if selected into the pilot, or deny letter within 90 days of receipt.

In selecting INDs for the pilot program, FDA intends to consider factors such as: (1) anticipated clinical benefits of facilitating earlier patient access to the product, (2) novelty of the product, (3) complexity of the product or its manufacturing process, including technology, and (4) anticipated CMC challenges. Overall, FDA intends to seek balance and diversity in product types and therapeutic indications to obtain a variety of relevant experience and learnings from the pilot.

D. FDA-Sponsor Interactions During the Pilot

During this CDRP program, sponsors will have the ability to discuss their product development strategies and goals with FDA review staff during the two dedicated Type B meetings, as well as in additional CMC-focused discussions. Besides additional interactions and collaboration with FDA, for those INDs in the pilot, FDA will assemble a team to support the CMC development and readiness of the IND, *e.g.,* participating in the meetings and other discussions under the pilot.

In preparation for a meeting, sponsors should submit written questions along with a background information package clearly marked as a ''PDUFA VII CDRP meeting'' as part of the cover letter to enable FDA review staff to address the questions. The briefing package should be submitted to the corresponding IND. Meetings associated with the pilot should be requested by sponsors. For additional information on meetings and other communications between the sponsors and FDA, see the FDA guidance for industry titled ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (August 2026) (Ref. 7), CDER MAPP 6025.6: ''Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics'' (Rev. 1) (February 2024) (Ref. 8), CBER ''SOPP 8101.1: Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products'' (December 2025) (Ref. 9), and CBER ''SOPP 8212: Breakthrough Therapy Products—Designation and Management'' (April 2026) (Ref. 10).

III. Paperwork Reduction Act of 1995

Collections of information from fewer than 10 respondents within any 12-month period are not subject to the Paperwork Reduction Act of 1995 (PRA) (5 CFR 1320.3(c)(4)). To the extent this information collection involves 10 or more respondents within any 12-month period, the collections of information are subject to the PRA. These collections of information are subject to review by the Office of Management and Budget (OMB) under the PRA (44 U.S.C. 3501–3521). The collections of information for NDAs, formal meetings with sponsors and applicants for PDUFA products, and the PDUFA VII Commitment Letter have been approved under OMB control number 0910–0001. The collections of information for INDs have been approved under OMB control number 0910–0014. The collections of information for BLAs have been approved under OMB control number 0910–0338. The collections of information pertaining to CGMP requirements have been approved under OMB control number 0910–0139. The collections of information pertaining to expedited programs for serious conditions for drugs and biologics and breakthrough therapy-designation for drugs and biologics have been approved under OMB control number 0910–0765.

IV. References

The following references are on display at the Dockets Management Staff (HFA–305), Food and Drug Administration, 5630 Fishers Lane, Rm. 1061, Rockville, MD 20852, 240–402–7500, and are available for viewing by interested persons between 9 a.m. and 4 p.m., Monday through Friday; they are also available electronically at *https://www.regulations.gov.* Although FDA verified the website addresses in this document, please note that websites are subject to change over time.

1. ''PDUFA Reauthorization Performance Goals and Procedures Fiscal Years 2023 Through 2027.'' Available at *https://www.fda.gov/media/151712/download.*
2. FDA, Guidance for Industry: ''Expedited Programs for Serious Conditions—Drugs and Biologics'' (May 2014). Available at *https://www.fda.gov/media/86377/download.*
3. FDA's Strategy Document on Facilitating Chemistry, Manufacturing, and Controls Readiness for Products with Accelerated Clinical Development (July 2026). Available at *https://www.fda.gov/media/193747/download?attachment.*
4. FDA, Guidance for Industry: ''Providing Regulatory Submissions in Electronic Format—Certain Human Pharmaceutical Product Applications and Related Submissions Using the eCTD Specifications'' (Rev. 8) (September 2024). Available at *https://www.fda.gov/media/135373/download.*
5. FDA, Guidance for Industry: ''Process Validation: General Principles and Practices'' (Rev. 1) (January 2011): *https://www.fda.gov/media/71021/download.*
6. CDER MAPP 5015.13: ''Quality Assessment for Products in Expedited Programs'' (Rev. 1) (July 2025). Available at *https://www.fda.gov/media/187958/download?attachment.*
7. FDA, Guidance for Industry: ''Formal Meetings Between the FDA and Sponsors or Applicants of PDUFA Products'' (August 2026): *https://www.fda.gov/media/172311/download.*
8. CDER MAPP 6025.6: ''Good Review Practice: Management of Breakthrough Therapy-Designated Drugs and Biologics'' (Rev. 1) (February 2024). Available at *https://www.fda.gov/media/89155/download.*
9. CBER ''SOPP 8101.1: ''Regulatory Meetings with Sponsors and Applicants for Drugs and Biological Products'' (December 2025). Available at *https://www.fda.gov/media/84040/download?attachment.*
10. CBER ''SOPP 8212: Breakthrough Therapy Products—Designation and Management'' (April 2026). Available at *https://www.fda.gov/media/98351/download?attachment.*

