it satisfies the requirements of the applicable statutes and regulations.

As we develop final guidance on this topic, FDA will consider comments on costs or cost savings the guidance may generate, relevant for Executive Order 14192.

II. Paperwork Reduction Act of 1995

While this guidance contains no collection of information, it does refer to previously approved FDA collections of information. The previously approved collections of information are subject to review by the Office of Management and Budget (OMB) under the Paperwork Reduction Act of 1995 (PRA) (44 U.S.C. 3501–3521). The collections of information in 21 CFR parts 50 and 56 pertaining to institutional review boards and the protection of human subjects, respectively, have been approved under OMB control number 0910–0130. The collections of information under 21 CFR part 312 pertaining to Investigational New Drug Applications, including clinical trials and formal meetings, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 601 pertaining to the submissions of biologics license application product for development have been approved under OMB control number 0910–0338. The collections of information described in FDA's guidance entitled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' have been approved under OMB control number 0910–0297.

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Persons with access to the internet may obtain the draft guidance at *https://www.fda.gov/vaccines-blood-biologics/guidance-compliance-regulatory-information-biologics/biologics-guidances,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. 2025–18651 Filed 9–24–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0373]

Agency Information Collection Activities; Submission for Office of Management and Budget Review; Comment Request; Registration of Food Facilities

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 0910–0502. 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.

Registration of Food Facilities

OMB Control Number 0910–0502—Extension

This information collection supports FDA regulations. The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (the Bioterrorism Act) amended the Federal Food, Drug, and Cosmetic Act (FD&C Act), to require, among other things, domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States to register with FDA. Sections 1.230 to 1.235 of our regulations (21 CFR part 1, subpart H) set forth the requirements for the registration of food facilities. Information provided to us under these regulations helps us to quickly notify the facilities that might be affected by a deliberate or accidental contamination of the food supply. In addition, data collected through registration is used to support FDA enforcement activities and to screen imported food shipments.

Advanced notice of imported food allows FDA, with the support of U.S. Customs and Border Protection, to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. If a facility is not registered or the registration for a facility is not updated when necessary, we may not be able to contact the facility and may not be able to target import inspections effectively in case of a known or potential threat to the food supply or other food-related emergency, putting consumers at risk of consuming hazardous food products that could cause serious adverse health consequences or death.

To assist respondents of the information collection we developed the following forms. Each facility that manufactures, processes, packs, or holds food for human or animal consumption in the United States must register with FDA using Form FDA 3537 entitled, ''Food Facility Registration'' (§ 1.231), unless exempt under § 1.226 from the requirement to register. To cancel a registration, respondents must use Form FDA 3537a entitled, ''Cancellation of Food Facility Registration'' (§ 1.235). The terms ''Form FDA 3537'' and ''Form FDA 3537a'' refer to both the paper version of each form and the electronic system known as the Food Facility Registration Module, which is available at *https://www.access.fda.gov.* Registrations, updates, and cancellations are required to be submitted electronically. Domestic facilities are required to register regardless of whether food from the facility enters interstate commerce. Foreign facilities that manufacture, process, pack, or hold food also are required to register unless food from that facility undergoes further processing (including packaging) by another foreign facility outside the United States. However, if the further manufacturing/processing conducted by the subsequent facility consists of adding labeling or any similar activity of a de minimis nature, the former facility is required to register. In addition to the initial registration requirements, a

facility is required to submit timely updates within 60 days of a change to any required information on its registration form, using Form FDA 3537 (§ 1.234), and to cancel its registration when the facility ceases to operate or is sold to new owners or ceases to manufacture, process, pack, or hold food for consumption in the United States, using Form FDA 3537a (§ 1.235).

Registration is one of several tools under the Bioterrorism Act that enables us to act quickly in responding to a threatened or actual bioterrorist attack on the U.S. food supply or other food-related emergency. Further, in the event of an outbreak of foodborne illness, the information provided helps us determine the source and cause of the event and enables us to quickly notify food facilities that might be affected by an outbreak, terrorist attack, or other emergency. Finally, the registration requirements enable us to quickly identify and remove from commerce an article of food for which there is a reasonable probability that the use of or exposure to such article of food will cause serious adverse health consequences or death to humans or animals.

Description of Respondents: Respondents to this collection of information are owners, operators, or agents in charge of domestic or foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

In the **Federal Register** of June 27, 2025 (90 FR 27619), FDA published a 60-day notice requesting public comment on the proposed collection of information. Although two comments were received, they were not responsive to the four collection of information topics solicited under 5 CFR 1320.8(d).

We estimate the burden of this collection of information as follows:

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity; 21 CFR Section	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New domestic facility registration; 1.230–1.233	7,420	1	7,420	2.7	20,034
New foreign facility registration; 1.230–1.233	17,592	1	17,592	8.7	153,050
Updates; 1.234	124,001	1	124,001	1.2	148,801
Cancellations; 1.235	464	1	464	1	464
Biennial renewals; 1.235	89,182	1	89,182	0.38	33,889
3rd party registration verification	6,491	1	6,491	0.25	1,623
U.S. Agent verification	15,655	1	15,655	0.25	3,914
Total			260,805		361,775

[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 increased our burden estimate by 83,393 hours (from 278,382 to 361,775), although the number of responses decreased by 19,122 (from 279,927 to 260,805). Among other considerations, we attribute this adjustment primarily due to a significant increase in the number of foreign facility registrations and updates submitted coupled with a drastic decrease in the number of cancellations and third-party registration and U.S. Agent verifications submitted.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–D–3049]

Postapproval Methods To Capture Safety and Efficacy Data for Cell and Gene Therapy Products; Draft Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) is announcing the availability of a draft document entitled ''Postapproval Methods to Capture Safety and Efficacy Data for Cell and Gene Therapy Products; Draft Guidance for Industry.'' The draft guidance document discusses methods and approaches for capturing postapproval safety and efficacy data for cell and gene therapy (CGT) products. Given the potential for long-lasting effects of CGT products, and the generally limited number of participants treated in clinical trials, the collection of postapproval study data for CGT products is important for gathering data on product safety and effectiveness over time.

DATES: Submit either electronic or written comments on the draft guidance by December 24, 2025 to ensure that the Agency considers your comment on this draft guidance before it begins work on the final version of the guidance.

ADDRESSES: You may submit comments on any guidance at any time as follows:

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.*