United States Food and Drug Administration
Center for Tobacco Products
Establishment Registration and Product Listing for Tobacco Products

OMB Control No. 0910-0650 – REVISION
RIN 0910-AH59

SUPPORTING STATEMENT PART A

Terms of Clearance: None

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). The Tobacco Control Act was enacted on June 22, 2009, amending the FD&C Act and providing FDA with the authority to regulate tobacco products.

The Agency is proposing a rule, in accordance with section 905 of the FD&C Act, requiring owners or operators of domestic and foreign establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products, to register their establishments. Further, the proposed rule would require owners or operators of both domestic and foreign establishments to, at the time of registration, list all tobacco products which are being manufactured, prepared, compounded, or processed by that person for commercial distribution. Currently, in accordance with section 905 of the FD&C Act, only domestic owners and operators are required to register their establishments and list their tobacco products with FDA while foreign owners and operators are not subject to these requirements, creating significant gaps in Agency information. If finalized, this rule would extend registration and listing requirements to include owners and operators of foreign establishments.

This proposed rule would require owners or operators of an establishment engaged in the manufacture, preparation, compounding, or processing of a tobacco product to register those establishments and list their tobacco products that are being manufactured, prepared, compounded, or processed by that person for commercial distribution. The proposed rule applies to owners or operators of domestic and foreign establishments. Manufacturers of tobacco products include specification developers, third-party manufacturers, bulk tobacco product manufacturers, repackagers/relabelers, any owner or operator of any domestic establishment that manufactures a tobacco product for export, or any owner or operator of an establishment that manufactures free smokeless tobacco samples. The proposed rule includes some exceptions, including persons who solely manufacture a tobacco product intended solely for investigational use under section 910(g) of the FD&C Act; manufacturers of only raw materials other than tobacco used in manufacturing a component or part of a tobacco product who would not otherwise be required to register; and common carriers in the receipt, carriage, holding, or delivery of a tobacco product in the usual course of business as carriers. This rule enables FDA to get a full and accurate inventory of establishments that engage in the manufacture, preparation, compounding, or processing of tobacco products, including their corporate structure, if applicable, and their supply chain. To avoid unnecessary duplicate registrations and listings, proposed § 1108.20(a) would permit a

parent, subsidiary, or affiliate company to submit registration information for all establishments when operations are conducted at more than one establishment and the establishments are under common or joint ownership or control.

Proposed § 1108.22(a) provides that an owner or operator of a domestic establishment engaged in an operation described in § 1108.20(a) would have to register the establishment and submit tobacco product listing information within five business days from first engaging in the operation. Further, this regulation would require owners or operators of foreign establishments engaged in an operation described in § 1108.20(a) to register the establishment and submit tobacco product listing information before any tobacco product manufactured, prepared, compounded or processed at the establishment is imported or offered for import into the United States, which comports with FDA's initial drug registration requirements for foreign establishments (see 21 CFR 207.21(b)). Proposed § 1108.50 would describe additional conditions and exceptions for foreign tobacco product establishments.

Proposed § 1108.22(b)(1) would require that annual registration be completed and submitted to FDA by December 31st of each year, even if there are no changes to the establishment registration.

As required by section 905(i)(3) of the FD&C Act, proposed § 1108.22(b)(2) would require owners or operators to review and update their tobacco product listing information in June and December of every year. Owners or operators would be required to report any changes or deletions to listings described in § 1108.28 and list any new products not previously reported. For example, if the labeling for a product is changed in October, the product listing information would have to be updated accordingly in December of the same year. This information would be used to help ensure the products marketed are in compliance with the FD&C Act and implementing regulations.

Proposed § 1108.24(a) would specify the information required for tobacco product establishment registration (e.g., information about the establishment, owner and operator, official correspondent, trade names, website address(es), registration ID number (RGID#), FEI number, Tribe). Proposed § 1108.24(e) would specify the tobacco listing information to be provided for each tobacco product listed (e.g., RGID # and name of each establishment, product information, product numbers and tracking information, operation and process information, product standard information, marketing authority, labeling information). In addition, proposed § 1108.24(f) would specify that owners or operators may be required to submit to FDA upon request information for products that have been determined to not be subject to tobacco product standards or products manufactured for distribution under a label other than its own.

