

United States Food and Drug Administration
Center for Tobacco Products

Tobacco Product Establishment Registration and Submission of Certain Health Information

OMB Control No. 0910-0650—REVISION

SUPPORTING STATEMENT

Terms of Clearance: The data to be collected by CTP in this ICR (OMB Control No. 0910-0650) and that collected by the Centers for Disease Control and Prevention (CDC) in OMB Control Nos. 0920-0210 and 0920-0338 overlap in terms of the similar tobacco product ingredient collections being conducted. However, at this time, the CTP data cannot be used by CDC due to both logistical reasons and restrictions on the use of information collected. OMB encourages the agencies to consider future efforts to eliminate duplication and reduce burden on respondents.

Part A. Justification

1. Circumstances Making the Collection of Information Necessary

This information collection supports the Food and Drug Administration (FDA, us or we) 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).

Tobacco Products Containing Nicotine That is Not Made or Derived From Tobacco

The Consolidated Appropriations Act of 2022 (the Appropriations Act), enacted on March 15, 2022, amended the definition of the term “tobacco product” in section 201(rr) of the FD&C Act to include products that contain nicotine from any source. As a result, non-tobacco nicotine (NTN) products that were not previously subject to the FD&C Act (e.g., products containing synthetic nicotine) are now subject to all of the tobacco product provisions in the FD&C Act beginning on April 14, 2022.

Registration and Listing (Section 905)

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 FDA Commissioner the responsibility for administering the FD&C Act, including section 905.

Section 905 of FD&C Act requires owners or operators of each establishment to register:

- 1) their name (905(b))
- 2) places of business (905(b))
- 3) a list of all tobacco products which are manufactured by that person (905(i)(1))
- 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) (905(i)(1)(A))
- 5) a copy of all consumer information and other labeling (905(i)(1)(B))
- 6) a representative sampling of advertisements (905(i)(1)(B))
- 7) upon request made by the Secretary for good cause, a copy of all advertisements for a particular tobacco product (905(i)(1)(B))
- 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, a brief statement of the basis upon which the registrant made such determination (905(i)(1)(C)).

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 (trlm-ng-industry.fda.gov/login), and through paper forms for those individuals who are unable to submit online through TRLM NG. In the electronic portal and paper form FDA is requesting the following information:

- Registrant information
 - registrant's association to the establishment's being registered
- Owner information
 - owner name, title, address, email, and position title
 - company name, address, telephone & fax numbers, owner Dun & Bradstreet Data Universal Numbering System (D-U-N-S[®]) number (optional), any other owner doing business as (DBA) names, type of business structure, names of individuals associated with business structure, and state of incorporation
- Establishment information
 - establishment name, address, telephone & fax numbers, establishment Dun & Bradstreet D-U-N-S number (optional), and functions performed by establishment
- Operator information
 - Operator name, address, operator Dun & Bradstreet D-U-N-S number (optional), any other operator DBA names, type of business structure, names of individuals associated with business structure, and state of incorporation
- Product listing, details

- unique product name & identification number, intended use, category, and flavor
- Product listing, labeling
 - all labeling for each product including identification of type of labeling, internal identification number, Universal Product Code, and date label was first disseminated
- Product listing, consumer information
 - all consumer information for each product including type of material, internal identification number, and date material was first disseminated
- Product listing, advertising
 - a representative sampling of advertising for each product including type of advertising material, internal identification number, and date advertisement was first disseminated
- Confirmation statement
 - certification of truth and accuracy
 - authorized agent name, title, address, email, and position title
 - authorized agent company name, address, and telephone & fax numbers

FDA has also published a guidance for industry entitled “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments.” (March 2023) (www.fda.gov/regulatory-information/search-fda-guidance-documents/registration-and-product-listing-owners-and-operators-domestic-tobacco-product-establishments). This guidance is intended to assist persons making tobacco product establishment registration and product listing submissions to FDA.

The current paper forms to collect this information are Form FDA 3741 (“Registration and Listing for Owners and Operators of Domestic Tobacco Product Establishments,” available at 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 www.fda.gov/media/99863/download). However, FDA is making 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, such as material file uploads;
- 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 adding a new product listing spreadsheet (Form 3741b) to this information collection. FDA anticipates the new Form FDA 3741b will streamline product listing submissions and subsequent FDA review.

