payment application, for online electronic payment. The *Pay.gov* feature is available on the FDA website upon receipt of an invoice or after completing the User Fee Cover Sheet and generating the user fee ID number.

Secure electronic payments to FDA can be submitted using the User Fees Payment Portal at *https://userfees.fda.gov/pay.* (*Note:* Only full payments are accepted; no partial payments can be made online.) Once an invoice or cover sheet is located, ''Pay Now'' should be selected to be redirected to *Pay.gov*. Electronic payment options are based on the balance due. Payment by credit card is available for balances less than $25,000. If the balance exceeds this amount, only the ACH option is available. Payments must be made using U.S. bank accounts as well as U.S. credit cards.

For payments made by wire transfer, include the unique user fee ID or invoice number to ensure that the payment is applied to the correct fee(s). Without the unique user fee ID or invoice number, the payment may not be applied. If the payment amount is not applied, the invoice balance due amount will be referred to collections. The originating financial institution may charge a wire transfer fee. Include applicable wire transfer fees with payment to ensure fees are fully paid. Questions about wire transfer fees should be addressed to the financial institution. The following account information should be used to send payments by wire transfer: U.S. Department of the Treasury, TREAS NYC, 33 Liberty St., New York, NY 10045, Account No: 75060099, Routing No. 021030004, SWIFT: FRNYUS33. FDA's tax identification number is 53–0196965.

III. Electronic Federal Payment Methods

All entities receiving funds from FDA, including but not limited to vendors or other entities receiving reimbursements or refunds, must have a valid and active electronic payment method on file with the Agency, such as ACH Direct Deposit or other Treasury-authorized payment methods (FedWire or International ACH). Failure to provide this information may result in delays in payment or inability to receive funds.

Dated: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11920 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–0351]

Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission

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 tobacco health document submissions.

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 postmarked or the delivery service acceptance receipt is 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–0351 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Tobacco Health Document Submission.'' 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.

Tobacco Health Document Submission

OMB Control Number 0910–0654—Extension

This information collection supports FDA guidance. The Federal Food, Drug, and Cosmetic Act (FD&C Act) authorizes FDA to regulate the manufacture, marketing, and distribution of tobacco products to protect the public health generally and to reduce tobacco use by minors.

Section 904(a)(4) of the FD&C Act ((21 U.S.C. 387d(a)(4)) requires each tobacco product manufacturer or importer, or agent thereof, to submit all documents developed after June 22, 2009, ''that relate to health, toxicological, behavioral, or physiologic effects of current or future tobacco products, their constituents (including smoke constituents), ingredients, components, and additives'' (herein referred to as ''tobacco health documents'' or ''health documents'').

The guidance document ''Health Document Submission Requirements for Tobacco Products (Revised)'' (2023) (*https://www.fda.gov/regulatory-information/search-fda-guidance-documents/tobacco-health-document-submission*) requests tobacco health document submissions from manufacturers and importers of tobacco products based on statutory requirements and compliance dates.[1] As indicated in the guidance, all manufacturers and importers of tobacco products are now subject to the FD&C Act and are required to comply with section 904(a)(4), which requires immediate and ongoing submission of health documents developed after June 22, 2009 (the date of enactment of the Family Smoking Prevention and Tobacco Control Act (Pub. L. 111–31)). However, FDA generally does not intend to enforce the requirement at this time with respect to all such health documents, so long as a specified set of documents, those developed between June 23, 2009, and December 31, 2009, are provided at least 90 days prior to the delivery for introduction of tobacco products into interstate commerce. Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA. All Agency guidance documents are issued in accordance with our good guidance practice regulations in 21 CFR 10.115, which provide for public comment at any time.

FDA has been collecting the information submitted pursuant to section 904(a)(4) of the FD&C Act through a facilitative electronic form and through a paper form (Form FDA 3743) for those individuals who choose not to use the electronic method. You may access the electronic and paper forms on our website, at *https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal* and *https://www.fda.gov/media/78652/download,* respectively. In addition to the electronic and paper forms, FDA issued the guidance on this collection to assist persons making tobacco health document submissions. For further assistance, FDA has provided a technical guide, embedded hints, and a web tutorial on the electronic portal via *www.fda.gov/media/78631/download?attachment, https://www.fda.gov/tobacco-products/manufacturing/submit-documents-ctp-portal#what%20can,* and *https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions.*

In this information collection, FDA is proposing to continue its compliance plan and request all manufacturers and importers of tobacco products, if not previously submitted, at least 90 days prior to the delivery for introduction into interstate commerce. Thereafter, manufacturers should preserve all health documents, including those that relate to products for further manufacturing and those developed after December 31, 2009, for future submission to FDA.

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

[1] FDA announced the availability of a guidance on this collection in the **Federal Register** on April 20, 2010 (75 FR 20606) [revised December 5, 2016 (81 FR 87565), August 10, 2017 (82 FR 37459), and March 20, 2023 (88 FR 16636)].

TABLE 1—ESTIMATED ANNUAL REPORTING BURDEN

Activity	Number of respondents	Number of responses per respondent	Total annual responses	Average burden per response	Total hours
Tobacco Health Document Submissions and Form FDA 3743	10	3.2	32	50	1,600

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

FDA estimates that a tobacco health document submission as required by section 904(a)(4) of the FD&C Act, will take approximately 50 hours per submission based on FDA experience. We anticipate documents will be submitted annually for a total of 10 respondents. FDA estimates the total annual reporting burden to be 1,600 hours.

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: June 24, 2025.

Grace R. Graham,

Deputy Commissioner for Policy, Legislation, and International Affairs.

[FR Doc. 2025–11955 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–0123]

Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notifications and Convening Panels

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 collections of information associated with provisions of the notification procedure for substances generally recognized as safe (GRAS) and with recommended activities found in the guidance for convening a GRAS panel.

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

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- *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–0123 for ''Agency Information Collection Activities; Proposed Collection; Comment Request; Substances Generally Recognized as Safe: Notifications and Convening Panels.'' 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