Proposed § 1108.26 would require owners or operators who manufacture a tobacco product to maintain a historical file containing a copy of all consumer information, labeling, and advertisements in use as of the effective date of the rule for all tobacco products contained in the product list for four years (including any information which has had a material change after the effective date of the rule). Additionally, those who distribute smokeless samples must keep, for four years after the date of the event, information about the events (e.g., compliance information, details about the event). The authority for the proposed § 1108.26 recordkeeping requirements comes from sections 905 and 909 of the FD&C Act.

Proposed § 1108.28 would include requirements for updating tobacco product listing information, including what changes would require an update; the timeframe for making updates; and how to add, discontinue, or renew product listings.

FDA currently collects the information (OMB control number 0910-0650) 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 FDA Forms 3741 and 3741b. TRLM NG is designed to streamline the data entry process for registration and product listing. Electronic submission through TRLM NG, available at https://www.fda.gov/tobacco-products/manufacturing/tobacco-registration-and-listing-module-next-generation-trlm-ng-instructions , would be required under proposed § 1108.40 unless a registrant receives a waiver from FDA under proposed § 1108.40(b). To request a waiver from electronic submission, § 1108.40(b) would require applicants to send a letter to FDA's Center for Tobacco Products with information about the establishment and a signed statement explaining the need for a waiver. For owners or operators that have obtained a waiver, if information changes that might result in termination of the waiver, § 1108.40(d) would require that the owner or operator notify FDA within 30 calendar days.

FDA based many of the requirements in this proposed rule on the recommendations and interpretations originally outlined in an FDA guidance for industry entitled "Registration and Product Listing for Owners and Operators of Domestic Tobacco Product Establishments" originally published in November 2009 and revised in 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.

We therefore request revision of the information collection per the new requirements in the proposed rule.

2. Purpose and Use of the Information Collection

The proposed rule would establish requirements for establishment registration and product listing that apply to owners or operators of both domestic and foreign establishments engaged in the manufacture, preparation, compounding, or processing of tobacco products intended for distribution within the United States. The information will be used to identify marketed tobacco products and establishments producing specific tobacco products, plan inspections and surveillance programs, identify products and establishments that are in violation of the law, as well as identifying imported tobacco products. Additionally, we rely on current up-to-date registration and listing information to help us comply with several other statutory provisions.

The proposed rule applies to owners or operators of establishments located in any State or Territory who manufactures a tobacco product for export, and any person who manufactures free smokeless tobacco samples. Manufacturers of tobacco products also include specification developers, third-party manufacturers, bulk tobacco product manufacturers, repackagers/relabelers, any owner or operator of any domestic establishment that manufactures a tobacco product for export, or any owner or operator of an establishment that manufactures free smokeless tobacco samples.

3. Use of Improved Information Technology and Burden Reduction

The proposed rule would require that respondents submit Forms FDA 3741 and FDA 3741b capturing establishment registration and listing in an electronic format unless a waiver for paper submission is requested by the applicant and granted by FDA. 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. FDA estimates that based on its experience with submittal of this type of information, approximately 96 percent of the respondents will submit the information in an electronic format. Although FDA believes most respondents will submit electronically, to be conservative we estimate that 4% of applicants may submit a waiver to submit by paper.

4. Efforts to Identify Duplication and Use of Similar Information

We are unaware of duplicative information collection.

5. Impact on Small Businesses or Other Small Entities

The information submission requirements in section 905 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 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 section 905 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 authorized the requirement of registration information submission under section 905 to be completed annually by December 31 of each year. Section 905 further states that those persons who own or operate domestic manufacturing establishments engaged in manufacturing tobacco products are required to register with FDA and submit product listings. Foreign manufacturing establishments will be required to comply with the registration and listing requirements of section 905 of the FD&C Act after this proposed registration and listing rule is final and effective. Section 905(i)(1) of the FD&C Act requires the complete product list information to be submitted at the time of first registration. In addition, section 905(i)(3) of the FD&C Act requires that certain changes to previously submitted product listing information be reported to FDA biannually (21 U.S.C. 387e(i)(3)).