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19277 Filed 9–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10033]

Agency Information Collection Activities; Proposed Collection; Comment Request; Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002

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 Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.

DATES: Either electronic or written comments on the collection of information must be submitted by November 20, 2026.

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 November 20, 2026. 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–2026–N–10033 for ''Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002.'' 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: Amber Barrett, 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: 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.

Prior Notice of Imported Food Under the Public Health Security and Bioterrorism Preparedness and Response Act of 2002—21 CFR 1.278 to 1.285

OMB Control Number 0910–0520—Extension

The Public Health Security and Bioterrorism Preparedness and Response Act of 2002 (Bioterrorism Act) added section 801(m) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 381(m)), which requires that FDA receive prior notice for food, including food for animals, that is imported or offered for import into the United States. Sections 1.278 to 1.282 of FDA regulations (21 CFR 1.278 to 1.282) set forth the requirements for submitting prior notice; §§ 1.283(d) and 1.285(j) (21 CFR 1.283(d) and 1.285(j)) set forth the procedure for requesting Agency review after FDA has refused admission of an article of food under section 801(m)(1) of the FD&C Act or placed an article of food under hold under section 801(l) of the FD&C Act; and § 1.285(i) sets forth the procedure for post-hold submissions.

Section 304 of the FDA Food Safety Modernization Act (Pub. L. 111–353)

amended section 801(m) of the FD&C Act to require a person submitting prior notice of imported food, including food for animals, to report, in addition to other information already required, ''any country to which the article has been refused entry.'' Advance notice of imported food allows FDA, with the support of the U.S. Customs and Border Protection (CBP), to target import inspections more effectively and help protect the nation's food supply against terrorist acts and other public health emergencies. By requiring that a prior notice contain specific information that indicates prior refusals by any country and identifies the country or countries, the Agency may better identify imported food shipments that may pose safety and security risks to U.S. consumers.

This information collection enables FDA to make better informed decisions in managing the potential risks of imported food shipments into the United States. Any person with knowledge of the required information may submit prior notice for an article of food. Thus, the respondents to this information collection may include importers, owners, ultimate consignees, shippers, and carriers.

FDA regulations require that prior notice of imported food be submitted electronically using CBP's Automated Broker Interface of the Automated Commercial Environment (ABI/ACE) (§ 1.280(a)(1)) or the FDA Prior Notice System Interface (PNSI) (Form FDA 3540) (§ 1.280(a)(2)). PNSI is an electronic submission system available on the FDA Industry Systems page at *https://www.access.fda.gov.* Information the Agency collects in the prior notice submission includes: (1) the submitter and transmitter (if different from the submitter); (2) entry type and CBP entry identifier; (3) the article of food, including complete FDA product code, common or usual name or market name, and quantity; (4) the manufacturer, for an article of food no longer in its natural state; (5) the grower, if known, for an article of food that is in its natural state; (6) the FDA Country of Production; (7) the name of any country that has refused entry of the article of food; (8) the shipper; (9) the country from which the article of food is shipped or, if the food is imported by international mail, the anticipated date of mailing and country from which the food is mailed; (10) the anticipated arrival information or, if the food is imported by international mail, the U.S. recipient; (11) the importer, owner, and ultimate consignee, except for food imported by international mail or transshipped through the United States; (12) the carrier and mode of transportation, or name of the mail service for international mail shipments; and (13) planned shipment information, or mail tracking number for food imported by international mail (§ 1.281).

