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.

User Fees for Domestic Manufacturers and Importers of Tobacco Products

OMB Control Number 0910–0749—Extension

This information collection supports Food and Drug Administration regulations. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387–387t). Specifically, section 919 of the FD & C Act (21 U.S.C. 387s) governs tobacco user fees.

Section 919(a) requires FDA to ''assess user fees on, and collect such fees from, each manufacturer and importer of tobacco products'' subject to the tobacco product provisions of the FD&C Act. Accordingly, section 919(b)(2)(B)(i) of the FD&C Act (21 U.S.C. 387s (b)(2)(B)(i)) identifies those tobacco products as: cigarettes, cigars, snuff, chewing tobacco, pipe tobacco, and roll-your-own tobacco.

To implement the tobacco user fee program as prescribed in the FD&C Act (as summarized above), FDA must collect the information needed to accurately calculate tobacco user fee assessments. On May 10, 2016, FDA published a final rule that requires domestic manufacturers and importers of the applicable tobacco products (listed above) to submit this information to the FDA (81 FR 28707).

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

21 CFR section	Number of respondents	Number of responses per respondent	Total number of annual responses	Average burden per response in hours	Total hours
1150.5(a), (b)(1) and (2), and Form FDA 3852; Identification and removal information (monthly)	820	12	9,840	3	29,520
1150.5(b)(3); Certified copies (monthly)	820	12	9,840	1	9,840
Voluntary premium cigar data submission (monthly)	50	12	600	1.5	900
1150.13; Payment of user fee assessment (quarterly)	319	4	1,276	1	1,276
1150.15(a); Submission of user fee dispute (at discretion of respondent)	2	1	2	10	20
1150.15(d); Submission of request for further review of dispute of user fee (at discretion of respondent)	1	1	1	5	5
Total	.....	.....	21,559	.....	41,561

[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.

21 CFR 1150.5 is reflecting an increase in 120 respondents from 700 to 820. FDA considered the number of active Alcohol and Tobacco Tax and Trade Bureau (TTB) permits (based on TTB data) in FY23 for domestic manufacturers and importers of tobacco products subject to tobacco user fees.

Voluntary premium cigar data submission (monthly) is reflecting a reduction in 50 respondents from 100 to 50 and a reduction in average burden per response from 2.5 to 1.5 hours. FDA updated this data based on reasonable estimates of the burden of voluntary submissions in FY24. There may be some fluctuations in this number.

Section 1150.13 (21 CFR 1150.13) is reflecting a reduction in 57 respondents from 376 to 319. FDA considered the number of user fee assessments issued to domestic manufacturers and importers of tobacco products subject to tobacco user fees on average each quarter for FY23. Note, entities may have more than one TTB permit, however, tobacco user fee assessments are aggregated based on Employer Identification Number and not TTB permit number. Therefore, we expect the number of respondents to be lower for § 1150.13.

21 CFR 1150.15(a) is reflecting a reduction in 3 respondents from 5 to 2, and 21 CFR 1150.15(d) is reflecting a reduction in 2 respondents from 3 to 1 and a reduction in average burden per response from 10 to 5 hours. FDA considered the historical submission of tobacco user fee disputes and requests for additional Agency review.

The cumulative changes to the estimated burden for this information collection reflects an overall increase of 3,377 burden hours and a corresponding increase of 2,047 responses.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07585 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0183]

Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of United States Establishments With Interest in Exporting Human Food Program-Regulated 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 the information collection associated with export lists for products regulated by the Human Food Program (HFP).

DATES: Either electronic or written comments on the collection of information must be submitted by June 30, 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 June 30, 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–0183 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Establishing and Maintaining Lists of United States Establishments with Interest in Exporting Human Food Program-Regulated 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 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.

Establishing and Maintaining Lists of U.S. Establishments With Interest in Exporting HFP-Regulated Products

OMB Control Number 0910–0509—Extension

This information collection supports Agency export programs and associated guidance. The United States exports a large volume and variety of foods in international trade. Foreign governments often require official certification from the responsible authority of the country of origin about imported foods and establishments involved in their production, storage, or distribution. Some foreign governments

establish additional requirements with which exporters are required to comply and ask for additional assurances from the responsible authority. Importing countries may require, and FDA may provide, official certification or assurances for food products in different forms, including certificates that accompany specific products or lists of establishments and products that comply with certain requirements.

To facilitate exports of food subject to importing country listing requirements, FDA has historically provided official certification in the form of country- and product-specific export lists that include establishments and their products when: (1) the establishment has expressed interest in exporting their products to these countries; (2) the establishment and the products are subject to FDA's jurisdiction; and (3) the establishment can demonstrate that it is in good regulatory standing for the products it intends to export, and the products are expected to comply with applicable FDA requirements. As we advised in the guidance document ''Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China,'' FDA considers ''good regulatory standing'' as meaning that an establishment is in substantial compliance with applicable FDA requirements and is not the subject of a pending enforcement action (*e.g.,* an injunction or seizure) or pending administrative action (*e.g.,* a warning letter).