Although these 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 that these updates will streamline the navigation and completion of Form FDA 3741, reduce redundancies, increase overall user efficiency, and ultimately enable industry to more accurately convey the required registration and listing information to FDA as required by section 905 of the FD&C Act.

Both current Form FDA 3741 and 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”). FDA also intends to update the “Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments” industry guidance upon implementation of the updated Form FDA 3741. FDA estimates that the updated Form FDA 3741 will be available and required to be used by tobacco product manufacturers starting at the beginning of Year 2 of the 3-year approved ICR period.

Ingredient Listing (Section 904)

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” of the Family Smoking Prevention and Tobacco Control Act (Tobacco Control Act) (Public Law 111-31; 123 Stat. 1776);
- 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 prior to 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 (CTP Portal NextGen: ctpportal-ng.fda.gov/portal/), and through a paper form (Form FDA 3742, “Listing of Ingredients in Tobacco Products” available at www.fda.gov/media/77661/download) for those individuals who choose not to use the electronic portal. In the electronic portal and paper form, FDA is requesting the following information:

- Type of submission
 - new submission, ingredient listing for tobacco products on the market as of June 22, 2009 (*for cigarettes, cigarette tobacco, roll-your-own (RYO), and smokeless tobacco*) or as of August 8, 2016 (*for deemed tobacco products*) or as of April 14, 2022 (*for tobacco products containing nicotine that is not made or derived from tobacco*)
 - new submission, ingredient listing for new tobacco products
 - update to previous submission to add, delete, or change the quantity of an additive
- Manufacturer (or importer) identification
 - submitter type, company name, address, country, company headquarters Dun and Bradstreet D-U-N-S number (optional), and company headquarters FDA-assigned Facility Establishment Identifier number
- Authorized representative
 - contact name, title, position title, mailing address, email, telephone & fax numbers
 - company name and address (if different than submitter)
- U.S. agent (importers only)
 - U.S. agent name, position title, email, telephone & fax numbers
 - U.S. agent company name and address
- Tobacco product identification
 - FDA-assigned tracking number, tobacco product brand/sub-brand name or other commercial name, submission tracking number (if appropriate), product identification number, type of product identification number, intended use of product, product category and subcategory, and whether the product is co-packaged
- Component identification
 - component type, manufacturer name, and manufacturer’s uniquely identifying component name and/or number
- Ingredient listing
 - product name, component type and name, ingredient name, ingredient number, and alternative ingredient using the ingredient number

- ingredient identification,
 - for a single chemical substance: unique scientific name or code, type of code, and identification of reaction product
 - for leaf tobacco: type, variety, cure method, heat source, and identification of any deoxyribonucleic acid (DNA) recombinant technology used to engineer the tobacco
 - for complex purchased ingredients: manufacturer name, unique identifying item name and/or numbers used by manufacturer, and identification if ingredient is made to submitter’s specifications
- ingredient details including quality unit of measure and value, expected function(s)
- quantity of ingredient including unit of measurement and how quantity is determined, limit of detection, quantity of additive increase or decrease with date of change, or date of introduction to market
- Confirmation statement
 - identification and signature of authorized representative including name, company name, address, position title, email, telephone & fax numbers

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) (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 www.fda.gov/tobacco-products/manufacturing/submit-ingredient-listing-tobacco-products.

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^{1, 2} to be subject to chapter IX of

¹ 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.

² 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

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").

D-U-N-S Number

The FDA Standards Council has designated Dun & Bradstreet's D-U-N-S® Number as the business entity standard to be used along with FDA's internal tracking numbers. Electronic registration for submitting Registration and Listing and Product Identifier information now will accept a D-U-N-S number and it can be used as an optional CTP registration number. However, the D-U-N-S number is not required to be used for CTP transactions. Obtaining a D-U-N-S number allows each business to be uniquely identified by FDA and is specific for each corporate entity and place of business.

We therefore request revision of OMB approval of information collection provisions found in guidance and in sections 904 and 905 of the FD&C Act as discussed in this supporting statement.

2. Purpose and Use of the Information Collection

FDA will use the information collected under these provisions of the FD&C Act to meet inspection requirements, and the information will inform FDA's development of good manufacturing practices and review standards for new tobacco products, among others.