Respondents to this collection of information include manufacturing establishments (foreign and domestic) engaged in tobacco product manufacturing. If this information were not collected, FDA would be unable to investigate or seize unregistered establishments or tobacco products. Under section 903(a)(6) of the FD&C Act (21 U.S.C. 387c), a tobacco product is deemed misbranded if

it was manufactured, prepared, propagated, compounded, or processed in an establishment not duly registered under section 905 or if it was not included in a list required by section 905(i).

A less frequent collection of information would not satisfy the requirements of the FD&C Act.

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

The special circumstance for this collection is that submitters are expected to retain records, other than health, medical, government contract, grant-in-aid, or tax records for more than three years. Respondents are required to maintain a historical file containing all consumer information, labeling, and advertisements, including all material changes made to their products. Distributors of smokeless tobacco samples must also keep a four-year record of distribution events and the corresponding compliance documentation. The authority for the proposed § 1108.26 recordkeeping requirements comes from sections 905 and 909 of the FD&C Act.

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

We are publishing a proposed rule in the *Federal Register* inviting public comment on the proposed information collection in accordance with 3508(d).

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 requesting, any registration filed under section 905 of the FD&C Act.

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: 2107988.

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

11. Justification for Sensitive Questions

The collection of information does not involve sensitive questions.

12. Estimates of Annualized Burden Hours and Cost

12a. Annualized Hour Burden Estimate

The currently approved information collection under OMB Control Number 0910-0650 includes the following annual burden estimates for establishment registration and product listing activities:

Table 1.—Existing Burden for OMB Control Number 0910-0650, 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
Total			974		321

[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.

The currently approved information collection also includes burden for ingredient listing activities under Form FDA 3742 (180 hours) and obtaining a D-U-N-S number (19 hours), which total 199 hours. These activities are not part of this proposed rule and are therefore excluded from the comparison. The total currently approved burden is 520 hours, but only 321 hours are relevant to the establishment registration and product listing activities covered by this proposed rule (see Table 4). The currently approved information collection does not include registration and listing requirements for foreign establishments and historical file maintenance requirements under proposed § 1108.26.

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

Table 2.—Estimated Annual Reporting Burden – Domestic Establishments

FDA Form/Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
First Time –Burden					
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	47	1	47	1.83 (110 minutes)	86
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" 1108.24, 1108.22(b)(2)	47	1	47	0.42 (25 minutes)	20
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 1108.24, 1108.28 (update to Product Listing)	947	1	947	0.33 (20 minutes)	313
Waiver from electronic submission requirement 1108.40	2	1	2	0.25 (15 minutes)	1
Total First Time Burden Hours – Domestic					419
Annual Recurring					
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	37	1	37	1.83 (110 minutes)	68
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" 1108.24, 1108.22(b)(2)	37	1	37	0.42 (25 minutes)	16
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 1108.24, 1108.28 (update to Product Listing)	910	1	910	0.33 (20 minutes)	300
Waiver from electronic submission requirement 1108.40	1	1	1	0.25 (15 minutes)	1
Total Annual Recurring Burden Hours – Domestic (year 2 and year 3)					384
Total Burden Hours– Domestic					803

Table 3.—Estimated Annual Reporting Burden – Foreign Establishments

FDA Form/Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response[1]	Total Hours
First Time –—Burden					
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 (foreign) Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	3,253	1	3,253	2.61 (157 minutes)	8,490
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" (foreign) 1108.24, 1108.22(b)(2)	3,253	1	3,253	0.60 (36 minutes)	1,952
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 (foreign) 1108.24, 1108.28 (update to Product Listing)	3,253	1	3,253	0.47 (28 minutes)	1,529
Waiver from electronic submission requirement 1108.40	130	1	130	0.36 (22 minutes)	47
Total First Time Burden Hours – Foreign					12,018
Annual Recurring - Foreign					
Establishment Registration (Initial), the initial registration of a tobacco product establishment using Form FDA 3741 Proposed 1108.22(a), 1108.24, 1108.22(b)(1)	134	1	134	2.61 (157 minutes)	350
Product Listing (Initial), the initial listing of tobacco products (New) Form FDA 3741b, "Product List Spreadsheet" 1108.24, 1108.22(b)(2)	134	1	134	0.60 (36 minutes)	80
Establishment Registration (Renewal), the registration renewal of a tobacco product establishment using Form FDA 3741 1108.24, 1108.28 (update to Product Listing)	3,253	1	3,253	0.47 (28 minutes)	1,529
Waiver from electronic submission requirement 1108.40	5	1	5	0.36 (22 minutes)	2
Total Annual Recurring Burden Hours – Foreign					1,961
Total Burden Hours - Foreign					13,979

