2013–D–0710 for ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection.'' Received comments 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.

You may submit comments on any guidance at any time (see 21 CFR 10.115(g)(5)).

Submit written requests for a single hard copy of the guidance entitled ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' to the Office of Policy, Compliance and Enforcement, Office of Regulatory Affairs, Food and Drug Administration, 12420 Parklawn Drive, Element Building, Rockville, MD 20857. Send one self-addressed adhesive label to assist that office in processing your request. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Lola Burford, Office of Regulatory Affairs, Division of Operational Policy, Food and Drug Administration, 12420 Parklawn Drive, Element Building, Rockville, MD 20857, *Lola.Burford@fda.hhs.gov,* 240–402–5865.

SUPPLEMENTARY INFORMATION:

I. Background

On July 9, 2012, the Food and Drug Administration Safety and Innovation Act (FDASIA) (Pub. L. 112–144) added section 501(j) to the FD&C Act (21 U.S.C. 351(j)) to deem adulterated a drug that ''has been manufactured, processed, packed, or held in any factory, warehouse, or establishment and the owner, operator, or agent of such factory, warehouse, or establishment delays, denies, or limits an inspection, or refuses to permit entry or inspection.'' Section 707(b) of FDASIA required the Food and Drug Administration to issue guidance that defined the circumstances that would constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, for purposes of section 501(j). In the **Federal Register** of October 22, 2014 (79 FR 63130), FDA announced the availability of a guidance for industry entitled, ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug Inspection'' (hereinafter, 2014 guidance).

Subsequently, on August 18, 2017, FDARA (Pub. L. 115–52) was signed into law. Section 702 of FDARA amended the scope of section 501(j) of the FD&C Act to provide that, as the case with drugs, devices are deemed to be adulterated if an FDA inspection is delayed, denied, limited, or refused by the owner, operator, or agent of the establishment at which the device is manufactured, processed, packed, or held. This final guidance supersedes the 2014 final guidance to incorporate devices and to explain the circumstances that FDA would consider to constitute delaying, denying, or limiting inspection, or refusing to permit entry or inspection, resulting in a drug or device manufactured in the facility being deemed adulterated.

This final guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). FDA considered the comments received on the draft guidance and did not make substantial changes from the draft to the final guidance. This final guidance represents the current thinking of FDA on ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' It does not establish any rights for any person and is not binding on FDA or the public. You can use an alternative approach if it satisfies the requirements of the applicable statutes and regulations.

II. Paperwork Reduction Act of 1995

This guidance contains no collection of information. Therefore, clearance by the Office of Management and Budget under the Paperwork Reduction Act of 1995 is not required.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at either *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/search-general-and-cross-cutting-topics-guidance-documents* or *https://www.regulations.gov.* Persons unable to download an electronic copy of ''Circumstances That Constitute Delaying, Denying, Limiting, or Refusing a Drug or Device Inspection'' may send an email request to *ORAPolicyStaffs@fda.hhs.gov* to receive an electronic copy of the document.

Dated: June 17, 2024.

Lauren K. Roth,

Associate Commissioner for Policy.

[FR Doc. 2024–13674 Filed 6–20–24; 8:45 am]

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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 July 22, 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 0910–0052. 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	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
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.

[FR Doc. 2024–13643 Filed 6–20–24; 8:45 am]

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