we have made no adjustments to our burden estimate.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11949 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–0350]

Agency Information Collection Activities; Proposed Collection; Comment Request; Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

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 Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act.

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–0350 for ''Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act.'' 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, 301–796–3794, *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.

Reporting Harmful and Potentially Harmful Constituents in Tobacco Products and Tobacco Smoke Under the Federal Food, Drug, and Cosmetic Act

OMB Control Number 0910–0732—Extension

This information collection supports FDA regulations. Tobacco products are governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 920) (21 U.S.C. 387 through 21 U.S.C. 387t). The FD&C Act provides FDA with the authority to regulate the manufacture, marketing, and distribution of cigarettes, cigarette tobacco, roll-your-own (RYO) tobacco, and smokeless tobacco products to protect the public health and to reduce tobacco use by minors. FDA has the authority to issue regulations deeming other products that meet the statutory definition of a tobacco product to be subject to chapter IX of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))). In accordance with that authority, FDA issued a rule deeming all products that meet the statutory definition of tobacco product, except accessories of newly deemed tobacco products, to be subject to FDA's tobacco product authority (81 FR 28974, May 10, 2016). The definition of the term ''tobacco product'' in section 201(rr) of the FD&C Act (21 U.S.C. 321(rr)) products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products (*e.g.,* products containing synthetic nicotine) are subject to all of the tobacco product provisions in the FD&C Act. Although NTN products are now subject to all of the tobacco product provisions in the FD&C Act, including section 904 provisions of the FD&C Act, FDA does not expect cigarettes, RYO tobacco, and smokeless tobacco products, for which Form FDA 3787a–j was developed, to also include NTN products.

Chapter IX of the FD&C Act applies to regulated tobacco products, including sections 904(a)(3) and (c)(1) (21 U.S.C. 387d(a)(3) and (c)(1)). Section 904(a)(3) of the FD&C Act requires the submission of an initial report from each tobacco product manufacturer or importer, or agents thereof, listing all constituents, including smoke constituents as applicable, identified as a harmful and potentially harmful constituent (HPHC) to health by FDA. Reports must be by brand and by quantity in each brand and subbrand.

Section 904(c)(1) of the FD&C Act provides that manufacturers of tobacco products not on the market as of June 22, 2009, must also provide the information reportable under section 904(a)(3) of the FD&C Act at least 90 days prior to introducing the product into interstate commerce.[1]

FDA has taken several steps to identify HPHCs to be reported under section 904 of the FD&C Act, including issuing a guidance discussing FDA's current thinking on the meaning of the term ''harmful and potentially harmful constituent'' in the context of implementing the HPHC list requirement under section 904(e) of the FD&C Act (76 FR 5387, January 31, 2011, revised guidance issued August 2016). The guidance is available on the internet at *https://www.fda.gov/regulatory-information/search-fda-guidance-documents/harmful-and-potentially-harmful-constituents-tobacco-products-used-section-904e-federal-food-drug.* The current established list of HPHCs also is available on the internet at *https://www.fda.gov/tobacco-products/rules-regulations-and-guidance/harmful-and-potentially-harmful-constituents-tobacco-products-and-tobacco-smoke-established-list* (77 FR 20034, April 3, 2012).

The purpose of the information collection is to collect statutorily mandated information regarding HPHCs in certain tobacco products and tobacco smoke, by brand and by quantity in each brand and subbrand.

To facilitate the submission of HPHC information, Forms FDA 3787a–j, for cigarettes, smokeless tobacco products, and RYO tobacco products, respectively, in both paper and electronic formats, are available. Additionally, FDA is developing forms to facilitate the submission of HPHC information for the deemed tobacco products. We intend to model these forms on the current HPHC reporting forms (*i.e.,* Forms FDA 3787a–j).

Manufacturers or importers, or their agents, will be able to submit HPHC information either electronically through new web forms within the Center for Tobacco Products (CTP) Portal Next Generation or in paper format. The modernized web forms will streamline data entry and submission for reporting HPHCs for cigarettes, smokeless tobacco products, and RYO tobacco products. This process will be more efficient than the current approach, which requires the use of the FDA's eSubmitter Desktop Tool for data entry and the CTP Portal web application for submission. With CTP Portal Next Generation, necessary tasks will be completed directly within the web forms, making HPHC submissions more user-friendly.

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
Reporting for Section 904(c)(1) Products					
1. Reporting of Manufacturer/Importer Company and Product Information by Completing Submission Forms					
Cigarette	243	1	243	1.82	442
RYO	10	1	10	0.43	4

[1] Note that section 904(c)(1) testing and reporting requirements are separate from the requirements that must be satisfied before a new tobacco product (sections 905 and 910 of the FD&C Act (21 U.S.C. 387e and 387j)), or modified risk tobacco product (section 911 of the FD&C Act (21 U.S.C. 387k)) may be marketed.

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