part 601 have been approved under OMB control number 0910–0338; the collections of information for expedited programs in ''Guidance for Industry: Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765.

III. Electronic Access

Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances, https://www.fda.gov/regulatory-information/search-fda-guidance-documents,* or *https://www.regulations.gov.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18653 Filed 9–24–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0426]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Agreement for Shipment of Devices for Sterilization

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 October 27, 2025.

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 0910–0131. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Agreement for Shipment of Devices for Sterilization—21 CFR 801.150

OMB Control Number 0910–0131—Extension

This information collection helps to support FDA regulations. Under sections 501(c) and 502(a) of the Federal Food, Drug, and Cosmetic Act (21 U.S.C. 351(c) and 352(a)), nonsterile devices that are labeled as sterile but are in interstate transit to a facility to be sterilized are adulterated and misbranded. FDA regulations at § 801.150(e) (21 CFR 801.150(e)) establish a control mechanism by which firms may manufacture and label medical devices as sterile at one establishment and ship the devices in interstate commerce for sterilization at another establishment, a practice that facilitates the processing of devices and is economically necessary for some firms.

Under § 801.150(e)(1), manufacturers and sterilizers may sign an agreement containing the following: (1) contact information of the firms involved and the identification of the signature authority of the shipper and receiver, (2) instructions for maintaining accountability of the number of units in each shipment, (3) acknowledgment that the devices that are nonsterile are being shipped for further processing, and (4) specifications for sterilization processing. This agreement allows the manufacturer to ship misbranded products to be sterilized without initiating regulatory action and provides FDA with a means to protect consumers from use of nonsterile products. During routine plant inspections, FDA normally reviews agreements that must be kept for 2 years after final shipment or delivery of devices (see § 801.150(a)(2)). The respondents to this collection of information are device manufacturers and contract sterilizers.

In the **Federal Register** of July 2, 2025 (90 FR 29022), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although one comment was received, it was not responsive to the four collection of information topics solicited.

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

TABLE 1—ESTIMATED ANNUAL RECORDKEEPING BURDEN [1]

21 CFR part; activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Record retention, 801.150(a)(2)	218	37.5	8,175	.5 (30 minutes)	4,088

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

FDA's estimate of the reporting burden is based on data obtained from industry in recent years. It is estimated that each of the firms subject to this requirement prepares an average of 37.5 written agreements each year. This estimate varies greatly, from 1 to 218, because some firms provide sterilization services on a part-time basis for only 1 customer, while others are large facilities with many customers. The average time required to prepare each written agreement is estimated to be 4 hours. This estimate varies depending on whether the agreement is the initial agreement or an annual renewal, on the format each firm elects to use, and on the length of time required to reach agreement. The estimate applies only to those portions of the written agreement that pertain to the requirements imposed by this regulation. The written agreement generally also includes contractual agreements that are a usual and customary business practice. The recordkeeping requirements of § 801.150(a)(2) consist of making copies and maintaining the records required under the third-party disclosure section of this collection.

TABLE 2—ESTIMATED ANNUAL THIRD-PARTY DISCLOSURE BURDEN [1]

21 CFR part; activity	Number of respondents	Number of disclosures per respondent	Total annual disclosures	Average burden per disclosure	Total hours
Agreement and labeling requirements, 801.150(e)	218	37.5	8,175	4	32,700

[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 no adjustments to our burden estimate.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–18612 Filed 9–24–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2024–N–5944]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Sanitary Transportation of Human and Animal Food

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 October 27, 2025.

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 0910–0773. Also include the FDA docket number found in brackets in the heading of this document.

FOR FURTHER INFORMATION CONTACT: Amber Sanford, Office of Operations, Food and Drug Administration, Three White Flint North, 10A–12M, 11601 Landsdown St., North Bethesda, MD 20852, 301–796–8867, *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.

Sanitary Transportation of Human and Animal Food—21 CFR Part 1, Subpart O

OMB Control Number 0910–0773—Extension

This information collection supports FDA regulations regarding the sanitary transportation of human and animal food. Section 402(i) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 342(i)), establishes that food that is transported or offered for transport by a shipper, carrier by motor vehicle or rail vehicle, receiver, or any other person engaged in the transportation of food under conditions that are not in compliance with the regulations issued under section 416 is adulterated. Section 416 (21 U.S.C. 350e) of the FD&C Act, requires shippers, carriers by motor vehicle or rail vehicle, receivers, and other persons engaged in the transportation of food to use prescribed sanitary transportation practices to ensure that food is not transported under conditions that may render the food adulterated. Section 416 of the FD&C Act also directs that we prescribe appropriate human and animal food transportation practice requirements relating to: (1) sanitation; (2) packaging, isolation, and other protective measures; (3) limitations on the use of vehicles; (4) information to be disclosed to carriers and to manufacturers; and (5) recordkeeping.

Additionally, section 703 of the FD&C Act (21 U.S.C. 373) provides that a shipper, carrier by motor vehicle or rail vehicle, receiver, or other person subject to section 416 of the FD&C Act must, on request of an officer or employee designated by FDA, permit the officer or employee, at reasonable times, to have access to and to copy all records that are required to be kept under the regulations issued under section 416.

Accordingly, we issued regulations in 21 CFR part 1, subpart O (21 CFR 1.900 through 1.934) that establish requirements for the sanitary transportation of human and animal food, as well as prescribe procedures for respondents who wish to request a waiver for any requirement. Under section 1.924 of 21 CFR part 1, subpart O, waivers are requested in the same manner as prescribed in § 10.30 (21 CFR 10.30). Electronic submissions are accepted via *www.regulations.gov* as prescribed in § 10.30(b)(1). The collections of information in § 10.30 have been approved under OMB control number 0910–0191. For additional information regarding Agency implementation of sections 402(i), 416, and 703 of the FD&C Act, visit our website at *https://www.fda.gov/food/food-safety-modernization-act-fsma/fsma-final-rule-sanitary-transportation-human-and-animal-food.*

Description of Respondents: Respondents to this collection of information are domestic shippers and carriers, and in certain circumstances, foreign shippers of human and animal food. Respondents are from the private sector (for-profit businesses).

In the **Federal Register** of June 27, 2025 (90 FR 27628), FDA published a 60-day notice requesting public comment on the proposed collection of information. One comment was received in support of the information collection.

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