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

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Smokeless	32	1	32	0.63	20
Total					466
2. Testing of HPHC Quantities in Products					
Cigarette Filler and RYO	10	1	10	9.42	94
Smokeless	32	1	32	12.06	386
Total					480
3. Testing of HPHC Quantities in Mainstream Smoke					
Cigarette: ISO Regimen	243	1	243	23.64	5,745
Cigarette: Health Canada Regimen	243	1	243	23.64	5,745
Total					11,490
Total Section 904(c)(1) Reporting Burden Hours					12,436

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

We have revised our burden estimates to this information collection request. Our burden estimates have been updated based on the assumption that ''Each respondent represents a statutory tobacco product that receives authorization from FDA for which manufacturers and importers (or their agents), must report their product information to FDA under section 904(c)(1) of the FD&C Act at least 90 days prior to delivery for introduction into interstate commerce for all new products.'' Under this assumption, the number of respondents is equal to the number of total annual responses FDA estimated from previous submissions. This assumption will facilitate future burden estimates, allow us to refine the estimated burden to include only the products that need to report HPHCs under section 904(c)(1) of the FD&C Act, and avoid data suppression issues with disaggregated Alcohol and Tobacco Tax and Trade Bureau data.

- Cigarette—section 904(c)(1) Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms/Testing of HPHC is reflecting a reduction in 137 respondents from 380 to 243.
- Roll Your Own Tobacco Product—section 904(c)(1) Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms is reflecting a reduction in 9 respondents from 19 to 10.
- Smokeless—section 904(c)(1) Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms is reflecting an increase in 7 respondents from 25 to 32.

The cumulative changes to the estimated burden for this information collection reflects an overall decrease of 6,727 burden hours and a corresponding decrease of 139 responses.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11959 Filed 6–26–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–0373]

Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities

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 provisions of the Agency's regulations that require registration for domestic and foreign facilities that manufacture, process, pack, or hold food for human or animal consumption in the United States.

DATES: Either electronic or written comments on the collection of information must be submitted by August 26, 2025.

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 August 26, 2025. 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–2025–0373 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Registration of Food Facilities.'' 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: 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: 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.

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) 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 whether or not 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.

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.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11951 Filed 6–26–25; 8:45 am]

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DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2013–D–0744]

Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers; Guidance for Industry; Availability

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice of availability.

SUMMARY: The Food and Drug Administration (FDA or Agency) is announcing the availability of a final guidance for industry entitled ''Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers.'' This guidance assists in the clinical development of new antibacterial drugs to treat serious bacterial diseases in patients with unmet medical needs, including patients with a serious bacterial disease for which effective antibacterial drugs are limited or lacking. This guidance finalizes the draft guidance entitled ''Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers (Revision 1)'' issued on May 24, 2022.

DATES: The announcement of the guidance is published in the **Federal Register** on June 27, 2025.

ADDRESSES: You may submit either electronic or written comments on Agency guidances 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