The information collected by FDA will be used to register new and update existing tobacco product establishments required under section 905 of the FD&C Act and to register new product ingredient listings and update existing product ingredient listing required under sections 904(a) (1) and 904(c) of the FD&C Act. The collection of the D-U-N-S number information is optional, and the information can be used by FDA to identify tobacco establishments who must comply with the FD&C Act.

If this data is not able to be collected, FDA would be unable to effectively regulate tobacco products as directed by Congress in portions of chapter IX of the FD&C Act.

Respondents to this collection are expected to be tobacco product establishment for-profit businesses or their representatives from the private sector.

further information as it is available.

3. Use of Improved Information Technology and Burden Reduction

Pursuant to section 905 of the FD&C Act, FDA collects the registration and product listing information through electronic portals and through paper forms. Establishment registration and product listings can be submitted online via TRLM NG (www.fda.gov/tobacco-products/manufacturing/tobacco-registration-and-listing-module-next-generation-trlm-ng-instructions). TRLM NG allows establishments to upload and view their data at any time. Establishments can submit their information online from the website; can update files for product labeling, advertising, and consumer information without resubmitting the entire listing; and can report no changes to their registration or product listing by simply checking a box.

As described above, FDA is making 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. Although these 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 that these updates will streamline the navigation and completion of Form FDA 3741, reduce redundancies, increase overall user efficiency, and ultimately enable industry to more accurately convey the required registration and listing information to FDA as required by section 905 of the FD&C Act.

Ingredient listings (sections 904(a)(1) and 904(c) of the FD&C Act) may be submitted electronically through the CTP Portal NextGen (www.fda.gov/tobacco-products/manufacturing/submit-ingredient-listing-tobacco-products) or, if unable to submit ingredient listings electronically, then by mail using Form FDA 3742.

FDA estimates that approximately 96 and 99 percent of respondents will use the electronic portals to fulfill the agency's request for registration and listing (Form FDA 3741 and 3741a), and product ingredient listing (Form FDA 3742), respectively.

4. Efforts to Identify Duplication and Use of Similar Information

As stated in the previous terms of clearance, the data to be collected by CTP in this ICR (OMB Control No. 0910-0650) and that collected by CDC in OMB Control Nos. 0920-0210 and 0920-0338 overlap in terms of the similar tobacco product ingredient collections being conducted. However, at this time, the CTP and CDC data cannot be used by the other agency due to both logistical reasons and restrictions on the use of information. This information collection is not duplicative, and the FD&C Act requires the submission of this information. FDA is the only federal agency responsible for the collection of such specific information and is the primary federal regulatory authority with respect to the manufacture, marketing, and distribution of tobacco products. Therefore, we believe no duplication of data exists.

The CDC and FDA each rely on different statutory authorities to collect their respective data. CDC collects certain product ingredient information authorized under the Federal Cigarette Labeling and Advertising Act (FCLAA) (OMB Control No. 0920-0210) and the Comprehensive Smokeless Tobacco Health Education Act (CSTHEA) (OMB Control No. 0920-0338). FDA collects product ingredient information through this OMB Control No. 0910-0650 under the FD&C Act.

Although FDA's and CDC's tobacco ingredient data collections appear similar, the underlying authorities found in the FD&C Act, FCLAA, and CSTHEA to collect such information would not allow either agency's data collection (in solo) to fulfill both agencies' needs. Considering the potential benefits of sharing information, CDC and FDA continue to discuss opportunities for collaboration to enhance the overall usefulness of both CDC's and FDA's tobacco industry reporting programs. Additionally, FDA collects user fees from each manufacturer and importer of regulated tobacco products, which may only be used for the purpose of funding the costs for FDA to regulate tobacco products under the FD&C Act. FDA cannot use other funds for performing these duties, nor use tobacco product user fees to perform duties falling outside the regulation of tobacco products under the FD&C Act.

5. Impact on Small Businesses or Other Small Entities

The information submission requirements in sections 905 and 904 do not fall disproportionately upon small businesses as the FD&C Act requires the submission of this information from all owners and operators of a tobacco product establishment. FDA is providing an alternative paper form for those individuals who are unable, or choose not to, use the electronic portals. FDA continues to pursue means of reducing the reporting burden for both small and large respondents and will continue to employ the latest technology for receiving these submissions, consistent with the intent of the legislation.