[1]Foreign Hours per response = domestic hours *1.43 (adjustment for English Proficiency/Internet Access)

For this proposed rule, FDA has based the estimates on the experience with current registration and listing submissions through OMB Control Number 0910-0650, tobacco import data, and FDA experience and subject matter expertise as discussed in the regulatory impact analysis for this proposed rule. Taking into consideration the clarification of industry requirements

provided by this rule and the extension of establishment registration and product listing requirements to foreign establishments, FDA estimates an increase in registrants and consequently an increase in estimated annual burden.

The currently approved total annual hours for domestic establishments, covering registration and listing only, is 321 hours, as reflected in Table 1 above. Under the proposed rule, the total annual recurring hours for domestic establishments would increase to 384 hours, representing an increase of 63 hours. This increase is attributable to enhanced data elements and clarified requirements introduced by the proposed rule. The proposed rule includes a total first-time burden of 419 hours due to 10 additional domestic establishments expected to register in the initial year of implementation, reflecting the transition to the new requirements. The proposed rule includes a total first-time burden of 12,018 hours for foreign establishments in the initial year of implementation, reflecting the new requirement for foreign establishments to register and list their products. We expect a total annual recurring burden for foreign establishments to be 1,961 hours.

Further, FDA estimates an overall increase in average hours per response associated with initial registration using Form FDA 3741 (from 100 minutes to 110 minutes), and the initial product listing spreadsheet (Form FDA 3741b) submission (from 20 minutes to 25 minutes) for domestic entities. Separate tables for domestic and foreign estimated annual hourly burden are provided.

Table 2 displays the estimated annual reporting burden for domestic tobacco establishments and Table 3 displays the estimated annual reporting burden for foreign tobacco establishments. The foreign hours per response rate were adjusted by multiplying the domestic hours per response by 1.43. This adjustment accounts for potential differences in English proficiency and availability of internet access.

Proposed § 1108.22(a) and § 1108.24 set forth when to submit initial establishment registration and product listing and the information required for submission. FDA estimates that domestic establishments will need approximately 110 minutes (1.83 hours) to complete the initial Form FDA 3741 for establishment registration and labeling, advertising, and consumer information submission, while foreign establishments will require 157 minutes (=1.43 x 1.83 hours, or 2.61 hours). The Agency estimates that with 47 domestic and 3,253 foreign tobacco establishments each submitting one initial form, the total burden would result in 3,300 total respondents and 8,576 burden hours (86 hours domestic + 8,490 hours foreign) for the initial year after the rule goes into effect. In the following years, FDA estimates the number of initial registrations to decrease to 37 domestic and 134 foreign establishments submissions via Form FDA 3741, resulting in a total burden of 418 hours (68 hours domestic + 350 hours foreign) annually.

FDA also estimates that it would take approximately 25 minutes (0.42 hours) to prepare and complete the initial product listing registration using Form FDA 3741b for a domestic establishment, and approximately 36 minutes (=1.43 x 0.42 hours, or 0.60 hours) for foreign establishments. The Agency estimates that the same 3,300 total respondents will each submit 1 initial product listing Form FDA 3741b, for a combined total of 1,972 burden hours (20 hours domestic + 1,952 hours foreign). In the following years, FDA estimates these numbers to decrease to 37 domestic and 134 foreign establishments submitting initial product listings via Form FDA 3741b, resulting in a total burden of 96 hours (16 hours domestic + 80 hours foreign) annually.

