



## DEPARTMENT OF HEALTH AND HUMAN SERVICES

### Food and Drug Administration

[Docket No. FDA-2024-N-5943]

**Agency Information Collection Activities; Proposed Collection; Comment Request;**

**Tobacco Product Establishment Registration and Listing**

**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 revision of an existing collection of information, and to allow 60 days for public comment in response to the notice. This notice solicits comments on “Tobacco Product Establishment Registration and Listing.”

**DATES:** Either electronic or written comments on the collection of information must be submitted by [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*].

**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 [INSERT DATE 60 DAYS AFTER DATE OF PUBLICATION IN THE *FEDERAL REGISTER*]. 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-2024-N-5943 for "Tobacco Product Establishment Registration and Listing." 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 Sanford, 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](mailto: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 revision 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 Product Establishment Registration and Listing

OMB Control Number 0910-0650--Revision

This information collection supports the Food and Drug Administration regulations and guidance. Tobacco products are generally governed by chapter IX of the Federal Food, Drug, and Cosmetic Act (FD&C Act) (sections 900 through 921) (21 U.S.C. 387 through 21 U.S.C. 387u).

Section 905 of the FD&C Act requires the annual registration of any “establishment in any State engaged in the manufacture, preparation, compounding, or processing of a tobacco

product or tobacco products.” Section 905 of the FD&C Act requires this registration be completed by December 31 of each year. The Secretary of Health and Human Services (Secretary) has delegated to the Commissioner of Food and Drugs the responsibility for administering the FD&C Act, including section 905. Section 905 of the FD&C Act requires owners or operators of each establishment to register: (1) their name; (2) places of business; (3) a list of all tobacco products which are manufactured by that person; (4) a copy of all labeling and a reference to the authority for the marketing of any tobacco product subject to a tobacco product standard under section 907 of the FD&C Act (21 U.S.C. 387g) or to premarket review under section 910 of the FD&C Act (21 U.S.C. 387j); (5) a copy of all consumer information and other labeling; (6) a representative sampling of advertisements; (7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product; and (8) upon request made by the Secretary, if the registrant has determined that a tobacco product contained in the product list is not subject to a tobacco product standard established under section 907 of the FD&C Act, a brief statement of the basis upon which the registrant made such determination.

FDA collects the information submitted pursuant to section 905 of the FD&C Act through the Tobacco Registration and Product Listing Module Next Generation (TRLM NG) electronic portal, and through paper forms; Form FDA 3741, “Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments,” available at <https://www.fda.gov/media/77915/download>, and Form FDA 3741a, “Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments,” available at <https://www.fda.gov/media/99863/download>) for those individuals who are unable to submit online through TRLM NG. TRLM NG is designed to streamline the data entry process for registration and product listing. FDA strongly encourages electronic submission through TRLM NG, available at <https://www.fda.gov/tobacco-products/manufacturing/tobacco-registration-and->

listing-module-next-generation-trlm-ng-instructions, to facilitate efficiency and timeliness of data submission and management.

FDA has also published a guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments” (March 2023; <https://www.fda.gov/downloads/TobaccoProducts/Labeling/RulesRegulationsGuidance/UCM191940.pdf>). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

At this time, FDA is proposing several updates to the information submitted pursuant to section 905 of the FD&C Act through Form FDA 3741, Form FDA 3741a, and the corresponding information submitted electronically through TRLM NG. The updates include: (1) merging the contents of Form FDA 3741a into Form FDA 3741 to create an updated and comprehensive Form FDA 3741, “Registration and Product Listing of Tobacco Product Manufacturing Establishments”; (2) restructuring and developing sections of the updated Form FDA 3741 for ease of navigation and data input; (3) updating terminology of the updated Form FDA 3741 for clarity; (4) updating instructions of the updated Form FDA 3741 for clarity; and (5) aligning tobacco product categories and subcategories of the updated Form FDA 3741 to be consistent with other FDA tobacco forms. Finally, FDA is proposing to add a new product listing spreadsheet (Form FDA 3741b) to this information collection. FDA anticipates the new Form FDA 3741b will streamline product listing submissions and subsequent FDA review.

