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]

BILLING CODE 4164–01–P

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

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–2013–D–0744 for ''Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers.'' 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 single copies of this guidance to the Division of Drug Information, Center for Drug Evaluation and Research, Food and Drug Administration, 10001 New Hampshire Ave., Hillandale Building, 4th Floor, Silver Spring, MD 20993–0002. Send one self-addressed adhesive label to assist that office in processing your requests. See the **SUPPLEMENTARY INFORMATION** section for electronic access to the guidance document.

FOR FURTHER INFORMATION CONTACT: Ramya Gopinath, Center for Drug Evaluation and Research, Food and Drug Administration, 10903 New Hampshire Avenue, Bldg. 22, Rm. 6150, Silver Spring, MD 20993, 240–402–5328.

SUPPLEMENTARY INFORMATION:

I. Background

FDA is announcing the availability of a guidance for industry entitled ''Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers.'' The Federal Food, Drug, and Cosmetic Act (FD&C Act) provides several regulatory programs that are intended to expedite development and review of drugs for serious conditions. For example, section 3042 of the 21st Century Cures Act (Pub. L. 114–255) established the limited population pathway for antibacterial and antifungal drugs (LPAD), to facilitate the development of certain drugs that are intended to treat a serious or life-threatening infection in a limited population of patients with unmet medical needs. The purpose of this guidance is to assist sponsors in the clinical development of new antibacterial drugs to treat serious bacterial diseases in patients with unmet medical needs. FDA considered the applicability of Executive Order 14192, per OMB guidance in M–25–20, and finds this action to be deregulatory in nature.

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 (87 FR 31568). FDA provided clarifying edits to the final guidance and included additional information after considering comments received on the draft guidance. Edits included deleting the nested noninferiority trials/superiority clinical trials section because of difficulty in interpreting such trials, updating the add-on superiority trial design section, and updating to include subjects with infections across body sites in trials.

This guidance is being issued consistent with FDA's good guidance practices regulation (21 CFR 10.115). The guidance represents the current thinking of FDA on ''Antibacterial Therapies for Patients With an Unmet Medical Need for the Treatment of Serious Bacterial Diseases—Questions and Answers.'' 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

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 (44 U.S.C. 3501–3521). The collections of information in 21 CFR part 312 for the submissions of investigational new drug applications, including clinical trial design, have been approved under OMB control number 0910–0014. The collections of information in 21 CFR part 314 pertaining to the submissions of new drug applications have been approved under OMB control number 0910–0001. The collections of information in the guidance for industry entitled ''Expedited Programs for Serious Conditions—Drugs and Biologics'' have been approved under OMB control number 0910–0765. The collections of information in 21 CFR 201.56 and 201.57 for the content and format requirements for labeling of drugs and

biologics have been approved under OMB control number 0910–0572.

III. Electronic Access

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

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11928 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–N–0378]

Agency Information Collection Activities; Proposed Collection; Comment Request; Exemptions From Substantial Equivalence Requirements for Tobacco Products

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 ''Exemptions From Substantial Equivalence Requirements for Tobacco Products.''

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–N–0378 for ''Exemptions From Substantial Equivalence Requirements for Tobacco Products.'' 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