FDA has generally published guidance documents for these country and product-specific lists under the authority of section 701(h) of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (21 U.S.C. 371(h)), which authorizes the Secretary of Health and Human Services (the Secretary) to develop guidance documents with public participation presenting the views of the Secretary on matters under the jurisdiction of FDA. The guidance documents generally explain what information establishments should submit to FDA to be considered for inclusion on the lists and what criteria FDA intends to use to determine eligibility for placement on the lists. The guidance documents also explain how FDA intends to update the lists and communicate any new information to the governments that requested the lists. Finally, the guidance documents note that the information is provided voluntarily by establishments with the understanding that it may be posted on FDA's external website and that it will be communicated to, and possibly further disseminated by, the government that requested the list; thus, FDA considers the information on the lists to be information that is not protected from disclosure under 5 U.S.C. 552(b)(4). The guidance documents include ''Establishing and Maintaining a List of U.S. Dairy Product Manufacturers/Processors with Interest in Exporting to Chile'' (November 2018) and ''Establishing and Maintaining a List of U.S. Milk and Milk Product, Seafood, Infant Formula, and Formula for Young Children Manufacturers/Processors with Interest in Exporting to China'' (November, 2018) available at *https://www.fda.gov/food/guidance-regulation-food-and-dietary-supplements/guidance-documents-regulatory-information-topic-food-and-dietary-supplements.* Additional information about FDA's Food Export Lists program is available at *https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists.* FDA has also published guidance on export certification that contains useful information that applies to export lists: ''FDA Export Certification'' (August 2021) available at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/fda-export-certification.*

Foreign governments are increasingly relying on certification as a strategy for ensuring the safety of imported food products, and many countries have announced new requirements for lists of establishments and products certified to comply with certain food safety requirements. FDA is committed to facilitating compliance with new listing requirements for U.S. establishments that export FDA-regulated food products by establishing and maintaining country- and product-specific export lists.

Application for inclusion on all export lists will continue to be voluntary. However, some foreign governments may require inclusion on export lists as a precondition for market access or to satisfy other importing country registration or approval requirements. FDA uses the Export Listing Module (ELM), an electronic system (Form FDA 3972), to receive and process applications for inclusion on export lists for HFP-regulated products. The ELM allows applicants to provide information about the products intended for export, the establishment that produces those products, evidence of the establishment's compliance with applicable requirements for the products intended for export, and any additional data or information (such as third-party certifications) that foreign governments may require. We request that this information be updated every 2 years. Additional information and screenshots of the ELM are available at *https://www.fda.gov/food/exporting-food-products-united-states/food-export-lists.* If an establishment is unable to submit an application via the ELM, it may contact HFP and request assistance.

We use the information submitted by establishments to determine eligibility for certification and inclusion on the export lists, which may be published on our website or the websites of foreign governments. The purpose of the lists is to help HFP-regulated industries meet the import requirements of foreign governments. This collection of information is intended to cover all of HFP's existing export lists, as well as any additional export lists established by the program.

FDA notes section 801 of the FD&C Act (21 U.S.C. 381) also provides that FDA may charge a fee of up to $175 if the Agency issues export certification within 20 days of receipt of a complete request for such certification.

Description of Respondents: Respondents to this collection of information include U.S. establishments subject to FDA/HFP jurisdiction that wish to be included on export lists.

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

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN [1]

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
New request	167	5	835	1	835
New request + third-party certification	85	2	170	22	3,740
Biennial update	132	4	528	0.5 (30 minutes)	264
Biennial update + third-party certification	58	2	116	22	2,552

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
Occasional updates	60	2	120	0.5 (30 minutes)	60
Total			1,769		7,451

[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.

Dated: April 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–07591 Filed 4–30–25; 8:45 am]

BILLING CODE 4164–01–P

DEPARTMENT OF HEALTH AND HUMAN SERVICES

Food and Drug Administration

[Docket No. FDA–2025–N–0338]

Agency Information Collection Activities; Proposed Collection; Comment Request; Export Notification and Recordkeeping Requirements

AGENCY: Food and Drug Administration, HHS.

ACTION: Notice.

SUMMARY: The Food and Drug Administration (FDA, Agency, or we) 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 information collection associated with notifications and records required for human drug, biological product, device, animal drug, food, cosmetic, and tobacco product exports.

DATES: Either electronic or written comments on the collection of information must be submitted by June 30, 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 June 30, 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–0338 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Export Notification and Recordkeeping Requirements.'' 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