Both domestic and foreign establishment submissions would be required to be completed electronically using Form FDA 3741 and Form FDA 3741b via TRLM-NG or, if FDA has granted a waiver, through paper submission.

In terms of proposed § 1108.22 (b) and § 1108.28, continued establishment registration and product list filing 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 estimates that it will take each domestic respondent approximately 20 minutes (0.33 hours) to complete the renewal submission, while foreign establishments will require approximately 28 minutes (=1.43 x 0.33 hours, or 0.47 hours). FDA estimates that up to 947 domestic and 3,253 foreign owners or operators will be submitting registration renewals during the first year after the proposed rule goes into effect. This results in a total of 4,200 respondents and a total burden of 1,842 hours (313 hours domestic + 1,529 hours foreign) for the initial year after the rule goes into effect. These renewals may encompass an acknowledgment of accurate product listing through a certification statement, or a more substantive review that includes updates to product listings, with updates typically occurring in June and the completion of the renewal processes taking place in December. In the following years, FDA estimates these renewal submission numbers to decrease to 910 for domestic establishments and to remain at 3,253 for foreign establishments submitting renewal registrations and product listings via Form FDA 3741, resulting in a total burden of 1,829 hours (300 hours domestic + 1,529 hours foreign) annually.

Proposed § 1108.40 would require an applicant to submit Forms FDA 3741 and 3741b and all supporting and related documents to FDA in electronic format that FDA can process, review, and archive unless an applicant requests, and FDA grants, a waiver from this requirement under proposed § 1108.40(b). FDA estimates that 4 percent of the respondents may request a waiver. Consistent with our other application estimates for waivers, we estimate it would take 15 minutes (0.25 hours) per waiver for domestic establishments, and approximately 22 minutes (=1.43 x 0.25 hours, or 0.36 hours) for foreign establishments. During the initial year after the proposed rule takes effect, the Agency estimates that approximately 2 domestic and 130 foreign waiver applications will be submitted, for a total of 48 burden hours (1 hour domestic + 47 hours foreign). In the following years, FDA estimates these numbers to decrease to 1 domestic and 5 foreign waiver application, resulting in a total burden of 3 hours (1 hour domestic + 2 hours foreign) annually. To request a waiver, applicants must send a letter to FDA. If a change regarding the availability of electronic submission is noted, the respondent has 30 days to terminate the waiver and submit their submission electronically through TRLM NG.

Table 4.—Estimated Annual Recordkeeping Burden

FDA Form/Activity/21 CFR Section	No. of Respondents	No. of Responses per Respondent	Total Annual Responses	Hours per Response	Total Hours
First Time – Single Year Burden (Domestic and Foreign)					
Maintaining historical file 1108.26	4,200	1	4,200	0.10 (6 minutes)	420
Recurring Annual (Domestic and Foreign)					
Maintaining historical file 1108.26	4,163	1	4,163	0.10 (6 minutes)	416
Total Recordkeeping Burden					836

Table 4 describes the annual recordkeeping burden per the requirements in this proposed rule. The currently approved collection has no recordkeeping burden, therefore all burden hours for recordkeeping are new. FDA estimates that in the initial year 4,200 recordkeepers, encompassing both domestic and foreign establishments, will maintain records at 0.10 hours per record, for a total of 420 hours. In the following years, FDA estimates these numbers to decrease

to 4,163 recordkeepers, resulting in a total burden of 416 hours annually. Firms would have already established the required records when submitting the initial or renewal registration and listing submission. We believe this time is usual and customary for these firms and it would take 6 minutes to establish and/or update the required historical file. Proposed § 1108.26 requires respondents to maintain a historical file for 4 years and keep records related to smokeless tobacco product sample distribution for 4 years.

FDA estimates that the total burden for the activities in this rulemaking is 14,782 hours of reporting activities for years 1 and 2, and 836 hours of recordkeeping activities annually.

If finalized, the new collections of information will revise OMB Control Number 0910-0650. Our estimated burden for the proposed rule reflects an overall increase of 15,098 hours from the currently approved information collection. We attribute this increase to the proposed rule's clarification of industry requirements and the extension of establishment registration and product listing requirements to foreign establishments.