FDA aids small businesses in dealing with the information submission requirements of sections 905 and 904 by providing guidance, which further describes the statutory requirement, for submitting this information. FDA also offers assistance to small tobacco businesses through CTP's Office of Small Business Assistance and TRLM NG Support.

6. Consequences of Collecting the Information Less Frequently

The FD&C Act requires the registration information submission under section 905 of the FD&C Act to be completed annually by December 31 of each year. As of the effective date of the final deeming rule, those persons who own or operate domestic manufacturing establishments engaged in manufacturing newly deemed tobacco products (including those that engage in the blending of pipe tobacco and the mixing of e-liquids) are required to register with FDA and submit product listings under section 905. This final deeming rule does not require foreign manufacturing establishments to register their establishments or to list their tobacco products in order to sell them in the United States. However, foreign manufacturing establishments will be

required to comply with the registration and listing requirements of section 905 of the FD&C Act after a registration and listing rule is final and effective.

A less frequent collection of information would not satisfy the requirements of the FD&C Act. The FD&C Act requires the ingredient listing information submission under section 904(a)(1) of the FD&C Act to be completed by December 22, 2009, and submissions under 904(c) to be submitted according to a clearly identified timeline. A less frequent collection of this information would also not satisfy the requirements of the FD&C Act.

7. Special Circumstances Relating to the Guidelines of 5 CFR 1320.5

There are no special circumstances for this collection of information.

8. Comments in Response to the Federal Register Notice and Efforts to Consult Outside the Agency

FDA published a 60-day notice for public comment in the *Federal Register* of January 17, 2025 (90 FR 5909). No comments were received.

9. Explanation of Any Payment or Gift to Respondents

There are no incentives, payments, or gifts associated with this information collection.

10. Assurance of Confidentiality Provided to Respondents

Among the laws governing the disclosure of registration and listing data submitted under section 905 of the FD&C Act are the Freedom of Information Act (FOIA) (5 U.S.C. 552) and section 905(f) of the FD&C Act (21 U.S.C. 387e(f)), as well as FDA's implementing regulations. Under FOIA, the public has broad access to agency records, unless the records (or a part of the records) are protected from disclosure by any of the law's nine exemptions. Under section 905(f) of the FD&C Act, FDA shall make available for inspection, to any person so requesting, any registration filed under section 905 of the FD&C Act.

Information submitted under section 904 of the FD&C Act may include, but is not limited to, a company's non-public trade secret or confidential commercial information. Several laws govern the confidentiality of ingredient information submitted under section 904 of the FD&C Act, including sections 301(j) and 906(c) of the FD&C Act (21 U.S.C. 331(j) and 387f(c)), the Trade Secrets Act (18 U.S.C. 1905), and FOIA (5 U.S.C. 552), as well as FDA's implementing regulations.

Section 906(c) of the FD&C Act prohibits FDA from disclosing any information reported to or otherwise obtained by FDA under section 904, among other provisions, if that information is confidential commercial or trade secret information exempt from disclosure under FOIA Exemption 4 (5 U.S.C. 552(b)(4)). The provision contains exceptions allowing disclosure of the information to other officers or employees concerned with carrying out the tobacco products

chapter of the FD&C Act and, when relevant, in any proceeding under the tobacco products chapter of the FD&C Act. Section 301(j) of the FD&C Act generally prohibits release of trade secret information obtained by FDA under section 904, among other provisions, outside of the Department of Health and Human Services (HHS), except to courts when relevant in any judicial proceeding under the FD&C Act and to Congress in response to an authorized Congressional request.

CTP consulted with FDA's Privacy office, which conducted a Privacy Impact Assessment (PIA). CTP received HHS approval on the privacy impact assessment and was assigned PIA ID: FDA2107988.

FDA's general regulations concerning the public availability of FDA records are contained in 21 CFR part 20.

11. Justification for Sensitive Questions

This information collection does not involve questions of a sensitive nature.

12. Estimates of Annualized Burden Hours and Costs

12 a. Annualized Hour Burden Estimate

We estimate the burden of this collection of information as follows:

In the burden table below, we calculate a total of 1,397 annual responses.