Although these proposed updates will increase the overall length of the updated and comprehensive Form FDA 3741 and the corresponding information submitted electronically through TRLM NG, FDA anticipates these updates will streamline the navigation and completion of Form FDA 3741, cut down on redundancies, increase overall user efficiency and ultimately enable industry to more accurately and efficiently convey the required registration and listing information to FDA as required by section 905 of the FD&C Act. Both “Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments”; Form FDA

3741 and “Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments”; Form FDA 3741a will be discontinued upon implementation of the updated and comprehensive Form FDA 3741; “Registration and Product Listing of Tobacco Product Manufacturing Establishments”.

Section 904(a)(1) of the FD&C Act requires that each tobacco product manufacturer or importer submit “a listing of all ingredients, including tobacco, substances, compounds, and additives that are, as of such date, added by the manufacturer to the tobacco, paper, filter, or other part of each tobacco product by brand and by quantity in each brand and subbrand” by December 22, 2009. This section applies only to those tobacco products manufactured and distributed before June 22, 2009, and which are still manufactured as of the date of the ingredient listing submission.

Section 904(c) of the FD&C Act requires that a tobacco product manufacturer: (1) provide all information required under section 904(a) of the FD&C Act to FDA “at least 90 days prior to the delivery for introduction into interstate commerce of a tobacco product not on the market on the date of enactment”; (2) advise FDA in writing at least 90 days prior to adding any new tobacco additive or increasing in quantity an existing tobacco additive, except for those additives that have been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use; and (3) advise FDA in writing at least 60 days of such action of eliminating or decreasing an existing additive, or adding or increasing an additive that has been designated by FDA through regulation as not a human or animal carcinogen, or otherwise harmful to health under intended conditions of use.

FDA collects the information submitted pursuant to section 904(a)(1) and 904(c) of the FD&C Act through an electronic portal, and through a paper form (Form FDA 3742, “Listing of Ingredients in Tobacco Products” available at <https://www.fda.gov/media/77661/download>) for those individuals who choose not to use the electronic portal.

In addition to the development of the electronic portal and paper form, FDA published a guidance entitled “Listing of Ingredients in Tobacco Products” (March 2023; <https://www.fda.gov/regulatory-information/search-fda-guidance-documents/listing-ingredients-tobacco-products>). This guidance is intended to assist persons making tobacco product ingredient listing submissions. FDA also provides a technical guide, embedded hints, and a web tutorial to the electronic portal, available at <https://www.fda.gov/industry/fda-esubmitter/using-esubmitter-prepare-tobacco-product-submissions>.

The Tobacco Control Act also gave FDA the authority to issue a regulation deeming all other products that meet the statutory definition of a tobacco product<sup>1 2</sup> to be subject to Chapter 9 of the FD&C Act (section 901(b) of the FD&C Act (21 U.S.C. 387a(b))). On May 10, 2016, FDA issued that rule, extending FDA’s tobacco product authority to all products that meet the definition of tobacco product in the law (except for accessories of newly regulated tobacco products), including electronic nicotine delivery systems, cigars, hookah tobacco, pipe tobacco, nicotine gels, and dissolvables that were not already subject to the FD&C Act, and other tobacco products that may be developed in the future (81 FR 28974 at 28976) (“the final deeming rule”).

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

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Table 1.--Estimated Annual Reporting Burden<sup>1</sup>

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<sup>1</sup> Tobacco Product: as stated in section 201(rr) of the FD&C Act in relevant part, a tobacco product: (1) means any product made or derived from tobacco, or containing nicotine from any source, that is intended for human consumption, including any component, part, or accessory of a tobacco product (except for raw materials other than tobacco used in manufacturing a component, part, or accessory of a tobacco product); and (2) does not mean an article that is a drug defined under section 201(g)(1) of the FD&C Act, a device defined under section 201(h) of the FD&C Act, or a combination product described in section 503(g) of the FD&C Act, or a food under section 201(f) of the FD&C Act if it contains no nicotine, or no more than trace amounts of naturally occurring nicotine.