12b. Annualized Cost Burden Estimate

To estimate reporting costs for domestic respondents, we use the Bureau of Labor Statistics mean hourly wage in the tobacco manufacturing industry for management occupations ($76.92) and office and administrative support occupations ($27.10) (Department of Labor's Bureau of Labor Statistics May 2024 National Industry-Specific Occupational Employment and Wage Estimates, NAICS 312200 – Tobacco Manufacturing, https://data.bls.gov/oes/#/industry/312200). We use the mean hourly wages and assume that, for every hour or fraction of an hour spent filling out a registration information, three quarters of that time would be spent by an administrative worker and one quarter would be spent by an owner, operator, person in charge or official correspondent (someone in a management occupation) to certify the information before submitting to FDA. Doubling the mean hourly wages to account for benefits and overhead, these assumptions result in a weighted average hourly wage rate of $79.11 (= 2 x [(0.75 x $27.10) + (0.25 x $76.92)]). Multiplying this hourly wage rate by the estimated annual burden hours for domestic establishments, we estimate that the annual reporting and recordkeeping cost to respondents for this collection of information is $38,605.68 (=(396 hours of average annual reporting + 92 hours of annual recordkeeping) x $79.11).

For foreign establishments, we similarly calculate weighted average wages in U.S. dollars for the occupations for office and administrative support production worker, manager, general manager, and legal staff across the 20 foreign countries that exported the largest count of tobacco products to the United States by total dollar value, using as weights each country's share of their combined total dollar value of tobacco product exports to the United States. Doubling to account for potential benefits and overhead, we use these wage estimates to calculate a single, fully loaded, weighted average hourly wage rate for foreign manufacturers of $8.17 (USD). Multiplying this hourly wage rate by the estimated annual burden hours for foreign establishments, we estimate that the annual reporting cost to respondents for this collection of information is $46,062.46 (= (5,313 average annual reporting + 325 hours of annual recordkeeping hours on average x $8.17).

Table 5.—Estimated Annual Cost Burden

Type of Respondent	Total Burden Hours	Hourly Wage Rate (USD)	Total Respondent Costs (USD)
Domestic Tobacco Product Establishment Employees	488	$79.11	$38,605.68
Foreign Tobacco Product Establishment Employees	5,638	$8.17	$46,062.46
Total			$84,668.14

13. Estimates of Other Total Annual Costs to Respondents/Recordkeepers or 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 2 x 8).

15. Explanation for Program Changes or Adjustments*

Program Changes

The information collections in the proposed rule would represent a significant expansion of current section 905 requirements to registration and listing requirements for foreign owners and operators. Currently, only domestic owners and operators of establishments engaged in manufacturing, preparation, compounding, or processing of tobacco products are required to register their establishments and list their products with the FDA, while foreign owners and operators remain exempt from these requirements, creating a substantial information gap for the Agency.

This rule is accompanied with updated and improved online submission Forms FDA 3741 and Form FDA 3741b (submitted via TRLM-NG). With this rule, there would be a new associated burden for requesting a waiver from electronic format requirement. Submitters with an approved waiver would be able to submit by paper.

Additionally, the proposed rule will newly include a recordkeeping element encompassing historical file containing a copy of all consumer information, labeling, and advertisements in use as of the effective date of the rule for all tobacco products contained in the product list for four years. This requirement will be for both domestic and foreign establishments.

FDA estimates an overall increase in average hours per response associated with initial registration using Form FDA 3741 (from 100 minutes to 110 minutes), and the initial product listing spreadsheet (Form FDA 3741b) submission (from 20 minutes to 25 minutes) for domestic

entities since the last extension of this collection. In addition, the increase in burden also reflects burden hours from foreign entities.

Adjustments

All adjustments are the result of a deliberate federal action.

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 from display of the OMB expiration date and is also not seeking OMB approval to exclude the expiration date for this information collection.

18. Exceptions to Certification for Paperwork Reduction Act Submissions

There are no exceptions to the certification.