Table 1.—Estimated Annual Reporting Burden

FDA Form/Activity/FD&C Act Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741, Form FDA 3741a, and the new Form FDA 3741 (Electronic and Paper submissions) ¹ Sections 905(b), 905(c), 905(d), 905(h), or 905(i)	37	1	37	1.65 (99 minutes)	61
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741, Form FDA 3741a, and the new Form FDA 3741 (Electronic and Paper submissions) ² Sections 905(b), 905(c), 905(d), 905(h), or 905(i)	900	1	900	0.28 (17 minutes)	252
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, “Tobacco Product List Spreadsheet”	37	1	37	0.22 (13 minutes)	8
Tobacco Product Listing Form FDA 3742, “Listing of Ingredients in Tobacco Products” Section 904(a)(1)	16	1	16	2.00 (120 minutes)	32
Tobacco Product Listing Form FDA 3742, “Listing of Ingredients” Section 904(c)	37	10	370	0.40 (24 minutes)	148
Obtaining a Dun & Bradstreet D-U-N-S Number	37	1	37	0.5 (30 minutes)	19
Total			1,397		520

¹ This initial submission is averaged over the three years of the information collection utilizing the current Form FDA 3741 and 3741a, which will be combined in updated Form FDA 3741 in Spring 2026.

² This renewal submission is averaged over the three years of the information collection utilizing the current Form FDA 3741 and 3741a, which will be combined in Form FDA 3741 “Registration and Product Listing of Tobacco Product Manufacturing Establishments” with product listing and material file information updates.

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.

We have updated Form FDA 3741 and Form FDA 3741a to consolidate them both to create one comprehensive form named, Form FDA 3741, “Registration and Product Listing of Tobacco Product Manufacturing Establishments.” It will also include material files information. FDA estimates that the updated Form FDA 3741 will be available and required to be used by tobacco product manufacturers in Spring 2026.

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. Based on FDA’s experience with current establishment registration and product listing information submitted to the agency, FDA has lowered the estimated annual respondents for (1) initial tobacco product establishment registration and listing (via Form FDA 3741) from 200 to 37 respondents, and (2) renewal of tobacco product establishment registration and listing (via Form FDA 3741) from 2,572 to 900.

The agency retains the hours per response estimate of 1.60 hours (or 96 minutes) for the initial tobacco product establishment registration and listing via the current Form FDA 3741, which FDA estimates manufacturers will need to use through the first year of the 3-year ICR approval period. Once the updated Form FDA 3741 is released, FDA estimates its completion to take 1.67 hours (100 minutes) for an initial registration of a tobacco product establishment and material file submission. As shown in Table 1, averaged across the 3-year ICR period, FDA estimates an average annual burden of 1.65 hours (99 minutes) for a total of 61 burden hours (across the 37 annual respondents).

The agency estimates that up to 37 tobacco establishments will each submit 1 initial product listing spreadsheet each year using the new Form FDA 3741b, which is expected to take 0.33 hours (20 minutes), for a total of 12 burden hours. Averaged across the 3-year ICR approval period, FDA estimates an average annual hours per response of 0.22 hours (8 average total hours) because, as noted above, the agency estimates that tobacco product manufacturers will not start using this new form until Year 2 of the 3-year ICR approval period.

In terms of establishment registration renewal via Form FDA 3741 (i.e., the confirmation or updating of establishment registration and product listing information as required by section 905 of the FD&C Act), FDA has lowered the estimated annual number of respondents from 2,572 to 900, based on updated data. FDA retains the hours per response estimate of 10 minutes (0.17 hours) for the registration renewal via the current Form FDA 3741, which FDA estimates manufacturers will need to use through the first year of the 3-year ICR approval period. For Years 2 and 3, FDA estimates that the updated Form FDA 3741 will take 20 minutes (0.33 hours) for registration renewal. The renewal time increases with the updated Form FDA 3741 because the consolidated registration renewal process now encompasses establishment

registration, product listing updates, and material file updates. Averaged across the 3-year ICR period, FDA estimates an average annual burden of 0.28 hours (17 minutes) for a total of 252 burden hours (across the 900 annual respondents).

