Adverse Experience Reporting for Licensed Biological Products; and General Records

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 April 11, 2024.

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 0910–0308. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Domini Bean, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–5733, *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.

Adverse Experience Reporting for Licensed Biological Products; and General Records—21 CFR Part 600

OMB Control Number 0910–0308—Extension

This information collection helps support implementation of statutory and regulatory authorities that govern adverse experience reporting. Under the Public Health Service Act (PHS Act) (42 U.S.C. 262), FDA may only approve a biologics license application for a biological product that is safe, pure, and potent. When a biological product is approved and enters the market, the product is introduced to a larger patient population in settings different from clinical trials. New information generated during the postmarketing period offers further insight into the benefits and risks of the product, and evaluation of this information is important to ensure its safe use. Regulations implementing adverse experience reporting (AER) requirements applicable to biological products are codified in part 600 (21 CFR part 600). Regulations applicable to combination products subject to regulations in part 600 are found in part 4 (21 CFR part 4)—Regulation of Combination Products. The collections of information are intended to enable FDA to take actions necessary for the protection of the public health in response to reports of adverse experiences related to biologics licensed under any provision of section 351 of the PHS Act.

To assist respondents with the reporting provisions of the information collection, FDA has created both paper-based and electronic forms. Information may be submitted electronically through *MEDWATCH* or the *Vaccine Adverse Experience Reporting System* (VAERS). AER reports are filed using the MEDWATCH Form FDA–3500A (approved under OMB control numbers 0910–0291 and 0910–0645) or the VAERS–1. Both versions of the forms and instructions are available from the internet at *https://vaers.hhs.gov.* The forms may also be downloaded, completed, and submitted to the Agency by mail or facsimile.

For operational efficiency, on March 20, 2023, we requested, and OMB has approved, the addition of burden attributable to provisions set forth in part 4, subpart B, previously included in OMB control number 0910–0834. When information regarding an event that involves a death or serious injury, or an adverse event, associated with the use of the combination product is received by the product sponsor, the information must be provided to the other constituent part applicant(s) no later than 5 calendar days after receipt under § 4.103. Relatedly, § 4.104 explains how and where to submit reports.

In the **Federal Register** of September 28, 2023 (88 FR 66856), we published a 60-day notice requesting public comment on the proposed collection of information. We received one comment regarding our estimate of 28 hours per response for periodic adverse experience reports. The comment suggested we lower that estimate but provided no data or explanation in support of the proposed reduction. While we have therefore made no adjustment in our burden estimate, we encourage further comment regarding a basis for assessing burden for the scope of information collection activity covered by the applicable regulations and associated forms.

Respondents: Respondents to this collection of information are manufacturers of biological products (including blood and blood