<sup>2</sup> Premium Cigars: on August 9, 2023, the U.S. District Court for the District of Columbia issued an order vacating FDA’s rule deeming tobacco products to be subject to FDA’s tobacco product authorities “insofar as it applies to premium cigars.” *Cigar Ass’n of Am. v. FDA*, No. 16-cv-01460, Dkt. No. 277 (D.D.C. Aug. 9, 2023), appeal filed No. 23-5220 (D.C. Cir. Sep. 29, 2023).

For purposes of its ruling, the court specified that premium cigars are those cigars that: (1) are wrapped in whole tobacco leaf; (2) contain a 100 percent leaf tobacco binder; (3) contain at least 50 percent (of the filler by weight) long filler tobacco; (4) are handmade or hand rolled; (5) have no filter, nontobacco tip, or nontobacco mouthpiece; (6) do not have a characterizing flavor other than tobacco; (7) contain only tobacco, water, and vegetable gum with no other ingredients or additives; and (8) weigh more than 6 pounds per 1,000 units. FDA recognizes that, absent further relief, it is bound by the District Court’s order. The Agency is continuing to evaluate the evolving legal and practical circumstances surrounding premium cigars and will provide further information as it is available.

FDA Form/Activity/FD&C Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
<p>Establishment Registration (Initial), the initial registration of a tobacco product establishment</p> <p>(Current) Form FDA 3741, Registration and Product Listing for Owners and Operators of Domestic Establishments; Form FDA 3741a - Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments (Electronic and Paper submissions)</p> <p>Sections 905(b), 905(c), 905(d), 905(h), or 905(i)</p>	75	1	75	1.6 (96 minutes)	120
<p>Establishment Registration (Initial), the initial registration of a tobacco product establishment</p> <p>(Updated) Form FDA 3741, Registration and Product Listing of Tobacco Product Manufacturing Establishments</p> <p>Sections 905(b), 905(c), 905(d), 905(h), or 905(i)</p>	75	1	75	1.5 (90 mins)	113
<p>Establishment Registration (Renewal), the registration renewal of a tobacco product establishment</p> <p>(Current) Form FDA 3741, Registration and Product Listing for Owners and Operators of Domestic Establishments; Form 3741a - Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments (Electronic and Paper submissions)</p> <p>Sections 905(b), 905(c), 905(d), 905(h), or 905(i)</p>	1,003	1	1,003	.17 (10 minutes)	171
<p>Establishment Registration (Renewal), the registration renewal of a tobacco product establishment</p> <p>(Updated) Form FDA 3741, Registration and Product Listing of Tobacco Product Manufacturing Establishments</p> <p>Sections 905(b), 905(c), 905(d), 905(h), or 905(i)</p>	1,003	1	1,003	.33 (20 min)	331
<p>Product Listing (Initial), the initial listing of tobacco products</p> <p>(New) Form FDA 3741b, (New) Product List and Material File Information Spreadsheet</p>	75	1	75	2 (120 mins)	150

Product Listing (Renewal) updates to the tobacco product listings  (New) Form FDA 3741b, (New) Product List and Material File Information Spreadsheet	1,003	1	1,003	.5 (30 mins)	502
Tobacco Product Listing  Form FDA 3742, Listing of Ingredients  Section 904(a)(1)	16	1	16	.2 (120 mins)	32
Tobacco Product Listing  Form FDA 3742, Listing of Ingredients  Section 904(c)	37	10	370	.40 (24 minutes)	148
Obtaining a Dun and Bradstreet D-U-N-S Number	100	1	100	0.5 (30 minutes)	50
Total			2,642		1,617

We have revised our burden estimates to this information collection. FDA has based these estimates on experience with this information collection, information we have available from interactions with industry, registration and listing reports, and TRLM NG.