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 Next Generation 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 D-U-N-S 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 D-U-N-S number. FDA estimates that up to 37 establishments would need to obtain this number each year. Therefore, the total annual industry burden to obtain a D-U-N-S number is 19 hours.

12b. Annualized Cost Burden Estimate

The estimated annualized reporting cost to all respondents for this collection of information is \$36,660. This estimate assumes that the tobacco manufacturing industry (all occupations) labor category will account for the submissions at an average (mean) hourly wage of \$35.25 (Department of Labor’s Bureau of Labor Statistics May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 312200 – Tobacco Manufacturing, data.bls.gov/oes/#/industry/312200). We double this to account for benefits and overhead, yielding an hourly wage rate of \$70.50.

Table 2.—Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate	Total Respondent Costs
Tobacco Product Establishment Employees	520	\$70.50	\$36,660
Total			\$36,660

13. Estimates of Other Total Annual Costs to Respondents and/or Recordkeepers/Capital Costs

There are no additional capital, start-up, or maintenance costs associated with this collection of information.

14. Annualized Cost to the Federal Government

Our estimated cost to the federal government reflects the allocation of 2 full-time equivalent employees (FTEs) who will maintain the electronic portals and 6 FTEs who will review, process, and approve applications submitted to the system or submitted on paper form under this collection of information. Using 2025 Grade 13 Step 4 salary and wage data for the Washington DC-Metropolitan area found at www.opm.gov/policy-data-oversight/pay-leave/salaries-wages/salary-tables/25Tables/html/DCB.aspx and doubling for benefits and overhead, we calculate a total cost of \$2,122,208 (\$132,638 x 8 x 2).

15. Explanation for Program Changes or Adjustments

Program Changes

As described above, 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”; for use in Spring 2026 (2) restructuring and developing sections of the updated Form FDA 3741 for ease of navigation and data input, such as material file uploads; (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 of initial submission.

FDA anticipates these updates will streamline the navigation and completion of Form FDA 3741, reduce redundancies, increase overall user efficiency, and ultimately enable industry to more accurately convey the required registration and listing information to FDA as required by section 905 of the FD&C Act. FDA estimates that the updated Form FDA 3741 will be available and required to be used by tobacco product manufacturers starting in Spring 2026. Based on our analysis, the updated Form FDA 3741 will result in a slightly increase in respondent burden for an initial tobacco product establishment registration, extending the time requirement from 96 minutes to 100 minutes. For registration renewals, the time burden will increase from 10 to 20 minutes per submission. Although both initial and renewal submissions will require additional time, the enhanced renewal process will provide operational efficiencies by consolidating all required updates in one comprehensive submission.

Averaged over the entire 3-year ICR period (assuming the current forms will continue to be used in Year 1 and the updated forms will be used in Years 2 and 3), FDA estimates an overall

increase in average hours per response associated with initial registration (100 minutes) and an overall increase in average hours per response associated with registration renewal (20 minutes). As part of these Form FDA 3741 updates, the agency also is adding a new product listing spreadsheet (Form FDA 3741b) used only for initial submission, which we estimate will take 20 minutes.

Adjustments

As described above, FDA has adjusted respondent values based on experience with this information collection, information we have available from interactions with industry, registration and listing reports, and TRLM NG. Based on the updated data and forms, the tobacco product establishment initial registration and listing (Form FDA 3741, “Registration and Product Listing of Tobacco Product Manufacturing Establishments.”) reflects a reduction from 200 to 37 respondents. The tobacco product establishment renewal registration and listing (Form FDA 3741, “Registration and Product Listing of Tobacco Product Manufacturing Establishments.”) reflects a reduction from 2,572 to 900 respondents.

Total Burden Impacts

Based on the combined impacts of program changes and adjustments, our estimated burden for the information collection reflects an overall decrease of 442 annual burden hours and a decrease of 1,861 annual responses.

16. Plans for Tabulation and Publication and Project Time Schedule

Collected information will not be published or tabulated.

17. Reason(s) Display of OMB Expiration Date is Inappropriate

FDA is not requesting an exemption for display of the OMB expiration date. Consistent with established practice FDA the OMB control number will be displayed on the guidance document cover page and include a link to www.reginfo.gov to identify the current expiration date.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.