Much of the information collected for prior notice is identical to the information collected for FDA importer's entry notice, which has been approved under OMB control number 0910–0046. The information in an importer's entry notice is collected electronically via CBP's ABI/ACE at the same time the respondent files an entry for import with CBP. To avoid double-counting the burden hours already counted in the importer's entry notice information collection, the burden hour analysis in table 1 reflects FDA's estimate of the reduced burden for prior notice submitted through ABI/ACE in column 6 entitled ''Average Burden per Response.''

In addition to submitting a prior notice, a submitter should cancel a prior notice and must resubmit the information to FDA if information changes after the Agency has confirmed a prior notice submission for review (*e.g.,* if the identity of the manufacturer changes) (§ 1.282). However, changes in the estimated quantity, anticipated arrival information, or planned shipment information do not require resubmission of prior notice after the Agency has confirmed a prior notice submission for review (§ 1.282(a)(1)(i) to (iii)). If FDA refuses admission of an article of food under section 801(m)(1) of the FD&C Act, § 1.283(c) sets forth the procedure for submitting prior notice after refusal. In the event that FDA refuses admission to an article of food under section 801(m)(1) or the Agency places it under hold under section 801(l) of the FD&C Act, §§ 1.283(d) and 1.285(j) set forth the procedure for requesting FDA's review and the information required in a request for review. In the event that the Agency places an article of food under hold under § 801(l) of the FD&C Act, § 1.285(i) sets forth the procedure for, and the information to be included in, a post-hold submission.

This information collection incorporates the reporting requirements established by the final rule, *Prior Notice: Adding Requirement to Submit Mail Tracking Number for Articles of Food Arriving by International Mail and Timeframe for Post-refusal and Post-hold Submissions* (90 FR 46046, September 25, 2025). The final rule amended § 1.281(b)(10) (21 CFR 1.281(b)(10)) to require submitters of prior notice for articles of food arriving by international mail to provide the name of the mail service and the mail tracking number beginning October 1, 2026. The rule also amended §§ 1.283 and 1.285 (21 CFR 1.283 and 1.285) to establish timeframes for post-refusal prior notice submissions and post-hold food facility registration submissions. These reporting requirements are incorporated into this information collection and reflected in the burden estimates below.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Prior Notice Submissions:						
Through ABI/ACE.						
1.280 through 1.281	N/A	3,294	5,898	19,428,012	0.167 (10 minutes)	3,244,478
Through PNSI.						
1.280 through 1.281	[3] 3540	225,075	24	5,401,800	0.384 (23 minutes)	2,074,291
Subtotal						5,318,769
Cancellations:						
Through ABI/ACE						
1.282	N/A	27,666	1	27,666	0.25 (15 minutes)	6,917
Through PNSI:.						

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

21 CFR section	FDA form No.	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
1.282 and 1.283(a)(5)	3540	64,621	1	64,621	0.25 (15 minutes)	16,155
Subtotal						23,072
Requests for Review and Post-hold Submissions:						
1.283(d) and 1.285(j)	N/A	1	0	1	8	8
1.285(i)	N/A	189	1	189	1	189
Subtotal						189
Mail Service and Tracking Number:						
One-Time Burden		5,460	1	5,460	0.50 (30 minutes)	2,730
Recurring Burden			143	780,780	0.07 (4 minutes)	54,655
Subtotal						57,385
Overall Total		331,765		25,761,671		5,419,656

[1] There are no capital costs or operating and maintenance costs associated with this collection of information.
[2] The term ''Form FDA 3540'' refers to the electronic submission system known as PNSI, which is available at *https://www.access.fda.gov.*

Since the last OMB approval, FDA has revised this information collection to consolidate the previously approved information collection under OMB Control No. 0910–0923, which covers the reporting requirements for the mail service and mail tracking number associated with prior notice submissions for articles of food arriving by international mail. Our estimated burden for this information collection reflects an overall increase of 7,629,528 hours and a corresponding increase of 1,721,959 responses. We attribute this adjustment to the overall growth in United States food importation, changes in *de minimis* exemptions, and the aforementioned new requirements for international mail shipments.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2026–19281 Filed 9–18–26; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2026–N–10363]

Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit Applications

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 reporting requirements contained in existing FDA regulations governing temporary marketing permit applications.

DATES: Either electronic or written comments on the collection of information must be submitted by November 20, 2026.

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 November 20, 2026. 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–2026–N–10363 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Temporary Marketing Permit