Based on updated data, we have revised our estimate for sections 905(b), 905(c), 905(d), 905(h), or 905(i) of the FD&C Act. “Tobacco Product Establishment Initial Registration and Listing”; Form FDA 3741: “Registration and Product Listing for Owners and Operators of Domestic Establishments”; Form FDA 3741a: “Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments” (Electronic and Paper submissions) reflects a reduction from 200 to 75 respondents and “Tobacco Product Establishment Renewal Registration and Listing”; Form FDA 3741: “Registration and Product Listing for Owners and Operators of Domestic Establishments”; Form FDA 3741a: “Registration and Listing for Owners and Operators of Domestic Deemed Tobacco Product Establishments” (Electronic and Paper submissions) reflects a reduction from 2,572 to 1,003 respondents.

Under sections 905(b), 905(c), 905(d), 905(h), or 905(i) of the FD&C Act, FDA estimates up to 75 new establishments will submit one initial establishment registration and product listing report each year. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. The Agency estimates that up to 75 tobacco establishments will each submit 1

initial establishment registration and product listing report each year using the new Form FDA 3741, “Registration and Product Listing of Tobacco Product Manufacturing Establishments”, which is expected to take 1.5 hours, for a total 113 burden hours.

FDA estimates up to 75 establishments will submit one initial listing of tobacco products report each year. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. The Agency estimates that up to 75 tobacco establishments will each submit 1 initial product list and material file information spreadsheet each year using the new Form FDA 3741b, which is expected to take 2 hours, for a total 150 burden hours.

FDA estimates that the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act will take 20 minutes annually per confirmation or update per establishment. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. Based on FDA’s experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 1,003 establishments will each submit one confirmation or updated report each year, using the new Form FDA 3741, which is expected to take 0.33 hour (20 minutes) for a total 331 burden hours.

FDA estimates that the confirmation or updating of listing of tobacco products will take 30 minutes annually per confirmation or update per establishment. These estimates reflect the burden that will be associated with this information collection upon OMB approval of the revision and implementation of the proposed updates. Based on FDA’s experience with current establishment registration and product listings submitted to the Agency, the Agency estimates that on average 1,003 establishments will each submit one confirmation or updated report each year, using the new Form FDA 3741b, which is expected to take 0.5 hour (30 minutes) for a total 502 burden hours.

FDA estimates that the submission of ingredient listings required by section 904(a)(1) of the FD&C Act for each establishment will take 2 hours initially. Ingredients may be submitted electronically through the CTP portal or if unable to submit ingredients electronically then by mail using Form FDA 3742. FDA estimates that 16 establishments will initially submit one report annually at 2 hours per report, for a total of 32 hours.

Based on FDA's experience and the number of new products authorized to be introduced or delivered for introduction into interstate commerce submitted over the past 3 years, FDA estimates that 37 establishments will each submit 10 reports (one every 6 months). FDA also estimates that the confirmation or updating of product (ingredient) listing information required by section 904(c) of the FD&C Act is expected to take 0.40 hour (24 minutes) for a total 148 burden hours. FDA estimates that obtaining a DUNS (data universal numbering system) number will take 30 minutes. FDA assumes that all new establishment facilities that will be required to initially register under section 905 of the FD&C Act would obtain a DUNS number. FDA estimates that up to 100 establishments that would need to obtain this number each year. The total industry burden to obtain a DUNS number is 50 hours.

Our estimated burden for the information collection reflects an overall increase of 655 hours and a decrease of 616 responses. We attribute this adjustment to the proposed revisions to this information collection to add the updated and comprehensive Form FDA 3741, "Registration and Product Listing of Tobacco Product Manufacturing Establishments" and add Form FDA 3741b, "Product List and Material File Information Spreadsheet".

Dated: January 14, 2025.

**P. Ritu Nalubola,**

*Associate Commissioner for Policy.*